

Core Gel Study of the Safety and Effectiveness of Mentor Round Low Bleed Silicone Gel-filled Mammary Prostheses in Patients who are undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision (Revised protocol with 11/17/06 approval conditions)



MENTOR

201 Mentor Drive
Santa Barbara, CA 93111 USA
(805) 879-6000
www.mentorcorp.com

Table of Contents

	Synopsis	i
1.0	Introduction	1
2.0	Objectives	1
3.0	Risks and Benefits of the Procedure	2
4.0	Study Design	8
5.0	Device Description	9
6.0	Patient Population	9
7.0	Patient Enrollment	10
8.0	Patient Inclusion Criteria	10
9.0	Patient Exclusion Criteria	11
10.0	Study Evaluations	11
10.1	Baseline Visit	11
10.2	Operative Day	13
10.3	Follow-up Visits	13
10.4	MRI Scan	14
10.5	Missed Visits	14
10.6	Interim Visits	15
10.7	Secondary Procedures/Reimplantation	15
10.8	Final Evaluation	15
10.9	Discontinuation from Study	15
10.10	Conditions for Modifying/Terminating Study	15
11.0	Returned Devices	16
12.0	Monitoring Procedures	16
13.0	Medical Director	17
14.0	Adverse Event Reporting	18
15.0	Serious Unanticipated Adverse Device Effects	18
16.0	Data Collection & Management	19
17.0	Statistical Consideration	19
17.1	Safety Endpoints	19
17.2	Effectiveness Endpoints	19
17.3	Sample Size	20
17.4	Statistical Analysis	23
18.0	Investigator Selection	24

19.0	IRB Approval	24
20.0	Informed Consent	24
21.0	Confidentiality	25
22.0	Investigator Compliance	25
23.0	Data Submission Requirements	26
24.0	References	29

ATTACHMENTS

ATTACHMENT 1	STUDY VISIT SCHEDULE
ATTACHMENT 2	PRODUCT INSERT DATA SHEET
ATTACHMENT 3	INFORMED CONSENT
ATTACHMENT 4	BAKER CLASSIFICATION SCALE
ATTACHMENT 5	QUALITY OF LIFE QUESTIONNAIRES
ATTACHMENT 6	INVESTIGATOR AGREEMENT
ATTACHMENT 7	MRI PROTOCOL
ATTACHMENT 8	STUDY DEFINITIONS
ATTACHMENT 9	STUDY DEVICES
ATTACHMENT 10	CASE REPORT FORMS
ATTACHMENT 11	CORE GEL RETRIEVAL PLAN

Synopsis - Core Gel Study of Mentor Round Low-Bleed Silicone Gel-filled Prostheses

Objective: Demonstrate safety and effectiveness of Mentor's Round Low-Bleed Silicone Gel-filled Mammary Prostheses in women who are undergoing primary augmentation, primary reconstruction, or revision.

Design:

- Multicenter
- Non-masked, open label
- Two year data submitted to FDA as part of PMA
- Following FDA clearance, follow up data collected: Rheumatic Disease Diagnosis, QoLs, silent rupture, and Adverse Events

Population:

- Total subject population: 1000
 - Augmentation: 550
 - Reconstruction: 250
 - Revision: 200
- Total number of investigational sites: up to 40
 - Augmentation: 20
 - Reconstruction: up to 20
 - Revision done by both Augmentation and Reconstruction sites
- Maximum number of subjects per site: 15% of cohort
 - Augmentation: 83
 - Reconstruction: 38
 - Revision: 30
- MRI Substudy: All study subjects

Study Device: Mentor Round Low Bleed Gel-filled Mammary Prostheses, both Siltex and smooth surface

Inclusion Criteria:

- Subject is Genetic female and at least 18 years old
- As defined in Section 6.0, a candidate for:
 - Primary breast augmentation (for post-lactational mammary involution or general breast enlargement)
 - Primary breast reconstruction (for cancer, trauma, surgical loss of breast or congenital deformity)
 - Revision surgery (previous augmentation or reconstruction with silicone-filled or saline-filled implants)
- Signs the Informed Consent
- Agrees to follow the procedures for explant analysis.
- Agrees to comply with follow-up procedures, including returning for all follow-up visits

Exclusion Criteria:

- Subject is pregnant
- Has nursed a child within three months of study enrollment.
- Been implanted with any silicone implant other than breast implants
- Confirmed diagnosis of rheumatic disease
- Currently has a condition that could compromise or complicate wound healing (except reconstruction patients).
- Patient in Augmentation cohort and has diagnosis of active cancer of any type.

Synopsis - Core Gel Study (continued)

Exclusion Criteria (continued):

- Infection or abscess anywhere in the body.
- Demonstrates tissue characteristics which are clinically incompatible with implant (e.g. tissue damage resulting from radiation, inadequate tissue, or compromised vascularity).
- Possesses any condition, or is under treatment for any condition which, in the opinion of the investigator and/or consulting physicians(s), may constitute an unwarranted surgical risk.
- Anatomic or physiologic abnormality which could lead to significant postoperative adverse events.
- Demonstrates characteristics that are unrealistic/unreasonable with the risks involved with the surgical procedure.
- Premalignant breast disease without a subcutaneous mastectomy.
- Untreated or inappropriately treated breast malignancy, without mastectomy.
- Implanted metal or metal devices, history of claustrophobia or other condition that would make a MRI scan prohibitive.

Study Evaluation Schedule Summary:

Data Collected	Timeframe				
	Baseline	Operative	6 Months	12 & 24 Months	3 – 10 Years*
Inclusion/Exclusion	X				
Subject Consent	X				
Medical/Breast History	X				
Breast Measurements	X		X	X	X
Mammography (if performed)	X		X	X	X
Quality of Life**	X			X	X
Nipple/Breast Sensitivity Assessment	X		X	X	X
Capsular Contracture			X	X	X
Rheumatology Assessment	X			X	X
Surgical Information		X			
MRI Scan ^θ				X	X
Adverse Events***		X	X	X	X

* At 3, 4, 5, 6, 7, 8, 9, and 10 years.

** Rosenberg Self Esteem Scale, SF-36, Body Esteem Scale, Tennessee Self-Concept Scale, FLIC (Cancer patients only)

θ MRI scan done on a subset of 405 subjects at 1, 2, 4, 6, 8, and 10 years

θ MRI scan done on all subjects at 6, 8 and 10 years

*** Including secondary procedures and reimplantations

Safety Endpoint: Incidence, severity, method of resolution, and duration for all adverse events on a per implant and per patient basis

Effectiveness Endpoints:

Primary: Changes in chest circumference and bra and cup size (may not be applicable to reconstruction subjects)

Secondary: Changes in Quality of Life results

1.0 INTRODUCTION

Silicone gel-filled breast implants were introduced in the early sixties and were in wide-scale distribution by the time the Medical Device Amendments to the Food Drug and Cosmetic Act was passed in 1976. In 1983, gel-filled breast implants were designated as Class III devices requiring premarket approval. In May 1990, the Food and Drug Administration (FDA) published a proposed request (515(b)) for Premarket Approval Applications (PMA) and in April 1991 published the final request. This final publication put manufacturers of gel-filled breast implants on notice that for continued marketing of gel-filled breast implants, a PMA was due to FDA in 90 days from the final publication date.

A premarket approval (PMA) for the Mentor gel-filled breast implants was filed with the FDA in July 1991. At the FDA General and Plastic Surgery Advisory Committee meeting in November 1991, the committee recommended the submission of additional information to establish the safety and effectiveness of gel-filled breast implants.

In January 1992, the FDA Commissioner announced a voluntary moratorium of the sale of gel-filled breast implants to allow the advisory panel time to assess additional information. In April 1992, the moratorium was lifted but only for reconstruction and revision patients. Every patient implanted had to be part of an adjunct study, and had to be offered participation in a registry of gel-filled breast implant patients. In order to be implanted with gel-filled implants for augmentation, women had to be enrolled in a core clinical study.

This protocol describes the study design procedures, population, variables and analyses for the evaluation of safety and effectiveness of Mentor silicone gel-filled smooth and textured breast implants for breast augmentation, reconstruction, and revision

2.0 OBJECTIVES

The objective of this study is to determine the safety and effectiveness of the smooth and textured surface Mentor Round Low-Bleed Silicone Gel-filled Mammary Prosthesis in women who are undergoing primary breast augmentation, primary breast reconstruction or revision.

Safety will be determined by:

- The incidence, severity, method of resolution, and duration for all adverse events on a per implant and a per patient basis

Effectiveness will be determined by:

- Primary - changes in chest circumference and bra and cup size
- Secondary - changes in quality of life questionnaire results

3.0 RISKS AND BENEFITS OF THE PROCEDURE

Patient Notification

The implanting physician must insure that the patient clearly understands the potential risks and benefits of the procedure and agrees that the potential benefits associated with the procedure outweigh the risks. The risks of the procedure are outlined in the Product Insert Data Sheet (Attachment 2) and the Patient Informed Consent (Attachment 3). The physician must discuss these with the patient.

3.1 Benefits of the Procedure

Breast augmentation surgery is an elective cosmetic surgery designed to provide both physical and psychological benefits. The physical benefits include increased options and choices in selection and fit of clothing. Psychologically, the procedure may improve the woman's self-esteem, sense of body image and quality of life. The primary motivation of women seeking this procedure is to enhance appearance by enlarging the breast, usually associated with an improvement in shape. The anatomic variances perceived as a deformity by the woman include: size smaller than her perceived ideal, ptosis, asymmetry, and post partum or post lactation involution. For the vast majority of patients, this represents a single focus concern in an otherwise satisfactory life environment.

Breast reconstruction is usually performed to restore the breast after surgical loss of one or both breasts due to cancer, severe cystic disease as well as congenital deformity. Women have reported that breast reconstruction with mammary implants has been an aid in their recovery from breast cancer and has reduced emotional stress by helping to return their bodies to a more natural appearance, as opposed to not having reconstructive surgery or wearing an external prosthesis.

The effectiveness of the implants will be measured by assessing the increase in the size of the breast and by administering validated quality of life questionnaires.

3.2 Surgical Risks of the Procedure

All surgical procedures have a small risk of complication inherent to the surgery itself and to anesthesia. These risks include:

3.2.1 Infection: (severe infection on rare occasions results in Toxic Shock Syndrome or TSS). An infection can result from any surgery and produce swelling, tenderness, pain and fever. Almost all infections appear within a few days of the operation but may appear at any time after surgery.

3.2.2 Hematoma: formation (a collection of blood in the surgical area)

3.2.3 Seroma: (fluid accumulation around the implant which may or may not require removal). The body will absorb both areas of fluid accumulation (seromas) and small hematomas, but large ones may have to be drained surgically to permit proper healing.

3.2.4 Scarring: Any incision in the skin will leave a scar that is permanent. While surgeons will use plastic surgical techniques to make this as inconspicuous as possible, some patients have a skin quality that results in more conspicuous scars no matter how the incision is repaired.

3.2.5 Anesthetics: There are risks from anesthetics as well.

3.3 Risks Specific to Breast Implants

Risks specific to breast implants include:

3.3.1 Capsular Contracture

Capsular contracture is the most common side effect of breast implants. To accept the implant, a surgical pocket behind the breast is made somewhat larger than the implant itself. Normally a healing scar forms an envelope around the implant, which, on occasion, will shrink sufficiently to squeeze the implant, producing varying degrees of firmness. The implant can feel hard, be painful and/or distorted. This can occur soon after surgery or years later and may be unilateral, bilateral or asymmetric. Surgical release or excision of the scar is often successful but recurrence is not uncommon. The cause of the contracture phenomenon is poorly understood and is probably related to an idiosyncratic response to the presence of normal, benign skin bacteria, *Staphylococcus epidermidis*. In the past, closed disruption of the scar by squeezing the breast was common, but this is rarely practiced today. This practice will be prohibited in this study. Capsular contracture is graded in severity on a scale of I to IV by Baker classification. (Attachment 4).

Calcification of the capsule can also occur. This is usually associated with Grade IV contracture. Calcification is a phenomenon that is occasionally seen with long term scarring especially if there is irritation such as tight burn scars that cross joints. Calcified capsules may require removal if the patient wishes relief from her contracture but otherwise seem to be harmless. Small foci of calcification are commonly seen anywhere in the breast parenchyma. They can usually be identified as benign by the radiologist but on occasion may require biopsy to rule out a malignancy. These do not seem to be more common in the augmented patient. (Please see section 3.3.6 for further information)

3.3.2 Rupture of the Implant

Breast implants may not last a lifetime. While the silicone material itself has not been shown to biodegrade, the shell may rupture due to wear and tear, or direct injury. If the implant shell is ruptured, the escaping gel is usually contained by the scar envelope in the surgical pocket (intracapsular) and may be undetectable except by Magnetic Resonance Imaging (silent rupture) which is about 85% effective in detecting rupture. If the scar envelope is torn, the gel can be driven into the local tissue planes and breast tissue (extracapsular). Most of the escaped gel remains in the immediate environment of the breast but on rare occasions it has been reported to migrate down the arm, into nerve sheaths or into the abdominal wall. The free silicone may cause lumps called granulomas to form in the breast or other tissues where the silicone has migrated. Some studies indicate that silicone may escape the capsule in 10-20% of rupture cases.⁴⁷

Ultrasound, mammography and physical examination may also diagnose these ruptures which have escaped the scar envelope.

The rate at which silicone gel-filled implants rupture is uncertain. However, using different methods of detection, published studies suggest a rupture rate between 5 and 51 percent.^{47a} A study of screening mammograms suggested that 5% of asymptomatic women had experienced "silent rupture" of their implants. Mammography is of limited value in detecting implant rupture.

The mammogram readings of rupture were not confirmed by surgical removal of the implant. Robinson et al. studied 300 women who had their implants for 1 to 25 years and had their implants removed for a variety of reasons.^{47b} They found visible signs of ruptures in 51 percent of the women studied. Severe silicone leakage -- silicone outside the implant without visible tears or holes -- was seen in another 20 percent, without visible tears or holes. Robinson et al. also noted that the probability of rupture increases as the implant ages and recommended removal of all gel-filled implants preferably before 8 years of implantation.

Rupture should be suspected if there is a change in character of the device such as a new, persistent unilateral burning sensation or a change in softness, texture or shape of the implant. Because of the silent nature of most ruptures and the difficulty of diagnosis without surgical exploration, the true incidence is unknown. Caution should be used when comparing expected or actual rupture rates of current devices to historical incidences, especially when, as is often the case, the brand, vintage and type of device is unknown. Explantation and/or replacement may be indicated if the implant fails, especially if it is seen in the breast parenchyma as it could be confused with or mask a tumor.

Causes of implant rupture include, but are not limited to: damage from surgical instruments, intraoperative or postoperative trauma, excessive stresses or manipulations as may occur during daily routines such as vigorous exercise, contact athletics, routine manual massage, intimate physical contact and from compression required during mammography.

Most of the reported cases occurred in the more fragile, thinner shell devices implanted in the late 1970's. Current products have thicker and stronger shells and more cohesive gel contents. Caution should be used when comparing expected or actual rupture rates of current devices to historical incidences, especially when, as is often the case, the brand, vintage and type of device is unknown.

3.3.3 Gel Bleed

The gel in an implant consists of a three-dimensional crosslinked structure that constitutes about 15 % of the total volume. The interstices are filled with silicone oil. This oil is similar to the materials available in many products including anti-gas medication, available without prescription for infants and adults. The shell of the implant is slightly permeable to the oils. Depending on the age, brand, chemical characteristics and environmental mechanics of a given device, varying small amounts of the oil diffuses or "bleeds" through the shell.

Some amount diffuses into the scar envelope where it can be picked up by macrophages, the probable mechanism by which it is transported into regional lymph nodes. The oil has been detected in the breast and surrounding subcutaneous tissues in amounts diminishing with distance. It is assumed that minute amounts of silicone from all ingested and injected sources are distributed throughout the body. Because silicone is hydrophobic, it is unlikely to be transported by any mechanism other than macrophage migration or local diffusion. There is no evidence to suggest that the gel contents have any different metabolic effect on the body than the solid silicone envelope.³⁷

3.3.4 Changes in Nipple and Breast Sensation/Breast Pain

Any surgery of the breast can result in undersensitive or oversensitive nipple-areolar complexes and/or undermined areas of breast skin. These changes can vary in degree and may be temporary or permanent. Changes in nipple/breast sensation may, on occasion, affect sexual response or comfort while nursing. These changes are believed to be a result of nerve damage from the surgery and not the presence of the implant itself.

Most women undergoing augmentation or reconstruction with a mammary prosthesis will experience some breast and/or chest pain postoperatively. While this pain normally subsides in most women as they heal after surgery, it can become a chronic problem in other women. Chronic pain can be associated with hematoma, migration, infection, and implants that are too large or capsular contracture. Sudden severe pain may be associated with implant rupture.

3.3.5 Interference with Mammography in Detection of Cancer

As silicone is opaque to x-rays, an implant may interfere with the early detection of cancer by mammography as it may obscure part of the breast.

Newer techniques of breast compression improve the amount of breast that can be visualized. Alternatively, most surgeons feel that the device may improve the detection of tumors by palpation. While of considerable theoretical concern, delayed detection due strictly to the presence of an implant has not been reported. Women at high risk of developing breast cancer should consider getting implants with caution. Since the breast is compressed during mammography, it is possible for the implant to rupture, but this is rare and should not deter a woman from regular, routine mammographic screening. Before the mammography exam, women should inform the technologist that they have implants.

3.3.6 Calcium Deposits

Calcium deposits are seen occasionally in old scars anywhere in the body and this is true of the implant capsule. This usually does not occur until years after implant surgery. Benign calcifications are also commonly seen on mammography in otherwise normal breast parenchyma even in breasts that have never been operated on. These benign calcium deposits usually have a different x-ray appearance than the calcifications that signal a malignancy. An expert radiologist can usually determine if a calcium spot is benign or malignant but occasionally a biopsy may be necessary to rule out malignancy.

There is no evidence that these deposits occur more or less frequently in women with implants than those who have not received implants.

After many years, some patients may develop a thin layer of calcium in the scar capsule that surrounds the implant. This is almost always associated with capsular contracture but otherwise causes no known problem. (Please see capsular contracture section 3.3.1 for information on risk of developing calcium deposits with implants)

3.3.7 Delayed Wound Healing

In some cases, the incision site fails to heal normally.

3.3.8 Extrusion

Unstable or compromised tissue covering and/or interruption of wound healing may result in extrusion, which is when the breast implant comes through the skin.

3.3.9 Necrosis

Necrosis is the formation of dead tissue around the implant. This may prevent wound healing and require surgical correction and/or implant removal. Permanent scar deformity may occur following necrosis. Factors associated with increased necrosis include infection, use of steroids in the surgical pocket, smoking, chemotherapy/radiation, and excessive heat or cold therapy.

3.3.10 Breast Tissue Atrophy/Chest Wall Deformity

The pressure of the breast implant may cause the breast tissue to thin and shrink. This can occur while implants are still in place or following implant removal without replacement.

3.3.11 Dissatisfaction with Cosmetic Results

Visible and/or palpable wrinkles in an implant are related to the thinness of the overlying tissue cover, the degree of capsular contracture and the texturing of the implant shell surface. Traditional smooth walled gel devices rarely demonstrate wrinkles.

Surgical error, preexisting asymmetry or deformity, keloid formation of the incisional scar, vagaries of time, weight gain or loss, pregnancy and nursing can all contribute to an immediate or late poor aesthetic result. With time most breasts, with or without implants, become ptotic to some degree. Asymmetry is usually related to the inability to totally correct for pre-existing disparity between the two breasts. It can also be attributed to surgical error, asymmetric contracture, or rupture of the implant.

Excessive buildup of collagen at the incision site during the healing process causes some patients to develop scars of cosmetic concern. Keloid scars, which do not respond well to treatment, often extend beyond the edges of the original scars and can continue to enlarge over time. Hypertrophic scars are generally confined to the original site and respond well to scar revision treatment, which may include steroid injections to break down the collagen or surgery to revise the position, direction or line of the scar.

3.3.12 Granulomas

It is possible for a granuloma to form around a tiny amount of silicone. Although these lumps are non-cancerous, they can be difficult to distinguish from cancerous lumps without being removed (biopsied) and examined.

3.3.13 Resurgery

Women should understand there is a high chance they will need to have additional surgery at some point to replace or remove the implant. Also, problems such as rupture, capsular contracture, infection, shifting, and calcium deposits can require removal of the implants. Many women decide to have the implants replaced, but some women do not. Those who do not may have cosmetically unacceptable dimpling and/or puckering of the breast following removal of the implant.

3.4 Unknown Risks

The issue of the possible relationship between silicone (and other implantable materials) and various diseases has been the subject of significant scientific debate. Concerns include immunological and neurological disorders, carcinogenicity and connective tissue disorders.

3.4.1 Connective Tissue Disease

The term Connective Tissue Disorder has been used to describe a variety of symptoms thought to be related to silicone breast implants. Some cases of these disorders have been reported in women with breast implants, and some of these women have reported a reduction in symptoms after their implants have been removed. Several studies have explored whether a possible link exists between silicone breast implants and connective tissue disorders or other immunological diseases.^{7,8,9,10,11,12,13,14,38,39}

3.4.2 Neurological Disorders

Co-incident neurological problems such as multiple sclerosis and amyotrophic lateral sclerosis (ALS) have occurred in a small number of breast implant patients.^{15,16,17,18,19,20}

3.4.3 Cancer

Case reports in the medical literature have associated tumors with the presence of silicone breast implants. Several studies have been conducted to determine the carcinogenic risk of breast implants and no evidence of increased risk of cancer has been demonstrated.^{21,22,23,24,25,26,27,40,41,42} Continuing assessment of both known and possible carcinogenic risks associated with breast implant surgery is ongoing.

3.4.4 Birth Defects

No credible reports on birth defects or other reproductive effects in humans associated with implantation of silicone mammary prostheses of any type have been identified in the literature. Recent studies^{28,29,30} provide further evidence that silicone materials used in mammary prosthesis do not cause adverse reproductive effects in experimental animals.

3.4.5 Breast Feeding

Although any breast surgery, including breast implantation, could theoretically interfere with the adequacy of the woman's milk supply, many women with breast

implants have nursed their babies successfully. It is known that any breast surgery such as breast biopsy can affect the quantity of milk produced.

In recent years, the question has been raised regarding the potential transfer of silicone into the breast milk of women with silicone breast prostheses and possible effects on the health of breast fed children.^{31,32}

However, more recent studies have provided strong evidence of the lack of association between silicone breast implants and adverse effects in breast fed children.^{33,34}

3.5 Minimization of Risks

Mentor will select investigators qualified by experience and training to participate in the clinical study. Mentor will require each investigator to submit a copy of his/her curriculum vitae and medical license (see Section 18.0).

Mentor will insure that all investigator's conduct the clinical study properly by:

- following the requirements of the protocol and IDE regulations, including supervising the use of the implants, which are outlined in the Investigator Agreement (Attachment 6)
- protect the rights, safety and welfare of subjects and to ensure that an informed consent is obtained before they begin study participation (Section 20.0).
- insuring that the investigator will obtain IRB approval prior to enrolling patients (Section 19.0).
- Mentor will conduct periodic audits of patient logs, device accountability records, source documentation and case report forms to insure that the protocol is strictly followed. (Section 12.1.)

The investigator may be disqualified from the study by failing to comply with any of the requirements of the protocol or any FDA regulations. (Section 22.0)

4.0 STUDY DESIGN

This trial is designed as an open label, multi-center study, with each patient as her own control. There will be three treatment groups:

- Primary augmentation
- Primary reconstruction
- Revision

Mentor will submit the PMA after completion of two-years of patient follow-up. All patients will continue to make follow-up visits at 3, 4, 5, 6, 7, 8, 9 and 10 years post surgery. The study will include 10 years of long term follow-up data for each patient.

There will be up to 40 centers with a total of 1000 patients. Up to 20 centers will be designated to recruit the primary augmentation cohort, and up to 20 will be designated to recruit the primary reconstruction cohort. Both groups will recruit the revision cohort.

- Ratio of siltex surface to smooth surface will be determined by market demand.
- No more than 15% of the total number of patients in a cohort may be enrolled at one center (see table below)
- Assuming the proportion of patients lost to follow-up is no greater than 20%, there should be at least 800 evaluable subjects at the end of 2 years.

All patients at each study center who meet inclusion and exclusion criteria will be offered participation in this study. The study will be open to augmentation, reconstruction, and revision patients. It is expected that no more than 550 of the women will be breast augmentation patients, no less than 250 of the women will be reconstruction patients, and no less than 200 will be revision patients.

Total Number of Patients in Each Cohort

Cohort	Study Total	Maximum/Site (15% of Total)
Augmentation (20 sites)	550	83
Reconstruction (20 sites)	250	38
Revision (From both Augmentation and Reconstruction Cohort sites)	200	30

Depending on the rate of enrollment, all sites may not be able to enroll the allocated number of patients.

All patients enrolled in the study will participate in the Mentor patient registry. This registry of confidential information has been established for Mentor’s other breast implant studies, including the Adjunct Study. The registry will enable Mentor to inform patients of safety related information in a timely manner.

5.0 DEVICE DESCRIPTION

Two types of Mentor Round Low-Bleed Silicone Gel-filled Mammary Prostheses will be used in the study: the Siltex textured surface device and the smooth surface device. The original study protocol included the Mentor MemoryGel™ Silicone Gel-Filled Breast Implants Moderate Profile Style 7000. The PMA-approved devices now also include High Profile Style 4000 and Moderate Plus Profile Style 8000. Each implant is a silicone elastomer mammary device that is supplied individually packaged in a doubled wrapped packaging system, sterile, and non-pyrogenic. Each device consists of a silicone shell encasing a silicone gel filler material with a patch on the posterior side of the device. The basic smooth device shell consists of a crosslinked phenyl silicone elastomer layer sandwiched in between crosslinked methyl silicone elastomer layers. The phenyl layer acts as a barrier to slow the diffusion of any gel filler materials through the shell. The Siltex textured shell consists of a smooth shell to which is bonded an additional layer of silicone with a textured pattern imprinted into its surface.

The Siltex shell is intended to provide a disruptive surface for connective tissue ingrowth. The gel filler is a crosslinked silicone polymer. All study devices will be manufactured from SiTech/NuSil silicone materials.

See Attachment 9 for a list of the sizes and catalogue numbers of study devices.

6.0 PATIENT POPULATION

The study population will consist of women aged 18 or over who are undergoing primary breast augmentation, primary breast reconstruction or revision.

Augmentation

The Augmentation cohort will include patients who have post-lactational mammary involution or wish general breast enlargement.

Reconstruction

The Reconstruction cohort will include patients with loss of breast due to mastectomy or with deformities secondary to disease, malignancy, trauma, and congenital deformity.

Congenital deformities will include deformities of the breast itself as well as skeletal abnormalities reflected in breast deformity or asymmetry.

Asymmetry is one or more of the following conditions:

- One cup size difference in breast size.
- The need to differentially pad one bra cup to match the opposite breast size.
- Asymmetry due to chest wall deformity such as scoliosis or other deformities of the thoracic cage and/or associated visible differences in shoulder height that can make one breast appear to be at a different height than the other.

Revision

Patients in this cohort will have had previous breast augmentation or reconstruction with silicone or saline filled implants.

Both Augmentation and Reconstruction sites will enroll patients into the Revision cohort. Augmentation cohort sites will enroll augmentation revision patients only, while Reconstruction Cohort sites will enroll reconstruction revision patients. Revision Cohort patients will not have been previously enrolled in the Core Gel Study. If a patient was previously enrolled in the Core Gel study as an Augmentation or Reconstruction patient, they will remain in that cohort throughout the study, even if they have a reoperation or revision.

7.0 PATIENT ENROLLMENT

A total of 1000 patients will be enrolled at up to 40 centers. A minimum of 800 assessable patients is required to be evaluable at two years. Patients will be considered enrolled in the study after implantation. Enrollment is targeted to be complete in approximately eight months.

8.0 PATIENT INCLUSION CRITERIA

Study subjects will be allowed to enter the study if the following inclusion criteria are met:

- Patient is genetic female, 18 years of age or older.
- As defined in Section 6.0, a candidate for:
 - Primary breast augmentation (for post-lactational mammary involution or general breast enlargement)
 - Primary breast reconstruction (for cancer, trauma, surgical loss of breast or congenital deformity)
 - Revision surgery (previous augmentation or reconstruction with silicone-filled or saline-filled implants)
- Signs the Informed Consent.
- Agrees to follow the procedures for explant analysis.
- Agrees to comply with follow-up procedures, including returning for all follow-up visits.

9.0 PATIENT EXCLUSION CRITERIA

Study subjects will not be allowed to enter the study if they have any of the following exclusion criteria:

- Patient is pregnant.
- Has nursed a child within three months of study enrollment.
- Been implanted with any silicone implant other than breast implants (e.g. silicone artificial joints or facial implants).
- Confirmed diagnosis of the following rheumatic diseases or syndromes: SLE, Sjogren's syndrome, scleroderma, polymyositis, or any connective tissue disorder, rheumatoid arthritis, crystalline arthritis, infectious arthritis, spondyarthropathies, any other inflammatory arthritis, osteoarthritis, fibromyalgia, or chronic fatigue syndrome.
- Currently has a condition that could compromise or complicate wound healing (except reconstruction patients).
- Patient in Augmentation cohort and has diagnosis of active cancer of any type.
- Infection or abscess anywhere in the body.
- Demonstrates tissue characteristics which are clinically incompatible with implant (e.g. tissue damage resulting from radiation, inadequate tissue, or compromised vascularity).
- Possesses any condition, or is under treatment for any condition which, in the opinion of the investigator and/or consulting physicians(s), may constitute an unwarranted surgical risk.
- Anatomic or physiologic abnormality which could lead to significant postoperative adverse events.
- Demonstrates characteristics that are unrealistic/unreasonable with the risks involved with the surgical procedure.
- Premalignant breast disease without a subcutaneous mastectomy.
- Untreated or inappropriately treated breast malignancy, without mastectomy.
- Implanted metal or metal devices, history of claustrophobia or other condition that would make a MRI scan prohibitive.

10.0 STUDY EVALUATIONS

All assessments for each patient will be performed by the investigator and/or coordinator according to the “Study Visit Schedule” (Attachment 1). Section 10 describes all study evaluations that will be monitored during study visits.

The study is composed of the following study intervals:

- Baseline (within 30 days of surgery)
- Operative Day
- Follow-up visits (6 months, 1, 2, 3, 4, 5, 6, 7, 8, 9 and 10 years post surgery)
- MRI scan at 1, 2, 4, 6, 8,10 years post surgery (subgroup only)
- MRI scan at 6, 8, and 10 years post surgery (all patients)

10.1 Baseline (within 30 days of surgery)

Patients who meet the inclusion criteria for the study will have the informed consent explained to them. The patients will also be given an information booklet that explains eligibility requirements, the history of breast implants, surgical procedures, requirements of study participation and the risks and benefits of implant surgery.

If the patient agrees to participate in the study and signs the informed consent, the **Baseline** case report form will be completed. The following assessments will be recorded on this form:

- Baseline nipple and breast sensitivity
- Baseline breast size will be measured by both bra and cup size and the chest/bust circumference
- Medical history and physical exam
- Breast History (includes previous surgeries, radiation and chemotherapy treatments)
- Rheumatic Disease Diagnosis Questionnaire
- Concomitant medications
- Psychometric testing with the following Quality of Life Questionnaires will be administered to all patients at this visit (Attachment 6):
 1. Rosenberg Self Esteem Scale
 2. Body Esteem Scale
 3. Tennessee Self Concept Scale
 4. SF-36 Health Survey
 5. The Manitoba Cancer Treatment and Research Foundation Functional Living Index (FLIC) (cancer patients only)

The Rheumatic Disease Diagnosis Questionnaire captures rheumatic disease, symptom and rheumatic physical exam data. In addition, the Investigator is asked, in his or her medical opinion, do the patient’s symptom(s) warrant a rheumatological exam? If yes, a rheumatological confirmation is required. This information ensures that “confirmed” rheumatologic conditions are captured. Examination by mammography is not required in this study. However, if the patient undergoes a mammogram within 30 days of surgery, the results will be recorded under “Mammography Results” on the Baseline form.

10.2 Operative day

The operative procedure is to take place no more than 30 days following the screening visit. The investigator will record the type and size of the prosthesis along with the catalogue numbers and lot numbers, the type of surgery and anesthesia, and other procedure related information on the **Operative Report** case report form. In addition, the lot numbers, catalogue numbers and demographic information will be recorded on the **Patient Registry** form. Any adverse events, which occur during the procedure, will be recorded on the **Adverse Event Report form**.

10.3 Postoperative Follow-up Evaluation Visits

Follow-up evaluations will take place at 6 months and 1, 2, 3, 4, 5, 6, 7, 8, 9 and 10 years after surgery.

Any unscheduled postoperative visits will also be recorded and submitted to Mentor on the **Interim Visit** form. Adverse events will be documented upon occurrence.

6 Month Postoperative Follow-up Visit

At the 6 month postoperative follow-up visit, the following procedures and evaluations will be performed and recorded on the **6 Month Visit** case report form:

- Nipple and breast sensitivity assessment
- Breast measurements
- Capsular contracture assessment
- Concomitant medication
- Adverse Event Evaluation

Postoperative Follow-up Visits at 1, 2, 3, 4, 5, 6, 7, 8, 9 and 10 years

At each scheduled follow-up visit, the following procedures and evaluations will be performed and recorded on the appropriate case report forms for that visit (i.e. **1 Year Visit, 2 Year Visit, etc**):

- Nipple and breast sensitivity assessment
- Breast measurements
- Capsular contracture assessment
- Concomittant medication
- Quality of Life Questionnaires (at 1, 2, 4, 6, 8, and 10 year visits only)
- Adverse Event Evaluation
- MRI scan on subset of patients (at 1, 2, 4, 6, 8, and 10 year visits only)
- Rheumatic Disease Diagnosis Questionnaire

The Rheumatic Disease Diagnosis Questionnaire captures rheumatic disease, symptom and rheumatic physical exam data. In addition, the Investigator is asked, in his or her medical opinion, do the patient's symptom(s) warrant a rheumatological exam? If yes, a rheumatological confirmation is required. This information ensures that "confirmed" rheumatologic conditions are captured.

Examination by mammography is not required in this study. However, if the patient undergoes a mammogram while enrolled in the study, the results will be recorded under "Mammography Results" on the postoperative follow up forms.

10.4 MRI Scan

In addition to the examinations listed above, a subset of all patients will undergo a MRI scan at 1, 2, 4, 6, 8 and 10 years post surgery to detect silent rupture (Attachment 7). Patients will be informed at study entry that they possibly may be randomized to undergo the MRI scans. All patients will undergo an MRI scan at 6, 8, 10 years post surgery.

MRI centers in close proximity to the study sites will be identified. The participating MRI facility will be required to have at least a 1.5 Tesla magnet with a dedicated breast coil. Adequacy of the MRI site will be judged at the time the site is selected.

As a silent rupture rate of 5% is anticipated ⁴⁸, initially 405 patients will undergo a MRI scan. After all patients have been enrolled, these patients will be randomly selected so that of the 405 patients, 55% will be from the augmentation cohort, 25% will be from the reconstruction cohort and 20% will be from the revision cohort. Consistent with approval conditions, all patients will receive MRI scans starting at year 6 post surgery.

All patients will be directed to see their physician whenever the patient believes a rupture has occurred. These patients will undergo a MRI scan. The scans will be sent to a central reading center to be read by an independent breast MRI radiologist. This radiologist will be blinded to the patient name and site.

The results will be recorded on the MRI Silicone Breast Evaluation Data Sheet (Attachment 7) and entered into the study database.

10.5 Missed Visits

Every effort will be made to assure that study subjects comply with the study visit schedule listed in Attachment 1. If a patient misses her scheduled appointment, she will be contacted and another appointment will be made.

If she misses two consecutive follow-up visits, the subject will be withdrawn from the study and considered lost to follow-up. Subject withdrawal will be documented by completing the **End of Study** form. The patient will be in compliance with the visit schedule if she is evaluated within the following visit windows relative to the date of surgery:

- 6-month: \pm 4 weeks
- 1-year: \pm 6 weeks
- 2 years: \pm 8 weeks

- 3, 4, 5, 6, 7, 8, 9 and 10 years: \pm 4 months

10.6 Interim Visits

If any complication or other problem arises outside the window of scheduled study visits, the patient may be seen at an interim appointment. The information gathered at the interim visit will be entered on the **Interim Visit** case report form. This case report form is a duplicate of the scheduled visit case report forms. If any adverse events are noted during an interim visit, that information should be recorded on the **Adverse Event Report**. The information should include type of complication, date of onset, therapy or other action (if any), date of resolution, severity, and relatedness to the device.

10.7 Secondary Procedures/Reimplantation

For each instance of explantation, revision, re-implantation or other secondary procedures, the date and reason will be collected and the **Secondary Procedures Report** case report form will be completed. If a new device is implanted, the **Reimplantation Report** will be completed. **Any adverse events related to reoperative procedure, as well as the surgery itself, will be recorded on the Adverse Events Report.**

10.8 Final Evaluation Visit

The final evaluation will be made at the ten year follow-up examination. In the event that a woman withdraws from the study, every effort will be made by Mentor to have her evaluated before withdrawal with a final evaluation visit. The last study visit will be documented by completing the **End of Study** case report form.

10.9 Discontinuation from Study

In the event that a patient indicates her intention to withdraw from the study, the reason for the withdrawal will be recorded on the **End of Study** case report form. If possible, she will be requested to come in for a final evaluation visit. The final evaluation visit will include breast measurements, adverse event report and psychometric testing. If the patient moves from the implanting surgeon's area an investigator appropriate to her new location will be requested to assume follow-up. A patient with all study device(s) explanted, without reimplantation, will not be discontinued. She should be seen at yearly postoperative visits through ten years. The same information will be collected on explanted patients as will be collected on patients still implanted with study device(s).

10.10 Conditions for Modifying or Terminating the Study

Any modification of the study parameters will be made only with the approval of the Sponsor and Investigator(s). Protocol amendments that impact on patient safety or the science of the study must be approved by the IRB responsible for the review and approval of the study (Investigator responsibility). The changes must also be submitted to the FDA for review (Sponsor responsibility) as required by the Code of Federal Regulations (CRF 21 Part 812.35).

If the Investigator or Sponsor discovers conditions during the study which indicate it should be terminated, a recommendation to terminate the study may be made after consultation between the Sponsor and Investigator. The study will be

terminated under an appropriate schedule designed so as not to jeopardize the health of any patient (CFR 21 Part 812.46)

11.0 RETURNED DEVICES

All explanted breast prostheses should be returned to Mentor Product Evaluation. The investigator should contact Mentor Clinical Programs Department by phone at 800-525-0245 extension 6411. Arrangements will be made for the site to be sent an explant kit, which includes a “Field Experience Report”. In addition, the “Secondary Procedures” and “Reimplantation Report” case report form should be completed and sent to Mentor Clinical Programs.

Upon receipt of the implant, Mentor Product Evaluation will examine the returned implant in order to evaluate the complaint. Product Evaluation will conduct a comprehensive investigation including visual and physical testing of the explanted device to try and determine the cause for the complaint, in accordance with established procedures and protocols. The Core Gel Retrieval Protocol will be utilized to evaluate explanted devices specifically from this study (Attachment 11). Each complaint will be evaluated for MDR determination per the requirements of “MDR Reporting Guidance for Breast Implants.”

12.0 SITE MONITORING PROCEDURES

Effective and efficient technical and medical communication between Mentor and the investigators will, in part, be accomplished by clinical monitoring procedures. These monitoring procedures will ensure that the Sponsor knows about each investigator’s participation in enough detail to assess adherence to the clinical study protocol. In addition, the following monitoring procedures will allow the Sponsor to secure investigator compliance with:

1. The signed investigator agreement,
2. The investigational plan,
3. Adherence to applicable FDA regulations, and
4. Any conditions of approval imposed by the IRB or FDA.

If it is determined that the investigator violates any of the above provisions, the Sponsor will promptly secure compliance or cease breast implant shipments.

In addition, the non-compliant investigator will return the breast implants immediately without jeopardizing the rights, safety, or welfare of a subject (21 CFR 812.46 [a]). The following study managers, along with other qualified persons, will undergo product training and be properly oriented in monitoring procedures prior to study initiation:

- Ginny Siegel, Project Lead at (805) 879-6462
- Rosalyn Cole, Program Manager at (805) 879-6717

12.1 Clinical Site Monitoring Procedures

Monitoring procedures will, at minimum, consist of the following:

12.1.1 Initial on-site visit. The Clinical Monitor will review the terms of the protocol with the investigator and confirm the investigator's access to facilities required to conduct the study. The Clinical Monitor will answer any questions the investigator may have concerning the protocol, case report form completion and submission, investigator responsibilities, device tracking, source documentation and regulatory requirements.

Investigators will be provided with a Study Reference Manual, which outlines all study procedures. No devices will be sent to a site until the initial on-site visit has been satisfactorily completed and IRB approval has been received by the sponsor.

12.1.2 In-house review of data. The Sponsor will conduct an ongoing in-house review of data submitted by investigators, with checks for accuracy and completeness. Investigators will be contacted and asked to submit any missing information or clarify any questionable data. As data are entered into the database, edit checks will be performed and data queries will be resolved.

12.1.3 Periodic follow-up with investigators. The Clinical Monitor will periodically contact investigators, either by written correspondence or by telephone, to assess the current status of the clinical study.

Notes from telephone conversations and copies of written correspondence between the Clinical Monitor and the investigators will be maintained in the study file. Periodic visits to clinical sites may also be required to assure that the facilities and personnel being used continue to be acceptable; the clinical protocol terms are being followed, and accurate, complete, and current records are being maintained and submitted to Mentor on a timely basis.

12.1.4 Final on-site visit (Study Completion). The Clinical Monitor will visit each investigator at the end of the 10 year follow-up period for all implanted patients. The purpose of this visit will be to discuss the study ending with the investigator and complete closeout activities.

A final review of study records will be completed to ensure the presence of all relevant documents maintained by the investigator, including IRB approvals, informed consent (original and revisions), protocol, correspondence, monitoring logs, study procedure manuals, device tracking logs, medical records, correspondence, source documents and study agreements. Patient files will be reviewed to ensure all case report forms have been submitted, all data queries have been resolved and all adverse events have been reported. The investigator will be informed of requirements for records retention, follow-up procedures and IRB notification of study closure. The Clinical Monitor will review the inventory log and confirm the disposition of all prostheses that have been shipped to the site. If applicable, all devices and device-related equipment should be returned to Mentor

13.0 MEDICAL DIRECTOR

Mentor has designated Dr. Gary Brody as Medical Director for this study:
Garry Brody, M.D.
1450 San Pablo St., Suite 2000

Los Angeles, CA. 90033
(323) 442-6462

The Medical Director is responsible for providing professional guidance to the Sponsor on matters of a clinical nature. Dr. Brody will review all serious adverse events. He will also review any clinical submissions to be sent to FDA, such as Annual Reports. Dr. Brody will be available throughout this study to provide clinical expertise to the investigators participating in this study.

In addition to Dr. Brody, other qualified individuals may be consulted as necessary. For example, Rebecca Anderson, Ph.D. will provide guidance on effectiveness endpoints, relating to Quality of Life questionnaires, and Dr. David Gorczyca has developed the MRI substudy protocol and was the initial MRI masked reviewer. Nanette DeBruhl is the current MRI masked reviewer

Rebecca Anderson, Ph.D.
Medical College of Wisconsin
Clinics of Froedtert
9200 West Wisconsin Avenue
Milwaukee, Wisconsin 53226
(414) 454-5464

David Gorczyca, MD
9037 Eagle Hills Drive
Las Vegas, NV 89134
(702) 731-8060

Nanette DeBruhl, MD
Dept. of Radiological Sciences
200 UCLA Medical Plaza
Room 165-53
Los Angeles, CA 90095
(310) 794-1352

14.0 ADVERSE EVENTS

An adverse event is defined as any undesirable clinical occurrence in a subject whether it is considered to be device related or not (Clinical Investigation of Medical Devices for Human Subjects - EN 540:1993). During the procedure and at each follow-up visit, the investigator will record all adverse events, device related or non-device related, on the **Adverse Event Report** form.

Adverse events associated with breast implants and the surgical procedure include, but are not limited to, Baker III or Baker IV capsular contracture, hematoma, seroma, delayed wound healing, necrosis, breast pain, new diagnosis of breast cancer, lactation difficulties, ptosis, irritation/inflammation, asymmetry, hypertrophic scarring, lymphadenopathy, extrusion, wrinkling, calcification, nipple/breast sensitivity change, silicone granuloma, fluid accumulation, infection and any secondary surgical procedures.

Implant change due to cosmetic dissatisfaction is considered an adverse event. Staged reconstruction, nipple tattooing or nipple reconstruction are not considered adverse events and will be recorded on the Secondary Procedures Report.

15.0 SERIOUS UNANTICIPATED ADVERSE DEVICE EFFECTS

Serious, unanticipated adverse events, are defined as any adverse occurrence, side effect, injury, toxicity, or sensitivity reaction that reasonably suggests adverse events from the implant which involve death, life threatening conditions or permanent impairment of body function which have not been addressed in the product literature or which has been addressed, but is occurring with unexpected severity or frequency. These include rheumatologic conditions.

Any unanticipated adverse event associated with the device or procedure which occur during the clinical study must be reported to the Mentor Clinical Monitor by telephone and the associated Adverse Event Report will be faxed to Mentor within 72 hours of report of occurrence. Information required to be reported includes the time the reaction occurred or was first observed, a complete description of the event, its severity, probable cause, the patient's condition, and any actions or treatment taken by the investigator.

An Investigator or Sponsor who determines that an unanticipated adverse device effect presents an unreasonable risk to subjects shall terminate all or a portion of investigations as soon as possible so as not to jeopardize the health of any patient.

Termination shall occur not later than 5 working days after the sponsor makes this determination and not later than 15 working days after the sponsor first receives notice of effect. Resumption of terminated studies can occur only with IRB and FDA approval.

16.0 DATA COLLECTION AND MANAGEMENT

The clinical data described in this protocol will be gathered using the specified case report forms (Attachment 10). Data will be recorded on appropriate forms for each visit. Data entry will be by double entry with cross validation of entries.

16.1 Data Validation

Discrepancies in the database will be queried and reconciled. Range checks of the continuous variables will be performed and non-valid entry errors for categorical variables will be resolved. Errors emanating from the CRF will be traced to source documentation for resolution. A random sample of records will be 100% audited for accuracy.

17.0 STATISTICAL CONSIDERATIONS

17.1 Safety Study Endpoints

Safety endpoints include point prevalence on a per patient and per device basis of the following:

- Rates of occurrence of all adverse events, including infection, seroma, capsular contracture by Baker classification, rupture, explant, and silent rupture.
- Time to occurrence of the complication.

17.2 Effectiveness Study Endpoints

Effectiveness endpoints include:

- Change in breast size measured by both bra and cup size and the chest/bust circumference. These measurements were chosen because they have proven effective as a measure of breast size change in other studies and they are universally accepted measures.
- Patient satisfaction measured by the following validated quality of life questionnaires:
 1. Rosenberg Self Esteem Scale
 2. Body Esteem Scale
 3. SF-36 Health Survey
 4. Tennessee Self Concept Scale
 5. The Manitoba Cancer Treatment and research Foundation Functional Living Index (FLIC) (cancer patients only)

The Rosenberg Self Esteem was chosen because self-esteem is an important quality of life measure particularly as it relates to body image change. Global measures of self-esteem will be obtained from the Tennessee Self-Concept Scale.

Global quality of life measures will be assessed by the use of the SF-36 Health Survey, which provides a measure of both physical and mental health. The Body Esteem Scale provides a measure of general body esteem, sexual attractiveness, weight concern, and physical condition.

17.3 Sample Size

The estimation of a sample size is usually based on either statistical estimation or hypothesis testing. Since the aim of the Core Gel Study is to estimate the rate of complication in breast implant patients, the sample size for this study will be based on the statistical estimation of a complication rate within a specified level of precision. This is accomplished by making the half-width of a confidence interval about the mean an acceptable value. Since this study is intended to estimate complication rates, the estimation process will focus on limiting the upper confidence limit.

This is accomplished by using one-sided confidence limits. One-sided 95% confidence limits will be used for these sample size determinations.

To obtain a sample size estimate, the exact binomial distribution is used, in iterative fashion, to find the sample size that provides the acceptable level of precision for the rate being estimated. The computations provided below were performed using StatXact, Version 4.01.

In the Adjunct Study, the rate of infection from reconstruction patients who returned for their one-year examination ranges between 3.7% to 4.5% depending on the subgroup chosen for evaluation. The rate for reconstruction patients who

only returned for their one-year visit was 4.5%. Assuming that the infection rate for augmentation and reconstruction patients will be similar, the 4.5% rate is chosen for the infection sample size calculations given in the table below.

Total Sample Size to Estimate the Rate of Infection within the Stated Level of Precision

Sample Size	Rate (%)	Exact One-sided Upper Confidence Limit (%)	Interval Half-Width (%)
150	4.7	8.6	3.9
175	4.6	8.1	3.5
200	4.5	7.7	3.2
250	4.4	7.2	2.8
300	4.7	7.2	2.5
350	4.6	6.9	2.3

A sample size of 350 yields an upper 95% one-sided confidence limit of 6.9 with an interval half-width of 2.3.

The current rate of capsular contracture (Baker Class III or IV) for reconstruction patients in the Adjunct Study ranges from 9.4% to 15.7% depending on the subgroup used for estimation.

As above, assuming that the rate for augmentation and reconstruction patients will be similar to that for reconstruction patients in the Adjunct study, the rate of 15.7% for reconstruction patients who had both one and three-year examinations will be used in the table below will be used to estimate the sample size for augmentation and reconstruction patient rate of capsular contracture.

Total Sample Size to Estimate the Rate of Capsular Contracture of Baker Class III or IV within the Stated Level of Precision

Sample Size	Rate(%)	Exact One-sided Upper Confidence Limit (%)	Interval Half-Width (%)
175	15.4	20.6	5.2
200	15.5	20.3	4.8
225	15.6	20.1	4.5

A sample of 225 subjects will provide an estimate of 15.7% with a precision of 4.5%.

Rupture is a long-term and somewhat rare event. The current rate of rupture for reconstruction patients in the Adjunct Study ranges from 1.2% to 2.0% depending on the subgroup used for estimation with one to two years of implant experience. For the purposes of this sample size evaluation, the 2.0% value from reconstruction patients who had both one and three-year examinations will be used in table below.

Total Sample Size to Estimate the Rate of Rupture within the Stated Level of Precision

Sample	Rate (%)	Exact One-sided Upper	Interval Half-
---------------	-----------------	------------------------------	-----------------------

Size		Confidence Limit (%)	Width (%)
400	2.0	3.6	1.6
450	2.0	3.5	1.5
500	2.0	3.4	1.4
550	2.0	3.3	1.3
600	2.0	3.2	1.2
650	2.0	3.2	1.2
700	2.0	3.1	1.1
750	2.0	3.1	1.1
800	2.0	3.0	1.0

A sample of 800 patients will provide an estimate of a 2% rupture rate with a precision of 1.0. This sample size and precision is consistent with that discussed in the January 11, 1996 draft guidance for breast implant manufacturers. Thus a sample size of 800 patients, followed for two years, will be used in the Core Gel Study. Assuming that the withdrawal rate will be 20% or less, the total number of patients to be enrolled into the study is $800/0.8=1000$ of which at least 25% will be primary reconstruction patients. The estimate of the point prevalence of infection with 800 or more patients at two years will be 4.8% with an upper one-sided 95% confidence limit of 6.2% (precision of 1.6%). Further, the estimate of the point prevalence of capsular contracture of Baker Class III or IV is 15.8% with an upper limit of 18.0% (precision of 2.2%).

The rate of silent rupture has been reported to be between 5.0% to 10.0%. The sample size calculations given in the table below provide estimates of sample size for three rates, 5.0%, 7.5%, and 10.0%. Based on estimates of rupture incidence in FDA sponsored trials, a rate of 5% was chosen.⁴⁸

Total Sample Size to Estimate the Rate of Silent Rupture within the Stated Level of Precision

Sample Size	Rate(%)	Exact One-sided Upper Confidence Limit (%)	Interval Half-Width (%)
250	5.2	8.1	2.9
300	5.0	7.6	2.6
324	4.9	7.4	2.5
175	7.4	11.6	4.2
200	7.5	11.3	3.8
210	7.6	11.3	3.7
100	10.0	16.4	6.4
125	10.4	16.0	5.6
150	10.0	15.0	5.0

If the silent rupture rate is 5%, at 2 years, then a sample size of 324 yields an estimate of 4.9% with an upper 95% one-sided confidence limit of 7.4 and an interval half-width of 2.5%. If the silent rupture rate is 7.5%, then a sample of 210 subjects produces an estimate of 7.6% with an upper 95% one-sided confidence limit of 11.3 and an interval half-width of 3.7.

If the silent rupture rate were 10%, then a sample of 150 patients would yield a rate of 10% with a 95% one-sided upper confidence limit of 15% and an interval

half-width of 5%. To be conservative a rate of 5% was chosen by Mentor, resulting in an MRI sample size of 324. To assure a sample size of 324 at two-years, $324/0.8=405$ patients must be enrolled in the MRI substudy.

The recent October 1999 draft guidance from FDA indicated that follow-up for ten years should be considered in the sample size computations. The draft guidance provides an example of the follow-up of 500 patients though ten years with about 25% from reconstruction and a possible lost-to-follow-up rate of 40%. The sample size obtained in the Core Gel study using the same assumptions is 600 subjects at ten years and would yield the following estimates and one-sided upper 95% limits of the rate of rupture.

Estimates and Rate of Rupture within the Stated Level of Precision for 600 Subjects Followed for Ten Years

Sample Size	Rate(%)	Exact One-sided Upper Confidence Limit (%)	Interval Half-Width (%)
600	50.0	53.4	3.4
600	40.0	43.4	3.4
600	30.0	33.2	3.2
600	25.0	28.1	3.1
600	20.0	22.9	2.9
600	15.0	17.6	2.6
600	10.0	12.3	2.3
600	5.0	6.7	1.7
600	2.0	3.2	1.2

These estimates are clearly in the range of those discussed in the draft guidance and should support the rupture rates at ten years.

The distribution recommended at ten years in the draft guidance is about 25% reconstruction and 75% augmentation. This relative ratio may not be possible to achieve at ten years. While a minimum of 25% of the patients are reconstruction patients at the start of the study, the agency should clearly understand that these are cancer patients whose survival to ten years may be severely compromised.

It is unlikely that the survival of these patients will be similar to that of an otherwise healthy augmentation population. Even with no loss to follow-up, a proportion of the reconstruction group will have only a 50% five-year survival. Even in the most favorable circumstances, the five-year survival is likely to be around 90%. It is unlikely that any sponsor can meet this suggested target.

17.4 Statistical Analysis

The appropriate statistic for demographic and prognostic variables gathered at baseline will be estimated with associated 95% confidence intervals. A statistical justification for pooling across study sites will be done. Deviations will be noted and those variables found to be dissimilar between the two groups will be considered covariates in further analyses.

For continuous variables such as patient age, the analysis will be done by a two-sample t-test or a Wilcoxon signed rank test. For categorical variables such as nodal status, Fisher's exact test will be used.

17.4.1 Safety Analysis

The statistical analysis of this open label single arm trial of silicone gel-filled breast implants is consistent with the draft FDA "Points to Consider" document of August 1999. For all adverse events observed in this Core Gel Study the time to occurrence and time-weighted rate of freedom from complication will be analyzed by Kaplan-Meier survival analysis. Further, the time relationship of the complication will be modeled with Cox regression to examine risk factors for adverse events. The non-cumulative point prevalence and incidence per patient and per device will be calculated with associated exact 95% confidence intervals. If the same complication occurs in a patient on more than one follow-up visit and it is determined to be a new complication, that patient will be counted as having two adverse events of the same type.

17.4.2 Effectiveness Analysis

The breast size and chest/bust circumference will be compared at each follow-up examination to that at baseline. For the continuous measures, a paired t-test will be used for this analysis.

The psychometric variables will be analyzed consistent with the validation methods of the instrument. Since these measures are at least ordinal, repeated measures analysis of variance (paired t-test for only two time periods) will be used to compare the results of post-procedure follow-up examination results with that of baseline.

18.0 INVESTIGATOR SELECTION AND TRAINING

Each physician participating as an investigator in the clinical evaluation of the Mentor Round Low-Bleed Silicone Gel-filled Mammary Prosthesis must submit a copy of his/her medical license; a curriculum vitae for review by Mentor Clinical Programs; and sign an Investigator's Agreement (Attachment 7) stating his/her commitment to the terms of the agreement.

The CV should include the following information:

- Education (schools, dates, and degrees)
- Postgraduate training (institutions, dates, and nature of training)
- Teaching or research experience (institutions, dates and brief descriptions)
- Medical and professional experience (institutional affiliation, dates, and nature of practice)
- Pertinent publications (journals, titles, and identifying references)

Investigators selected for this clinical trial will be Board Certified in Plastic Surgery and have a current, unrestricted medical license. Investigators will be required to provide documentation of the number of gel breast implants and replacement implants they have performed. Investigators will be required to provide evidence that office operating rooms are accredited by the American Association of Accreditation of Ambulatory Surgical Facilities or other agency.

Hospital operating rooms and outpatient surgery centers will be required to have accreditation as well.

Prior to enrolling patients in the study, each investigator must review the training materials provided by Mentor. Each investigator will be given an Investigator's Manual with copies of training materials arranged for reference and subsequent review. Also provided will be the telephone number(s) and address of the Medical Director, and the telephone number(s) and address to be used for reporting serious adverse events to Mentor.

19.0 INSTITUTIONAL REVIEW BOARD APPROVAL

Each site will have a designated principal investigator with co-investigators within the same practice. For each site, the principal investigator must secure Institutional Review Board (IRB) approval from each hospital or medical facility where the clinical study will be conducted.

This approval will cover all physicians designated as co-investigators within that practice. A copy of such written approval must be forwarded to Mentor before any prostheses can be shipped. As IRB approvals are received, the FDA will be notified in an IDE Supplement and the investigation at those centers can then be initiated.

An independent IRB may be used by those facilities that do not have their own IRB, but use of such an IRB is subject to prior approval of Mentor.

20.0 INFORMED CONSENT

Written informed consent must be obtained before each patient is entered into the study. Each investigator is to discuss in detail with the patient the surgical procedure associated with breast implantation.

The investigator should clearly explain that this is an elective procedure and should discuss the potential risks and benefits associated with silicone gel breast prostheses and alternative procedures. Patients should be advised that breast implants should not be considered lifetime implants due to the inherent nature of silicone implants, implant procedures, and potential physiological reactions.

The Patient Informed Consent must be signed before a patient can be enrolled in the study. A copy of this document appears in Attachment 3.

21.0 CONFIDENTIALITY

The identity of patients enrolled in the study and the information contained in their study records will be kept confidential by Mentor. As part of the investigator training session, investigators will be instructed in the importance of confidentiality and the techniques for protecting patients' privacy and rights.

Each patient will be assigned a study identification number to be used on study Case Report Forms (CRFs). The first three digits will correspond to the unique site number, and the last three will correspond to a patient number assigned by each investigator.

Confidentiality will be protected as much as possible throughout the study. Medical records will be reviewed by representatives of Mentor Clinical Programs and will be made available for review as required by the FDA and the IRB. Results of data collected will be reported as statistical information only. The patient's name will not be used or otherwise disclosed. If supporting documentation, such as a hospital procedure record, is requested, the site will copy it with patient identifying information concealed. Before sending these data to Mentor, the on-site clinical coordinator will enter the patient's study identification number on the top portion of each page.

Both investigators and patients will be made aware that, in unusual circumstances, the FDA or a court of law might request original patient records. In that instance, Mentor and/or the investigator would be required to comply.

22.0 INVESTIGATOR COMPLIANCE

In addition to the requirements of the protocol, investigators shall comply with all applicable state and federal laws, rules, and regulations. An investigator may be disqualified from participation in the study for failing to do so or for failing to comply with any of the requirements of this protocol. The procedure for disqualification will include suspension with time to correct deficiencies. Suspensions will be routinely reported to the investigator's IRB. In accordance with the Investigational Device Regulations, the FDA and the investigator's IRB will be notified if investigators are disqualified. No additional devices will be shipped to any investigator who has been disqualified or who is suspended at the time.

23.0 DATA SUBMISSION REQUIREMENTS

In order for the clinical investigation of this device to yield valid and significant data and to protect the well-being of the patients, careful and detailed record keeping is required by each investigator. To facilitate record-keeping, standard case report forms (CRFs) will be used. (See Attachment 10). They will be described in detail at the investigators training session as well as in written instructions to be distributed at that time. Each page of the CRFs will be NCR (no carbon required), allowing an original copy to remain at the site, while another original is sent to Mentor for data entry. A telephone number at Mentor will be available to investigators where they may call with questions about the study or the reporting forms as well as to report adverse events.

Inventory Control Log: The log will be located in the Investigator Notebook. During the study the investigator will record on the log the patient number for each unit used; if units are for any reason not used but removed from their packages, the investigator will also note that information, including the reason for wasted units. At the conclusion of the study, the Clinical Monitor will verify the number of used units against the inventory control log. The investigator will also retain the packing slips from each shipment.

Baseline: The Baseline CRF will include eligibility criteria, patient demographics, and physical examination results including vital signs and weight. A complete medical history will be obtained prior to the procedure, and the Rheumatic Disease Diagnosis Questionnaire will be completed. Breast measurements will be recorded and breast history will be record. Quality of Life Questionnaires will be administered.

Operative Record: This record will be filled out at the time the prosthesis is implanted and for any resurgery; it will include the date of the procedure, the size of the prosthesis, type of prosthesis, and the type of anesthesia used.

Secondary Procedures Record and Reimplantation Record: In the event of explantation, revision, or other reoperative procedure, the hospital operative report will be submitted with a Secondary Procedure record and a Serious Adverse Event Report. If a new prosthesis is implanted it will be recorded on the Reimplantation Record.

Follow-up Visits: At each scheduled post-operative visit, and at any unscheduled visits, the investigator will record the date and reason for the visit. If there are adverse events, they will be recorded on the Adverse Event Report. Any subsequent secondary procedures such as explantation, will be recorded on the Secondary Procedures Report and subsequent reimplantation will be recorded on the Reimplantation Report. The investigator will measure the breasts, assess nipple and breast sensitivity and capsular contracture. Quality of Life questionnaires and the Rheumatic Disease Diagnosis Questionnaire will be administered at the 1 Year, 2 Year, 4 Year, 6 Year, 8 Year and 10 Year visit.

End of Study Form: Whenever a patient leaves the study, whether voluntarily or involuntarily, reasons for discontinuation will be recorded. If possible, the

evaluations that are done at the 24-month follow up visit would be done at the time of discontinuation.

Adverse Events Report: At the time of the implant procedure, as well as at each scheduled or nonscheduled visit, any adverse events reported by the patient or observed by the investigator will be recorded on the Adverse Event Report. The duration, severity, and attribution of each event will be recorded. The investigator will also note any resulting action or treatment.

Serious, unanticipated adverse events, are defined as any adverse occurrence, side effect, injury, toxicity, or sensitivity reaction that reasonably suggests adverse events from the implant which involve death, life threatening conditions or permanent impairment of body function which have not been addressed in the product literature or which has been addressed, but is occurring with unexpected severity or frequency. These include rheumatologic conditions. Serious, unanticipated adverse events will be reported to Mentor Clinical Monitor by telephone and the Adverse Event Report will be faxed to Mentor within 72 hours of receipt of report by physician, including, if applicable, information about death and/or hospitalization. Any operative procedure will be entered on the Adverse Event Report and all device ruptures will be entered on the Adverse Event Report.

24.0 REFERENCES

3. Hetter G. "Patient Satisfaction Following Augmentation Mammoplasty with the Gel Prosthesis", *Aesthetic Plastic Surgery* 3:251-259, 1979.
4. Strom S., Baldwin B., et al: Cosmetic Saline Breast Implants: A Survey of Satisfaction, Breast –Feeding Experience, Cancer Screening, and Health", *Plastic and Reconstructive Surgery*, 100: 1553-1557, November 1997.
5. Young VL, Nemecek J, Nemecek D, "The Efficacy of Breast Augmentation: Breast Size Increase, Patient Satisfaction, and Psychological Effects", *Plastic and Reconstructive Surgery* 94:958-969, 1994.
6. Gabriel SE, Woods J, et al: "Complications Leading to Surgery after Breast Implantation", *New England Journal of Medicine* 336:677-682, 1997.
7. Englert HJ, Brooks P., "Scleroderma and Augmentation Mammoplasty: A Causal Relationship?" *Australia New Zealand Journal of Medicine* 24:74-80, 1994.
8. Gabriel SE, O'Fallon, et al: "Risk of Connective-Tissue Diseases and other Diseases after Breast Implantation", *New England Journal of Medicine* 330:1697-1702, 1994.
9. Hochberg MC, Perlmutter DL, et al: "Lack of Association Between Augmentation Mammoplasty and Systemic Sclerosis (Scleroderma)", *Arthritis Rheumatology* 39:1125-1131, 1996.
10. Burns CJ, Laing TJ, et al: "The Epidemiology of Scleroderma Among Women: Assessment of Risk from Exposure to Silicone and Silica", *Journal of Rheumatology* 23:1904-1911, 1996.
11. Goldman JA, Greenblatt R, et al: "Breast Implants, Rheumatoid Arthritis, and Connective Tissue Disease in a Clinical Practice", *Journal of Clinical Epidemiology* 48:571-582, 1995.
12. Strom BL, Reidenberg B, et al: "Breast Silicone Implants and Risk of Systemic Lupus-Erythematosus", *Journal of Clinical Epidemiology* 47:1211-1214, 1994.
13. Williams HJ, Weisman MH, Berry CC, "Breast Implants in Patients with Differentiated and Undifferentiated Connective Tissue Disease", *Arthritis & Rheumatology* 40:437-440, 1997.
14. Sanchez-Guerrero J, et al: "Silicone Breast Implants and the Risk of Connective Tissue Diseases and Symptoms", *New England Journal of Medicine* 332:1666-1670, 1995.

15. Shoaib BO, Patten BM, Calkins DS, “”Adjuvant Breast Disease: An Evaluation of 100 Symptomatic Women with Breast Implants or Silicone Fluid Injections”, *Keio Journal of Medicine* 43: 79-87, 1994.
16. Shoaib BO, Patten MB, “Human Adjuvant Disease: Presentation as a Multiple Sclerosis-Like Syndrome” *Southern Medical Journal* 89:179-188, 1996.
17. Sanger JR, Kolachalam R, et al: “Short-term Effect of Silicone Gel on Peripheral Nerves: A Histologic Study”, *Plastic and Reconstructive Surgery* 89:931-940, 1992.
18. Sanger, JR, Kolachalam R, et al: “Silicone Gel Infiltration of a Peripheral Nerve and Constrictive Neuropathy Following Rupture of a Breast Prosthesis”, *Plastic and Reconstructive Surgery* 89:949-952, 1992.
19. Rosenberg NL, “The Neuromythology of Silicone Breast Implants”, *Neurology* 46:308-314, 1996.
20. Ferguson JH, “Silicone Breast Implants and Neurologic Disorders Report of the Practice Committee of the American Academy of Neurology”, *Neurology* 48:1504-1507, 1997.
21. Deapen DM, Brody GS, “The Relationship Between Breast Cancer and Augmentation Mammoplasty: An Epidemiologic Study”, *Plastic and Reconstructive Surgery* 77:361-368, 1986.
22. Deapen DM, Brody GS, “Augmentation Mammoplasty and Breast Cancer: A Five Year Update of the Los Angeles Study”, *Plastic and Reconstructive Surgery* 89:660-665, 1992.
23. Deapen DM, Brody GS, Augmentation Mammoplasty and Breast Cancer: A Five Year Update of the Los Angeles Study”, *Journal of Clinical Epidemiology* 48:545-550, 1995.
24. Deapen DM, Brody GS, “Are Breast Implants Anticarcinogenic? A 14 Year Follow-up of the Los Angeles Study”, *Plastic and Reconstructive Surgery* 89:660-665, 1997.
25. Berkel J, Birdsell DC, Jenkins H, “Breast Augmentation: A Risk Factor for Breast Cancer?”, *New England Journal of Medicine* 326:1649-1653.
26. McLaughlin JK, Fraumeni JF et al: “Re: Breast Implants, Cancer, and Systemic Sclerosis (letter)”, *Journal of the National Cancer Institute* 86:1424, 1994.
27. McLaughlin JK, Fraumeni JF et al, “Silicone Breast Implants and Risk of Cancer (letter)”, *JAMA* 273:1116, 1995.
28. UBTL, Inc. “A Reproduction/Teratology Study in Female Sprague-Dawley Rats Following Subcutaneous Implantation with Low Bleed Shell

with Patch, Siltex Becker with Valve, RVT Smooth Shell with Diaphragm Valve and RTV Textured Shell with Mentor Leaf Valve”, Final Report. UBTL No. 66325. Prepared for Mentor Corporation. May 23, 1994.

29. Siddiqui WH, et al:”Reproductive and Developmental Toxicity Studies of Silicone Gel Q7-2159A in Rats and Rabbits”, *Fundamentals of Applied Toxicology* 23:370-376, 1994.
30. Siddiqui WH, et al, “Reproductive and Developmental Toxicity Studies of Silicone Elastomer Q7-2423/Q7-2551 in Rats and Rabbits”, *Fundamentals of Applied Toxicology* 23:377-81, 1994.
31. Levine JJ, Ilowite NT, “Scleroderma-Like Esophageal Disease in Children Breast-Fed by Mother’s with Silicone Breast Implants”, *JAMA* 271:213-216, 1994.
32. Teuber SS, Gershwin ME, “Autoantibodies and Clinical Rheumatic Complaints in Two Children of Women with Silicone Gel Breast Implants”, *Int. Arch. Allergy Immunol.* 103:105-108, 1994.
33. Lugowski S, Smith DC, et al:”Silicon Levels in Blood, Breast Milk, and Breast Capsules of Patients with Silicone Breast Implants and Controls”. Fifth World Biomaterials Congress, May 29-June 2, 1996, Toronto, Canada.
34. Rasco DS, Greene WB, “The Absence of Esophageal Lesions In Maternal progeny of Silicone-Injected Rats”, *Plastic and Reconstructive Surgery* 99:1784-1785, 1997.
35. European Committee on Quality Assurance and Medical Devices in Plastic Surgery (EQUAM). Consensus Declaration EQUAM – June 28, 1996.
36. Institute of Medicine (IOM) of the National Academy of Sciences Committee Report, “Safety of the Silicone Breast Implants, July 1999.
37. Brody G., “Safety of Breast Implants”, *Plastic and Reconstructive Surgery*, vol 100, no.5, pp:1314-1321, October 1997.
38. Hennekens C, Lee M, et. Al: “Self-Reported breast Implants and Connective Tissue Diseases in Female Health Professionals”, *JAMA* 275:616-621, 1996.
39. Schusterman M, Kroll S. et. al. “Incidence of Autoimmune Disease in Patients after Breast Reconstruction with Silicone Gel Implants versus Autogenous Tissue: A Preliminary Report”, *Ann. Plastic Surgery* 31:1-6, 1993.
40. Kern K, Flannery J, Kuehn P, “Carcinogenic Potential of Silicone Breast Implants” A Connecticut Statewide Study”, *Plast. Reconstructive Surgery* 100:737, 1997.

41. Bryant H, Brasher P, “Breast Implants and Breast Cancer – Reanalysis of a Linkage Study”, *New Eng. J. Medicine* 332:1535, 1995.
42. Brinton L, Malone K, Coates R, et. Al., “Breast Enlargement and Reduction: Results from a Breast Cancer Case-Control Study”, *Plast. Recon. Surgery* 97:269, 1996.
43. Kjoller K, McLaughlin JK, Friis S, Blot William, Mellemkjaer L, Hogsted C, Winther J, Olsen, MD, “Health Outcomes in Offspring of Mothers With Breast Implants”, *Pediatrics* 102:5, November 1998, 1112-1115.
44. Tairysh GV, Kuzbari R, Rigel S, Todoroff B, Schneider B, Deutinger M, “Normal Cutaneous Sensibility of the Breast”, *Plastic and Reconstructive Surgery* 102:3, September 1998, 701-704.
45. Slezak S, Dellon AL, “Quantitation of Sensibility in Gigantomastia and Alteration Following Reduction Mammoplasty”, *Plastic and Reconstructive Surgery* 91:7, June 1993,1265-1269.
46. Liew S, Hunt J, Pennington D, “Sensory Recovery Following Free TRAM Flap Breast Reconstruction”, *British Journal of Plastic Surgery* 49:4, 1996, 210-213.
47. Vinnik CA. Migratory silicon - clinical aspects. Silicone in Medical Devices - Conference Proceedings. 1991 February 1-2; Baltimore, MD: U.S. Department of Health and Human Services, FDA Publication No. 92-4249 (p 59-67).
- 47a. “Breast Implants: An Informational Update”, Food and Drug Administration, November 1998.
- 47b. Robinson OG, Bradley EL, Wilson DS. Analysis of explanted silicone implants: A report of 300 patients *Ann Plast Surg* 1995; 34:1-7.
48. Personal communication- S. Lori Brown, Ph.D., MPH, Research Scientist Officer, Office of Surveillance and Biometrics, CDRH, Epidemiology Branch, Rockville, Maryland 20850.

ATTACHMENT 1
STUDY VISIT SCHEDULE



**Table 1
STUDY VISIT SCHEDULE**

Data and Events to be Captured	Baseline	Operative Report ^A	Post-Operative Follow-up Visits and Forms ^H										
			6 Month (± 4 weeks)	1 Year Visit (± 6 weeks)	2 Year Visit (± 8 weeks)	3 Year Visit (± 16 weeks)	4 Year Visit (± 16 weeks)	5 Year Visit (± 16 weeks)	6 Year Visit (± 16 weeks)	7 Year Visit (± 16 weeks)	8 Year Visit (± 16 weeks)	9 Year Visit (± 16 weeks)	10 Year Visit (± 16 weeks)
Inclusion/Exclusion Criteria	X												
Patient Consent	X												
Demographics/Medical History/ Indication for Surgery/Breast History & Exam/Physical Exam	X												
Patient Registry		X											
Surgical Information		X											
Concomitant Medication	X		X	X	X	X	X	X	X	X	X	X	X
Breast Measurements	X		X	X	X	X	X	X	X	X	X	X	X
Mammography Results (if performed)	X		X	X	X	X	X	X	X	X	X	X	X
Postoperative Visit Report			X	X	X	X	X	X	X	X	X	X	X
Capsular Contracture Assessment			X	X	X	X	X	X	X	X	X	X	X
Nipple/Breast Sensitivity	X		X	X	X	X	X	X	X	X	X	X	X
Rheumatic Disease Questionnaire	X			X	X	X	X	X	X	X	X	X	X
Quality of Life Questionnaires ^C	X			X	X		X		X		X		X
Adverse Event ^G		X	X	X	X	X	X	X	X	X	X	X	X
Secondary Procedures and/or Reimplantation ^F			X	X	X	X	X	X	X	X	X	X	X
Magnetic Resonance Imaging ^{D,E}				X	X		X		X		X		X
End of Study ^B			X	X	X	X	X	X	X	X	X	X	X

^AWithin 30 days of screening

^BEnd of Study form is completed when patient completes all study visits, elects to drop, misses two consecutive visits, and/or is discontinued for other reasons

^CRosenberg Self Esteem Scale, SF-36, Tennessee Self-Concept Scale, Body Esteem Scale and Functional Living Index: Cancer (FLIC) for cancer patients

^DSubstudy of 405 randomly selected patients

^EAll patients with suspected silent rupture should be evaluated by MRI

^FDocument upon occurrence. Document all postoperative explantations, revisions, and other secondary procedures on Secondary Procedures Report. Report reimplantations on Re-Implantation Report

^GDocument upon occurrence by completing an Adverse Event Report

^HDocument any unscheduled post-operative visit on the Interim Visit form

ATTACHMENT 2
PRODUCT INSERT DATA SHEET



MENTOR MEMORYGEL™ SILICONE GEL-FILLED BREAST IMPLANTS

102872-001 Rev. C Effective November 2006

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

INTRODUCTION - DIRECTIONS TO THE PHYSICIAN

The information supplied in this physician labeling document is intended to provide an overview of essential information about Mentor's MemoryGel Silicone Gel-Filled Breast Implants, including a device description, the indications for use, contraindications, warnings, precautions, important factors to discuss with a patient, adverse events, other reported conditions, a summary of clinical study results, returned devices, product evaluation, medical device reporting, and returned goods authorization.

Patient Counseling Information

You should review this document and patient labeling prior to counseling the patient about Mentor's MemoryGel Silicone Gel-Filled Breast Implants and breast implant surgery. MemoryGel implant labeling materials are part of physician training, a requirement described below in this Introduction. Please familiarize yourself with the content of this document and resolve any questions or concerns prior to proceeding with use of the device. As with any surgical procedure, breast implantation is NOT without risks. Breast implantation is an elective procedure, and the patient must be well counseled and understand the risk/benefit relationship.

Before making the decision to proceed with surgery, the surgeon or a designated patient counselor should instruct the patient to read ***Important Information for Augmentation/Reconstruction Patients About Mentor MemoryGel™ Silicone Gel-Filled Breast Implants*** (patient labeling) and discuss with the patient the warnings, contraindications, precautions, important factors to consider, complications, Mentor Core Study results, and all other aspects of the patient labeling. The physician should advise the patient of the potential complications and that medical management of serious complications may include additional surgery and explantation.

Informed Decision

Each patient should receive Mentor's ***Important Information for Augmentation/Reconstruction Patients About Mentor MemoryGel™ Silicone Gel-***

Filled Breast Implants during her initial visit/consultation, to allow her sufficient time to read and adequately understand the important information on the risks, follow-up recommendations, and benefits associated with silicone gel-filled breast implant surgery.

Allow the patient at least 1-2 weeks after reviewing and considering this information before deciding whether to have primary breast augmentation surgery. In the case of a revision-augmentation and revision-reconstruction, it may be medically necessary to perform surgery sooner.

In order to document a successful informed decision process, the patient labeling includes an **Acknowledgment of Informed Decision** form at the end of the document, which is to be signed by both the patient and the surgeon and then retained in the patient's file.

PHYSICIAN TRAINING - Completion of Mentor's Device Access Education Course is required for all physicians in order to gain access to Mentor's MemoryGel Silicone Gel-Filled Breast Implants. The Food and Drug Administration (FDA) will allow a 90-day transition period for all current Mentor Core Study and Adjunct Study investigators, after which these physicians/surgeons must also have completed the training program in order to have access to the Mentor product. Physician certification provides documentation of training in the use of these devices. Mentor has developed an online training and certification of participation process (The Device Access Education Course) that may be accessed via MemoryGel.com, or you may obtain a DVD of the training and certification material by contacting your Mentor sales representative.

DEVICE TRACKING - Silicone gel-filled breast implants are subject to Device Tracking by Federal regulation. Your compliance with this requirement is mandatory. This means that you will be required to report to Mentor the serial number of the device(s) you implant in a patient, the date of her surgery, her social security number, her personal contact information, and information relating to your practice. This information will be recorded on a Device Tracking Form supplied by Mentor with each silicone gel-filled breast implant.

Mentor strongly recommends that all patients receiving silicone gel-filled breast implants participate in Mentor's device tracking program. This will help ensure that Mentor has a record of each patient's contact information so that patients can be contacted in the event of a recall or other problems with the implants that they should

be made aware of. If a patient declines to provide personal, identifying information, you must still provide all other non-patient specific information.

DEVICE DESCRIPTION

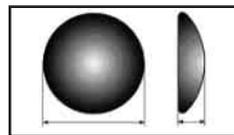
Mentor Silicone Gel-Filled Breast Implants are devices with shells constructed from silicone elastomer. The shell is filled with MemoryGel™, Mentor's proprietary formulation of silicone gel. The shell is constructed of successive cross-linked layers of silicone elastomer, which give the prosthesis its elasticity and integrity. There are two styles of shell: smooth and textured.

Prior to receiving Mentor's MemoryGel breast implants, a surgeon must complete a Device Access Education Course, which consists of 3 modules specific to these products and breast implant surgery.

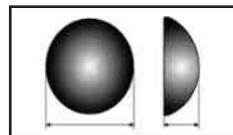
The following lists the catalog numbers and styles of Mentor MemoryGel round implants:

- 350-7100BC/7800BC: Moderate Profile, smooth shell surface
- 354-1007/8007: Moderate Profile, textured shell surface
- 350-1001BC/8001BC: Moderate Plus Profile, smooth shell surface
- 354-1001/8001: Moderate Plus Profile, textured surface
- 350-1254BC/8004BC: High Profile, smooth shell surface
- 354-4125/4800: High Profile, textured surface

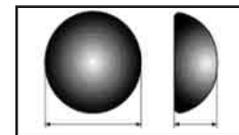
The following diagrams illustrate the Moderate, Moderate Plus, and High Profiles.



Moderate Profile



Moderate Plus Profile



High Profile

INDICATIONS

Mentor MemoryGel Silicone Gel-Filled Breast Implants are indicated for females for the following uses (procedures):

- **Breast augmentation for women at least 22 years old.** Breast augmentation includes primary breast augmentation to increase the breast size, as well as revision surgery to correct or improve the result of a primary breast augmentation surgery.
- **Breast Reconstruction.** Breast reconstruction includes primary reconstruction to replace breast tissue that has been removed due to cancer or trauma or that has failed to develop properly due to a severe breast abnormality. Breast reconstruction also includes revision surgery to correct or improve the results of a primary breast reconstruction surgery.

CONTRAINDICATIONS

Patient Groups in which the product is contraindicated:

- Women with active infection anywhere in their body.
- Women with existing cancer or pre-cancer who have not received adequate treatment for those conditions.
- Women who are currently pregnant or nursing.

WARNINGS**1. Avoiding Implant Damage During Surgery and Medical Treatment or Procedures**

Iatrogenic events inadvertently induced by a physician or surgeon, or by medical treatment or procedures, may contribute to premature implant failure.

- Do not allow sharp instruments, such as scalpels or needles, to contact the device during the implantation or other surgical procedures. Patients should be instructed to inform other treating physicians to observe this warning.
- The technique for inserting a gel device is significantly different than for a saline implant. Ensure that excessive force is not applied to a very small area of the shell during insertion of the device through the incision. Instead, apply force over as large an area of the implant as possible when inserting it. Avoid pushing the device into place with one or two fingers in a localized area, as this may create an area of weakness on the shell.
- An incision should be of appropriate length to accommodate the style, size, and profile of the implant. The incision will be longer than the one typically made for a saline breast augmentation. This will reduce the potential for creating excessive

stress to the implant during insertion. The range, mean, and mode of incision sizes used in Mentor's Core Study were as follows:

Cohort	Surgical Approach	Incision Size (cm)		
		Mean	Mode	Maximum
Augmentation	Periareolar	2.7	3.0	3.0
	Inframammary	3.2	3.0	5.0
	Axillary	3.4	3.0	5.0
	Mastectomy Scar	4.0	4.0	4.0
Revision-Augmentation	Periareolar	4.1	3.0	14.0
	Inframammary	3.4	3.0	6.0
	Axillary	4.3	4.0	0
	Mastectomy Scar	7.0	6.0, 8.0	8.0
Reconstruction	Periareolar	4.0	3.0	6.0
	Inframammary	5.4	3.0	10.0
	Mastectomy Scar	4.7	4.0	8.0
Revision-Reconstruction	Periareolar	4.0	3.0	6.0
	Inframammary	4.4	4.0	6.0
	Mastectomy Scar	6.3	7.0	9.0

- The anatomical limitations of periareolar and axillary incision sites may make insertion of the implant more difficult, increasing the risk of damage to the implant.
- Avoid creating wrinkles or folds in the device during the implantation or other procedures (e.g., revision surgery). A typical practice is to run your finger around the implant before closing to ensure the implant is lying flat and has no folds or wrinkles. Submuscular placement of the device makes the inspection for wrinkles or folds more difficult.
- Do not treat capsular contracture by closed capsulotomy or forceful external compression, which will likely result in implant damage, rupture, folds, and/or hematoma.
- Use care in subsequent procedures such as open capsulotomy, breast pocket revision, hematoma/seroma aspiration, biopsy, and lumpectomy to avoid damage to the implant shell. Re-positioning of the implant during subsequent procedures should be carefully evaluated by the medical team and care taken to avoid contamination of the implant. Use of excessive force during any subsequent procedure can contribute to localized weakening of the breast implant shell potentially leading to decreased device performance.

- Do not contact the implant with cautery devices.
- Do not immerse the implant in Betadine solution. If Betadine is used in the pocket, ensure that it is rinsed thoroughly so no residual solution remains in the pocket.
- Do not alter the implants or attempt to repair or insert a damaged implant.
- Do not re-use or resterilize any product that has been previously implanted. Breast implants are intended for single use only.
- Do not place more than one implant per breast pocket.
- Do not use the periumbilical approach to place the implant.

2. *Microwave Diathermy*

Do not use microwave diathermy in patients with breast implants, as it has been reported to cause tissue necrosis, skin erosion, and implant extrusion.

PRECAUTIONS

1. *Specific Populations*

Safety and effectiveness has not been established in patients with:

- Autoimmune diseases (e.g., lupus and scleroderma).
- A compromised immune system (e.g., currently receiving immunosuppressive therapy).
- Patients with conditions or medications which interfere with wound healing ability (e.g., poorly controlled diabetes, or corticosteroid therapy) or blood clotting (such as concurrent coumadin therapy).
- Reduced blood supply to breast or overlying tissue.
- Patients undergoing radiation therapy.
- Clinical diagnosis of depression or other mental health disorders, including body dysmorphic disorder and eating disorders. Please advise the patient to discuss any history of mental health disorders with you prior to surgery. Patients with a diagnosis of depression, or other mental health disorders, should wait until resolution or stabilization of these conditions prior to undergoing breast implantation surgery.

There may be other patients with complicated medical histories, who in the surgeon's judgment present risk factors such that breast implant safety and effectiveness have not been established. As with all surgery, you should review your patient's medical history to ensure that she is an appropriate candidate for breast implant surgery.

2. **Surgical Precautions**

- **Device integrity** – The device should be tested for patency and shell integrity immediately prior to use. This can be accomplished by gently manipulating the prosthesis with hand and fingers, while carefully examining for rupture or leakage sites.
- **Surgical technique** – The implantation of silicone gel-filled breast implants involves a variety of surgical techniques. Therefore, the surgeon is advised to use the method which her/his own practice and discretion dictate to be best for the patient, consistent with this product insert data sheet. It is advisable to have more than one size breast implant in the operating room at the time of surgery to allow for flexibility in determining the appropriate size implant to be used. A backup implant should also be available.

- **Implant Selection**

Some of the important surgical and implant sizing variables that have been identified include the following:

- > The implant should be consistent in size with the patient's chest wall dimensions, including base width measurements, bearing in mind the laxity of the tissue and the projection of the implant.
 - > A thorough discussion should be conducted with the patient, employing appropriate visual aids such as imaging, sizing implants, or other options to clarify their objectives and reduce the incidence of reoperation for size change.
 - > The following may cause implants to be more palpable: textured implants, larger implants, subglandular placement, and an insufficient amount of skin/tissue available to cover the implant.
 - > Available tissue must provide adequate coverage of the implant.
 - > A recent report indicates that larger sized implants (>350cc) may increase the risk of developing complications such as implant extrusion, hematoma, infection, palpable implant folds, and visible skin wrinkling requiring surgical intervention to correct these complications.¹
- **Incision Site Selection**
- > The periareolar site is typically more concealed, but it is associated with a higher likelihood of difficulties in successfully breast feeding as compared to other incision sites.² A periareolar incision may result in changes in nipple sensation.
 - > The inframammary incision is generally less concealed than the periareolar, but it is associated with less breast feeding difficulty than the periareolar incision site.³
 - > The axillary incision is less concealed than the periareolar site.

- > The periumbilical approach has not been studied in Mentor's Core Study and should not be used for a wide variety of reasons, including potential damage to the implant shell.
- **Implant Placement Selection**
 - > A well-defined, dry pocket of adequate size and symmetry must be created to allow the implant to be placed flat on a smooth surface.
 - > Submuscular placement may make surgery last longer, may make recovery longer, may be more painful, and may make it more difficult to perform some reoperation procedures than subglandular placement. The possible benefits of this placement are that it may result in less palpable implants, less likelihood of capsular contracture,⁴ and easier imaging of the breast for mammography. Also, submuscular placement may be preferable if the patient has thin or weakened breast tissue.
 - > Subglandular placement may make surgery and recovery shorter, may be less painful, and may be easier to access for reoperation than the submuscular placement. However, this placement may result in more palpable implants, greater likelihood of capsular contracture,^{5,6} and increased difficulty in imaging the breast with mammography.
- **Maintaining Hemostasis/Avoiding Fluid Accumulation**
 - > Careful hemostasis is important to prevent postoperative hematoma formation. Should excessive bleeding persist, implantation of the device should be delayed until bleeding is controlled. Postoperative evacuation of hematoma or seroma must be conducted with care to avoid breast implant contamination, or damage from sharp instruments, retraction, or needles.
- **Recording Procedure**
 - > Each breast implant is supplied with two Patient Record Labels showing the catalog number and lot number for that device. Patient Record Labels are located on the internal product packaging attached to the label. To complete the Patient ID Card, adhere one Patient Record Label for each implant on the back of the Patient ID Card. The other label should be affixed to the patient's chart. The implanted position (left or right side) should be indicated on the label. If a Patient Record Label is unavailable, the lot number, catalog number, and description of the device may be copied by hand from the device label. The patient should be provided with the Patient ID Card for personal reference.

- **Postoperative Care**

- > You should advise your patient that she will likely feel tired and sore for several days following the operation, and that her breasts may remain swollen and sensitive to physical contact for a month or longer. You should also advise her that she may experience a feeling of tightness in the breast area as her skin adjusts to her new breast size. For at least a couple of weeks, the patient should avoid any strenuous activities that could raise her pulse and blood pressure. She should be able to return to work within a few days. Breast massage exercises may also be recommended as appropriate.

INFORMATION FACTORS TO BE DISCUSSED WITH PATIENTS AS PART OF PHYSICIAN CONSULTATION

Breast implantation is an elective procedure and the patient must be thoroughly counseled on the risks, as well as the benefits, of these products and procedures. You should advise your patient that she must read the patient brochures for either augmentation or reconstruction, as applicable. You must read the patient brochures in their entirety. The brochures are intended as the primary means to relate uniform risk and benefit information to assist your patient in making an informed decision about primary breast augmentation and revision-augmentation, or primary reconstruction and revision-reconstruction surgery (as applicable), but are not intended to replace consultation with you. The patient should be advised to wait at least 1-2 weeks after reviewing and considering this information, before deciding whether to have this surgery, unless an earlier surgery is deemed medically necessary.

Both you and your patient will be required to sign the “Acknowledgement of Informed Decision” form prior to surgery. The form can be found on the last page of each brochure. The form, once signed, acknowledges the patient’s full understanding of the information provided in the brochure. The form should be retained in the patient’s permanent clinical record.

Below are some of the important factors your patients need to be aware of when using silicone gel-filled breast implants. Section 1.4 of the patient brochures provides a more detailed listing of important factors for patients.

- **Rupture** – Rupture of a silicone gel-filled breast implant is most often silent (i.e., there are no symptoms experienced by the patient and no physical sign of changes with the implant) rather than symptomatic. The sensitivity of plastic surgeons familiar with implants to diagnose rupture is 30%⁷ compared to 89% for MRI.⁸ **Therefore, you**

should advise your patient that she will need to have regular MRIs over her lifetime to screen for silent rupture even if she is having no problems. The first MRI should be performed at 3 years postoperatively, then every 2 years, thereafter. The

importance of these MRI evaluations should be emphasized. If rupture is noted on MRI, then you should advise your patient to have her implant removed. You should provide her with a list of MRI facilities in her area that have at least a 1.5 Tesla magnet, a dedicated breast coil, and a radiologist experienced with breast implant MRI films for signs of rupture. Diagnostic procedures will add to the cost of having breast implants, and patients should be told that these costs may exceed the cost of their initial surgery over their lifetime and that these costs may not be covered by their insurance carrier.

- **Explantation** – Implants are not considered lifetime devices, and patients likely will undergo implant removal(s), with or without replacement, over the course of their life. When implants are explanted without replacement, changes to the patient's breasts may be irreversible. Complication rates are higher following revision surgery (removal with replacement).
- **Reoperation** – Additional surgeries to the patients' breasts and/or implants will likely be required, either because of rupture, other complications, or unacceptable cosmetic outcomes. Patients should be advised that their risk of future complications increases with revision surgery as compared to primary augmentation or reconstruction surgery. There is a risk that implant shell integrity could be compromised inadvertently during reoperation surgery, potentially leading to product failure
- **Infection** – Signs of acute infection reported in association with breast implants include erythema, tenderness, fluid accumulation, pain, and fever. In rare instances, as with other invasive surgeries, Toxic Shock Syndrome (TSS) has been noted in women after breast implant surgery, and it is a life-threatening condition. Symptoms of TSS occur suddenly: a high fever (102°F, 38.8°C or higher), vomiting, diarrhea, a sunburn-like rash, red eyes, dizziness, lightheadedness, muscle aches and drops in blood pressure which may cause fainting. Patients should contact a physician immediately for diagnosis and treatment for any of these symptoms.
- **Breast Examination Techniques** – Patients should perform breast self-examinations monthly and be shown how to distinguish the implant from their breast tissue. The patient should not manipulate or squeeze the implant excessively. The patient should be told that the presence of lumps, persistent pain, swelling, hardening, or change in the implant shape may be signs of symptomatic rupture of the implant. If the patient has any of these signs, she should be told to report them, and possibly have an MRI evaluation to screen for rupture.

- **Mammography** – Patients should be instructed to undergo routine mammography exams as per their primary care physician’s recommendations. The importance of having these exams should be emphasized. Patients should be instructed to inform their mammographers about the presence, type, and placement of their implants. Patients should request a diagnostic mammography, rather than a screening mammography, because more pictures are taken with diagnostic mammography. Breast implants may complicate the interpretation of mammographic images by obscuring underlying breast tissue and/or by compressing overlying tissue. Accredited mammography centers, technicians with experience in imaging patients with breast implants, and use of displacement techniques are needed to adequately visualize breast tissue in the implanted breast. The current recommendations for preoperative/screening mammograms are no different for women with breast implants than for those women without implants. Presurgical mammography with a mammogram following the procedure may be performed to establish a baseline for routine future mammography in augmentation patients.
- **Lactation** – Breast implant surgery may interfere with the ability to successfully breast feed, either by reducing or eliminating milk production.
- **Avoiding Damage During Treatment** – Patients should inform other treating physicians of the presence of implants to minimize the risk of damage to the implants.
- **Smoking** – Smoking may interfere with the healing process.
- **Radiation to the Breast** – Mentor has not tested the *in vivo* effects of radiation therapy in patients who have breast implants. The literature suggests that radiation therapy may increase the likelihood of capsular contracture, necrosis, and implant extrusion.
- **Insurance coverage** – Patients should be advised that health insurance premiums may increase, insurance coverage may be dropped, and/or future coverage may be denied based on the presence of breast implants. Treatment of complications may not be covered as well. Patients should check with their insurance company regarding coverage issues before undergoing surgery.
- **Mental Health and Elective Surgery** – It is important that all patients seeking to undergo elective surgery have realistic expectations that focus on improvement rather than perfection. Request that your patient openly discuss with you, prior to surgery, any history that she may have of depression or other mental health disorders.
- **Long-Term Effects** - Mentor will continue its Core Study through 10 years. In addition, Mentor has undertaken a separate 10-year postapproval study to address specific issues for which the Mentor Core Study was not designed to fully answer, as well as to

provide a real-world assessment of some endpoints. The endpoints in the large postapproval study include long-term local complications, connective tissue disease (CTD), CTD signs and symptoms, neurological disease, neurological signs and symptoms, offspring issues, reproductive issues, lactation issues, cancer, suicide, mammography issues, and MRI compliance and results. Mentor will update its labeling as appropriate with the results of its Mentor Core Study and separate postapproval study. It is also important for you to relay any new safety information to your patients as it becomes available.

ADVERSE EVENTS

Potential adverse events that may occur with silicone gel-filled breast implant surgery include: implant rupture, capsular contracture, reoperation, implant removal, pain, changes in nipple and breast sensation, infection, scarring, asymmetry, wrinkling, implant displacement/migration, implant palpability/visibility, breast feeding complications, hematoma/seroma, implant extrusion, necrosis, delayed wound healing, breast tissue atrophy/chest wall deformity, calcium deposits, and lymphadenopathy.

Below is a description of these adverse events. For specific adverse event rates/outcomes for Mentor implants, refer to the Mentor Core Study section below.

• Rupture

Breast implants are not lifetime devices. Breast implants rupture when the shell develops a tear or hole. Rupture can occur at any time after implantation, but they are more likely to occur the longer the implant is implanted. The following things may cause implants to rupture: damage by surgical instruments; stressing the implant during implantation and weakening it; folding or wrinkling of the implant shell; excessive force to the chest (e.g., during closed capsulotomy, which is contraindicated); trauma; compression during mammographic imaging; and severe capsular contracture. Breast implants may also simply wear out over time. Laboratory studies have identified some of the types of rupture for Mentor's product; however, it is not conclusively known whether these tests have identified all causes of rupture. These laboratory studies will continue postapproval.

Silicone gel-filled implant ruptures are most often silent. (MRI examination is currently the best method to screen for silent rupture.) This means that most of the time neither you nor your patient will know if the implant has a tear or hole in the shell. This is why MRI is recommended at 3 years and then every 2 years, thereafter, to screen for rupture. Sometimes there are symptoms associated with gel implant rupture. These symptoms

include hard knots or lumps surrounding the implant or in the armpit, change or loss of size or shape of the breast or implant, pain, tingling, swelling, numbness, burning, or hardening of the breast.

When MRI findings of rupture are found (such as subcapsular lines, characteristic folded wavy lines, teardrop sign, keyhole sign, noose sign), or if there are signs or symptoms of rupture, you should remove the implant and any gel you determine your patient has, with or without replacement of the implant. It also may be necessary to remove the tissue capsule, as well as the implant, which will involve additional surgery, with associated costs. If your patient has symptoms, such as breast hardness, a change in breast shape or size, and/or breast pain, you should recommend that she has an MRI to determine whether rupture is present.^{9,10}

There are also consequences of rupture. If rupture occurs, silicone gel may either remain within the scar tissue capsule surrounding the implant (intracapsular rupture), move outside the capsule (extracapsular rupture), or gel may move beyond the breast (migrated gel). There is also a possibility that rupture may progress from intracapsular to extracapsular and beyond. There have also been health consequences reported in the literature. See below for details.

Rupture Information on Mentor Implants

In Mentor's Core Study, rupture was assessed for patients who had scheduled MRIs to screen for silent rupture (i.e., part of the MRI cohort) and those who were not assessed for rupture by MRI (i.e., part of the non-MRI cohort). Mentor's Core Study included rupture rate data from the non-MRI cohort at years 1, 2, and 3 and from the MRI cohort at years 1 and 2. All reported ruptures were from patients in the MRI cohort. The rupture rates were 0.5% for primary augmentation, 7.7% for revision-augmentation, 0.9% for primary reconstruction, and 0% for revision-reconstruction. There were 8 ruptured/suspected ruptured implants in 6 patients through 3 years. Only 2 of the implants were explanted and confirmed to be ruptured; the other implants remain as suspected rupture based on MRI evaluation. Of these 8 implants, 4 showed intracapsular gel and 4 showed extracapsular gel on MRI (3 implants with extracapsular gel were in 2 revision-augmentation patients and 1 was in a primary reconstruction patients). For one of these implants with extracapsular gel, this was a confirmed case in which the device was explanted and the intracapsular gel rupture progressed into an extracapsular gel rupture as shown by MRIs at approximately 10 months and approximately 2 years. There were no cases of migrated gel.

Further rupture rate information on Mentor implants is provided from an unpublished European study known as the U.K. Sharpe and Collis Study. Silent rupture was assessed by a single MRI on 101 augmentation patients implanted with textured Mentor implants by one surgeon. The average age of the implants was approximately 9 years. Silent rupture was found in approximately 10% of these augmentation patients, which includes one patient for which the device was not explanted to confirm rupture. There were no cases of extracapsular rupture or migrated gel.

Additional information on rupture will be collected through Mentor's postapproval Core Study and large postapproval study.

Additional Information on Consequences of Rupture from Literature

Studies of Danish women evaluated with MRI involving a variety of manufacturers and implant models showed that about three-fourths of implant ruptures are intracapsular and the remaining one-fourth is extracapsular.¹¹ Additional studies of Danish women indicate that over a 2-year period, about 10% of the implants with intracapsular rupture progressed to extracapsular rupture as detected by MRI.¹² Approximately half of the women whose ruptures had progressed from intracapsular to extracapsular reported that they experienced trauma to the affected breast during this time period or had undergone mammography. In the other half, no cause was given. In the women with extracapsular rupture, after 2 years, the amount of silicone seepage outside the scar tissue capsule increased for about 14% of these women. This type of information pertains to a variety of silicone implants from a variety of manufacturers and implant models, and is not specific to Mentor's implants.

Below is a summary of information related to the health consequences of implant rupture, which have not been fully established. These reports were in women who had implants from a variety of manufacturers and implant models.

- Local breast complications reported in the published literature that were associated with rupture include breast hardness, a change in breast shape or size, and breast pain.¹³ These symptoms are not specific to rupture, as they also are experienced by women who have capsular contracture.
- There have been rare reports of gel movement to nearby tissues such as the chest wall, armpit, or upper abdominal wall, and to more distant locations down the arm or into the groin. This has led to nerve damage, granuloma formation and/or breakdown of tissues in direct contact with the gel in a few cases. There have been reports of silicone presence in the liver of patients with silicone breast implants. Movement of silicone gel material to lymph nodes in the axilla also has been reported, even in women without

evidence of rupture, leading to lymphadenopathy, as discussed below¹⁴

- Concerns have been raised over whether ruptured implants are associated with the development of connective tissue or rheumatic diseases and/or symptoms such as fatigue and fibromyalgia.^{15,16,17,18} A number of epidemiology studies have evaluated large populations of women with breast implants from a variety of manufacturers and implant models. These studies do not, taken together, support an association of breast implants and a diagnosed rheumatic disease. Other than one small study¹⁹, these studies do not distinguish whether the women had ruptured or intact implants.

- **Capsular Contracture**

The scar tissue (capsule) that normally forms around the implant may tighten over time and compress the implant, making it feel firm and leading to what is called capsular contracture. Capsular contracture may be more common following infection, hematoma, and seroma, and the chance of it happening may increase over time. Capsular contracture occurs more commonly in patients undergoing revision surgery than in patients undergoing primary implantation surgery. Capsular contracture is a risk factor for implant rupture, and it is the most common reason for reoperation in augmentation and reconstruction patients.

Symptoms of capsular contracture range from mild firmness and mild discomfort to severe pain, distorted shape of the implant, and palpability (ability to feel the implant). Capsular contracture is graded into 4 levels depending on its severity. Baker Grades III or IV are considered severe and often additional surgery is needed to correct these grades:

Baker Grade I:	the breast is normally soft and looks natural
Baker Grade II:	the breast is a little firm but looks normal
Baker Grade III:	the breast is firm and looks abnormal
Baker Grade IV:	the breast is hard, painful, and looks abnormal

In Mentor's Core Study, the risk of capsular contracture Baker Grade III/IV through 3 years was 8.1% for primary augmentation, 18.9% for revision-augmentation, 8.3% for primary reconstruction, and 16.3% for revision-reconstruction.

Patients should also be advised that additional surgery may be needed in cases where pain and/or firmness are severe. This surgery ranges from removal of the implant capsule tissue, to removal and possible replacement of the implant itself. This surgery may result in loss of breast tissue. Capsular contracture may happen again after these additional surgeries. Capsular contracture may increase the risk of rupture.²⁰

- **Reoperation**

The patient should assume that she will need to have additional surgeries (reoperations). Patients may decide to change the size or type of their implants, requiring a reoperation, or they may have a reoperation to improve or correct their outcome. In Mentor's Core Study, the risk rate of reoperation at least one time through 3 years was 15.4% for primary augmentation, 28.0% for revision-augmentation, 27.0% for primary reconstruction, and 29.1% for revision-reconstruction. Problems, such as, but not limited to, rupture, capsular contracture, hypertrophic scarring (irregular, raised scar), asymmetry, infection, and shifting can require additional surgery. Summary tables are provided in the Mentor Core Study section that describes the reasons for reoperation during the first 3 years after receiving the implants.

- **Implant Removal**

For women receiving primary augmentation implants in Mentor's Core Study, 4.7% had their implants removed at least once through 3 years. Patient choice and severe capsular contracture were the most common reasons for implant removal. For women receiving revision-augmentation implants in Mentor's Core Study, 12.3% had their implants removed at least once through 3 years. The most common reasons were patient choice and severe capsular contracture.

For women receiving primary reconstruction implants in Mentor's Core Study, 12.4% had their implants removed at least once through 3 years. Patient choice and asymmetry were the most common reasons for implant removal. For women receiving revision-reconstruction implants in Mentor's Core Study, 13.6% had their implants removed at least once through 3 years. The most common reason was asymmetry.

Most women who have their implants removed, have them replaced with new implants, but some women do not. If patients choose not to replace their implants, they should be advised that they may have cosmetically unacceptable dimpling, puckering, wrinkling, and/or other potentially permanent cosmetic changes of the breast following removal of the implant. Even if a patient has her implants replaced, implant removal may result in loss of breast tissue. Also, implant replacement increases a patient's risk of future complications. For example, the risks of severe capsular contracture double for both augmentation and reconstruction patients with implant replacement compared to first time placement. Patients should consider the possibility of having their implants replaced and its consequences when making their decision to have implants.

- **Pain**

Pain of varying intensity and length of time may occur and persist following breast implant surgery. In addition, improper size, placement, surgical technique, or capsular contracture may result in pain. The surgeon should instruct his or her patient to inform them if there is significant pain or if pain persists.

- **Changes in Nipple and Breast Sensation**

Feeling in the nipple and breast can increase or decrease after implant surgery, and are typically lost after complete mastectomy where the nipple itself is removed, and can be severely lessened by partial mastectomy. Radiation therapy also can significantly reduce sensation in the remaining portions of the breast or chest wall. The placement of breast implants for reconstruction may further lessen the sensation in the remaining skin or breast tissue. The range of changes varies from intense sensitivity to no feeling in the nipple or breast following surgery. While some of these changes can be temporary, they can also be permanent, and may affect the patient's sexual response or ability to nurse.

- **Infection**

Infection can occur with any surgery or implant. Most infections resulting from surgery appear within a few days to weeks after the operation. However, infection is possible at any time after surgery. In addition, breast and nipple piercing procedures may increase the possibility of infection. Infections in tissue with an implant present are harder to treat than infections in tissue without an implant. If an infection does not respond to antibiotics, the implant may have to be removed, and another implant may be placed after the infection is resolved. As with many other surgical procedures, in rare instances, toxic shock syndrome has been noted in women after breast implant surgery, and it is a life-threatening condition. Symptoms include sudden fever, vomiting, diarrhea, fainting, dizziness, and/or sunburn-like rash. Patients should be instructed to contact a doctor immediately for diagnosis and treatment if they have these symptoms.

- **Hematoma/Seroma**

Hematoma is a collection of blood within the space around the implant, and a seroma is a build-up of fluid around the implant. Having a hematoma and/or seroma following surgery may result in infection and/or capsular contracture later on. Symptoms from a hematoma or seroma may include swelling, pain, and bruising. If a hematoma or seroma occurs, it will usually be soon after surgery. However, this can also occur at any time after injury to the breast. While the body absorbs small hematomas and seromas, some will require surgery, typically involving draining and potentially placing a surgical drain in the wound temporarily for proper healing. A small scar can result from surgical draining.

Implant rupture also can occur from surgical draining if there is damage to the implant during the draining procedure.

- **Unsatisfactory Results**

Unsatisfactory results such as wrinkling, asymmetry, implant displacement/migration, incorrect size, implant palpability/visibility, scar deformity, and/or hypertrophic scarring, may occur. Some of these results may cause discomfort. Pre-existing asymmetry may not be entirely correctable by implant surgery. Revision surgery may be recommended to maintain patient satisfaction, but carries additional considerations and risks. Careful preoperative planning and surgical technique can minimize but not always prevent unsatisfactory results.

- **Breast Feeding Complications**

Breast feeding difficulties have been reported following breast surgery, including breast reduction and breast augmentation. If you use a periareolar surgical approach, it may further increase the chance of breast feeding difficulties.

- **Calcium Deposits in the Tissue Around the Implant**

Calcium deposits can form in the tissue capsule surrounding the implant. Symptoms may include pain and firmness. Deposits of calcium can be seen on mammograms and can be mistaken for possible cancer, resulting in additional surgery for biopsy and/or removal of the implant to distinguish calcium deposits from cancer. If additional surgery is necessary to examine and/or remove calcifications, this may cause damage to the implants. Calcium deposits also occur in women who undergo breast reduction procedures, in patients who have had hematoma formation, and even in the breasts of women who have not undergone any breast surgery. The occurrence of calcium deposits increases significantly with age.

- **Extrusion**

Extrusion may occur when the wound has not closed or when breast tissue covering the implants weakens. Radiation therapy has been reported to increase the likelihood of extrusion. Extrusion requires additional surgery and possible removal of the implant, which may result in additional scarring and/or loss of breast tissue.

- **Necrosis**

Necrosis may prevent or delay wound healing and require surgical correction, which may result in additional scarring and/or loss of breast tissue. Implant removal may also be necessary. Factors associated with increased necrosis include infection, use of steroids, smoking, chemotherapy, radiation, and excessive heat or cold therapy.

- **Delayed Wound Healing**

Some patients may experience a prolonged wound healing time. Smoking may interfere with the healing process. Delayed wound healing may increase the risk of infection, extrusion, and necrosis. Depending on the type of surgery or the incision, wound healing times may vary.

- **Breast Tissue Atrophy/Chest Wall Deformity**

The pressure of the breast implant may cause breast tissue thinning (with increased implant visibility and palpability) and chest wall deformity. This can occur while implants are still in place or following implant removal without replacement. Either of these conditions may result in additional surgeries and/or unacceptable dimpling/puckering of the breast.

- **Lymphadenopathy**

Literature reports associate lymphadenopathy with both intact and ruptured silicone breast implants. One study reported that armpit lymph nodes from women with both intact and ruptured silicone gel implants had abnormal tissue reactions, granulomas, and the presence of silicone.²¹ These reports were in women who had implants from a variety of manufacturers and implant models.

Other Reported Conditions

There have been reports in the literature of other conditions in women with silicone gel-filled breast implants. Many of these conditions have been studied to evaluate their potential association with breast implants. Although no cause and effect relationship has been established between breast implants and the conditions listed below, you should be aware of these reports. Furthermore, there is the possibility of risks, yet unknown, which in the future could be determined to be associated with breast implants. It should also be noted that the cited references include data from augmentation and/or reconstruction patients, as well as from a variety of manufacturers and implant models.

- **Connective Tissue Disease (CTD)**

Connective tissue diseases include diseases such as lupus, scleroderma, and rheumatoid arthritis. Fibromyalgia is a disorder characterized by chronic pain in the muscles and soft tissues surrounding joints, with tenderness at specific sites in the body. It is often accompanied by fatigue. There have been a number of published epidemiological studies which have looked at whether having a breast implant is associated with having a typical or defined connective tissue disease. The study size needed to conclusively rule out a smaller risk of connective tissue disease (≤ 2) among women with silicone gel-filled breast implants would need to be very large.^{22,23,24,25,26,27,28,29,30,31} The published studies taken

together show that breast implants are not significantly associated with a risk of developing a typical or defined connective tissue disease.^{32,33,34,35} These studies do not distinguish between women with intact and ruptured implants. Only one study evaluated specific connective tissue disease diagnoses and symptoms in women with silent ruptured versus intact implants, but it was too small to rule out a small risk.³⁶

- **CTD Signs and Symptoms**

Literature reports have also been made associating silicone breast implants with various rheumatological signs and symptoms such as fatigue, exhaustion, joint pain and swelling, muscle pain and cramping, tingling, numbness, weakness, and skin rashes. Scientific expert panels and literature reports have found no evidence of a consistent pattern of signs and symptoms in women with silicone breast implants.^{37,37,39,40,41} Having these rheumatological signs and symptoms does not necessarily mean that a patient has a connective tissue disease; however, you should advise your patient that she may experience these signs and symptoms after undergoing breast implantation. If a patient has an increase in these signs or symptoms, you should refer your patient to a rheumatologist to determine whether these signs or symptoms are due to a connective tissue disorder or autoimmune disease.

- **Cancer**

Breast Cancer – Reports in the medical literature indicate that patients with breast implants are not at a greater risk than those without breast implants for developing breast cancer.^{42,43,44,45,46} Some reports have suggested that breast implants may interfere with or delay breast cancer detection by mammography and/or biopsy; however, other reports in the published medical literature indicate that breast implants neither significantly delay breast cancer detection nor adversely affect cancer survival of women with breast implants.^{47,48,49,50,51}

Brain cancer – One recent study has reported an increased incidence of brain cancer in women with breast implants as compared to the general population.⁵² The incidence of brain cancer, however, was not significantly increased in women with breast implants when compared to women who had other plastic surgeries. Another recently published review of four large studies in women with cosmetic implants concluded that the evidence does not support an association between brain cancer and breast implants.⁵³

Respiratory/lung cancer – One study has reported an increased incidence of respiratory/lung cancer in women with breast implants.⁵⁴ Other studies of women in Sweden and Denmark have found that women who get breast implants are more likely to

be current smokers than women who get breast reduction surgery or other types of cosmetic surgery.^{55,56,57}

Cervical/vulvar cancer – One study has reported an increased incidence of cervical/vulvar cancer in women with breast implants.⁵⁸ The cause of this increase is unknown.

Other cancers – One study has reported an increased incidence of stomach cancer and leukemia in women with breast implants compared to the general population.⁵⁹ This increase was not significant when compared to women who had other types of plastic surgeries.

- **Neurological Disease, Signs, and Symptoms**

Some women with breast implants have complained of neurological symptoms (such as difficulties with vision, sensation, muscle strength, walking, balance, thinking or remembering things) or diseases (such as multiple sclerosis), which they believe are related to their implants. A scientific expert panel report found that the evidence for a neurological disease or syndrome caused by or associated with breast implants is insufficient or flawed.⁶⁰

- **Suicide**

In several studies, a higher incidence of suicide was observed in women with breast implants.^{61,62,63,64} The reason for the observed increase is unknown, but it was found that women with breast implants had higher rates of hospital admission due to psychiatric causes prior to surgery, as compared with women who had breast reduction or in the general population of Danish women.⁶⁵

- **Effects on Children**

At this time, it is not known if a small amount of silicone may pass through from the breast implant silicone shell into breast milk during breastfeeding. Although there are no current established methods for accurately detecting silicone levels in breast milk, a study measuring silicon (one component in silicone) levels did not indicate higher levels in breast milk from women with silicone gel-filled implants when compared to women without implants.⁶⁶

In addition, concerns have been raised regarding potential damaging effects on children born to mothers with implants. Two studies in humans have found that the risk of birth defects overall is not increased in children born after breast implant surgery.^{67,68} Although low birth weight was reported in a third study, other factors (for example, lower pre-

pregnancy weight) may explain this finding.⁶⁹ This author recommended further research on infant health.

- **Potential Health Consequences of Gel Bleed**

Small quantities of low molecular weight (LMW) silicone compounds, as well as platinum (in zero oxidation state), have been found to diffuse (“bleed”) through an intact implant shell.^{70,71} The evidence is mixed as to whether there are any clinical consequences associated with gel bleed. For instance, studies on implants implanted for a long duration have suggested that such bleed may be a contributing factor in the development of capsular contracture⁷² and lymphadenopathy.⁷³ However, evidence against gel bleed being a significant contributing factor to capsular contracture and other local complications, is provided by the fact that there are similar or lower complication rates for silicone gel-filled breast implants than for saline-filled breast implants. Saline-filled breast implants do not contain silicone gel and, therefore, gel bleed is not an issue for those products. Furthermore, toxicology testing has indicated that the silicone material used in the Mentor implants does not cause toxic reactions when large amounts are administered to test animals. It should also be noted that studies reported in the literature have demonstrated that the low concentration of platinum contained in breast implants is in the zero oxidation (most biocompatible) state.⁷⁴ In addition, two separate studies sponsored by Mentor have demonstrated that the low concentration of platinum contained in its breast implants is in the zero oxidation (most biocompatible) state.

Mentor performed a laboratory test to analyze the silicones and platinum (used in the manufacturing process), which may bleed out of intact implants into the body. The test method was developed to represent, as closely as possible, conditions in the body surrounding an intact implant. The results indicate that only the LMW silicones D4, D5, and D6, and platinum, bled into the serum in measurable quantities. In total, 4.7 micrograms of these three LMW silicones were detected. Platinum levels measured at 4.1 micrograms by 60 days, by which time an equilibrium level was reached and no more platinum was extracted from the device. Over 99% of the LMW silicones and platinum stayed in the implant. The overall body of available evidence supports that the extremely low level of gel bleed is of no clinical consequence.

MENTOR CORE STUDY

The safety and effectiveness of Mentor’s silicone gel-filled implants were evaluated in an open-label multicenter clinical study, referred to as the Mentor Core Study.

As a note, supplemental safety information was also obtained from the Mentor Adjunct Study, the U.K. Sharpe/Collis Study, and the literature to help assess long-term rupture rate and the consequences of rupture for this product. The literature, which had the most available information on the consequences of rupture, was also used to assess other potential complications associated with silicone gel-filled breast implants. The key literature information is referenced in this document.

Mentor's Core Study results indicate that the risk of any complication (including reoperation) at some point through 3 years after implant surgery is 36.6% for primary augmentation patients, 50.1% for revision-augmentation patients, 49.4% for primary reconstruction patients, and 47.5% for revision-reconstruction patients. The information below provides more details about the complications and benefits your patients may experience.

The results of the Mentor Core Study are discussed below.

Study Design:

The Mentor Core Study is a 10-year study to assess safety and effectiveness in augmentation, reconstruction, and revision (augmentation and reconstruction) patients. The Mentor Core Study consisted of 1,007 patients, including 551 primary augmentation patients, 146 revision-augmentation patients, 251 primary reconstruction patients, and 59 revision-reconstruction patients. Patients' medical histories were collected at baseline. Patient follow-up is at 6 months, 12 months, 24 months, and annually through 10 years. MRI scans to detect silent rupture of the implant for a subset of patients are scheduled at 1, 2, 4, 6, 8, and 10 years. Safety assessments include complication rates and rates of reoperation. Effectiveness assessments include circumferential chest size change and bra cup size change (augmentation patients only), and measures of patients' satisfaction and assessments of quality of life (QoL). The results through 3 years are currently being reported, and the study is currently ongoing. Mentor will periodically update this labeling as more information becomes available.

Patient Accounting and Baseline Demographic Profile:

The Mentor Core Study consisted of 1,007 patients, including 551 primary augmentation patients, 146 revision-augmentation patients, 251 primary reconstruction patients, and 59 revision-reconstruction patients. Of these, 202 primary augmentation patients, 57 revision-augmentation patients, 134 primary reconstruction patients, and 27 revision-reconstruction patients are in the MRI cohort, which means that they are assessed for silent rupture by MRI at years 1, 2, 4, 6, 8, and 10. At this time, MRIs have been

performed at years 1 and 2, and the follow-up rates for the MRI cohort ranged from 84% to 93% at the 2-year timepoint across indications. However, as a whole, data are available through 3 years post-implantation for 88% of the eligible augmentation patients, 87% of the eligible revision-augmentation patients, 82% of the eligible reconstruction patients, and 86% of the revision-reconstruction patients.

Demographic information for the Mentor Core Study with regard to race is as follows: 90% of the Mentor Core Study patients were Caucasian, 2% were Asian, 2% were African American, and 6% were other. The mean age at surgery was 35 years for primary augmentation patients, 42 for revision-augmentation patients, 45 years for primary reconstruction patients, and 51 years for revision-reconstruction patients. Most of the Mentor Core Study patients were married (56% of the primary augmentation patients, 60% for revision-augmentation, 69% of the primary reconstruction patients, and 66% of the revision-reconstruction patients). Approximately 82% had some college education.

With respect to surgical baseline factors in the Mentor Core Study, for primary augmentation patients, the most frequently used devices were smooth surface implants, the most common incision site was inframammary, and the most frequent site of placement was submuscular. For revision-augmentation patients, the most frequently used devices were smooth implants, the most common incision site was inframammary, and the most frequent site of placement was submuscular. With regard to primary reconstruction patients, the most frequently used devices were textured surface implants, the most common incision site was the mastectomy scar, and submuscular placement was the site of placement. For revision-reconstruction patients, the most frequently used devices were smooth implants, the most common incision site was mastectomy scar, and the most frequent site of placement was submuscular.

Core Effectiveness Outcomes:

Effectiveness was assessed by cup/circumferential chest size measurements, patient satisfaction, and quality of life (QoL). Mentor's patient satisfaction was based on a single question of "Would the patient have this breast surgery again?" The QoL measures were the Rosenberg Self Esteem Scale, the Body Esteem Scale, the Tennessee Self Concept Scale (TSCS), the SF-36, and the Functional Living Index of Cancer.

Primary Augmentation Patients: For primary augmentation patients, 370 (67%) out of the original 551 patients were included in the analysis of cup size at 3 years. Of these 370 patients, 359 (97%) experienced at least one cup size increase; the average increase in circumferential chest size was 2.8 inches.

At 3 years, 456 (83%) of the 551 patients enrolled completed the patient satisfaction question. Of these 456 patients, 445 (98%) stated to their surgeon that they would have the breast implant surgery again.

With regard to QoL measures at 3 years, an increase in self esteem was noted for 45% of patients after primary breast augmentation on the Rosenberg Self Esteem Scale. There was no change on the overall score of the Body Esteem Scale, but the Sexual Attractiveness Subscale and the Chest Score of the Body Esteem Scale increased. There was no change in the SF-36 after primary augmentation. There was no change in the overall score for the TSCS.

Revision-Augmentation Patients: For revision-augmentation patients, 116 (79%) out of the original 146 patients were included in the analysis at 3 years. For these 116 patients, the average increase in circumferential chest size was 2.4 inches.

At 3 years, 118 (81%) of the 146 patients enrolled answered the patient satisfaction question. Of these 118 patients, 111 (94%) stated to their surgeon that they would have the breast implant surgery again.

With regard to QoL measures at 3 years, no change in self esteem was noted following revision-augmentation surgery on the Rosenberg Self Esteem Scale. No changes were noted in the Body Esteem scale. There were no changes in SF-36. There was no change in the overall TSCS score.

Primary Reconstruction Patients: For primary reconstruction patients, 183 (72.9%) out of the original 251 patients were included in the analysis of circumferential chest size at 3 years. Of these 183 patients, the average increase in circumferential chest size was 1.3 inches.

At 3 years, 189 (75%) of the 251 patients enrolled answered the patient satisfaction question. Of these 189 patients, 185 (98%) stated to their surgeon that they would have the breast implant surgery again.

With regard to QoL measures at 3 years for primary reconstruction patients, a significant improvement in functioning was observed as measured by the Functional Living Index of Cancer. No change was observed on Rosenberg Self Esteem Scale. There was no change in the overall score for the TSCS. There was no change on the overall score of the Body Esteem Scale. The Sexual Attractiveness Subscale of the Body Esteem Scale significantly improved. There was no change in any of the ten SF-36 scales.

Revision-Reconstruction Patients: For revision-reconstruction patients, 45 (76%) out of the original 59 patients were included in the analysis of circumferential chest size at 3 years. Of these patients, the average increase in circumferential chest size was 0.9 inches.

At 3 years, 48 (81%) of the 59 patients enrolled answered the patient satisfaction question. Of these 48 patients, 47 (98%) stated to their surgeon that they would have the breast implant surgery again.

With regard to QoL measures at 3 years for revision-reconstruction patients, no change was observed on the Rosenberg Self Esteem Scale or in the Tennessee Self Concept Scale. For the Body Esteem Scale, two of six scales worsened over time, but, after adjusting for the aging effect, none of the changes were significant. The Sexual Attractiveness Subscale of the Body Esteem Scale significantly improved over time. Although some of the SF-36 scales showed decreases over time, after adjusting for the aging effect, changes in seven of ten SF-36 scales were not statistically significant.

Safety Outcomes – Complications:

Mentor's 10-year Core Study of 1,007 patients is continuing. All patients available for follow-up have been evaluated at the 3-year timepoint. Complications from this study are provided in Tables 1a-1d below. Note: Complications are defined as adverse events occurring in connection with the breast implant surgery, breast implants and/or the breast mound, and systemic diseases.

Table 1a. Mentor Core Study: 3-Year Cumulative Kaplan-Meier Adverse Event Risk Rates (95% Confidence Interval), By Patient for Primary Augmentation Cohort
N=551

Key Complications	%	CI
Reoperation	15.4	12.3, 18.4
Capsular Contracture Baker Grade III / IV	8.1	5.8, 10.4
Implant Removal with Replacement with Study Device	2.8	1.4, 4.2
Implant Removal without Replacement	2.3	1.0, 3.6
Infection	1.5	0.5, 2.5
Rupture (MRI Cohort) ¹	0.5	0, 1.6
Other Complications $\geq 1\%$²	%	CI
Nipple Complications ³	10.4	7.8, 12.9
Scarring/Hypertrophic Scarring ³	6.7	4.6, 8.8
Breast Mass ³	3.1	1.6, 4.6
Hematoma ³	2.6	1.2, 3.9
Ptosis ³	2.3	1.0, 3.6
Breast Sensation Changes ³	2.2	1.0, 3.4
Breast Pain ³	1.7	0.6, 2.8
Miscarriage ⁴	1.5	0.5, 2.6
Trauma ⁵	1.3	0.2, 2.3

- 1 - There was 1 patient with signs of rupture by MRI of one of her implants through the 3-year point. This has not yet been confirmed with removal and visual inspection of the implant.
- 2 - The following complications were reported at a rate less than 1%: anaphylaxis, asymmetry, biopsy pending, bruising, deep vein thrombosis, granuloma, implant malposition/displacement, inflammation, lactation difficulties, new diagnosis of rheumatic disease (1 patient with Hashimoto's Thyroiditis, 1 patient with rheumatoid arthritis, and 1 patient with hypothyroidism), necrosis, placement damage (damage to breast implants during insertion, which were then removed while the patient was still on the operating table), position dissatisfaction, positive antinuclear antibodies negative for lupus, suture reaction, rash, seroma, and wrinkling.
- 3 - Mild occurrences were excluded.
- 4 - Preoperative miscarriage data were not collected.
- 5 - Lifted child and stroller; trauma sustained from motor vehicle accident; trauma to breast from fall; and first and second degree frostbite from ice bags placed on breasts the day after surgery to relieve operative pain.

Table 1b. Mentor Core Study: 3-Year Cumulative Kaplan-Meier Adverse Event Risk Rates (95% Confidence Interval), By Patient for Revision-Augmentation Cohort
N=146 Patients

Key Complications	%	CI
Reoperation	28.0	20.4, 35.6
Capsular Contracture Baker Grade III / IV	18.9	12.5, 25.4
Rupture (MRI Cohort) ¹	7.7	0.4, 15.0
Implant Removal with Replacement with Study Device	6.5	2.4, 10.6
Implant Removal without Replacement	5.9	1.9, 9.8
Infection	1.4	0, 3.4
Other Complications $\geq 1\%$²	%	CI
Nipple Complications ³	10.5	5.5, 15.5
Scarring/Hypertrophic Scarring ³	8.4	3.9, 13.0
Breast Mass ³	6.6	2.4, 10.7
Hematoma ³	2.8	0.09, 5.4
Breast Sensation Changes ³	2.1	0, 4.5
Seroma	2.1	0, 4.4
Delayed Wound Healing ³	2.1	0, 4.4
Wrinkling ³	2.1	0, 4.5
Ptosis ³	1.5	0, 3.6
Breast Pain ³	1.5	0, 3.4
Inflammation ³	1.4	0, 3.3
Implant Malposition ³	1.4	0, 3.3
Implant Extrusion	1.4	0, 3.3

1 - Of the 4 patients who had signs of rupture on MRI, 1 patient had removal of her implants which showed rupture (tears and holes) of both of her implants. This occurred 2 years after she entered the Mentor Core Study as a revision-augmentation patient.

2 - The following complications occurred at a rate less than 1%: back and neck pain related to large implants, ectopic pregnancy, false positive for rupture on mammogram, granuloma, lactation difficulties, miscarriage, muscle spasm, new diagnosis of rheumatic disease (1 patient with rheumatoid arthritis), implant palpability/visibility, and trauma (blunt injury to left breast from being hit by fireworks).

3 - Mild occurrences were excluded.

Table 1c. Mentor Core Study: 3-Year Cumulative First Occurrence Kaplan-Meier Adverse Event Risk Rates (95% Confidence Interval), By Patient for Primary Reconstruction Cohort N=251 Patients

Key Complications	%	CI
Reoperation	27.0	21.4, 32.6
Capsular contracture Baker Grade III/IV	8.3	4.7, 11.9
Implant Removal with Replacement with Study Device	7.4	4.1, 10.7
Implant Removal without Replacement	5.7	3.3, 9.6
Infection	5.7	2.8, 8.6
Rupture (MRI Cohort) ¹	0.9	0, 2.5
Other Complications $\geq 1\%$²	%	CI
Ptosis ³	6.9	2.7, 11.2
Scarring/Hypertrophic Scarring ³	6.8	3.6, 10.0
Asymmetry ³	6.7	3.4, 10.0
Seroma	4.9	2.2, 7.5
Breast Mass ³	3.6	1.1, 6.0
Nipple Complications ³	3.3	0.8, 5.7
Wrinkling ³	2.6	0.5, 4.6
Breast Pain ³	2.2	0.3, 4.2
Metastatic Disease	1.8	0.05, 3.6
Implant Malposition ³	1.7	0.05, 3.3
Recurrent Breast Cancer ⁴	1.7	0.05, 3.4
Hematoma ⁴	1.3	0, 2.8
Implant Extrusion	1.2	0, 2.6
Breast Sensation Changes ³	1.0	0, 2.5
Rash ³	1.0	0, 2.3

1 - There was 1 patient with signs of ruptures by MRI of one of her implants through the 3-year point. This has not been confirmed with removal and visual inspection of the implants.

2 - The following complications occurred at a rate less than 1%: deep vein thrombosis, delayed wound healing, lymphadenopathy, miscarriage, muscle spasm, necrosis, new diagnosis of breast cancer, new diagnosis of rheumatic disease (1 patient with fibromyalgia), redness, stitch abscess, tight benilli suture, trauma to breast due to car accident.

3 - Mild occurrences were excluded.

4 - The general recurrence rate for breast cancer reported in the medical literature ranges from 5 to 25%.^{75,76,777}

Table 1d. Mentor Core Study: 3-Year Cumulative Kaplan-Meier Adverse Event Risk Rates (95% Confidence Interval), By Patient for Revision-Reconstruction Cohort
N=59 Patients

Key Complications	%	CI
Reoperation	29.1	17.4, 40.7
Capsular Contracture Baker Grade III/IV	16.3	5.0, 27.6
Implant Removal with Replacement with Study Device	8.8	3.8, 19.9
Implant Removal without Replacement	5.2	1.7, 15.2
Infection	0	-
Rupture (MRI Cohort)	0	-
Other Complications $\geq 1\%$¹	%	CI
Asymmetry ²	8.9	1.4, 16.3
Implant Malposition ²	8.5	1.4, 15.7
Wrinkling ²	7.0	0.4, 13.6
Breast Mass ²	7.0	0.4, 13.7
Granuloma	5.1	0, 10.7
Scarring/Hypertrophic Scarring ²	3.6	0, 8.4
Breast Pain ²	3.5	0, 8.2
Hematoma ²	3.5	0, 8.2
New Diagnosis of Rheumatic Disease ³	3.5	0, 8.1
Ptosis ²	3.4	0, 8.0
Breast Sensation Changes ²	1.9	0, 5.7
Numbness in Both Hands at Night	1.8	0, 5.3
Seroma	1.7	0, 5.0
Nipple Complications ²	1.7	0, 5.0
Inflammation	1.7	0, 5.1
Recurrent Breast Cancer ⁴	1.7	0, 5.0
New Diagnosis of Breast Cancer	1.7	0, 5.1
Delayed Wound Healing	1.7	0, 5.0
Trauma ⁵	1.7	0, 5.0
Capsule Tear	1.7	0, 5.0
Implant Extrusion	1.7	0, 5.0

- 1 - No complications occurred at a rate of <1%.
- 2 - Mild occurrences were excluded.
- 3 - These rheumatic diagnoses were fibromyalgia (1 patient) and pyoderma gangrenosum (1 patient).
- 4 - The general recurrence rate for breast cancer reported in the medical literature ranges from 5 to 25%.^{78,79,80}
- 5 - Trauma to breast from fall.

Safety Outcomes - Main Reasons for Reoperation:

This section includes the main reasons for reoperation. The rates exclude planned secondary surgeries and reoperations. If more than one reason for the reoperation was reported, the hierarchy used was: rupture/deflation; infection; capsular contracture; necrosis/extrusion; hematoma/seroma; delayed wound healing; breast pain; implant malposition; wrinkling; palpability/visibility; asymmetry; ptosis; scarring; nipple complications; device injury/iatrogenic; breast cancer mass; biopsy; and patient request for style/size change.

Of the 551 augmentation patients, there were 83 (15%) who underwent 176 surgical procedures in 109 reoperations over the 3 years of follow-up in the Mentor Core Study. The most common reason for reoperation through 3 years was because of capsular contracture Baker Grade II, III, or IV (36.7% of 109 reoperations). Table 2a below provides the main reason for each reoperation following initial implantation that was performed through 3 years for primary augmentation patients.

Table 2a: Main Reasons for Reoperation through 3-Years for Primary Augmentation Cohort

Reason for Reoperation	n	% (of 109 Reoperations)
Capsular Contracture Baker Grade II/III/IV	40	36.7
Patient Request For Style/Size Change	16	14.7
Hematoma/Seroma	12	11.0
Scarring/Hypertrophic Scarring	12	11.0
Biopsy	6	5.5
Asymmetry	5	4.6
Ptosis	4	3.7
Infection	3	2.8
Delayed Wound Healing	2	1.8
Implant Malposition	2	1.8
Wrinkling	2	1.8
Breast Pain	1	0.9
Implant Extrusion	1	0.9
Necrosis	1	0.9
Suspected Rupture ¹	1	0.9
Tear in Capsule	1	0.9
Total	109	100

1 - The device was removed and found to be intact.

There were 105 additional surgical procedures performed in 58 reoperations involving 39 revision-augmentation patients. The most common reason for reoperation through 3 years was capsular contracture Baker Grade II, III, or IV (39.6% of the 58 reoperations). Table 2b below provides the main reason for each reoperation following initial implantation that was performed through 3 years for revision-augmentation patients.

Table 2b: Main Reasons for Reoperation through 3 Years for Revision-Augmentation Cohort

Reason for Reoperation	n	% (of 58 Reoperations)
Capsular Contracture Baker Grade II/III/IV	23	39.7
Patient Request For Style/Size Change	7	12.1
Biopsy	6	10.3
Hematoma/Seroma	5	8.6
Delayed Wound Healing	5	8.6
Scarring/Hypertrophic Scarring	3	5.2
Implant Extrusion	2	3.4
Implant Malposition	2	3.4
Asymmetry	1	1.7
Ptosis	1	1.7
Infection	1	1.7
Wrinkling	1	1.7
Suspected Rupture ¹	1	1.7
Total	58	100

1 - The device was removed and found to be intact.

There were 143 additional surgical procedures performed in 79 reoperations involving 66 primary reconstruction patients. The most common reason for reoperation through 3 years was because of asymmetry (20.3% of 79 reoperations). Table 2c below provides the main reasons for the reoperations following initial implantation that were performed through 3 years for primary reconstruction patients.

Table 2c: Main Reasons for Reoperation through 3 Years for Primary Reconstruction Cohort

Reason for Reoperation	n	% (of 79 Reoperations)
Asymmetry	16	20.3
Biopsy	11	13.9
Capsular Contracture Baker Grade II/III/IV	10	12.7
Implant Malposition	9	11.4
Patient Request for Style/Size Change	9	11.4
Infection	4	5.1
Scarring/Hypertrophic Scarring	3	3.8
Ptosis	3	3.8
Hematoma/Seroma	3	3.8
Breast Cancer	3	3.8
Implant Extrusion	2	2.5
Nipple Complications (unplanned)	2	2.5
Delayed Wound Healing	1	1.3
Breast Pain	1	1.3
Implant Palpability/Visibility	1	1.3
Muscle Spasm	1	1.3
Total	79	100

There were 54 additional surgical procedures performed in 24 reoperations involving 17 revision-reconstruction patients. The most common reason for reoperation through 3 years was because of biopsy (29.2% of 24 reoperations). Table 2d below provides the main reason for each reoperation following initial implantation that was performed through 3 years for revision-reconstruction patients.

Table 2d: Main Reasons for Reoperation through 3 Years for Revision-Reconstruction Cohort

Reason for Reoperation	n	% (of 24 Reoperations)
Biopsy	7	29.2
Other ¹	3	12.5
Capsular Contracture Baker Grade III/IV	3	12.5
Implant Malposition	2	8.3
Suspected Rupture ²	1	4.2
Asymmetry	1	4.2
Breast Cancer	1	4.2
Implant Extrusion	1	4.2
Hematoma/Seroma	1	4.2
Nipple Complications (unplanned)	1	4.2
Patient Request For Style/Size Change	1	4.2
Ptosis	1	4.2
Wrinkling	1	4.2
Total	24	100

1 - Includes 1 follicular cyst palpable nodule, 1 palpable nodule, and 1 pocket tear

2 - The device was removed and found to be intact.

Safety Outcomes - Reasons for Implant Removal:

The main reasons for implant removal among primary augmentation patients in the Mentor Core Study over the 3 years are shown in Table 3a below. Of the 551 primary augmentation patients, there were 26 patients (5%) who had 45 implants removed over the 3 years of follow-up. Of the 45 primary augmentation implants removed, 24 implants (53%) were replaced. The most common reason for implant removal was patient request (68.9% of the 45 implants removed) for primary augmentation patients.

Table 3a. Main Reasons for Implant Removal through 3 Years for Primary Augmentation Cohort

Reason for Removal	n	% (of 45 Explants)
Patient Request for Style/Size Change	31	68.9
Capsular Contracture Baker Grade III/IV	5	11.1
Breast Pain	2	4.4
Infection	2	4.4
Necrosis	2	4.4
Suspected Rupture ¹	1	2.2
Contralateral Explantation	1	2.2
Wrinkling	1	2.2
Total	45	100

1 - The device was removed and found to be intact.

The main reasons for implant removal among revision-augmentation patients in the Mentor Core Study over the 3 years are shown in Table 3b below. Of the 146 revision-augmentation patients, there were 18 patients (12.3%) who had 30 implants removed over the 3 years of follow-up in the Mentor Core Study. Of the 30 implants removed, 14 (47%) were replaced. The most common reason for implant removal was patient request (40.0% of the 30 implants removed) for revision-augmentation patients.

Table 3b. Main Reasons for Implant Removal through 3 Years for Revision-Augmentation Cohort

Reason for Removal	n	% (of 30 Explants)
Patient Request for Style/Size Change	12	40.0
Capsular Contracture Baker Grade III/IV	10	33.3
Patient Dissatisfied with Appearance	2	6.7
Asymmetry	1	3.3
Implant Extrusion	1	3.3
Scarring/Hypertrophic Scarring	1	3.3
Infection	1	3.3
Suspected Rupture ¹	1	3.3
Abnormal Mammogram	1	3.3
Total	30	100

1 - The device was removed and found to be intact.

The main reasons for implant removal among primary reconstruction patients in the Mentor Core Study over the 3 years are shown in Table 3c below. Of the 251 primary reconstruction patients, there were 31 patients (12%) who had 41 implants removed over the 3 years of follow-up in the Mentor Core Study. Of the 41 primary reconstruction implants removed, 23 (56.1%) were replaced. The most common reason for implant removal was patient request (36.6% of the 41 implants removed) for primary reconstruction patients.

Table 3c. Main Reasons for Implant Removal through 3 Years for Primary Reconstruction Cohort

Reason for Removal	n	% (of 41 Explants)
Patient Request for Style/Size Change	15	36.6
Asymmetry	10	24.4
Capsular Contracture Baker Grade II/III/IV	5	12.2
Implant Malposition	3	7.3
Implant Extrusion	2	4.9
Infection	2	4.9
Hematoma	1	2.4
Lack of Projection	1	2.4
Muscle Spasm	1	2.4
Recurrent Breast Cancer	1	2.4
Total	41	100

The main reasons for implant removal among revision-reconstruction patients in the Mentor Core Study over the 3 years are shown in Table 3d below. Of the 59 revision-reconstruction patients, there were 8 patients (13.6%) who had 11 implants removed over the 3 years of follow-up in the Mentor Core Study. Of the 11 implants removed, 7 (63.6%) were replaced. The most common reason for implant removal was capsular contracture III/IV (27.3% of the 11 implants removed) for revision-reconstruction patients.

Table 3d. Main Reasons for Implant Removal through 3 Years for Revision-Reconstruction Cohort

Reason for Removal	n	% (of 11 Explants)
Capsular Contracture Baker Grade III/IV	3	27.3
Asymmetry	2	18.2
Patient Request for Style/Size Change	2	18.2
Symmastia	2	18.2
Implant Extrusion	1	9.1
Pocket Tear	1	9.1
Total	1	100

Other Clinical Data Findings

Below is a summary of clinical findings from Mentor's Core Study with regard to connective tissue disease (CTD); CTD signs and symptoms; cancer; lactation complications, reproduction complications; and suicide. These issues, along with other endpoints, are being further evaluated as part of a Mentor postapproval study of patients followed through 10 years.

CTD Diagnoses

Three primary augmentation patients and one revision-augmentation patient in the Mentor Core Study were reported to have a new diagnosis of CTD according to a rheumatologist. These diagnoses were Hashimoto's Thyroiditis at 2 years, two cases of rheumatoid arthritis at 2 and 3 years, and hypothyroidism at 2 years. One primary reconstruction patient and two revision-reconstruction patients in the Mentor Core Study were reported to have a new diagnosis of CTD according to a rheumatologist. These diagnoses were two cases of fibromyalgia, both at 1 year, and pyoderma gangrenosum at 1 year. These

data should be interpreted with caution because there was no comparison group of similar women without implants.

CTD Signs and Symptoms

Data on over 100 self-reported signs and symptoms, including about 50 self-reported rheumatological symptoms, were collected. Compared to before having the implants, significant increases were found for fatigue, exhaustion, joint swelling, joint pain, numbness of hands, frequent muscle cramps, and the combined categories of fatigue, pain, and fibromyalgia-like symptoms in primary augmentation patients and for joint pain in revision-augmentation and primary reconstruction patients. These increases were not found to be related to simply getting older over time. No significant increases were found for any individual signs and symptoms in the revision-reconstruction patients. The Mentor Core Study was not designed to evaluate cause and effect associations because there is no comparison group of women without implants, and because other contributing factors, such as medications and lifestyle/exercise, were not studied. Therefore, it cannot be determined whether these increases were due to the implants or not. However, your patient should be aware that she may experience an increase in these symptoms after receiving breast implants.

Cancer

There were no primary augmentation patients with new diagnoses of breast cancer through 3 years in Mentor's Core Study. As previous breast cancer was an exclusion criteria for primary augmentation patients, there were no reports of breast cancer reoccurrence in this cohort. There were no reports of new diagnoses or reoccurrence in revision-augmentation patients. For primary reconstruction patients, 1 (0.5%) patient had a new diagnosis of breast cancer and 4 (1.7%) patients had a reoccurrence of breast cancer. For revision-reconstruction, 1 (1.7%) patient had a new diagnosis of breast cancer and 1 (1.7%) patient had a recurrence of breast cancer. There were no reports of other cancers, such as brain, respiratory, or cervical/vulvar in any indication.

Lactation Complications

Two (8%) of the 25 primary augmentation patients who attempted to breast feed following breast implantation in Mentor's Core Study through 3 years experienced difficulty with breast feeding. Of the 7 revision-augmentation patients who attempted to breast feed after

receiving breast implants, 1 (14%) had difficulty breast feeding. For primary reconstruction patients, of the 3 women who attempted to breastfeed, none experienced lactation difficulties. None of the revision-reconstruction patients attempted to breast feed.

Reproduction Complications

Eight (1.5%) of the primary augmentation patients in Mentor's Core Study reported a miscarriage through 3 years. For primary reconstruction patients, 2 (0.9%) patients reported a miscarriage. There were no reports of miscarriage in revision-augmentation or revision-reconstruction patients.

Suicide

There were no reports of suicide in any of the four cohorts in Mentor's Core Study through 3 years.

DEVICE IDENTIFICATION CARD

Enclosed with each silicone gel-filled breast implant is a Patient ID Card. To complete the Patient ID Card, place one device identification sticker for each implant on the back of the card. Stickers are located on the internal product packaging attached to the label. If a sticker is unavailable, the lot number, catalog number and description of the device may be copied by hand from the device label. Patients should be provided with these cards for personal reference.

DEVICE RETRIEVAL EFFORTS

Mentor requests that any explanted devices be sent to Mentor Corporation, Product Evaluation Department, 3041 Skyway Circle North, Irving, TX 75038 USA for examination and analysis. Please call 1-800-258-3487 for instructions and shipping information for return of explanted devices.

PRODUCT EVALUATION

Mentor requires that any complications or explantation resulting from the use of this device be brought to the immediate attention of the Product Evaluation Department at Mentor, 3041 Skyway Circle North, Irving, TX 75038 USA.

HOW TO REPORT PROBLEMS WITH AN IMPLANT

FDA requires that serious injuries (defined as those that need medical or surgical intervention to prevent permanent damage) be reported by hospitals if they are aware of the serious injuries. In addition, injuries or complications can be voluntarily reported directly by the patient to FDA's MedWatch.

If you have a patient who has experienced one or more serious problems related to her breast implants, you are encouraged to report the serious problem(s) to the FDA through the MedWatch voluntary reporting system. Examples of serious problems include disability, hospitalization, harm to offspring, and medical or surgical intervention to prevent lasting damage.

You are also required to report any product problem or serious adverse event to Mentor. Deaths must be reported to Mentor and FDA. You can report by telephone to 1-800-FDA-1088; by FAX, use Form 3500 to 1-800-FDA-0178; electronically at <http://www.fda.gov/medwatch/index.html>; or by mail to MedWatch Food and Drug Administration, HF-2, 5600 Fishers Lane Rockville, MD 20857-9787. **Keep a copy of the completed MedWatch form for your records.**

This information reported to MedWatch is entered into databases to be used to follow safety trends (patterns) of a device and to determine whether further follow-up of any potential safety issues related to the device is needed.

RETURNED GOODS AUTHORIZATION**• U.S. Customers**

Merchandise returned must have all manufacturers' seals intact and must be returned within 60 days from date of invoice to be eligible for credit or replacement. Please contact Mentor Customer Service Department for details. Returned products may be subject to restocking charges.

• International Customers

Authorization for return of merchandise should be obtained from your respective dealer. Other conditions noted above also apply.

• Product Replacement Policy and Limited Warranties

The following is a description of the assistance available from Mentor Lifetime Product

Replacement Policy, and the Mentor Advantage and Enhanced Advantage Limited Warranties.

Mentor's free Lifetime Product Replacement Policy involves the free lifetime product replacement for its gel-filled and saline-filled breast implants, worldwide. When implant replacement is required and the Mentor Product Replacement Policy applies (see below), Mentor will provide, throughout a patient's lifetime, the same or similar Mentor breast implant at no cost. If a more expensive product is requested, Mentor will invoice the surgeon for the price difference.

The **Mentor Standard Advantage Limited Warranty** is free of charge to all patients who are implanted with Mentor gel-filled or saline-filled breast implants in the United States and Puerto Rico. When the limited warranty applies, Mentor provides the following:

- Financial assistance: For the first ten years following a breast implant procedure, Mentor will provide financial assistance up to \$1200 to help cover operating room, anesthesia, and surgical charges not covered by insurance. Financial assistance applies to covered events only (see below). Operating room and anesthesia charges will be given payment priority. In order to qualify for financial assistance, the patient will need to sign a Release Form.
- Free contralateral (opposite side) implant replacement upon surgeon request.
- Non-cancelable terms.

The **Mentor Enhanced Advantage Limited Warranty** is an optional limited warranty available for women who are implanted with Mentor gel-filled or saline-filled breast implants in the United States and Puerto Rico. To be eligible, the Mentor Enhanced Advantage Limited Warranty must be purchased for an enrollment fee of \$100 within 45 days from implantation. When the warranty applies, Mentor provides the following:

- Financial assistance: For the first ten years following a breast implant procedure, Mentor will provide financial assistance up to \$2400 to help cover operating room, anesthesia, and surgical charges not covered by insurance. Financial assistance applies to covered events only (see below). Operating room and anesthesia charges will be given payment priority. In order to qualify for financial assistance, the patient will need to sign a Release Form.
- Free contralateral implant replacement upon surgeon request.
- Non-cancelable terms.

With both the Mentor Standard Advantage and Mentor Enhanced Advantage Limited Warranties, it is important for the patient to also maintain her own records to ensure validation of her enrollment.

Products Covered

The Mentor Standard Advantage Limited Warranty coverage applies to all Mentor gel-filled and saline-filled breast implants that are implanted in the United States and Puerto Rico, provided they have been:

- Implanted in accordance with the Mentor package insert, current to the date of implantation, and other notifications or instructions published by Mentor; and
- Used by appropriately qualified, licensed surgeons, in accordance with accepted surgical procedures.

Events Covered

The Mentor Lifetime Product Replacement Policy, and the Standard Mentor Advantage and Enhanced Advantage Limited Warranties coverages apply to the following:

- Rupture due to localized stress, folding, manufacturing defect, patient trauma, or unknown cause
- Other loss-of-shell integrity events, such as surgical damage may also be covered by these programs. Mentor reserves the right to determine if specific, additional events should be covered.

Events Not Covered

The Mentor Lifetime Product Replacement Policy and the Mentor Standard Advantage and Enhanced Advantage Limited Warranties coverages do not apply to the following:

- Removal of intact implants due to capsular contracture, or wrinkling.
- Loss of implant shell integrity resulting from reoperative procedures, open capsulotomy, or closed compression capsulotomy procedures.
- Removal of intact implants for size alteration.

Filing for Financial Assistance

- To file a Mentor Advantage claim for product replacement and/or financial assistance, the surgeon must contact the Mentor Product Evaluation Department at 1-866-250-5115 prompt #1 prior to replacement surgery.

- For financial assistance claims, a patient-specific Release form will be generated that the patient must sign and return.
- For either replacement or financial assistance claims, the surgeon must send the explanted, decontaminated Mentor breast implant(s) within six months of the date of explantation to:

Mentor Product Evaluation
3041 Skyway Circle North
Irving, Texas 75038-3540

- Upon receipt, review and approval of the completed claim, including receipt of the explanted product and the patient's completion of a full general release, financial assistance will be issued.

This is a summary of the coverage of the Mentor Advantage and Enhanced Advantage Limited Warranties. It is an overview only and not a complete statement of the program. A copy of the complete Mentor Advantage and Enhanced Advantage Limited Warranties for saline-filled and silicone gel-filled breast implants may be obtained by writing or calling:

Consumer Affairs Department
Mentor Corporation
201 Mentor Drive
Santa Barbara, CA 93111
1-800-525-0245

A copy of the complete programs may also be obtained from the surgeon or by going to www.mentorcorp.com.

THESE ARE LIMITED WARRANTIES ONLY AND ARE SUBJECT TO THE TERMS AND CONDITIONS SET FORTH AND EXPLAINED IN THE APPLICABLE MENTOR LIMITED WARRANTIES. ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, BY OPERATION OF LAW OR OTHERWISE, INCLUDING BUT NOT LIMITED TO, IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS ARE EXCLUDED.

Mentor reserves the right to cancel, change, or modify the terms of the Mentor Advantage and Enhanced Advantage coverages. Any such cancellation, change, or modification will not affect the currently stated terms of the Mentor Advantage and Enhanced Advantage coverages for those already enrolled.

REFERENCES

- ¹ Henriksen, T.F., et al. 2005. Surgical intervention and capsular contracture after breast augmentation: a prospective study of risk factors. *Ann. Plast. Surg.* 54(4):343-51.
- ² Hurst, N.M. 1996. Lactation after augmentation mammoplasty. *Obstet. Gynecol.* 87(1):30-4.
- ³ Hurst, N.M. 1996. Lactation after augmentation mammoplasty. *Obstet. Gynecol.* 87(1):30-4.
- ⁴ Bondurant, S., V.L. Ernster and R. Herdman, Eds. 2000. Safety of silicone breast implants. Committee on the Safety of Silicone Breast Implants, Division of Health Promotion and Disease Prevention, Institute of Medicine. Washington, D.C.: National Academy Press.
- ⁵ Henriksen, T.F., et al. 2005. Surgical intervention and capsular contracture after breast augmentation: a prospective study of risk factors. *Ann. Plast. Surg.* 54(4):343-51.
- ⁶ For example: Kulmala, I., et al. 2004. Local complications after cosmetic breast implant surgery in Finland. *Ann. Plast. Surg.* 53(5):413-9.
- ⁷ Hölmich, L.R., et al. 2005a. The diagnosis of silicone breast implant rupture. Clinical findings compared to findings at MRI. *Ann Plast Surg* 54 (6): 583-9.
- ⁸ Hölmich, L.R., et al. 2005b. The diagnosis of breast implant rupture: MRI findings compared to findings at explantation. 2005. *Eur J. Radiol.* 53: 213-25.
- ⁹ Bondurant, S., V.L. Ernster and R. Herdman, Eds. 2000. Safety of silicone breast implants. Committee on the Safety of Silicone Breast Implants, Division of Health Promotion and Disease Prevention, Institute of Medicine. Washington, D.C.: National Academy Press.
- ¹⁰ Hölmich, L.R., et al. 2004. Untreated silicone breast implant rupture. *Plast. Reconstr. Surg.* 114:204-214.
- ¹¹ Hölmich, L.R., et al. 2001. Prevalence of silicone breast implant rupture among Danish women. *Plast. Reconstr. Surg.* 108(4):848-858.
- ¹² Hölmich, L.R., et al. 2004. Untreated silicone breast implant rupture. *Plast. Reconstr. Surg.* 114:204-214.
- ¹³ Hölmich, L.R., et al. 2004. Untreated silicone breast implant rupture. *Plast. Reconstr. Surg.* 114:204-214.

- ¹⁴ Katzin, W.E., et al. 2005. Pathology of lymph nodes from patients with breast implants: a histologic and spectroscopic evaluation. *Am J Surg Pathol.*29(4):506-11.
- ¹⁵ Berner, I., M., et al. 2002. Comparative examination of complaints of patients with breast-cancer with and without silicone implants. *Eur. J Obstet. Gynecol. Reprod. Biol.* 102:61-66.
- ¹⁶ Brown, S.L., et al. 2001. Silicone gel breast implant rupture, extracapsular silicone, and health status in a population of women. *J. Rheumatol.* 28:996-1003.
- ¹⁷ Hölmich, L.R., et al. 2003b. Self-reported diseases and symptoms by rupture status among unselected Danish women with cosmetic silicone breast implants. *Plast. Reconstr. Surg.* 111:723-732.
- ¹⁸ Wolfe, F. and J. Anderson. 1999. Silicone filled breast implants and the risk of fibromyalgia and rheumatoid arthritis. *J. Rheumatol.* 26:2025-2028.
- ¹⁹ Hölmich, L.R., et al. 2003b. Self-reported diseases and symptoms by rupture status among unselected Danish women with cosmetic silicone breast implants. *Plast. Reconstr. Surg.* 111:723-732.
- ²⁰ Bondurant, S., V.L. Ernster and R. Herdman, Eds. 2000. Safety of silicone breast implants. Committee on the Safety of Silicone Breast Implants, Division of Health Promotion and Disease Prevention, Institute of Medicine. Washington, D.C.: National Academy Press.
- ²¹ Katzin, W.E., et al. 2005. Pathology of lymph nodes from patients with breast implants: a histologic and spectroscopic evaluation. *Am. J. Surg. Pathol.* 29(4):506-11.
- ²² Bondurant, S., V.L. Ernster and R. Herdman, Eds. 2000. Safety of silicone breast implants. Committee on the Safety of Silicone Breast Implants, Division of Health Promotion and Disease Prevention, Institute of Medicine. Washington, D.C.: National Academy Press.
- ²³ Brinton, L.A., et al. 2004. Risk of connective tissue disorders among breast implant patients. *Am. J. Epidemiol.* 160(7):619-27.
- ²⁴ Brown, S.L., et al. 2001. Silicone gel breast implant rupture, extracapsular silicone, and health status in a population of women. *J. Rheumatol.* 28:996-1003.
- ²⁵ Hölmich, L.R., et al. 2003b. Self-reported diseases and symptoms by rupture status among unselected Danish women with cosmetic silicone breast implants. *Plast. Reconstr. Surg.* 111:723-732.

- ²⁶ Janowsky, E.C., et al. 2000. Meta-Analyses of the Relation Between Silicone Breast Implants and the Risk of Connective-Tissue Diseases. *N. Engl. J. Med.* 342(11):781-90.
- ²⁷ Lipworth, L.R.E., et al. 2004. Silicone breast implants and connective tissue disease: An updated review of the epidemiologic evidence. *Ann. Plast. Surg.* 52:598-601.
- ²⁸ Tugwell, P., et al. 2001. Do silicone breast implants cause rheumatologic disorders? A systematic review for a court-appointed national science panel. *Arthritis Rheum.* (11):2477-84.
- ²⁹ Weisman, M.H., et al. 1988. Connective-tissue disease following breast augmentation: A preliminary test of the human adjuvant tissue hypothesis. *Plast. Reconstr. Surg.* 82(4):626-30.
- ³⁰ Williams, H.J., et al. 1997. Breast implants in patients with differentiated and undifferentiated connective tissue disease. *Arthritis and Rheumatism* 40(3):437-40.
- ³¹ Wolfe, F. and J. Anderson. 1999. Silicone filled breast implants and the risk of fibromyalgia and rheumatoid arthritis. *J. Rheumatol.* 26:2025-2028.
- ³² Bondurant, S., V.L. Ernster and R. Herdman, Eds. 2000. Safety of silicone breast implants. Committee on the Safety of Silicone Breast Implants, Division of Health Promotion and Disease Prevention, Institute of Medicine. Washington, D.C.: National Academy Press.
- ³³ Janowsky, E.C., et al. 2000. Meta-Analyses of the Relation Between Silicone Breast Implants and the Risk of Connective-Tissue Diseases. *N. Engl. J. Med.* 342(11):781-90.
- ³⁴ Lipworth, L.R.E., et al. 2004. Silicone breast implants and connective tissue disease: An updated review of the epidemiologic evidence. *Ann. Plast. Surg.* 52:598-601.
- ³⁵ Tugwell, P., et al. 2001. Do silicone breast implants cause rheumatologic disorders? A systematic review for a court-appointed national science panel. *Arthritis Rheum.* (11):2477-84.
- ³⁶ Hölmich, L.R., et al. 2003b. Self-reported diseases and symptoms by rupture status among unselected Danish women with cosmetic silicone breast implants. *Plast. Reconstr. Surg.* 111:723-732.
- ³⁷ Berner, I., M., et al. 2002. Comparative examination of complaints of patients with breast-cancer with and without silicone implants. *Eur. J Obstet. Gynecol. Reprod. Biol.* 102:61-66.
- ³⁸ Bondurant, S., V.L. Ernster and R. Herdman, Eds. 2000. Safety of silicone breast implants. Committee on the Safety of Silicone Breast Implants, Division of Health

Promotion and Disease Prevention, Institute of Medicine. Washington, D.C.: National Academy Press.

- ³⁹ Breiting, V.B., et al. 2004. Long-term health status of Danish women with silicone breast implants. *Plast. Reconstr. Surg.* 114:217-26.
- ⁴⁰ Fryzek, J.P., et al. 2001. Self-reported symptoms among women after cosmetic breast implant and breast reduction surgery. *Plast. Reconstr. Surg.* 107:206-13.
- ⁴¹ Kjølner, K., et al. 2004. Self-reported musculoskeletal symptoms among Danish women with cosmetic breast implants. *Ann Plast Surg.* 52(1):1-7.
- ⁴² Brinton, L.A., et al. 2000. Breast cancer following augmentation mammoplasty (United States). *Cancer Causes Control.* 11(9):819-27. *J. Long Term Eff. Med. Implants.* 12(4):271-9.
- ⁴³ Bryant, H., and Brasher, P. 1995. Breast implants and breast cancer--reanalysis of a linkage study. *N. Engl. J. Med.* 332(23):1535-9.
- ⁴⁴ Deapen, D.M., et al. 1997. Are breast implants anticarcinogenic? A 14-year follow-up of the Los Angeles Study. *Plast. Reconstr. Surg.* 1997 99(5):1346-53.
- ⁴⁵ Herdman, R.C., et al. 2001. Silicone breast implants and cancer. *Cancer Invest.* 2001;19(8):821-32.
- ⁴⁶ Pukkala, E., et al. 2002. Incidence of breast and other cancers among Finnish women with cosmetic breast implants, 1970-1999. *J. Long Term Eff. Med. Implants* 12(4):271-9.
- ⁴⁷ Brinton, L.A., et al. 2000. Breast cancer following augmentation mammoplasty (United States). *Cancer Causes Control.* 11(9):819-27. *J. Long Term Eff. Med. Implants.* 12(4):271-9.
- ⁴⁸ Deapen, D., et al. 2000. Breast cancer stage at diagnosis and survival among patients with prior breast implants. *Plast Reconstr Surg.* 105(2):535-40.
- ⁴⁹ Jakubietz, M.G., et al. 2004. Breast augmentation: Cancer concerns and mammography – A literature review. *Plast. Reconstr. Surg.* 113:117e122e.
- ⁵⁰ Miglioretti, D.L., et al. 2004. Effect of breast augmentation on the accuracy of mammography and cancer characteristics. *JAMA* 291(4):442-50.
- ⁵¹ Pukkala, E., et al. 2002. Incidence of breast and other cancers among Finnish women with cosmetic breast implants, 1970-1999. *J. Long Term Eff. Med. Implants* 12(4):271-9.

- ⁵² Brinton, LA., et al. 2001b. Cancer risk at sites other than the breast following augmentation mammoplasty. *Ann. Epidemiol.* 11:248-56.
- ⁵³ McLaughlin, J.K. and L. Lipworth. 2004. Brain cancer and cosmetic breast implants: A review of the epidemiological evidence. *Ann. Plast. Surg.* 52(2):15-17.
- ⁵⁴ Brinton, LA., et al. 2001b. Cancer risk at sites other than the breast following augmentation mammoplasty. *Ann. Epidemiol.* 11:248-56.
- ⁵⁵ Cook, L.S. 1997. Characteristics of women with and without breast augmentation. *J. Amer. Med. Assoc.* 20:1612-7.
- ⁵⁶ Fryzek, J.P., et al. 2000. Characteristics of women with cosmetic breast augmentation surgery compared with breast reduction surgery patients and women in the general population of Sweden. *Ann Plast Surg.* 45(4):349-56.
- ⁵⁷ Kjølner K., et al. 2003. Characteristics of women with cosmetic breast implants compared with women with other types of cosmetic surgery and population-based controls in Denmark. *Ann Plast Surg.* 50(1):6-12.
- ⁵⁸ Brinton, LA., et al. 2001b. Cancer risk at sites other than the breast following augmentation mammoplasty. *Ann. Epidemiol.* 11:248-56.
- ⁵⁹ Brinton, LA., et al. 2001b. Cancer risk at sites other than the breast following augmentation mammoplasty. *Ann. Epidemiol.* 11:248-56.
- ⁶⁰ Bondurant, S., V.L. Ernster and R. Herdman, Eds. 2000. Safety of silicone breast implants. Committee on the Safety of Silicone Breast Implants, Division of Health Promotion and Disease Prevention, Institute of Medicine. Washington, D.C.: National Academy Press.
- ⁶¹ Brinton, L.A., et al. 2001a. Mortality among augmentation mammoplasty patients. *Epidemiol.* 12(3):321-6.
- ⁶² Jacobsen, P.H., et al. 2004. Mortality and suicide among Danish women with cosmetic breast implants. *Arch. Int. med.* 164(22):2450-5.
- ⁶³ Koot, V., et al. 2003. Total and cost specific mortality among Swedish women with cosmetic breast implants: prospective study. *Br. J. Med.* 326(7388):527-528.
- ⁶⁴ Pukkala, E., et al. 2003. Causes of death among Finnish women with cosmetic breast implants, 1971-2001. *Ann. Plast. Surg.* 51(4):339-42.
- ⁶⁵ Jacobsen, P.H., et al. 2004. Mortality and suicide among Danish women with cosmetic breast implants. *Arch. Int. med.* 164(22):2450-5.

-
- ⁶⁶ Lugowski, S.J., et al. 2000. Analysis of silicon in human tissues with special reference to silicone breast implants. *J. Trace Elem. Med. Biol.* 14(1):31-42.
- ⁶⁷ Kjølner, K., et al. 2002. Health outcomes in offspring of Danish mothers with cosmetic breast implants. *Ann. Plast. Surg.* 48:238-245.
- ⁶⁸ Signorello, L.B., et al. 2001. Offspring health risk after cosmetic breast implantation in Sweden. *Ann. Plast. Surg.* 46:279-286.
- ⁶⁹ Hemminki, E., et al. 2004. Births and perinatal health of infants among women who have had silicone breast implantation in Finland, 1967-2000. *Acta Obstet Gynecol Scand.* 83(12):1135-40.
- ⁷⁰ Flassbeck, D.B., et al. 2003. Determination of siloxanes, silicon, and platinum in tissues of women with silicone gel-filled implants. 375(3):356-62 (for example, data from Patients B & C).
- ⁷¹ Bondurant, S., V.L. Ernster and R. Herdman, Eds. 2000. Safety of silicone breast implants. Committee on the Safety of Silicone Breast Implants, Division of Health Promotion and Disease Prevention, Institute of Medicine. Washington, D.C.: National Academy Press.
- ⁷² Bondurant, S., V.L. Ernster and R. Herdman, Eds. 2000. Safety of silicone breast implants. Committee on the Safety of Silicone Breast Implants, Division of Health Promotion and Disease Prevention, Institute of Medicine. Washington, D.C.: National Academy Press.
- ⁷³ Katzin, W.E., et al. 2005. Pathology of lymph nodes from patients with breast implants: a histologic and spectroscopic evaluation. *Am J Surg Pathol.*29(4):506-11.
- ⁷⁴ Stein, J., et al. 1999. In situ determination of the active catalyst in hydrosilylation reactions using highly reactive Pt(0) catalyst precursors. *J. Am. Chem. Soc.* 121(15):3693-3703. Chandra, G., et al. 1987. A convenient and novel route to bis(alkyne)platinum(0) and other platinum(0) complexes from Speier's hydrosilylation catalyst. *Organometallics.* 6:191-2. Lappert, M.F. and Scott, F.P.A. 1995. The reaction pathway from Speier's to Karstedt's hydrosilylation catalyst. *J. Organomet. Chem.* 492(2):C11-C13. Lewis, L.N., et al. 1995. Mechanism of formation of platinum(0) complexes containing silicon-vinyl ligands. *Organometallics.* 14:2202-13.
- ⁷⁵ Bartelink, H., et al. 2001. Recurrence rates after treatment of breast cancer with standard radiotherapy with or without additional radiation. *NEJM* 345:1378-1387.

- ⁷⁶ Jagsi, R., et al. 2005. Locoregional recurrence rates and prognostic factors for failure in node-negative patients treated with mastectomy: Implications for postmastectomy radiation. *Int. J. Radiat. Oncol. Biol. Phys.* 62(4):1035-1039.
- ⁷⁷ National Institutes of Health, National Institutes of Health, National Library of Medicine. 2005. Medline Plus ® Medical Encyclopedia: Breast Cancer (available at <http://nlm.nih.gov/medlineplus/print/ency/article/00913.htm>)
- ⁷⁸ Bartelink, H., et al. 2001. Recurrence rates after treatment of breast cancer with standard radiotherapy with or without additional radiation. *NEJM* 345:1378-1387.
- ⁷⁹ Jagsi, R., et al. 2005. Locoregional recurrence rates and prognostic factors for failure in node-negative patients treated with mastectomy: Implications for postmastectomy radiation. *Int. J. Radiat. Oncol. Biol. Phys.* 62(4):1035-1039.
- ⁸⁰ National Institutes of Health, National Institutes of Health, National Library of Medicine. 2005. Medline Plus ® Medical Encyclopedia: Breast Cancer (available at <http://nlm.nih.gov/medlineplus/print/ency/article/00913.htm>).



MENTOR

For customer service call (800) 235-5731 in USA; outside of USA contact your local Mentor representative.

www.mentorcorp.com • www.mentordirect.com
www.mentor4me.com

Manufacturer

MENTOR
Irving, TX 75038 USA



European Representative

Mentor Medical Systems B.V.
Zemikedreef 2
2333 CL, Leiden
The Netherlands

ATTACHMENT 3
INFORMED CONSENT

Addendum to Informed Consent

Participation as a Research Subject in the “Study of the Safety and Effectiveness of the Mentor Round Low-Bleed Silicone Gel-filled Mammary Prostheses in Women Undergoing Primary Breast Augmentation, Reconstruction or Revision (Core Gel Study)”

Sponsor: Mentor Corporation, 201 Mentor Drive, Santa Barbara, CA 93111 USA

Subject: _____

Subject ID: _____

Principal Investigator: _____

1. PURPOSE OF THIS AMENDMENT

Mentor, the Sponsor of this Study, has made two changes to the Protocol, which may affect your participation in this Study. Your participation continues to be voluntary and your decision to agree or not agree with these Study changes will not result in loss of benefits to which you are otherwise entitled. You may drop out of the Study at any time and you will still receive all necessary medical care.

This amendment changes two parts of the Core Study Protocol:

- Follow-up on all patients who have study devices explanted (removed) and who are not reimplanted with a study device
- MRI scans to detect silent rupture (a rupture where there are no symptoms) in the non-MRI Substudy Cohort

2. DESCRIPTION OF CHANGES

2.1 Follow-Up On All Patients Who Have Their Study Devices Explanted And Are Not Reimplanted With A Study Device

The original Protocol said that if you had your study device(s) removed and not replaced with other study devices, your participation in the Study was complete. To assess the potential long-term health consequences of breast implants, all patients will now be followed for 10 years, even if your study device(s) are removed and not replaced with other study devices. This change to the Protocol will require you to come back for yearly visits at which time your doctor will assess you for complications. You will be paid \$150 for each completed visit.

If you do not have your original study devices removed or you are reimplanted with new study devices, this change in the protocol does not affect you.

2.2 MRI Scans to Detect Silent Rupture in the Non-MRI Substudy Cohort

In order to detect a “silent rupture” (a rupture without any symptoms or visible changes), the Protocol has been revised so that all subjects will have MRI (magnetic resonance imaging) scans. The MRI scan has been determined to be the best way to find out without performing surgery if your implant has ruptured. This type of examination produces a picture of your breasts without using x-rays and is commonly performed in the x-ray departments of most hospitals to detect problems in bones, lungs, and other areas of the body.

If you are not part of the MRI Substudy, you will be offered the opportunity to have an MRI scan at 6, 8, and 10 years. The results of the scan will be shared with you and your doctor. If you were originally chosen to be part of the MRI Substudy, your involvement does not change – you will continue to undergo MRI scans every other year through 10 years.

If you elect to have an MRI scan, you will have to lie on your stomach with your breast(s) in a special holder. You will then be placed in the machine, which may be open or may be like going into a tunnel. Some patients experience uneasiness at being in a closed space. While the machine is taking images of your breast, it will make a noise. In order to have an MRI scan, you cannot have a history of claustrophobia. The procedure should take about one hour. Mentor will pay for the MRI scans in this Study.

3. COSTS

It is not expected that you will incur any additional costs because of these two Protocol changes.

4. QUESTIONS

If you have any questions about this Informed Consent addendum, you should contact your doctor, Dr. _____ at () _____.

For questions regarding your participation in the Study and your rights as a research patient, please contact the local, national, or non-local independent reviewer of the research listed below:

IRB _____
Address _____

5. ACKNOWLEDGEMENT

I was provided this Addendum to the Informed Consent and have talked with my doctor to discuss this information. All my questions have been answered to my satisfaction and I have been provided a copy of this addendum for my records.

By signing below, and marking an “X” in the boxes next to the statements with which you agree, I agree to:

- Return for yearly exams even if I have my study devices explanted (removed).

- If I am not already part of the MRI Substudy, undergo MRI scans at 6, 8, and 10 years.
Note: there is no need to mark this box if you are part of the MRI Substudy.

Please sign, date, and print your name.

Subject’s Signature

Date

Subject’s Printed Name

Subject’s ID: _____

Signature of Person Obtaining Consent
(if applicable)

Date

Informed Consent

Participation as a Research Subject in the “Study of the Safety and Effectiveness of the Mentor Round Low-Bleed Silicone Gel-filled Mammary Prostheses in Women Undergoing Primary Breast Augmentation, Reconstruction or Revision (Core Gel Study)”

Sponsor: Mentor, 201 Mentor Drive, Santa Barbara, CA 93111 USA

Patient: _____ Study ID: _____

Principal Investigator: _____

1. PURPOSE AND BACKGROUND OF THIS STUDY

You are being asked to take part in a research study of breast implants. This study is sponsored by Mentor, a manufacturer of plastic surgery products. The purpose of this study is to determine the safety and effectiveness of the smooth and textured surface Mentor Round Low-Bleed Silicone Gel-filled Mammary Prostheses in women who are undergoing primary breast augmentation, primary breast reconstruction or revision. For example, safety information on the rate of capsular contracture, rupture, and infection will be collected, and used to help determine device safety. These implants are investigational devices. This Consent form gives you information about your breast implant procedure and your participation in this study. Your signature verifies that you have read this document and received a copy.

Approximately 1000 patients at centers across the United States will be enrolled in this research study. These patients will be implanted with silicone breast prostheses and monitored for 10 years to collect information on risks associated with the implant surgery as well as changes in the way these patients feel about themselves.

Breast implants have been used in nearly two million women since the early 1960s. There are known risks and potential complications from having breast implants. Since 1992 the Food and Drug Administration (FDA) has allowed limited silicone gel implants to clinical studies of breast reconstruction after mastectomy for cancer, correction of deformities, or replacement of damaged implants. The FDA has not formally approved these gel-filled breast implants as safe and effective because additional scientific evidence needs to be collected. Your participation will help answer the remaining questions.

Your participation is voluntary.

2. ELIGIBILITY REQUIREMENTS

INCLUSION CRITERIA

You will be allowed to enter the study if the following criteria are met:

- You were born female and 18 years of age or older.

- Are a candidate for one of the following:
 - Primary breast augmentation (general breast enlargement or sagging after breast feeding)
 - Primary breast reconstruction (for cancer, trauma, surgical loss of breast or congenital deformity)
 - Revision surgery (if you currently have a silicone filled implant or a saline filled implant).
- Sign the Informed Consent
- Agree to follow the procedures for explant analysis.
- Agree to comply with the follow-up procedures, including returning for all follow-up visits.

EXCLUSION CRITERIA

You will *not* be allowed to enter the study if you meet any of the following criteria:

- You are pregnant.
- Have nursed a child within three months of this study enrollment.
- Have been implanted with any silicone implant other than breast implants (e.g. silicone artificial joints or facial implants).
- Have a confirmed diagnosis of the following rheumatic diseases or syndromes: SLE, Sjogren's syndrome, scleroderma, polymyositis, or any connective tissue disorder, rheumatoid arthritis, crystalline arthritis, infectious arthritis, spondyarthropathies, any other inflammatory arthritis, osteoarthritis, fibromyalgia, or chronic fatigue syndrome.
- Currently have a condition that could increase risk or complicate wound healing (except reconstruction patients).
- Are an Augmentation patient and have a diagnosis of active cancer of any type.
- Have an infection or an accumulation of pus in a body tissue (abscess), anywhere in the body.
- Have a tissue condition that is clinically incompatible with the implant (e.g. tissue damage resulting from radiation, inadequate tissue, or compromised vascularity).
- Have any condition, or are under treatment for any condition, that your doctor determines to be an unwarranted surgical risk.
- Have a physical abnormality that could lead to significant postoperative complications.
- Have characteristics that are unrealistic/unreasonable with the risks involved with the surgical procedure.
- Have a premalignant breast disease without a subcutaneous mastectomy.
- Have untreated or inappropriately treated breast cancer, without mastectomy.
- Have an implanted metal or metal devices, history of claustrophobia, or other condition that would make a MRI scan prohibitive.

You should ask your doctor to clarify any terms you do not understand. Also, your doctor must provide a copy of this document to you.

3. DEVICE DESCRIPTION

Two types of Mentor Round Low-Bleed Silicone Gel-filled Mammary Prostheses will be used in the study: the Siltex textured surface device and the smooth surface device. Each implant is a silicone elastomer (rubber) mammary device that is supplied individually packaged in a doubled wrapped packaging system, sterile, and non-pyrogenic (does not cause fever). Each device consists of a silicone shell encasing a silicone gel filler material with a patch on the posterior side of the device. The basic smooth device shell consists of a silicone layer sandwiched in between two other silicone layers. This construction acts as a barrier to slow the diffusion of (spread) any gel filler materials through the shell. The Siltex textured shell consists of a smooth shell to which is bonded an additional layer of silicone with a textured pattern imprinted into its surface. The Siltex shell is intended to prevent tissue ingrowth. The implants will be available in sizes 100cc through 800ccs.

Your plastic surgeon will discuss these implants with you and explain why a particular implant may be best suited for you.

4. SECOND OPINIONS

If any problems or complications occur during the study, you may be asked or wish to obtain second opinions. You have the right to consult a physician of your choice.

5. STUDY PROCEDURES

You will talk about your procedure and participation in this Study with your doctor, in advance, and you should take sufficient time to think about your participation. You should check with your insurance company prior to the operation, as the surgery may affect your coverage.

Your participation in this study will be for a period of ten years. You will be seen at 6 months, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 years. It is very important that you come back for **all** postoperative visits, as the information obtained from those exams is extremely important in the study of these devices.

For patients who have undergone breast implantation either as a cosmetic or a reconstructive procedure, health insurance premiums may increase, coverage may be dropped, and/or future coverage may be denied. Treatment of complications may not be covered as well. Check with your insurance company regarding these coverage issues.

Baseline

If you agree to be in this research study, you will first have to be examined by your doctor to determine if you are a good candidate and if you are eligible. This screening may involve referral to other specialists. Follow-up visits to other specialists may also be required. During this visit, a medical history and physical examination will be completed.

Your doctor will ask you questions about any rheumatology diseases and symptoms you might have and you will be asked to fill out quality of life questionnaires.

Rheumatology Assessment

Your doctor will administer a rheumatic disease diagnosis questionnaire prior to your surgery. This is required to provide information about the possible relationship breast implants may have with connective tissue disorders, arthritis and rheumatic conditions. This questionnaire will be administered again at the 1, 2, 3, 4, 5, 6, 7, 8, 9, and 10 year visits after your surgery.

Quality of Life Questionnaires

You will be asked to complete Quality of Life questionnaires prior to your surgery. These are “paper and pencil” questionnaires, which will take approximately 30 minutes to complete. These are required to measure how you feel about your body before and after your breast implant procedure and are a very important part of the research. You will be asked to complete these questionnaires again at the 1, 2, 4, 6, 8, and 10 year visits after your surgery.

Description of the Operation

A surgeon using accepted standards of practice will perform your operation. The operation may be performed in a physician’s office, a hospital operating room or in an outpatient surgical center. Hospitalization may or may not be required. Your doctor will explain the particular type of implant that will be used, how and where it will be placed and the type of anesthesia to be used. He/she will also give you an overall description of the operation.

You may require surgery to correct any complications that may arise or revisions such as change in implant size that you may request.

Follow-up Visits

After your surgery, you will be asked to make visits at the following time periods after the surgery: 6 months, 1, 2, 3, 4, 5, 6, 7, 8, 9, and 10 years. Each visit will take about 60 minutes. Your doctor will perform an evaluation of the status of the implant and you will be examined for the presence of any post –surgical complications.

You are making a commitment to continue in the study for the duration and to complete all of these follow-up visits. The information obtained from these visits is important in the study of these breast implants. If you move, arrangements will be made with your doctor for follow-up with another doctor in your area.

Magnetic Resonance Imaging (MRI)

Breast implants may not last a lifetime. The shell may rupture due to wear and tear, or direct injury. Rupture should be suspected if there is a change in character of the implant such as a new, persistent burning sensation on one side or a change in softness, texture or shape of the implant and may be difficult to diagnose without surgical exploration or a magnetic resonance imaging (MRI) scan. This type of examination produces a picture of your breasts without using x-rays and is commonly used in the x-ray departments of most hospitals to detect problems in bones, lungs and all other areas of the body.

The MRI scan has been determined to be the best way to find out if your implant has ruptured without performing surgery. In order to detect a “silent rupture” (a rupture without any symptoms or visible changes), you may be in a subset of patients who will undergo an MRI scan at 1, 2, 4, 6, 8, and 10 years after your surgery. If you do, you will have to lay on your stomach with your breast in a special holder. You will then be placed in the machine, which may be open or may be like going into a tunnel. Some patients experience an uneasiness at being in a closed space. While the machine is taking images of your breast, it will make a noise. In order to have an MRI scan, you must not have any implanted metal or metal devices in your body, or a history of claustrophobia. The procedure should take about an hour. Mentor will pay for the MRI scans.

Any patient who is suspected of having a ruptured implant while in the study will be examined by her doctor and undergo an MRI scan to see if her implants are ruptured. Mentor will pay for these MRI scans.

6. IMPLANT REGISTRY

As a participant in this study you will be asked to participate in the breast implant patient registry. This will allow Mentor to notify you, if necessary, of any new information about the safety of your silicone-filled breast implant(s). Every effort will be made to keep the information in the registry confidential and that information will only be provided to the FDA upon their request. However, under certain circumstances, Congress has the right to get clinical data from the FDA or a court could order disclosure of certain information that could include your clinical study records.

Your doctor will provide you with identification information, which pertains to your implant(s) after your surgery. This will let you know what type of implant you have. This should be kept with your important papers for future reference. You should also remain in contact with your doctor to get current important information or, if you leave your doctor, you should leave a forwarding address.

7. BENEFITS OF BREAST IMPLANTS

Breast augmentation surgery is elective surgery designed to improve your appearance. Women with breast cancer have reported that breast reconstruction with mammary implants has aided in their recovery from breast cancer and has reduced emotional stress by helping to return their body to a more natural appearance.

You may benefit other women by providing information about possible health problems associated with breast implants and to help demonstrate the safety and effectiveness of the device. There are no direct additional benefits to you beyond receiving this implant.

8. RISKS AND DISCOMFORTS OF THE OPERATION

Breast surgery requires an incision. As with any surgical procedure, there are risks such as:

Infection: (severe infection on rare occasions results in Toxic Shock Syndrome or TSS). An infection can result from any surgery and produce swelling, tenderness, pain and fever. Almost all infections appear within a few days of the operation but may appear at any time after your surgery. If you get a serious infection, which doesn't go away with antibiotics, your implant may have to be removed.

Hematoma Formation: a collection of blood in the surgical area.

Seroma: (fluid accumulation around the implant which may or may not require removal). Your body will absorb both areas of fluid accumulation (seromas) and small hematomas, but large ones may have to be drained surgically to permit proper healing. Surgical techniques, under most circumstances, can minimize though not eliminate them.

Scarring: Any incision in the skin will leave a scar that is permanent. While your surgeon will use plastic surgical techniques to make this as inconspicuous as possible, some patients have a skin quality that results in more conspicuous scars no matter how the incision is repaired.

There are risks from anesthetics as well.

9. RISKS AND DISCOMFORTS OF BREAST IMPLANTS

Breast implants have certain specific risks and complications, which may include:

Capsular Contracture: The normal healing scar membrane that forms around the implant can, in some women, tighten and squeeze the implant. This can cause the implant to feel firm. This firmness can range from slight to quite hard and the firmest ones can cause varying degrees of discomfort or pain. In addition to the firmness capsular contracture can result in a misshapen breast, visible surface wrinkling and/or displacement of the implant. Detection of breast cancer by mammography may also be more difficult.

If you wish to have this contracture softened, the scar tissue can be released or removed by making an incision into the breast during an operation called an Open Capsulotomy.

Your surgeon may recommend a technique called a closed capsulotomy in which he/she will apply forceful external pressure to the breasts to "break up" the scar tissue. Mentor does not recommend this technique because it could result in several complications such as breakage of the implant, bleeding, displacement of the implant resulting in asymmetry or distortion.

Your surgeon will explain the possible complications, as well as help you determine the best method for correcting capsular contracture.

Calcification of the capsule surrounding the implant can also occur. This can contribute to the hardening of the tissue and may be painful. Sometimes it may be necessary to remove the implant and/or the calcified capsule.

Deflation/Rupture/Leakage

Breast implants **are not lifetime devices** and cannot be expected to last forever. Some implants deflate or rupture in the first few months after being implanted and some deflate after several years; others are intact 10 or more years after the surgery.

a. Silicone Gel-Filled Breast Implants – When silicone gel-filled implants rupture, some women may notice decreased breast size, nodules (hard knots), uneven appearance of the breasts, pain or tenderness, tingling, swelling, numbness, burning, or changes in sensation.

Other women may unknowingly experience a rupture without any symptoms (i.e., “silent rupture”). Magnetic resonance imaging (MRI) with equipment specifically designed for imaging the breast may be used for evaluating patients with suspected rupture or leakage of their silicone gel-filled implant.

Silicone gel which escapes the fibrotic capsule surrounding the implant may migrate away from the breast. The free silicone may cause lumps called granulomas to form in the breast or other tissues where the silicone has migrated, such as the chest wall, armpit, arm, or abdomen.

Plastic surgeons usually recommend removal of the implant if it has ruptured, even if the silicone is still enclosed within the scar tissue capsule, because the silicone gel may eventually leak into surrounding tissues. If you are considering the removal of an implant and the implantation of another one, be sure to discuss the benefits and risks with your doctor.

FDA completed a retrospective study on rupture of silicone gel-filled breast implants.¹ This study was performed in Birmingham, Alabama and included women who had their first breast implant before 1988. Women with silicone gel-filled breast implants had a MRI examination of their breasts to determine the status of their current breast implants.

The 344 women who received a MRI examination had a total of 687 implants. Of the 687 implants in the study, at least two of the three study radiologists agreed that 378 implants were ruptured (55%). This means that 69% of the 344 women had at least one ruptured breast implant. Of the 344 women, 73 (21%) had extracapsular silicone gel in one or both breasts. Factors that were associated with rupture included increasing age of the implant, the implant manufacturer, and submuscular rather than subglandular location of the implant. A summary of the findings of this study is also available on FDA’s website at <http://www.fda.gov/cdrh/breastimplants/studies/biinterview.pdf> and

¹ Brown SL, Middleton MS, Berg WA, Soo MS, Pennello G. Prevalence of rupture of silicone gel breast implants in a population of women in Birmingham, Alabama. American Journal of Roentgenology 2000; 175-1-8.

<http://www.fda.gov/cdrh/breastimplants/studies/birupture.pdf>.

Robinson et al. studied 300 women who had their implants for 1 to 25 years and had them removed for a variety of reasons.² Visible signs of rupture in 51% of the women studied were found. Severe silicone leakage (silicone outside the implant without visible tears or holes) was seen in another 20%. Robinson et al. also noted that the chance of rupture increases as the implant ages.

Other studies indicate that silicone may escape the capsule in 11-23% of rupture cases.^{3,4,5,6}

For the Core Gel Study, a randomly selected subset of 405 patients will undergo MRI scans at 1, 2, 4, 6, 8, and 10 years. The purpose of this substudy is to determine the rate of silent rupture. Scans will be sent to a central reading center to be read by an independent breast MRI radiologist. This radiologist will be blinded to the patient name and site. The results will be entered into the study database. All patients, whether or not they are randomized to undergo MRI scans, will be directed to see their physician whenever the patient believes a rupture has occurred.

Gel Bleed: Silicone gel is made up of a sponge like mesh filled with silicone in oil form. This oil is used in many medical products such as syringes, pills and anti-gas medications such as Mylanta. It is known that some very small amounts of the oil part of the gel “bleeds” through the implant’s covering or envelope. Although most of this stays in the implant pocket or is trapped in the surrounding scar, minute amounts of this silicone could possibly travel (migrate) to different parts of the body.

Silicone oil has not been demonstrated to cause cancer or other illnesses.

Changes in Nipple and Breast Sensation/Breast Pain: Any surgery on the breast, including a biopsy or breast implant surgery, can result in the breast and/or nipple being oversensitive or undersensitive on one or both sides. This change can vary in degree and may be temporary or permanent. It may affect comfort while nursing or sexual response.

Most women undergoing augmentation or reconstruction with a mammary prosthesis will experience some breast and/or chest pain postoperatively. While this pain normally subsides in most women as they heal after surgery, it can become a chronic problem in other women.

² Robinson OG, Bradley EL, Wilson DS. Analysis of explanted silicone implants: a report of 300 patients. *Ann Plast Surg.* 1995; 34:1-7.

³ Vinnik CA. Migratory silicone – clinical aspects. *Silicone in Medical Devices – Conference Proceedings.* 1991 February 1-2; Baltimore, MD: U.S. Department of Health and Human Services, FDA Publication No. 92-4249 (p.59-67).

⁴ Duffy MJ, Woods JE, Health risks of failed silicone gel breast implants: a 30-year clinical experience. *Plast Reconstr Surg* 1994;94:295-299.

⁵ Berg WA, Caskey CI, Hamper UM, Kuhlman JE, Anderson ND, Chang BW, Sheth S, Zerhouni EA. Single- and double-lumen silicone breast implant integrity: Prospective evaluation of MR and US criteria. *Radiology* 1995;197:45-52.

⁶ Gorczyca DP, Schneider E, DeBruhl ND, Foo TKF, Ahn CY, Sayre JW, Shaw WW, Bassett LW. Silicone breast implant rupture: Comparison between three-point Dixon and fast spin-echo MR imaging. *AJR* 1994;162:305-310.

Chronic pain can be associated with hematoma, migration, infection, and implants that are too large or capsular contracture. Sudden severe pain may be associated with implant rupture.

Interference with Mammography in Detection of Cancer: An implant may interfere with the detection of early breast cancer because it may “hide” suspicious lesions in the breast during an x-ray examination. It is especially important for women who are at high risk of developing breast cancer to consider this before having implants. The earlier cancer is detected, the better a chance for a cure.

Regular self-examination is very important for all women but especially if you have implants. You are urged to contact the American Cancer Society for literature and instructions on the early detection of cancer.

Since the breast is compressed during mammography, it is possible, but rare, for an implant to rupture. These problems can be reduced, but not eliminated, by asking if the personnel at the facility are experienced in performing mammography on women with implants. Before the mammography exam, you should tell the technologist that you have implants. The technologist should take special care when compressing the breast to avoid rupture. Also, an experienced technologist should know how to push the implant away from the breast tissue to get the best possible views of the tissue. Even when this special technique is used, some breast tissue may be missed in the x-ray. More x-ray views are necessary with these special techniques; therefore, women with breast implants will receive more radiation. However, the benefit of the mammogram in finding cancer outweighs the risk of the additional x-rays.

Calcium Deposits: Small spots of calcium in the breast are often found in any breast and can be seen on x-rays (mammography). These deposits may not occur in breasts with implants and may not appear for years after the implant surgery. They are benign (noncancerous) and cause no problems but must be differentiated from the calcium that is often seen in breast cancers. An expert radiologist can usually tell a benign (non-cancerous) calcium spot from a malignant one but occasionally a biopsy may be necessary to make this distinction. Some patients may develop a thin layer of calcium in the scar capsule that surrounds the implant. This is almost always associated with capsular contracture but otherwise causes no known problem.

Delayed Wound Healing: In some cases, the incision site fails to heal normally.

Extrusion: Unstable or compromised tissue covering and/or interruption of wound healing may result in extrusion, which is when the breast implant comes through the skin.

Necrosis: Necrosis is the formation of dead tissue around the implant. This may prevent wound healing and require surgical correction and/or implant removal. Permanent scar deformity may occur following necrosis. Factors associated with increased necrosis include infection, use of steroids in the surgical pocket, smoking, chemotherapy/radiation, and excessive heat or cold therapy.

Breast Tissue Atrophy/Chest Wall Deformity: The pressure of the breast implant may cause the breast tissue to thin and shrink. This can occur while implants are still in place or following implant removal without replacement.

Dissatisfaction with Cosmetic Results: You may not be satisfied with the appearance of your breasts after implants. The surgeon has only limited control over the final shape which is finally determined by how your chest, your breast and the implant all fit together. Incorrect implant size, excessive scarring and misplacement of implants may interfere with satisfactory appearance. Asymmetry (unequal breast size or shape) may not be totally corrected even by different sized implants. The implanted breast may sag or droop (ptosis) over time, much like a natural breast.

In addition, breast implants will not prevent your breast(s) from sagging after pregnancy. Very rarely the implant may change position or break through the skin, particularly if you have very thin breast tissue covering it. You may be able to feel or see wrinkles in the implant through your skin.

Granulomas: These are non-cancerous lumps that can form when certain body cells surround foreign material, such as silicone. Like any lump, it should be further evaluated to distinguish it from a lump that might be cancerous and require biopsy.

Resurgery: Whether you are undergoing augmentation or reconstruction, you should understand that there is a high chance that you will need to have additional surgery at some point to replace or remove the implant. Also, problems such as rupture, capsular contracture, infection, shifting, and calcium deposits can require removal of the implants. Many women decide to have the implants replaced, but some women do not. Those who do may have cosmetically unacceptable dimpling and/or puckering of the breast following removal of the implant.

10. UNKNOWN RISKS

The long-term biological effects of silicone compounds in women have received a great deal of attention over the last 25 years. Both rupture and gel bleed may result in silicone going to other parts of the body. Concerns have included connective tissue disease, immunological and neurological disorders, and the risk of cancer.

Connective Tissue Disorders: There have been reports describing an association between certain silicone-based products and certain connective tissue disorders. These are a group of disorders in which the body reacts to its own tissue as though it was foreign material. These disorders can cause long-term, serious, disabling health problems. Symptoms may include pain and swelling of joints, tightness, redness or swelling of the skin, swollen glands or lymph nodes, unusual and unexplained fatigue, swelling of the hands and feet, and unusual hair loss. Generally, people who have these relatively rare connective tissue disorders experience a combination of these and other symptoms.

Some cases of these disorders have been reported in women with breast implants. Some of these women have reported a reduction in symptoms after their implants were removed.

Neurological Symptoms: There have been some reports of patients experiencing neurological symptoms at variable times after breast implant surgery. Some of the complaints have involved difficulties with vision, sensation, muscle strength, walking, and balance.

Cancer: There is presently no established scientific evidence that links either silicone gel-filled or saline-filled breast implants with cancer. However, the possibility cannot be ruled out.

Birth Defects: Preliminary animal studies and a study in humans show no evidence that birth defects are caused by silicone implants. However, to rule out that possibility for humans, further scientific studies are necessary to show whether or not breast implants are associated with birth defects.

Breast feeding: Many women with breast implants have nursed their babies successfully. Any breast surgery, such as breast biopsy or partial mastectomy, that removes a great deal of breast tissue, or even breast implant surgery, could theoretically interfere with your ability to nurse your baby or the amount of milk available.

In recent years there has been some question as to whether small amounts of silicone that “bleeds” from gel-filled breast implants can find its way into breast milk, and, if this were to occur, could that affect the child. If you are considering breast-feeding, you are urged to check with your doctor or the FDA’s Breast Implant Information line at (800-532-4440) for the most current information. The American Academy of Pediatrics has stated that “there is no reason why a woman with implants should refrain from nursing.”

11. ALTERNATIVE PROCEDURES TO PARTICIPATION IN THIS STUDY

You may choose not to participate in this study. There are several alternative procedures to breast augmentation with silicone gel-filled breast implants. These include having nothing done or wearing an external prosthesis inside your bra. Breasts can be made by transferring fatty tissues from other parts of the body such as the stomach, buttock or back (flap procedure). For many women, saline-filled breast implants are also an alternative.

Your doctor will discuss these and other procedures and their relative risks and benefits.

12. IMPORTANT FACTORS TO CONSIDER WHEN DECIDING TO HAVE GEL-FILLED IMPLANTS

- Whether you are undergoing augmentation or reconstruction, be aware that breast implantation may not be a one time surgery. You are likely to need additional surgery and doctor visits over the course of your life.
- Breast implants are not considered lifetime devices. You will likely undergo implant removal with or without replacement over the course of your life.

- Many of the changes to your breast following implantation are irreversible (cannot be undone). If you later choose to have your implant(s) removed, you may experience unacceptable dimpling, puckering, wrinkling, or other cosmetic changes of the breast.
- Breast implants may affect your ability to produce milk for breast feeding. Also, breast implants will not prevent your breast from sagging after pregnancy.
- With breast implants, routine screening mammography will be more difficult, and you will need to have additional views, which means more time and radiation.
- For patients who have undergone breast implantation either as a cosmetic or a reconstructive procedure, health insurance premiums may increase, coverage may be dropped, and/or future coverage may be denied. Treatment of complications may not be covered as well. You should check with your insurance company regarding these coverage issues.

Augmentation - Insurance does not cover breast augmentation and may not cover reoperation (additional surgery) and additional doctor's visits following augmentation.

Reconstruction - Most insurance covers the first breast reconstruction operation. Insurance coverage for reoperation procedures or additional doctor's visits following reconstruction may not be covered, depending on the policy.

13. COSTS/FINANCIAL INCENTIVES

All costs incurred for this surgical procedure are between you and your doctor(s), including the cost of standard visits and any additional procedures or visits to another specialist that may be required for the operation. If, during the course of the study, you exhibit signs of a rheumatological condition, you will be referred to a rheumatologist for an evaluation at Mentor's expense. Mentor will also pay for the MRI examinations if you are in the group required to undergo MRI procedures, or if you are suspected of having a ruptured implant.

Mentor will provide to you installment payments that may assist with costs incurred as a result of your participation in this Study. Incentive checks will be made out in your name and mailed directly to your home. You will be paid after the completion of the following post-operative visits:

Payment	Visit	Payment	Visit
	Implantation		5 year visit
	6 month visit		6 year visit
	12 month visit		7 year visit
	24 month visit		8 year visit
	Bonus if no visits are missed through 24 months		9 year visit
	3 year visit		10 year visit
	4 year visit		Bonus if no visits are missed through 10 years (all 11 postoperative visits)
Total incentives for all visits			
Total incentive with no missed postoperative visits			

14. COMPENSATION FOR INJURY

Compensation for physical injuries, complications or medical treatment from your participation in this study is not available from Mentor other than outlined in the attached Mentor Warranty. If your complication is related to rupture, you will be reimbursed under the warranty policy. If a problem occurs, medical treatment will continue to be available. Your doctor will let you know what to do if you experience any complications while you are in this Study.

15. CONFIDENTIALITY

Your confidentiality will be protected as much as possible throughout this study. Records generated during this study which identify you by name will be maintained as confidential, with the exception that those records, as well as your medical records, may be reviewed by authorized representatives from your doctor’s office and from Mentor. In addition, authorized representatives from the U.S. Food and Drug Administration may inspect the records. Results of data collected will be reported as numbers only, no names. Under certain circumstances, your clinical records could be obtained by Congress or a court order. While every effort will be taken to keep this information confidential, under these special circumstances, this could mean public disclosure of your surgery and loss of your privacy.

16. LEGAL RISK AND ANALYSIS OF REMOVED IMPLANT

If your implant needs to be removed, Mentor requests the implant be returned to Product Evaluation to be analyzed. This could have implications in any legal action involving your implant. Mentor will ask your permission to analyze it, a process that may alter or destroy it. You will be contacted first through your doctor and asked whether you wish to give permission for such an evaluation. Results of the analysis will be made available to you, your doctor and/or the FDA upon request. Mentor and the FDA believe there is scientific benefit to testing an explanted implant

17. QUESTIONS

During the course of the study, you will be informed by your doctor regarding any new information about Mentor Round Low-Bleed Silicone Gel-filled Mammary Prostheses, which may become known during the study. You also have the right to ask questions and have them answered.

For questions about your procedure and any research related injury, you should contact your doctor, Dr. _____ at () _____.

For questions regarding your participation in the Study and your rights as a research patient, please contact the local, national, or non-local independent reviewer of the research listed below:

Western Institutional Review Board (WIRB)
3535 7th Ave., NW
Olympia, Washington 98502
206-943-1410 FAX 206-943-4522

18. VOLUNTARY PARTICIPATION AND WITHDRAWAL FROM STUDY

Your participation in this Study is voluntary and your decision not to participate will not result in loss of benefits to which you are otherwise entitled; however, you will not receive Mentor Round Low-Bleed Silicone Gel-filled Mammary Prostheses without being in this Study. You may drop out at any time and you will still receive all necessary medical care.

19. ACKNOWLEDGEMENT

I was provided this Informed Consent in advance and met with my doctor, to discuss the information. All my questions have been answered to my satisfaction and I have been provided a copy of this Informed Consent and the Experimental Patient's Bill of Rights (in California only).

Patient/Patient's Signature

Date

Patient/Patient's Printed Name

Signature of Person Obtaining Consent

Date

Warranty Summary for Mentor Round Low-Bleed Silicone Gel-filled Mammary Prostheses

A. What Does the Warranty Cover?

The warranty covers patients' uninsured, out-of pocket costs that are directly related to breast implant revision surgery. When the warranty applies, Mentor provides the following:

- **Free Lifetime Replacement:** Throughout a patient's lifetime Mentor will replace, at no cost, the same or a similar type of Mentor breast implant when implant replacement is required. If a more expensive product is requested, Mentor will invoice the surgeon for the price difference.
- **Financial Assistance:** For the first five years following a breast implant procedure, Mentor will provide financial assistance up to \$1,200, per revision surgery to help cover operating room expenses and anesthesia expenses not covered by insurance.

B. What Products are covered?

The Mentor breast implant warranty automatically applies to Mentor Round Low-Bleed Silicone Gel-filled Mammary Prostheses that are implanted as part of the this Study, provided these implants have been:

- Implanted in accordance with Mentor literature, current to the date of implantation, and other notifications or instructions published by Mentor.
- Used by appropriately qualified, licensed surgeons, in accordance with accepted surgical procedures.

C. What Events are Covered?

This Mentor breast implant warranty applies to rupture of any all Mentor Round Low-Bleed Silicone Gel-filled Mammary Prostheses.

Other loss-of-shell integrity events also may be covered by this warranty. A physician retained by Mentor will determine if specific, additional events should be covered. However, events listed in section D of this brochure will not be covered.

D. What Events are Not Covered?

The Mentor breast implant warranty does not cover the following:

- Removal of intact implants due to capsular contracture, wrinkling or rippling.
- Loss of implant shell integrity resulting from reoperative procedures, open capsulotomy, or closed compression capsulotomy procedures.
- Removal of intact implants for size alteration.

E. How are Claims Filed?

To file a warranty claim for covered events, the surgeon must contact Mentor's Consumer Affairs Department.

Warranty Summary for Mentor Round Low-Bleed Silicone Gel-filled Mammary Prostheses

- When necessary materials from the surgeon are received and confirmed by Mentor, replacement product(s) and/or a check will be issued to the appropriate party in accordance with Mentor's warranty.
- Prior to reimbursement for revision surgery, the surgeon must complete all forms and requested documentation about medical treatments and expenses

ATTACHMENT 4
BAKER CLASSIFICATION GRADING SCALE

BAKER CLASSIFICATION GRADING SCALE

Class	Description
1	The breast feels as soft as an unoperated one and the implant cannot be palpated.
2	The breast is less soft; the implant can be palpated but it is not visible.
3	The breast is more firm; the implant can be easily palpated and it (or distortion from it) can be seen.
4	The breast is hard, tender, painful, cold and distortion is often marked.

ATTACHMENT 5
QUALITY OF LIFE QUESTIONNAIRES

 MENTOR	Core Gel Breast IDE Clinical Trial			BASELINE			
	PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO.	PATIENT NO.	PATIENT INITIALS first middle last	

ROSENBERG SELF-ESTEEM SCALE (Page 1 of 1)

TO THE PATIENT: Below are some statements with which some people agree and disagree. Please read each statement and check **one** response to each statement.

	Strongly Agree 1	Agree 2	Disagree 3	Strongly Disagree 4
1. I feel that I am a person of worth, at least on an equal basis with others.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. I feel that I have a number of good qualities.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. All in all, I am inclined to feel that I am a failure.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. I am able to do things as well as most people.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. I feel I do not have much of which to be proud.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. I take a positive attitude towards myself.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. On the whole, I am satisfied with myself.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. I wish I could have more respect for myself.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. I certainly feel useless at times.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. At times I think I am no good at all.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

 MENTOR	Core Gel Breast IDE Clinical Trial			BASELINE				
	PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO.	PATIENT NO.	PATIENT INITIALS first middle last		

TENNESSEE SELF-CONCEPT SCALE (Page 1 of 4)

TO THE PATIENT: The statements below are to help you describe yourself as you see yourself. Please respond to them as if you were describing yourself **to yourself**. Do not omit any item. Read each statement carefully, then select one of the five responses listed below. On the test, put a **circle** around the response you chose. If you want to change an answer after you have circled it, do not erase it but put an X mark through the response and then circle the response you want.

<i>Remember, put a circle around the response number you have chosen for each statement.</i>	Completely False	Mostly False	Partly True and Partly False	Mostly True	Completely True
1. I have a healthy body.	1	2	3	4	5
2. I am an attractive person.	1	2	3	4	5
3. I consider myself a sloppy person.	1	2	3	4	5
4. I am a decent sort of person.	1	2	3	4	5
5. I am an honest person.	1	2	3	4	5
6. I am a bad person.	1	2	3	4	5
7. I am a cheerful person.	1	2	3	4	5
8. I am a calm and easygoing person.	1	2	3	4	5
9. I am a nobody.	1	2	3	4	5
10. I have a family that would always help me in any kind of trouble.	1	2	3	4	5
11. I am a member of a happy family.	1	2	3	4	5
12. My friends have no confidence in me.	1	2	3	4	5
13. I am a friendly person.	1	2	3	4	5
14. I am popular with men.	1	2	3	4	5
15. I am not interested in what other people do.	1	2	3	4	5
16. I do not always tell the truth.	1	2	3	4	5
17. I get angry sometimes.	1	2	3	4	5
18. I like to look nice and neat all the time.	1	2	3	4	5
19. I am full of aches and pains.	1	2	3	4	5
20. I am a sick person.	1	2	3	4	5
21. I am a religious person.	1	2	3	4	5
22. I am a moral failure.	1	2	3	4	5
23. I am a morally weak person.	1	2	3	4	5

 MENTOR	Core Gel Breast IDE Clinical Trial			BASELINE						
	TRIAL NO. 10-009	COUNTRY NO. 0 0 1			SITE NO.		PATIENT NO.		PATIENT INITIALS first middle last	

TENNESSEE SELF-CONCEPT SCALE (Page 2 of 4)

<i>Remember, put a circle around the response number you have chosen for each statement.</i>	Completely False	Mostly False	Partly True and Partly False	Mostly True	Completely True
24. I have a lot of self-control.	1	2	3	4	5
25. I am a hateful person.	1	2	3	4	5
26. I am losing my mind.	1	2	3	4	5
27. I am an important person to my friends and family.	1	2	3	4	5
28. I am not loved by my family.	1	2	3	4	5
29. I feel that my family doesn't trust me.	1	2	3	4	5
30. I am popular with women.	1	2	3	4	5
31. I am mad at the whole world.	1	2	3	4	5
32. I am hard to be friendly with.	1	2	3	4	5
33. Once in a while I think of things too bad to talk about.	1	2	3	4	5
34. Sometimes when I am not feeling well, I am cross.	1	2	3	4	5
35. I am neither too fat nor too thin.	1	2	3	4	5
36. I like my looks just the way they are.	1	2	3	4	5
37. I would like to change some parts of my body.	1	2	3	4	5
38. I am satisfied with my moral behavior.	1	2	3	4	5
39. I am satisfied with my relationship to God.	1	2	3	4	5
40. I ought to go to church more.	1	2	3	4	5
41. I am satisfied to be just what I am.	1	2	3	4	5
42. I am just as nice as I should be.	1	2	3	4	5
43. I despise myself.	1	2	3	4	5
44. I am satisfied with my family relationships.	1	2	3	4	5
45. I understand my family as well as I should.	1	2	3	4	5
46. I should trust my family more.	1	2	3	4	5
47. I am as sociable as I want to be.	1	2	3	4	5
48. I try to please others, but I don't overdo it.	1	2	3	4	5
49. I am no good at all from a social standpoint.	1	2	3	4	5

 MENTOR	Core Gel Breast IDE Clinical Trial			BASELINE						
	TRIAL NO. 10-009	COUNTRY NO. 0 0 1			SITE NO.		PATIENT NO.		PATIENT INITIALS first middle last	

TENNESSEE SELF-CONCEPT SCALE (Page 3 of 4)

<i>Remember, put a circle around the response number you have chosen for each statement.</i>	Completely False	Mostly False	Partly True and Partly False	Mostly True	Completely True
50. I do not like everyone I know.	1	2	3	4	5
51. Once in a while, I laugh at a dirty joke.	1	2	3	4	5
52. I am neither too tall nor too short.	1	2	3	4	5
53. I don't feel as well as I should.	1	2	3	4	5
54. I should have more sex appeal.	1	2	3	4	5
55. I am as religious as I want to be.	1	2	3	4	5
56. I wish I could be more trustworthy.	1	2	3	4	5
57. I shouldn't tell so many lies.	1	2	3	4	5
58. I am as smart as I want to be.	1	2	3	4	5
59. I am not the person I would like to be.	1	2	3	4	5
60. I wish I didn't give up as easily as I do.	1	2	3	4	5
61. I treat my parents as well as I should. <i>(Use past tense if parents are not living.)</i>	1	2	3	4	5
62. I am too sensitive to things my family says.	1	2	3	4	5
63. I should love my family more.	1	2	3	4	5
64. I am satisfied with the way I treat other people.	1	2	3	4	5
65. I should be more polite to others.	1	2	3	4	5
66. I ought to get along better with other people.	1	2	3	4	5
67. I gossip a little at times.	1	2	3	4	5
68. At times I feel like swearing.	1	2	3	4	5
69. I take good care of myself physically.	1	2	3	4	5
70. I try to be careful about my appearance.	1	2	3	4	5
71. I often act like I am "all thumbs".	1	2	3	4	5
72. I am true to my religion in my everyday life.	1	2	3	4	5
73. I try to change when I know I'm doing things that are wrong.	1	2	3	4	5
74. I sometimes do very bad things.	1	2	3	4	5
75. I can always take care of myself in any situation.	1	2	3	4	5

	Core Gel Breast IDE Clinical Trial			BASELINE				
	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO.	PATIENT NO.	PATIENT INITIALS first middle last			

TENNESSEE SELF-CONCEPT SCALE (Page 4 of 4)					
<i>Remember, put a circle around the response number you have chosen for each statement.</i>	Completely False	Mostly False	Partly True and Partly False	Mostly True	Completely True
76. I take the blame for things without getting mad.	1	2	3	4	5
77. I do things without thinking about them first.	1	2	3	4	5
78. I try to play fair with my friends and family.	1	2	3	4	5
79. I take a real interest in my family.	1	2	3	4	5
80. I give in to my parents. <i>(Use past tense if parents are not living.)</i>	1	2	3	4	5
81. I try to understand the other fellow's point of view.	1	2	3	4	5
82. I get along well with other people.	1	2	3	4	5
83. I do not forgive others easily.	1	2	3	4	5
84. I would rather win than lose in a game.	1	2	3	4	5
85. I feel good most of the time.	1	2	3	4	5
86. I do poorly in sports and games.	1	2	3	4	5
87. I am a poor sleeper.	1	2	3	4	5
88. I do what is right most of the time.	1	2	3	4	5
89. I sometimes use unfair means to get ahead.	1	2	3	4	5
90. I have trouble doing the things that are right.	1	2	3	4	5
91. I solve my problems quite easily.	1	2	3	4	5
92. I change my mind a lot.	1	2	3	4	5
93. I try to run away from my problems.	1	2	3	4	5
94. I do my share of work at home.	1	2	3	4	5
95. I quarrel with my family.	1	2	3	4	5
96. I do not act like my family thinks I should.	1	2	3	4	5
97. I see good points in all the people I meet.	1	2	3	4	5
98. I do not feel at ease with other people.	1	2	3	4	5
99. I find it hard to talk with strangers.	1	2	3	4	5
100. Once in a while I put off until tomorrow what I ought to do today.	1	2	3	4	5

 MENTOR	Core Gel Breast IDE Clinical Trial			BASELINE				
	PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO.	PATIENT NO.	PATIENT INITIALS first middle last		

SF-36 (Page 1 of 3)

TO THE PATIENT: This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Answer each question by circling **one** number. If you are unsure about how to answer a question, please give the best answer you can.

1. In general, would you say your health is: (Circle one number)	Excellent	Very Good	Good	Fair	Poor
	1	2	3	4	5

2. Compared to one year ago, how would you rate your health in general now? (Circle one number)	Much Better Now	Somewhat Better Now	About the Same	Somewhat Worse Now	Much Worse Now
	1	2	3	4	5

3. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much? (Circle one number for each question.)	Yes, Limited a Lot	Yes, Limited a Little	No, Not Limited at All
Vigorous activities , such as running, lifting heavy objects, participating in strenuous sports.	1	2	3
Moderate activities , such as moving a table, pushing a vacuum cleaner, bowling or playing golf	1	2	3
Lifting or carrying groceries	1	2	3
Climbing several flights of stairs	1	2	3
Climbing one flight of stairs	1	2	3
Bending, kneeling, or stooping	1	2	3
Walking more than a mile	1	2	3
Walking several blocks	1	2	3
Walking one block	1	2	3
Bathing or dressing yourself	1	2	3

 MENTOR	Core Gel Breast IDE Clinical Trial			BASELINE							
	PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1			SITE NO.		PATIENT NO.		PATIENT INITIALS first middle last	

SF-36 (Page 2 of 3)

4. During the past 4 weeks , have you had any of the following problems with your work or other regular daily activities as a result of your physical health? (Circle one number for each question.)	YES	NO
Cut down on the amount of time you spent on work or other activities	1	2
Accomplished less than you would like	1	2
Were limited in the kind of work or other activities	1	2
Had difficulty performing the work or other activities (for example, it took extra effort)	1	2

5. During the past 4 weeks , have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)? (Circle one number for each question.)	YES	NO
Cut down on the amount of time you spent on work or other activities	1	2
Accomplished less than you would like	1	2
Didn't do work or other activities as carefully as usual	1	2

6. During the past 4 weeks , to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups? (Circle one number)	Not at All	Slightly	Moderately	Quite a Bit	Extremely
	1	2	3	4	5

7. How much bodily pain have you had during the past 4 weeks? (Circle one number)	None	Very Mild	Mild	Moderate	Severe	Very Severe
	1	2	3	4	5	6

8. During the past 4 weeks , how much did pain interfere with your normal work (including both work outside the home and housework)? (Circle one number)	Not at All	A Little Bit	Moderately	Quite a Bit	Extremely
	1	2	3	4	5

 MENTOR	Core Gel Breast IDE Clinical Trial			BASELINE				
	PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO.	PATIENT NO.	PATIENT INITIALS first middle last		

SF-36 (Page 3 of 3)

9. These questions are about how you feel and how things have been with you **during the past 4 weeks**. For each question, please indicate the one answer that comes closest to the way you have been feeling. (Circle **one** number for each question.)

How much of the time during the past 4 weeks ...	All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	None of the Time
Did you feel full of pep?	1	2	3	4	5	6
Have you been a very nervous person?	1	2	3	4	5	6
Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
Have you felt calm and peaceful?	1	2	3	4	5	6
Did you have a lot of energy?	1	2	3	4	5	6
Have you felt downhearted and blue?	1	2	3	4	5	6
Did you feel worn out?	1	2	3	4	5	6
Have you been a happy person?	1	2	3	4	5	6
Did you feel tired?	1	2	3	4	5	6

10. During the past 4 weeks , how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)? (Circle one number.)	All of the Time	Most of the Time	Some of the Time	A Little of the Time	None of the Time
		1	2	3	4

11. How TRUE or FALSE is each of the following statements for you? (Circle one number for each question.)	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
	I seem to get sick a little easier than other people	1	2	3	4
I am as healthy as anybody I know	1	2	3	4	5
I expect my health to get worse	1	2	3	4	5
My health is excellent	1	2	3	4	5



MENTOR

**Core Gel Breast
IDE Clinical Trial**

BASELINE

PATIENT STUDY ID:

TRIAL NO.
10-009

COUNTRY NO.
0 | 0 | 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last

BODY ESTEEM SCALE (Page 1 of 1)

TO THE PATIENT: On this page are listed a number of body parts and functions. Please read each item and indicate how you feel about this part or function of ***your own body***, using the following scale:

- 1 = Have strong negative feelings
- 2 = Have moderate negative feelings
- 3 = Have no feeling one way or the other
- 4 = Have moderate positive feelings
- 5 = Have strong positive feelings

- | | |
|--|--|
| <input type="checkbox"/> 1. Body Scent | <input type="checkbox"/> 19. Arms |
| <input type="checkbox"/> 2. Appetite | <input type="checkbox"/> 20. Chest |
| <input type="checkbox"/> 3. Nose | <input type="checkbox"/> 21. Appearance of Eyes |
| <input type="checkbox"/> 4. Physical Stamina | <input type="checkbox"/> 22. Cheeks/Cheekbones |
| <input type="checkbox"/> 5. Reflexes | <input type="checkbox"/> 23. Hips |
| <input type="checkbox"/> 6. Lips | <input type="checkbox"/> 24. Legs |
| <input type="checkbox"/> 7. Muscular Strength | <input type="checkbox"/> 25. Physique |
| <input type="checkbox"/> 8. Waist | <input type="checkbox"/> 26. Sex Drive |
| <input type="checkbox"/> 9. Energy Level | <input type="checkbox"/> 27. Feet |
| <input type="checkbox"/> 10. Thighs | <input type="checkbox"/> 28. Sex Organs |
| <input type="checkbox"/> 11. Ears | <input type="checkbox"/> 29. Appearance of Stomach |
| <input type="checkbox"/> 12. Biceps | <input type="checkbox"/> 30. Health |
| <input type="checkbox"/> 13. Chin | <input type="checkbox"/> 31. Sex Activities |
| <input type="checkbox"/> 14. Body Build | <input type="checkbox"/> 32. Body Hair |
| <input type="checkbox"/> 15. Physical Coordination | <input type="checkbox"/> 33. Physical Condition |
| <input type="checkbox"/> 16. Buttocks | <input type="checkbox"/> 34. Face |
| <input type="checkbox"/> 17. Agility | <input type="checkbox"/> 35. Weight |
| <input type="checkbox"/> 18. Width of Shoulders | |



MENTOR

**Core Gel Breast
IDE Clinical Trial**

BASELINE

PATIENT STUDY ID:

TRIAL NO.
10-009

COUNTRY NO.
0 | 0 | 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last

MANITOBA CANCER TREATMENT & RESEARCH FOUNDATION FUNCTIONAL LIVING INDEX: CANCER (FLIC)

Page 1 of 3

N/A (not a cancer patient)

TO THE PATIENT: Please indicate your rating by drawing a vertical line (|).

1. Most people experience some feelings of depression at times. Rate how often you feel these feelings.

1	2	3	4	5	6	7
Never						Continually

2. How well are you coping with your everyday stress?

1	2	3	4	5	6	7
Not Well						Very Well

3. How much time do you spend thinking about your illness?

1	2	3	4	5	6	7
Constantly						Never

4. Rate your ability to maintain your usual recreation or leisure activities.

1	2	3	4	5	6	7
Able						Unable

5. Has nausea affected your daily functioning?

1	2	3	4	5	6	7
Not At All						A Great Deal

6. How well do you feel today?

1	2	3	4	5	6	7
Extremely Poor						Extremely Well

7. Do you feel well enough to make a meal or do minor household repairs today?

1	2	3	4	5	6	7
Very Able						Not Able



MENTOR

**Core Gel Breast
IDE Clinical Trial**

BASELINE

PATIENT STUDY ID:

TRIAL NO.
10-009

COUNTRY NO.
0 | 0 | 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last

MANITOBA CANCER TREATMENT & RESEARCH FOUNDATION FUNCTIONAL LIVING INDEX: CANCER (FLIC)

Page 3 of 3

N/A (not a cancer patient)

15. How much of your usual household tasks are you able to complete?

1	2	3	4	5	6	7
All						None

16. Rate how willing you were to see and spend time with those closest to you, in the past 2 weeks.

1	2	3	4	5	6	7
Unwilling						Very Willing

17. How much nausea have you had in the past 2 weeks?

1	2	3	4	5	6	7
None						A Great Deal

18. Rate the degree to which you are frightened of the future.

1	2	3	4	5	6	7
Constantly Terrified						Not Afraid

19. Rate how willing you were to see and spend time with friends, in the past 2 weeks.

1	2	3	4	5	6	7
Unwilling						Very Willing

20. How much of your pain or discomfort over the past 2 weeks was related to your cancer?

1	2	3	4	5	6	7
None						All

21. Rate your confidence in your prescribed course of treatment.

1	2	3	4	5	6	7
No Confidence						Very Confident

22. How well do you appear today?

1	2	3	4	5	6	7
Extremely Poor						Extremely Well

ATTACHMENT 6
INVESTIGATOR AGREEMENT

Attachment C

Addendum to Core Study Investigator Agreement

Sponsor: Mentor Corporation, 201 Mentor Drive, Santa Barbara, CA 93111

Investigator: _____

This amends the Investigator Agreement between Mentor Corporation (Sponsor) and _____, M.D, (Investigator) for Mentor's Silicone Gel-Filled Breast Implant Core Study.

Effective November 17, 2006, FDA has approved Mentor's Silicone Gel-Filled Breast Implants for commercial distribution. As a result of this approval, the Core Study has been converted to a post-approval study. While the Core Study is now a post-approval study, all aspects of the Core Study protocol remain in-force, including but not limited to, bringing subjects back for all remaining postoperative follow-up visits and insuring that MRI Substudy subjects return for their MRI scans. In addition, there are two new stipulations:

- 1) That all patients are followed for the duration of this ten year study, including those who have had their study devices explanted.
- 2) That all non-MRI Substudy patients get MRI scans at 4, 6, 8, and 10 years post-implantation

While all complications should continue to be reported as described in the Core Study protocol, as this is now an approved device, they should also be reported via Medical Device Reporting (MDR) as defined in 21 CFR, part 803.

With your signature, you are stating that you understand that Mentor's Silicone Gel-Filled Breast Implants have been approved by FDA for commercial distribution, that all aspects of the Core Study protocol remain in effect, and that you will not only report all complications as described in the Core Study protocol, but also report these complications via MDR. Your signature also attests that you received copies of the approved patient labeling/package labeling, and will disseminate the patient labeling to your Core Study patients at their next follow-up visit.

Investigator Signature

Date

Doug Goodner, Director
Clinical Studies, Compliance and Monitoring
Mentor

Date

Investigator Agreement

Core Gel Study of the Safety and Effectiveness of Mentor Round Low-Bleed Silicone Gel-filled Mammary Prostheses in Patients who are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision (Core Gel Study)
Sponsor: Mentor, 201 Mentor Drive, Santa Barbara, CA USA 93111

Investigator:

This Investigator Agreement (“Agreement”) is entered into as of _____, 200____, by and between _____ (“Investigator”) and Mentor Corporation, a Minnesota corporation (“Sponsor”).

1. Clinical Trial Requirements. Investigator’s participation in the Core Gel Study of the Safety and Effectiveness of Mentor Round Low-Bleed Silicone Gel-filled Mammary Prostheses in Patients who are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision (the “Trial”) is conditioned upon the following representations and warranties made by the Investigator to the Sponsor:

- a) The Investigator assumes full responsibility for the trial, and agrees to conduct the investigation in accordance with applicable FDA regulations, conditions of approval imposed by the reviewing IRB or FDA, this Agreement, and the protocol, with which Investigator has been provided a copy and which Investigator fully understands.
- b) The Investigator assumes full responsibility for all actions taken by the Investigator or his/her staff in conducting the trial.
- c) Supervise all testing of the device involving human subjects.
- d) The Investigator states he/she is qualified to implant breast prosthesis.
- e) Investigator shall provide Sponsor with a current copy of Investigator’s *curriculum vitae* (CV) to be accompanied with this Agreement. The CV will provide history on the Investigator’s relevant experience.
- f) If the Investigator was involved in an investigation or other research that was terminated, an explanation of the circumstances that led to termination.
- g) Investigator shall prepare and maintain adequate case histories designed to record all observations and other data pertinent to the Trial and as requested by Sponsor. Adequate case histories, for purposes of this Trial, include all Case Report Forms as specified in the Trial protocol and required for Trial follow-up. Originals or photocopies of additional specialty consultation reports and other clinical support data generated on subjects enrolled as Trial subjects shall be provided to Sponsor upon request. The Case Report Forms remain the property of the Sponsor.

- h) Investigator shall furnish Investigator's reports to Sponsor in a timely manner. Specifically, documentation will be submitted as specified in the Trial protocol. Documentation not specifically listed in the Trial protocol (e.g., clinical support documentation as specified) will be maintained in subject case files for a period of five years after conclusion of the Trial and submitted to Sponsor upon request.
- i) The Investigator shall immediately report any death, serious injury or malfunction of the studied devices which could lead to a death or serious injury, to the Sponsor. Investigator acknowledges that such reports are required routinely for all medical devices as part of Sponsor's Product Evaluation department and federal regulations on Medical Device Reporting (MDR), and are not unique to this Trial. Reportable events include but are not limited to medical complications and events which are life threatening or may cause permanent impairment to Trial subjects.
- j) Investigator certifies that Investigator shall inform all potential Trial subjects that the device is being used in a clinical trial. The Investigator will enroll all subjects who meet the Inclusion/Exclusion Criteria, where the subject agrees to participate in the trial. The Investigator will obtain written Informed Consent from the subjects before surgery using the Informed Consent included in the Trial protocol, and will provide the subjects with a copy of their signed Informed Consent before surgery. In addition to the Informed Consent, the Investigator will explain the procedures to the subjects and will answer the subject's questions to the best of his/her ability.
- k) All information entered onto the Case Report Forms on Investigator subjects shall be correct and consistent with the subjects' medical records.
- l) Investigator shall obtain Institutional Review Board (IRB) approval and follow any additional terms which may be required by the IRB responsible for monitoring Investigator's participation in the Trial. Investigator shall not use the breast implant in Trial subjects until written IRB approval has been obtained. A copy of the IRB approval letter must be submitted to the Sponsor prior to Trial participation. Investigator shall maintain IRB approval during the duration of the Trial.
- m) Investigator understands that the Trial is subject to audit by the Food and Drug Administration (FDA) and Investigator shall allow access to subject files and documentation accumulated during the Trial to FDA officials.
- n) Investigator shall permit a representative of the Sponsor to make regular site visits during the course of the trial. The Investigator shall also permit the sponsor to inspect all Case Report Forms and corresponding portions of the Trial subject's medical records and source documents at regular intervals during the course of the Trial. The Investigator shall be available to meet with the Sponsor to discuss Trial progress, document and sign off on corrections, respond to questions and attest to completeness and accuracy of Case Report Forms and other requested information.

- o) Investigator shall follow all procedural instructions in the Product Insert Data Sheet, especially as noted in the “CONTRAINDICATIONS” “WARNINGS” sections of the insert.
- p) Investigator shall protect the privacy of Trial subjects to the extent possible and ensure that case trial documentation is kept secure at all times. Investigator shall promptly report any compromise in privacy to Sponsor and to Investigator’s IRB.
- q) Investigator shall disclose sufficient and accurate financial disclosure information to allow the Sponsor to submit a complete and accurate disclosure statement. The Investigator will promptly update this information if any relevant changes occur during the course of the investigation and for one year following completion of the study.
- r) Investigator is not under any preexisting obligations inconsistent with the provisions of this agreement.

2. Confidentiality. Sponsor has disclosed or plans to disclose to Investigator certain confidential and proprietary information regarding its business and products, and specifically, information pertaining to the Trial (“Confidential Information”). Confidential information includes data gathered by Investigator as a result of participating in the trial. Mentor regards this information as confidential and requires that it remain secret. Investigator agrees that Investigator will:

- a) Hold all Confidential Information it receives from Sponsor in strict confidence and with the same degree of care that he/she gives to his/her own proprietary and confidential information, but not less than a reasonable degree of care, and not disclose such Confidential Information to others, except as may be required by law;
- b) Not use Confidential Information commercially or for any other purpose except to participate in the trial;
- c) Limit the dissemination of and access to Confidential Information to those personnel who have a need for access to such Confidential Information for Trial purposes and who are under an obligation of confidence consistent with this Agreement;
- d) Not copy or reproduce any records containing Confidential Information or divulge such records to others;
- e) Not disclose to others that Confidential Information is known to or used by Sponsor or those associated with Sponsor; and
- f) Return to Sponsor, within 30 calendar days of its written request or upon termination of this Agreement, all Confidential Information and any other records containing Confidential Information.

2.1 Inventions. All inventions reasonably related to the business of Sponsor's products or to any research, design, experiment, or production carried on by Sponsor, or to any matters specifically discussed with Investigator, including but not limited to improvements to products manufactured by Sponsor and research and development ideas or inventions of Sponsor, whether conceived, generated, or reduced to practice by Investigator alone or in conjunction with others, during the period of this Agreement or within a period of up to six months following this Agreement ("Inventions"), are the sole property of Sponsor and are hereby assigned to Sponsor. For purposes of this Agreement, inventions upon which Investigator files patent applications or enters into license or other agreements, within one year after termination of this Agreement shall be presumed to be Inventions as defined in this paragraph 2.1 and conceived by Investigator during the term of this Agreement and from consultations and discussions with Sponsor, subject to proof to the contrary in good faith, and written and duly corroborated records establishing that such invention or discovery was conceived and made by Investigator without the benefit of Investigator's relationship with Sponsor.

2.2 Assistance. Further, Investigator will give Sponsor all assistance Sponsor reasonably requires to perfect, protect, and use its rights to Inventions. In particular, without limitation, Investigator will sign all documents, do all things, and supply all information that Sponsor may deem necessary or desirable to (i) transfer or record the transfer of Investigator's entire right, title, and interest in Inventions and (ii) enable Sponsor to obtain patent, copyright, and trademark protection for Inventions anywhere in the world. The obligations of this paragraph 2.2 shall continue beyond the termination of this Agreement with respect to Inventions, discoveries, and improvements, whether patentable or not, conceived or made by Investigator during the term of this Agreement and shall be binding upon Investigator's assigns, executors, administrators and other legal representatives.

3. Subject Advertising. Subject advertisement is any notice, flyer, or brochure used to recruit subjects into a clinical trial. All advertisement for subject recruitment in clinical trials requires IRB approval prior to publication and copies of all proposed ads must be submitted to the Sponsor for prior approval.

4. Compensation. Sponsor shall compensate Investigator and the Investigator's Study Coordinator for participation in the Trial as set forth in Attachments A and B.

5. Amendment. All amendments or modifications of this Agreement shall be in writing and shall be signed by each of the parties hereto.

6. Waiver. Any waiver of any right, power, or privilege hereunder must be in writing and signed by the party being charged with the waiver. No delay on the part of any party hereto in exercising any right, power, or privilege hereunder shall operate as a waiver of any other right, power, or privilege hereunder, nor shall any single or partial exercise of any right, power, or privilege hereunder preclude any other or further exercise thereof or the exercise of any other right, power, or privilege.

7. Notices. All notices or other communications required or permitted to be given pursuant to this Agreement shall be in writing and shall be delivered personally or sent by overnight courier, by facsimile with confirmation by first-class mail, or by registered or certified mail, return receipt requested. Notices delivered personally or sent by overnight courier or by facsimile with confirmation by first-class mail shall be deemed to have been received and to be effective on the date received, while notices sent by registered or certified mail, return receipt requested, shall be deemed to have been received and to be effective three business days after deposit into the mails. Notices shall be given to the parties at the following respective addresses, or to such other addresses as any party shall designate in writing:

If to Sponsor: Mentor
Clinical Programs Department
201 Mentor Drive
Santa Barbara, CA 93111
Telephone: (805) 879-6000
Facsimile: (805) 879-6095

With a copy to: Legal Department
Mentor
201 Mentor Drive
Santa Barbara, California 93111
Telephone: (805) 879-6000
Facsimile: (805) 879-6006

If to the Investigator: _____

8. Successors and Assigns. This agreement and each of its provisions shall be binding upon and shall inure to the benefit of the parties hereto and their respective heirs, executors, administrators, successors, and assigns. Notwithstanding the foregoing, this agreement is personal to the Investigator and shall be assignable by the Investigator only with the written consent of Sponsor, which consent may be withheld in Sponsor's sole and absolute discretion.

9. Law Governing. This Agreement shall be governed by and construed and enforced in accordance with the laws of the State of California, without regard for its conflict of laws rules. The parties hereby submit to the exclusive jurisdiction of the courts of the State of California, in and for the County of Los Angeles, and the United States District Court for the Central District of California for the purpose of construing and enforcing this Agreement.

10. Damages. Mentor shall not be responsible for any damages, whether direct, indirect, consequential, special, punitive, or exemplary, whether foreseeable or unforeseeable, or any lost profits, incurred by the Investigator except for the payments contemplated by Article 4 of this Agreement.

11. Indemnification. Sponsor will have no liability for loss or damage and no duty to defend or hold harmless from any demands, claims, or costs of judgment resulting from:

- a) Investigator's failure to adhere to the terms of the protocol or Sponsor's written instruction concerning the use of the Trial device.
- b) Investigator's failure to comply with applicable FDA or other government requirements.
- c) Investigator's negligence or willful misconduct by the investigator, his agents or employees.

12. Insurance. Investigator shall maintain a policy or program of insurance at levels sufficient to cover any losses to Mentor and Trial participants.

13. Severability of Provisions. In the event any one or more of the provisions of this Agreement shall for any reason be held to be invalid, illegal, or unenforceable in any respect, such invalidity, illegality, or unenforceability shall not affect any other provision hereof, and this Agreement shall be construed as if such invalid, illegal, or unenforceable provision had never been contained herein.

14. Integration. This Agreement constitutes the entire understanding and agreement between the parties with respect to the transactions contemplated herein and supersedes all previous communications, representations, or understandings, either oral or written, between the parties relating to the subject matter hereof, all of which are merged herein.

15. Agreement Controls. This Agreement shall control whenever the provisions of any subordinated document conflict with this Agreement.

16. Termination. Sponsor may terminate the Trial and this Agreement at any time on ten days written notice to Investigator. Sponsor shall not be liable to Investigator for any costs or damages suffered due to such termination.

17. Publication. Sponsor acknowledges that the Investigator and his/her collaborators shall be free to publish the background, methods and results of their own research without restraint. Prior review of any proposed manuscript or abstract will be provided to Sponsor to prevent premature disclosure of trade secrets or proprietary information. This review will be done by the Investigator submitting to Sponsor a copy of any manuscript or abstract and submitted for consideration for publication or to a conference, as applicable, no later than 30 days before such manuscript or abstract is so submitted. The Investigator acknowledges that the Sponsor reserves the right to publish and present the overall study results, including assigning authorship. Sponsor acknowledges that all active Investigators will be recognized for their contributions with any manuscript or presentation.

18. Signatures.

Investigator Signature

Date

Director, Clinical Programs, Mentor Corporation

Date

ATTACHMENT 7
MRI SUBSTUDY PROTOCOL

Core Gel Study MRI Substudy Protocol

Prepared by: David Gorczyca, MD

Introduction:

Breast implants may not last a lifetime. While the silicone material itself has not been shown to biodegrade, the shell may rupture due to wear and tear, or direct injury. If the implant shell is ruptured, the escaping gel is usually contained by the scar envelope in the surgical pocket (intracapsular) and may be undetectable. If the scar envelope is torn, the gel can be driven into the local tissue planes and breast tissue (extracapsular).

A dependable estimate of implant failure is essential information to obtain for the benefit of manufacturers, regulatory agencies, plastic surgeons, and past and prospective patients. Several studies with surgical correlation have been published in peer reviewed journals demonstrating that Magnetic Resonance Imaging (MRI) is considered the superior imaging modality to detect silent rupture.

The chemical composition of most medical grade silicones is dimethyl polysiloxane with varying degrees of polymerization. The MR signal is derived from the protons of the methyl groups. The implant shell is also composed of silicone but differs from the gel because of the many additional cross linkages between the methyl groups that result in an elastic solid, therefore only minimal MR signal is produced from the silicone shell because of these cross linkages.

The method of evaluating implants by MRI is to make the silicone appear bright and everything else on the image appears dark, so that the implant shell (which is seen as a dark line) can be seen clearly against the bright silicone background. Intracapsular rupture is detected by seeing the collapsed implant shell (curvilinear low signal intensity lines-linguini signs) surrounded by high signal silicone gel. Soft tissue silicone is detected by seeing high signal silicone against a background of decreased signal soft tissues.

The selection of pulse sequences used to image breast images is determined by the Larmor frequencies and T1 and T2 properties of the tissues (fat, muscle, and silicone). T1 and T2 relaxation is an intrinsic property of each biological tissue. Since the frequency of silicone is close to fat, when chemical suppression techniques (fat or water suppression) are used, the MR signal from silicone behaves similar to fat.

Standard MRI sequences used to image breast implants are a sagittal T2 weighted fast spine echo (FSE) with water suppression and an axial T2 weighted fast spin echo (FSE). The heavily T2 weighted images with a TE of approximately 200, decreases the signal from the breast adipose tissue while keeping the signal from the silicone fairly high. These sequences can vary slightly on different manufacturers' machines and at different institutions, but the principles are the same.

Study Objective:

To determine the incidence and prevalence of silicone gel rupture, using standardized MRI based protocol.

Patient Population:

A subset of 405 women participating in the Mentor Core Gel Protocol who have been selected by random number generation

Scanning Intervals:

This subset of patients will undergo MRI scans of the breast at 1, 2, 4, 6, 8 and 10 years after the original implant surgery.

Study Design:

MRI centers located in close proximity to the investigative sites will be chosen. These centers must have at a minimum: a 1.5 Tesla magnet and a dedicated breast coil. Hardcopies of the imaging sequences, which will include the patient study number, will be made and sent to a central reading center, where the scans will be read by a recognized expert in breast MRI. The results will be entered into the study database. The information that will be collected will include location of the implant and any evidence of intracapsular or extracapsular rupture. The scan will be read locally, as well and a copy of the report will be placed in the patient's permanent medical record.

References

1. Gorczyca DP, Sinha S, Ahn CY, DeBruhl ND, Hayes MK, Gausche VR, Shaw WW, Bassett LW, "Silicone Breast Implants in Vivo: MR Imaging. Radiology 1992, 185:407-410.
2. Ahn CY, Shaw WW, Narayanna K, Gorczyca DP, Sinha S, DeBruhl ND. Bassett LW: Definitive Diagnosis of Breast Implant Rupture Using MRI", Plastic and Reconstructive Surgery, September 1993.
3. Gorczyca DP, DeBruhl ND, Ahn CY, Hoyt A, Sayre JW, Nudell P, McCombs M, Shaw WW, Bassett LW, "Silicone Breast Implant Ruptures in an Animal Model: Comparison of Mammography, MRI, US, and CT, Radiology 1994: 190:227-232.
4. Ahn, CY, DeBruhl ND, Gorczyca DP, Shaw WW, Bassett LW, "Comparative Silicone Breast Implant Evaluation using Mammography, Sonography, and Magnetic Resonance Imaging: Experience with 59 Implants", Plastic and Reconstructive Surgery 1994: 94(5):620-627.

MRI Imaging Sequences for the Mentor Protocol “Study of the Safety and Effectiveness of the Mentor Round Gel-filled Mammary Prosthesis in Patients who are Undergoing Primary Breast Augmentation, Primary Breast Reconstruction or Revision”

The following scanning sequences are the minimal sequences required for the study. Each site may perform additional sequences that are routine at their institution.

- Patients should be scanned 1 year, 2 years, 4 years, 6 years, 8 years and 10 years after the initial implantation.
- Sequences should be acquired using a 1.5 Tesla magnet.
- Patient should be in the prone position in a dedicated bilateral breast coil.
- Make 1 additional hardcopy for Mentor.
- Scan time will be approximately 20 minutes.
- Include patient study ID on hardcopy.
- Mail hardcopies to the following address:

Mentor Clinical Programs
Attention: Core Gel breast Monitor
Mentor Corp.
201 Mentor Drive
Santa Barbara, CA 93111

- Scout sagittal sequence – GRASS or other fast sequence (does not have to be hard copy imaged)
- Axial T2 weighted FSE
 - TR/TE 5000/200
 - Matrix 256 x 256
 - NEX 2
 - FOV 32 to 36 depending on patient size
 - Slice thickness 3 skip 1
- Sagittal T2 FSE with water suppression
 - TR/TE 5000/200
 - Matrix 256 x 256
 - NEX 2
 - FOV 18 to 24 depending on patient size
 - Slice thickness 3 skip 1

MRI Substudy Glossary

For purposes of this clinical study, the following basic definitions for interpreting clinical study MRI scans have been standardized:

Intracapsular Implant Rupture (silent rupture): rupture of the implant shell (elastomer envelope) allowing a release of silicone gel, which does not extend beyond the intact fibrous capsule. This is the most common type of implant rupture.

Extracapsular Implant Rupture: rupture of both the implant shell and the fibrous capsule with silicone leakage extending into the surrounding tissue.

Uncollapsed Implant Rupture: when a ruptured implant shell does not collapse or only partially collapses.

Silicone Gel Bleed: Gel bleed occurs in all silicone implants. The most widely accepted definition is microscopic silicone diffusion through an intact implant shell, which does not constitute device rupture.

ATTACHMENT 8
STUDY DEFINITIONS

Study Definitions

1. **Abscess:** A localized collection of pus usually caused by bacterial infection, in or around the breast tissue.
2. **Adverse Events:** An adverse event is defined as any undesirable clinical occurrence in a subject whether it is considered to be device related or not (Clinical Investigation of Medical Devices for Human Subjects - EN 540:1993).
 - Device leaks, tears, or ruptures and all instances of surgical removal of implant for those reasons
 - Removal of the implant for any reason.
 - Baker III or Baker IV capsular contracture, hematoma, seroma, delayed wound healing, necrosis, breast pain, new diagnosis of breast cancer, lactation difficulties, ptosis, irritation/inflammation, assymetry, hypertrophic scarring, lymphadenopathy, extrusion, wrinkling, calcification, nipple/breast sensitivity change, silicone granuloma, fluid accumulation, infection and any secondary surgical procedures.
 - Implant change due to cosmetic dissatisfaction.
 - Any secondary surgical procedure.
 - Examples of secondary procedures that would not be considered adverse events are nipple tattoo, staged reconstruction or port removal.
3. **ALS (amyotrophic lateral sclerosis):** Syndrome marked by muscular weakness and atrophy due to degeneration of motor neurons of the spinal cord, medulla, and cortex.
4. **Asymmetry** is one or more of the following conditions:
 - One cup size difference in breast size
 - Need to differentially pad one cup to fill bra to match the opposite breast size
 - More than 1.5cm difference of nipples as measured laterally from sternal midline and/or clavicular prominences
 - More than 1.5 cm differences in inframmary folds height.
 - Asymmetry due to chest wall deformity such as scoliosis or other deformities of the thoracic cage and/or associated visible differences in shoulder height.
5. **Breast Pain not associated with another complication:** Any post surgical breast pain that is not associated with capsular contraction, infection, abscess or other complication.
6. **Cancer:** A malignant tumor or neoplasm.
7. **Calcification:** Grossly visible calcification on the capsule walls.
8. **Congenital Deformity:** Includes, but is not limited to asymmetry, scoliosis, thoracic cage asymmetry, breast aplasia, hypomastia, deformity due to tumors (hemangiomas, lymphangiomas, giant fibroadenomas), tubular breasts, pectus excavatum or pectus carinatum

9. **Capsular Contracture:** Formation of scar tissue around the implant that tightens or squeezes the implant which can result in excessive firmness of the implanted breast.
10. **Capsulotomy, Open:** Technique used to correct or reduce capsular contracture through surgical intervention by incision into the breast; usually performed when the contracture is moderate; generally limited to replacement of the implant without surgical dissection of the capsule.
11. **Capsulectomy:** Technique used to correct or reduce capsular contracture, through surgical intervention, by incision into the breast; usually performed as a result of a firm, thick capsule marked contracture; generally requires surgical dissection of the capsule prior to replacement of the implant.
12. **Delayed wound healing:** Any incision that shows wound separation.
13. **Hypertrophic Scarring:** Any scar that is not flattened and mature at 18 months or that requires treatment with steroid injections or silicone pads, etc.
14. **Extrusion:** Any exposure of the implant.
15. **Granuloma:** Any foreign body (silicone) that is palpable or visible or seen at surgery.
16. **Hematoma:** Any blood collection large enough to require removal.
17. **Hypoplastic:** Characterized by incomplete or underdevelopment of the breast.
18. **Immediate Breast Reconstruction:** Implant may be inserted up to 1-week post mastectomy.
19. **Infection:** Any bacterial invasion that has systemic or regional signs and symptoms that require antibiotics for treatment (not prophylaxis).
20. **Migration:** Movement of the implant from desired position within or outside the original pocket.
21. **Multiple Sclerosis:** A chronic, slowly progressive disease of the central nervous system characterized by development of disseminated demyelinated glial patches called plaques.
22. **Necrosis:** Tissue death
23. **Pectus Carinatum:** Congenital convex chest wall deformity with abnormalities of the sternum and anterior ribs
24. **Pectus Excavatum:** Congenital concave chest wall deformity with abnormalities of the sternum and anterior ribs.
25. **Ptosis:** Standard grading of ptosis by nipple level.

26. **Secondary Procedure:** Any surgery on the breast taking place after the initial implant surgery. All subsequent surgeries on the breast are considered adverse events EXCEPT: staged reconstruction, port removal, and nipple tattoo. Examples of secondary procedures considered to be adverse events are: surgical capsular contracture intervention or explants.
26. **Serious Unanticipated Adverse Event:** Any other adverse occurrence, side effect, injury, toxicity, or sensitivity reaction that reasonably suggests adverse events from the implant which involve death, life threatening conditions or permanent impairment of body function which have not been addressed in the product literature or which has been addressed, but is occurring with unexpected severity or frequency. These include rheumatologic conditions.
27. **Seroma (fluid accumulation):** Sufficient peri-prosthetic fluid to cause a noticeable volume change or be considered abnormal when detected by breast imaging.
28. **Severity of Adverse Events:** mild – noticed by patient; moderate – noted by both patient and doctor; severe - requires treatment/intervention.
29. **Wrinkling:** Any detectable implant wrinkle, either visually or palpably.

ATTACHMENT 9
STUDY DEVICES

**Sizes, Catalog Number, Diameter, and Projection for Siltex®
Round Low Bleed Gel-filled Mammary Prosthesis, Moderate
Profile**

Device Volume	Catalog Number	Diameter	Projection
100 cc	354-1007G	8.8 cm	2.5 cm
125 cc	354-1257G	9.3 cm	2.8 cm
150 cc	354-1507G	10.2 cm	2.7 cm
175 cc	354-1757G	10.7 cm	2.8 cm
200 cc	354-2007G	11.2 cm	2.8 cm
225 cc	354-2257G	11.4 cm	3.0 cm
250 cc	354-2507G	11.5 cm	3.3 cm
275 cc	354-2757G	12.4 cm	3.4 cm
300 cc	354-3007G	12.6 cm	3.5 cm
325 cc	354-3257G	12.9 cm	3.6 cm
350 cc	354-3507G	13.4 cm	3.7 cm
375 cc	354-3757G	13.4 cm	3.8 cm
400 cc	354-4007G	13.5 cm	3.9 cm
450 cc	354-4507G	13.9 cm	4.1 cm
500 cc	354-5007G	14.2 cm	4.3 cm
550 cc	354-5507G	14.8 cm	4.4 cm
600 cc	354-6007G	15.4 cm	4.5 cm
700 cc	354-7007G	16.8 cm	4.3 cm
800 cc	354-8007G	17.2 cm	4.6 cm

**Sizes, Catalog Number, Diameter, and Projection for Smooth
Round Low Bleed Gel-filled Mammary Prosthesis, Moderate
Profile**

Device Volume	Catalog Number	Diameter	Projection
100 cc	350-7100BCG	9.3 cm	2.1 cm
125 cc	350-7125BCG	10.0 cm	2.2 cm
150 cc	350-7150BCG	10.3 cm	2.3 cm
175 cc	350-7175BCG	11.2 cm	2.4 cm
200 cc	350-7200BCG	11.7 cm	2.5 cm
225 cc	350-7225BCG	12.2 cm	2.6 cm
250 cc	350-7250BCG	12.3 cm	2.8 cm
275 cc	350-7275BCG	13.2 cm	2.9 cm
300 cc	350-7300BCG	13.5 cm	3.0 cm
325 cc	350-7325BCG	13.9 cm	3.0 cm
350 cc	350-7350BCG	14.2 cm	3.1 cm
375 cc	350-7375BCG	14.4 cm	3.2 cm
400 cc	350-7400BCG	14.5 cm	3.2 cm
450 cc	350-7450BCG	14.9 cm	3.4 cm
500 cc	350-7500BCG	15.2 cm	3.6 cm
550 cc	350-7550BCG	15.9 cm	3.6 cm
600 cc	350-7600BCG	16.5 cm	3.7 cm
700 cc	350-7700BCG	17.4 cm	3.9 cm
800 cc	350-7800BCG	18.2 cm	4.1 cm

Smooth Round Moderate Plus Profile*					
Volume Diameter Projection Catalog #					
100 cc	8.2 cm	2.7 cm	350-1001 BC	RSZ-1001	
125 cc	8.9 cm	2.8 cm	350-1251 BC	RSZ-1251	
150 cc	9.5 cm	2.9 cm	350-1501 BC	RSZ-1501	
175 cc	10.0 cm	3.1 cm	350-1751 BC	RSZ-1751	
200 cc	10.5 cm	3.2 cm	350-2001 BC	RSZ-2001	
225 cc	10.9 cm	3.3 cm	350-2251 BC	RSZ-2251	
250 cc	11.3 cm	3.4 cm	350-2501 BC	RSZ-2501	
275 cc	11.7 cm	3.5 cm	350-2751 BC	RSZ-2751	
300 cc	12.0 cm	3.6 cm	350-3001 BC	RSZ-3001	
325 cc	12.3 cm	3.8 cm	350-3251 BC	RSZ-3251	
350 cc	12.5 cm	3.9 cm	350-3501 BC	RSZ-3501	
375 cc	12.8 cm	4.0 cm	350-3751 BC	RSZ-3751	
400 cc	13.1 cm	4.0 cm	350-4001 BC	RSZ-4001	
450 cc	13.6 cm	4.2 cm	350-4501 BC	RSZ-4501	
500 cc	14.1 cm	4.3 cm	350-5001 BC	RSZ-5001	
550 cc	14.6 cm	4.5 cm	350-5501 BC	RSZ-5501	
600 cc	15.0 cm	4.6 cm	350-6001 BC	RSZ-6001	
700 cc	15.8 cm	4.9 cm	350-7001 BC	RSZ-7001	
800 cc	16.5 cm	5.1 cm	350-8001 BC	RSZ-8001	

Smooth Round High Profile*					
Volume Diameter Projection Catalog #					
125 cc	8.3 cm	3.5 cm	350-1254 BC	RSZ-1254	
150 cc	8.8 cm	3.7 cm	350-1504 BC	RSZ-1504	
175 cc	9.3 cm	3.9 cm	350-1754 BC	RSZ-1754	
200 cc	9.7 cm	4.0 cm	350-2004 BC	RSZ-2004	
225 cc	10.1 cm	4.2 cm	350-2254 BC	RSZ-2254	
250 cc	10.5 cm	4.3 cm	350-2504 BC	RSZ-2504	
275 cc	10.8 cm	4.4 cm	350-2754 BC	RSZ-2754	
300 cc	11.1 cm	4.5 cm	350-3004 BC	RSZ-3004	
325 cc	11.4 cm	4.6 cm	350-3254 BC	RSZ-3254	
350 cc	11.7 cm	4.8 cm	350-3504 BC	RSZ-3504	
375 cc	12.0 cm	4.8 cm	350-3754 BC	RSZ-3754	
400 cc	12.2 cm	5.0 cm	350-4004 BC	RSZ-4004	
425 cc	12.5 cm	5.0 cm	350-4254 BC	RSZ-4254	
450 cc	12.8 cm	5.1 cm	350-4504 BC	RSZ-4504	
500 cc	13.2 cm	5.3 cm	350-5004 BC	RSZ-5004	
550 cc	13.6 cm	5.5 cm	350-5504 BC	RSZ-5504	
600 cc	14.0 cm	5.6 cm	350-6004 BC	RSZ-6004	
650 cc	14.4 cm	5.7 cm	350-6504 BC	RSZ-6504	
700 cc	14.8 cm	5.8 cm	350-7004 BC	RSZ-7004	
800 cc	15.5 cm	6.0 cm	350-8004 BC	RSZ-8004	

Siltex® Round Moderate Plus Profile*			
Volume Diameter Projection Catalog #			
100 cc	8.1 cm	2.7 cm	354-1001
125 cc	8.8 cm	2.9 cm	354-1251
150 cc	9.4 cm	3.0 cm	354-1501
175 cc	10.0 cm	3.2 cm	354-1751
200 cc	10.5 cm	3.3 cm	354-2001
225 cc	10.9 cm	3.5 cm	354-2251
250 cc	11.3 cm	3.6 cm	354-2501
275 cc	11.7 cm	3.7 cm	354-2751
300 cc	12.0 cm	3.7 cm	354-3001
325 cc	12.3 cm	3.8 cm	354-3251
350 cc	12.6 cm	3.8 cm	354-3501
375 cc	12.9 cm	3.9 cm	354-3751
400 cc	13.2 cm	4.0 cm	354-4001
450 cc	13.7 cm	4.1 cm	354-4501
500 cc	14.1 cm	4.2 cm	354-5001
550 cc	14.4 cm	4.4 cm	354-5501
600 cc	14.7 cm	4.5 cm	354-6001
700 cc	15.7 cm	4.8 cm	354-7001
800 cc	16.6 cm	5.0 cm	354-8001

Siltex® Round High Profile*			
Volume Diameter Projection Catalog #			
125 cc	8.4 cm	3.6 cm	354-4125
150 cc	8.9 cm	3.8 cm	354-4150
175 cc	9.4 cm	4.0 cm	354-4175
200 cc	9.9 cm	4.1 cm	354-4200
225 cc	10.2 cm	4.3 cm	354-4225
250 cc	10.5 cm	4.5 cm	354-4250
275 cc	10.9 cm	4.6 cm	354-4275
300 cc	11.1 cm	4.7 cm	354-4300
325 cc	11.5 cm	4.8 cm	354-4325
350 cc	11.7 cm	4.9 cm	354-4350
375 cc	12.0 cm	5.0 cm	354-4375
400 cc	12.3 cm	5.1 cm	354-4400
425 cc	12.5 cm	5.2 cm	354-4425
450 cc	12.7 cm	5.2 cm	354-4450
500 cc	13.2 cm	5.4 cm	354-4500
550 cc	13.5 cm	5.6 cm	354-4550
600 cc	14.0 cm	5.7 cm	354-4600
650 cc	14.3 cm	5.8 cm	354-4650
700 cc	14.7 cm	6.0 cm	354-4700
800 cc	15.4 cm	6.3 cm	354-4800

**ATTACHMENT 10
CASE REPORT FORMS**

The data collected at years 2, 3, 4, 5, 6, 7, 8, 9, and 10 are identical to those collected at 1 year, and hence are not included in this attachment.



**Protocol Number
10-009-0799-01**

**Core Study of the Safety
and Effectiveness of the
Mentor Round Gel-filled Mammary Prosthesis
in Patients Who Are Undergoing
Primary Breast Augmentation or
Primary Breast Reconstruction or Revision
(Core Gel Breast IDE Clinical Trial)**

Site Number

--	--	--

Patient Number

--	--	--

Patient Initials

--	--	--

first middle last



PROTOCOL NO.
10-009

Site No.

--	--	--

Patient No.

--	--	--

Patient Initials

--	--	--

first middle last

Baseline

Operative Report

6 Month Visit

1 Year Visit

2 Year Visit

3 Year Visit

4 Year Visit

5 Year Visit

6 Year Visit

7 Year Visit

8 Year Visit

9 Year Visit

10 Year Visit

Interim Visits

Secondary Procedures
Report

Re-Implantation Report

End of Study

**Instructions for Completing Baseline CRF Packet
for Mentor
Core Gel Breast IDE Clinical Trial**

This package contains the Baseline CRFs (pages 1–25), which should be completed as the patient progresses through the screening period. As you complete the Baseline CRFs, remember these important points:

1. Complete Baseline CRFs with Patient's initials.
 - a. Please try to obtain Patient's middle initial.
 - b. If Patient has no middle initial, use “-”.
2. Leave Patient Number blank on every page until Patient is enrolled.
3. If Patient is enrolled:
 - a. Write the Patient Number on every page of the Baseline CRFs.
 - b. Place Baseline CRFs in Patient's CRF binder (behind the tabbed divider).
4. If Patient is not enrolled:

Discard the Baseline CRFs.
5. Do not leave any questions unanswered or blank.
6. Correct entries by drawing a single line through the data and initialing and dating the correction.
7. Always sign and date the forms where indicated.



MENTOR

**Core Gel Breast
IDE Clinical Trial**

BASELINE

PATIENT STUDY ID:

TRIAL NO.
10-009

COUNTRY NO.
0 0 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last

Visit Date:
month day year

INCLUSION CRITERIA

If any answer to questions 1–4 is **NO**, the patient must be excluded from the study.

- | | NO | YES |
|--|--------------------------|--------------------------|
| | 1 | 2 |
| 1. Is the patient a genetic female 18 years or older? | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. Is the patient a candidate for primary breast augmentation or primary reconstruction (for cancer, trauma, surgical loss of breast or congenital deformity) or revision surgery (previous augmentation or reconstruction with silicone-filled or saline-filled implants)? | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. Has the patient agreed to follow the procedures for explant analysis? | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. Has the patient agreed to comply with follow-up procedures, including returning for all follow-up visits? | <input type="checkbox"/> | <input type="checkbox"/> |

Date Informed Consent signed:
month day year

EXCLUSION CRITERIA

If any answer to questions 1–14 is **YES**, the patient must be excluded from the study.

- | | NO | YES |
|---|--------------------------|--------------------------|
| | 1 | 2 |
| 1. Is the patient pregnant or a nursing mother? | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. Has the patient nursed a child within 3 months of study enrollment? | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. Has the patient been implanted with any other silicone implant (e.g. silicone artificial joints or facial implants)? | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. Does the patient have a confirmed diagnosis of the following rheumatic diseases or syndromes: systemic lupus erythematosus, Sjogren's syndrome, scleroderma, polymyositis, any other connective tissue disorder, rheumatoid arthritis, crystalline arthritis, infectious arthritis, spondyarthropathies, any other inflammatory arthritic condition, osteoarthritis, fibromyalgia, chronic fatigue syndrome, or any other mechanical or degenerative non-inflammatory rheumatic condition? | <input type="checkbox"/> | <input type="checkbox"/> |
| | N/A | |
| 5. Does the patient have any condition that would inhibit wound healing? (N/A for reconstruction patient) | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. Does the patient have a diagnosis of active cancer of any type? (N/A for reconstruction patient) | <input type="checkbox"/> | <input type="checkbox"/> |
| 7. Does the patient have an infection or abscess anywhere in the body? | <input type="checkbox"/> | <input type="checkbox"/> |
| 8. Does the patient demonstrate tissue characteristics, which are clinically incompatible with implant (e.g. tissue damage resulting from radiation, inadequate tissue, or compromised vascularity)? | <input type="checkbox"/> | <input type="checkbox"/> |
| 9. Does the patient possess any condition, or is the patient under treatment for any condition, which, in the opinion of the investigator and/or consulting physician(s), may constitute an unwarranted surgical risk? | <input type="checkbox"/> | <input type="checkbox"/> |
| 10. Does the patient have any anatomic or physiologic abnormality, which could lead to significant postoperative complications? | <input type="checkbox"/> | <input type="checkbox"/> |
| 11. Does the patient demonstrate characteristics, such as inappropriate attitude or motivation, which, in the opinion of the investigator, are unreasonable/unrealistic with the risks involved with the surgical procedure? | <input type="checkbox"/> | <input type="checkbox"/> |
| 12. Does the patient have premalignant disease without a subcutaneous mastectomy? | <input type="checkbox"/> | <input type="checkbox"/> |
| 13. Does the patient have untreated or inappropriately treated breast malignancy, without mastectomy? | <input type="checkbox"/> | <input type="checkbox"/> |
| 14. Does the patient have any implanted metal or metal devices, history of claustrophobia or other condition that would make a MRI scan prohibitive? | <input type="checkbox"/> | <input type="checkbox"/> |



MENTOR

**Core Gel Breast
IDE Clinical Trial**

BASELINE

PATIENT STUDY ID:

TRIAL NO.
10-009

COUNTRY NO.
0 0 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last

DEMOGRAPHICS

DATE OF BIRTH

month	day	year
-------	-----	------

MARITAL STATUS

- 1 Single
- 2 Married
- 3 Separated
- 4 Divorced
- 5 Widowed

EDUCATIONAL LEVEL

- 1 Less than 12 years
- 2 High School Graduate
- 3 Some College
- 4 College Graduate
- 5 Post Graduate

ETHNICITY

- 1 African American
- 2 Asian
- 3 Caucasian
- 4 Other: _____

GENDER

- 1 Female

ANNUAL HOUSEHOLD INCOME LEVEL

- 1 \$0 - \$20,000
- 2 \$20,000 - \$40,000
- 3 \$40,000 - \$60,000
- 4 above \$60,000

MEDICAL HISTORY

<input type="checkbox"/> Check here if no medical history or Complete below:	Absent Present		Year of Onset or UNK	If PRESENT, please comment
	1	2		
Cardiovascular Disease	<input type="checkbox"/>	<input type="checkbox"/>		
Pulmonary Disease	<input type="checkbox"/>	<input type="checkbox"/>		
Neurological Disease	<input type="checkbox"/>	<input type="checkbox"/>		
Musculoskeletal Disease	<input type="checkbox"/>	<input type="checkbox"/>		
Dermatological Disease	<input type="checkbox"/>	<input type="checkbox"/>		
Lymphatic Disease	<input type="checkbox"/>	<input type="checkbox"/>		
Genitourinary Disease	<input type="checkbox"/>	<input type="checkbox"/>		
Gastrointestinal Disease	<input type="checkbox"/>	<input type="checkbox"/>		
Endocrine Disease	<input type="checkbox"/>	<input type="checkbox"/>		
Allergies, specify: _____	<input type="checkbox"/>	<input type="checkbox"/>		
Prior Surgeries, specify: _____	<input type="checkbox"/>	<input type="checkbox"/>		
Other, specify: _____	<input type="checkbox"/>	<input type="checkbox"/>		
Other, specify: _____	<input type="checkbox"/>	<input type="checkbox"/>		
Other, specify: _____	<input type="checkbox"/>	<input type="checkbox"/>		

Has the patient ever had any lactation complications?

- 1 No
- 2 Yes, list: _____

HABITS

Smoking History:

- 1 Never smoked
- 2 Currently smokes: _____ packs per day
- 3 Quit smoking in: _____ year

Current Alcohol Use:

- 1 No
- 2 Yes: _____ drinks per week



MENTOR

**Core Gel Breast
IDE Clinical Trial**

BASELINE

PATIENT STUDY ID:

TRIAL NO.
10-009

COUNTRY NO.
0 0 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last

INDICATION FOR SURGERY - RIGHT BREAST

- 0 Not to be Implanted with Study Device (no current implant)
- 1 Not to be Implanted with Study Device (has current implant)

Indicate the primary reason for study device implantation surgery by checking the appropriate boxes for this breast:

2 AUGMENTATION, Primary Reason for augmentation:

- 1 Post-lactational Mammary Involution
- 2 General Breast Enlargement
- 3 Ptosis
- 5 Augmentation to contralateral breast for post-reconstruction symmetry
- 6 Other, specify: _____

3 RECONSTRUCTION, Primary Reason for reconstruction:

- 1 Total-mastectomy—Immediate*
- 2 Total-mastectomy—Delayed*
- 3 Subtotal Mastectomy (lumpectomy, quadrantectomy)*

Mastectomy/Surgery Date:

month	day	year
-------	-----	------

*(complete the Breast Cancer History page)

- 4 Post-trauma
- 5 Mastopexy to correct contralateral breast for post-reconstruction symmetry
- 6 Congenital deformity, check one:
 - 1 Asymmetry (see Protocol for definition)
 - 2 Breast aplasia
 - 3 Deformity due to tumors (hemangiomas, lymphangiomas, giant fibroadenomas)
 - 4 Hypomastia
 - 5 Pectus Carinatum
 - 6 Pectus Excavatum
 - 7 Poland's Syndrome
 - 8 Scoliosis
 - 9 Spinal curvature
 - 10 Thoracic cage asymmetry
 - 11 Tubular breasts
 - 12 Other: _____

Flap used in reconstruction?

- 1 No
- 2 Yes, indicate type:
 - 1 TRAM
 - 2 Latissimus dorsi
 - 3 Other: _____

Tissue expander in place prior to implantation?

- 1 No
- 2 Yes, date of placement:

month	day	year
-------	-----	------

4 REVISION, specify type of revision:

- 1 Reconstruction revision (if original reconstruction due to breast cancer surgery, complete the Breast Cancer History page)

- 2 Augmentation revision

Original Implant Date:

month	year
-------	------

Primary Reason for current revision (check one):

- 1 Capsular Contracture
- 2 Distortion
- 3 Extrusion
- 4 Malposition
- 5 Post-op Hematoma
- 6 Post-op Infection
- 7 Ptosis
- 8 Rupture
- 9 Size Change-Down
- 10 Size Change-Up
- 11 Valve Retrieval
- 12 Other: _____

Type of implant being exchanged:

- 1 Gel
- 2 Saline
- 3 Unknown

Number of previous revisions:

For each previous revision, specify below:

First Revision:

Type of Implant Removed:

- 1 Gel
- 2 Saline
- 3 Unknown

Revision Date:

month	year
-------	------

Reason for Revision: _____

Second Revision

Type of Implant Removed:

- 1 Gel
- 2 Saline
- 3 Unknown

Revision Date:

month	year
-------	------

Reason for Revision: _____



MENTOR

**Core Gel Breast
IDE Clinical Trial**

BASELINE

PATIENT STUDY ID:

TRIAL NO.
10-009

COUNTRY NO.
0 0 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last

INDICATION FOR SURGERY - LEFT BREAST

- 0 Not to be Implanted with Study Device (no current implant)
- 1 Not to be Implanted with Study Device (has current implant)

Indicate the primary reason for study device implantation surgery by checking the appropriate boxes for this breast:

2 AUGMENTATION, Primary Reason for augmentation:

- 1 Post-lactational Mammary Involution
- 2 General Breast Enlargement
- 3 Ptosis
- 5 Augmentation to contralateral breast for post-reconstruction symmetry
- 6 Other, specify: _____

3 RECONSTRUCTION, Primary Reason for reconstruction:

- 1 Total-mastectomy—Immediate*
- 2 Total-mastectomy—Delayed*
- 3 Subtotal Mastectomy (lumpectomy, quadrantectomy)*

Mastectomy/Surgery Date:

month	day	year
-------	-----	------

*(complete the Breast Cancer History page)

- 4 Post-trauma
- 5 Mastopexy to correct contralateral breast for post-reconstruction symmetry
- 6 Congenital deformity, check one:
 - 1 Asymmetry (see Protocol for definition)
 - 2 Breast aplasia
 - 3 Deformity due to tumors (hemangiomas, lymphangiomas, giant fibroadenomas)
 - 4 Hypomastia
 - 5 Pectus Carinatum
 - 6 Pectus Excavatum
 - 7 Poland's Syndrome
 - 8 Scoliosis
 - 9 Spinal curvature
 - 10 Thoracic cage assymetry
 - 11 Tubular breasts
 - 12 Other: _____

Flap used in reconstruction?

- 1 No
- 2 Yes, indicate type:
 - 1 TRAM
 - 2 Latissimus dorsi
 - 3 Other: _____

Tissue expander in place prior to implantation?

- 1 No
- 2 Yes, date of placement:

month	day	year
-------	-----	------

4 REVISION, specify type of revision:

- 1 Reconstruction revision (if original reconstruction due to breast cancer surgery, complete the Breast Cancer History page)

- 2 Augmentation revision

Original Implant Date:

month	year
-------	------

Primary Reason for current revision (check one):

- 1 Capsular Contracture
- 2 Distortion
- 3 Extrusion
- 4 Malposition
- 5 Post-op Hematoma
- 6 Post-op Infection
- 7 Ptosis
- 8 Rupture
- 9 Size Change-Down
- 10 Size Change-Up
- 11 Valve Retrieval
- 12 Other: _____

Type of implant being exchanged:

- 1 Gel
- 2 Saline
- 3 Unknown

Number of previous revisions:

--

For each previous revision, specify below:

First Revision:

Type of implant removed:

- 1 Gel
- 2 Saline
- 3 Unknown

Revision Date:

month	year
-------	------

Reason for Revision: _____

Second Revision

Type of implant removed:

- 1 Gel
- 2 Saline
- 3 Unknown

Revision Date:

month	year
-------	------

Reason for Revision: _____



MENTOR

**Core Gel Breast
IDE Clinical Trial**

BASELINE

PATIENT STUDY ID:

TRIAL NO.
10-009

COUNTRY NO.
0 0 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last

BREAST CANCER HISTORY

N/A (never diagnosed with breast cancer in either breast)

RIGHT BREAST N/A (never diagnosed with breast cancer)

LEFT BREAST N/A (never diagnosed with breast cancer)

1. Date of Diagnosis: / /
month year

2. Location:
- Upper Medial
 - Upper Lateral
 - Lower Medial
 - Lower Lateral

3. Staging:
- 1 Stage Tis (*In situ*)
 - 2 Stage X (*cannot stage*)
 - 3 Stage I
 - 4 Stage II
 - 5 Stage IIIA
 - 6 Stage IIIB
 - 7 Stage IV

4. Pathology
- a. Histologic type:
- 1 Cancer, Not Otherwise Specified
 - 2 Ductal
 - 3 Lobular
 - 4 Nipple
 - 5 Other, specify: _____
- b. Differentiation:
- 1 Poor (G3–G4)
 - 2 Moderate (G2)
 - 3 Well (G1)
 - 4 Cannot be assessed (GX)

- c. Estrogen receptor:
- 1 Positive
 - 2 Negative

- d. Progesterone receptor:
- 1 Positive
 - 2 Negative

1. Date of Diagnosis: / /
month year

2. Quadrant:
- Upper Medial
 - Upper Lateral
 - Lower Medial
 - Lower Lateral

3. Staging:
- 1 Stage Tis (*In situ*)
 - 2 Stage X (*cannot stage*)
 - 3 Stage I
 - 4 Stage II
 - 5 Stage IIIA
 - 6 Stage IIIB
 - 7 Stage IV

4. Pathology
- a. Histologic type:
- 1 Cancer, Not Otherwise Specified
 - 2 Ductal
 - 3 Lobular
 - 4 Nipple
 - 5 Other, specify: _____
- b. Differentiation:
- 1 Poor (G3–G4)
 - 2 Moderate (G2)
 - 3 Well (G1)
 - 4 Cannot be assessed (GX)

- c. Estrogen receptor:
- 1 Positive
 - 2 Negative

- d. Progesterone receptor:
- 1 Positive
 - 2 Negative

Referring Oncologist

Name: _____

Address: _____

Phone:(_____) _____



MENTOR

**Core Gel Breast
IDE Clinical Trial**

BASELINE

PATIENT STUDY ID:

TRIAL NO.
10-009

COUNTRY NO.
0 | 0 | 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last

BREAST CANCER TREATMENT HISTORY

N/A (never treated for breast cancer)

Type of Adjunctive Therapy:

a. Radiation:

- 1 No
- 2 Yes

b. Chemotherapy:

- 1 No
- 2 Yes, specify drug names:

- 1. _____
- 2. _____
- 3. _____
- 4. _____

c. Hormonal therapy:

- 1 No
- 2 Yes, check all that apply:
 - Hormones
 - Endocrine surgery
 - Endocrine radiation
 - Recommended, unknown if administered

d. Biological response modifier therapy:

- 1 No
- 2 Yes, specify types: _____
- 3 Recommended, unknown if administered

e. Other breast cancer-directed therapy:

- 1 No
- 2 Yes, specify types: _____
- 3 Recommended, unknown if administered

 MENTOR	Core Gel Breast IDE Clinical Trial			BASELINE				
	PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO.	PATIENT NO.	PATIENT INITIALS first middle last		

INVESTIGATOR-COMPLETED RHEUMATIC DISEASE DIAGNOSIS QUESTIONNAIRE

If rheumatologist has examined the patient and reports that the patient has any of the following, then patient is excluded from the study.

Has the patient been diagnosed by a RHEUMATOLOGIST for any of the following?

RHEUMATIC DISEASE	NO	YES	Has disease been diagnosed in a blood relative?		
			NO	YES	UNKNOWN
Connective Tissue Disorders:					
SLE	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Sjogren's Syndrome	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Scleroderma	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Polymyositis	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other Connective Tissue Disorders	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Inflammatory Arthritis:					
Rheumatoid Arthritis	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Crystalline Arthritis	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Infectious Arthritis	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Spondyarthropathies	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other Inflammatory Arthritis	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Non-Inflammatory Rheumatic Conditions:					
Osteoarthritis	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Fibromyalgia	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Chronic Fatigue	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other Mechanical or Degenerative	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



**Core Gel Breast
IDE Clinical Trial**

BASELINE

PATIENT STUDY ID:	TRIAL NO.	COUNTRY NO.			SITE NO.	PATIENT NO.	PATIENT INITIALS		
	10-009	0	0	1			first	middle	last

RHEUMATOLOGY SYMPTOMS

No symptoms present

Please check any **current** symptoms which:

1. The patient experiences on a regular basis
2. The cause is unknown and cannot be attributed to any patient activity.

RHEUMATOLOGICAL SYSTEMS REVIEW	YES	DATE OF ONSET (if known)		RHEUMATOLOGICAL SYSTEMS REVIEW	YES	DATE OF ONSET (if known)	
		month	year			month	year
Loss of weight without dieting	<input type="checkbox"/>			Numbness of hands	<input type="checkbox"/>		
Fatigue	<input type="checkbox"/>			Jaw pain	<input type="checkbox"/>		
Insomnia	<input type="checkbox"/>			Open sores	<input type="checkbox"/>		
Weakness	<input type="checkbox"/>			Redness of eyes	<input type="checkbox"/>		
Exhaustion	<input type="checkbox"/>			Dryness of mouth	<input type="checkbox"/>		
Joint swelling	<input type="checkbox"/>			Back pain/stiffness	<input type="checkbox"/>		
Heel pain	<input type="checkbox"/>			Severe chest pains	<input type="checkbox"/>		
Frequent muscle cramps	<input type="checkbox"/>			Chronic cough	<input type="checkbox"/>		
Numbness of feet	<input type="checkbox"/>			Difficulty swallowing	<input type="checkbox"/>		
Ringling in ears	<input type="checkbox"/>			Frequent, severe or persistent diarrhea or constipation	<input type="checkbox"/>		
Pain/grittiness in eyes	<input type="checkbox"/>			Severe rashes	<input type="checkbox"/>		
Dryness of eyes, nose	<input type="checkbox"/>			Frequent muscle cramps	<input type="checkbox"/>		
Pain on swallowing or chewing	<input type="checkbox"/>			Severe dryness of skin	<input type="checkbox"/>		
Neck pain/stiffness	<input type="checkbox"/>			Tender lumps/bumps	<input type="checkbox"/>		
Pain on breathing	<input type="checkbox"/>			Excessive sensitivity to sun	<input type="checkbox"/>		
Heart murmurs	<input type="checkbox"/>			Color changes on hands or feet with cold exposure	<input type="checkbox"/>		
Loss of appetite	<input type="checkbox"/>			Joint pain	<input type="checkbox"/>		
Persistent fever	<input type="checkbox"/>			Frequent hives	<input type="checkbox"/>		
Night sweats	<input type="checkbox"/>			Numbness of hands	<input type="checkbox"/>		
Generalized aching	<input type="checkbox"/>			Tightness of skin	<input type="checkbox"/>		
Loss of height	<input type="checkbox"/>			Unusual hair loss	<input type="checkbox"/>		
Joint pain	<input type="checkbox"/>			Tenderness of scalp	<input type="checkbox"/>		
Frequent muscle pain	<input type="checkbox"/>			Severe bruising with little or no injury	<input type="checkbox"/>		



**Core Gel Breast
IDE Clinical Trial**

BASELINE

PATIENT STUDY ID:

TRIAL NO.
10-009

COUNTRY NO.
0 | 0 | 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last

RHEUMATOLOGICAL PHYSICAL EXAMINATION

No symptoms present

Check the box for each physical finding noted to be present and outside normal limits.

PHYSICAL FINDING	PRESENT AND OUTSIDE NORMAL LIMITS	PHYSICAL FINDING	PRESENT AND OUTSIDE NORMAL LIMITS	POSSIBLE INDICATION
Muscle weakness: Headlift from supine position against gravity	<input type="checkbox"/>	Hair loss	<input type="checkbox"/>	<i>Lupus, Scleroderma</i>
Inability to raise arms	<input type="checkbox"/>	Skin tightness, especially face and hands	<input type="checkbox"/>	<i>Scleroderma</i>
Inability to get out of chair	<input type="checkbox"/>	Raynaud's phenomenon	<input type="checkbox"/>	<i>Lupus, Scleroderma</i>
Joint swellings: Wrists	<input type="checkbox"/>	Calcinosis over tibia, ulna, elbows	<input type="checkbox"/>	<i>Scleroderma, Dermatomyositis</i>
Digits	<input type="checkbox"/>	Swollen digits	<input type="checkbox"/>	<i>Juvenile RA, Reiter's syndrome, Psoriatic arthritis, Early scleroderma, Reflex sympathetic dystrophy</i>
Elbows	<input type="checkbox"/>	Erythema over knuckles	<input type="checkbox"/>	<i>Dermatomyositis</i>
Knees	<input type="checkbox"/>	Bluish hue color on eyelids	<input type="checkbox"/>	<i>Dermatomyositis</i>
Ankles	<input type="checkbox"/>	Non-tender lumps or nodules on elbows	<input type="checkbox"/>	<i>Rheumatoid gout</i>
Joint deformities and flexion contracture: Bouttonnière ¹	<input type="checkbox"/>	Tender lumps-tibia	<input type="checkbox"/>	<i>Erythema nodosum</i>
Ulnar drift ²	<input type="checkbox"/>	Painless eye redness	<input type="checkbox"/>	<i>Conjunctivitis</i>
Swan neck ³	<input type="checkbox"/>	Painful eye redness with decreased vision, small pupils	<input type="checkbox"/>	<i>Uveitis</i>
Trigger fingers	<input type="checkbox"/>	Tenderness—insertion of deltoids	<input type="checkbox"/>	<i>Polymyalgia rheumatica</i>
Joint tenderness	<input type="checkbox"/>	Muscle tenderness	<input type="checkbox"/>	<i>Polymyositis</i>
Grip strength and motion-finger to palm crease (normal = 0 cm)	<input type="checkbox"/>	Nail pittings	<input type="checkbox"/>	<i>Psoriatic arthritis, Reiter's syndrome</i>
Neck motion—chin to chest or sternum (normal = 0 cm)	<input type="checkbox"/>	Tinels or Phalen's signs	<input type="checkbox"/>	<i>Carpal tunnel syndrome</i>
Chest expansion (normal = at least 5 cm)	<input type="checkbox"/>	Skin rashes	<input type="checkbox"/>	<i>Discoid lupus</i>
Occiput to wall (normal = 0 cm)	<input type="checkbox"/>	¹ <i>Bouttonnière</i> - Contractures of hand musculature characterized by proximal interphalangeal joint flexion and distal interphalangeal joint hyperextension.		
Jaw motion (normally upper-lower incisors 3 cm)	<input type="checkbox"/>	² <i>Ulnar Drift</i> - Joint change at the metacarpophalangeal joints. Long axis of fingers deviate in an ulnar direction.		
Back motion-measure 10 cm above posterior supine iliac spines-with forward bending motion at least 5 cm from first point (total distance at least 15 cm)	<input type="checkbox"/>	³ <i>Swan Neck</i> - Finger deformity characterized by flexion of distal interphalangeal joints and hyperflexion of the proximal interphalangeal joints due to hypermobility.		

1. Does the patient require an exam by a rheumatologist?

- No
- Yes

Rheumatologist's Name: _____

2. If yes, rheumatologist's findings:

- Presence of rheumatic disease. **Patient is excluded.**
- No indication of rheumatic disease.

	Core Gel Breast IDE Clinical Trial			BASELINE		
	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO.	PATIENT NO.	PATIENT INITIALS first middle last	

PHYSICAL EXAMINATION	
HEIGHT (in) _____	WEIGHT (lb) _____

Check the appropriate box for each body system indicated.

ND = Not Done N = Normal A = Abnormal, comment is required

	ND	N	A	COMMENT ONLY IF ABNORMAL
HEENT	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Cardiovascular	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Pulmonary	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Neurological	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Musculoskeletal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Dermatological	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Lymphatic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Genitourinary	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Gastrointestinal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



MENTOR

**Core Gel Breast
IDE Clinical Trial**

BASELINE

PATIENT STUDY ID:

TRIAL NO.
10-009

COUNTRY NO.
0 0 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last

BREAST EXAM HISTORY

Number of Pregnancies: (if none, enter "00")

Complications? 1 No
2 Yes, number of complications:

Number of Live Births: (if none, enter "00")

Breastfeeding? 1 No
2 Yes, was there adequate milk? 1 No
2 Yes, Number of Breastfed Children: (if none, enter "00")

Age of Menarche:

Age of Menopause: 0 N/A

Family History of Breast Cancer? 1 No
2 Yes

History of Fibrocystic Disease? 1 No
2 Yes

PREVIOUS BREAST SURGERY (excluding mastectomy)

RIGHT 0 None
Number of Previous Surgeries:
List most recent:
Surgery Type: _____
Reason: _____
Date: month year

LEFT 0 None
Number of Previous Surgeries:
List most recent:
Surgery Type: _____
Reason: _____
Date: month year

BREAST BIOPSY

RIGHT 0 None
List most recent:
Biopsy Type: _____
Reason: _____
Date: month year
Result: 1 Negative
2 Positive

LEFT 0 None
List most recent:
Biopsy Type: _____
Reason: _____
Date: month year
Result: 1 Negative
2 Positive

	Core Gel Breast IDE Clinical Trial		BASELINE		
	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO.	PATIENT NO.	PATIENT INITIALS <small>first middle last</small>

BREAST MEASUREMENTS	
RIGHT <input type="checkbox"/> Not to be Implanted with Study Device Circumferential Breast Measurement <input type="text"/> <input type="text"/> cm Bra Size (i.e. 32A) <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="checkbox"/> N/A (breast absent)	LEFT <input type="checkbox"/> Not to be Implanted with Study Device Circumferential Breast Measurement <input type="text"/> <input type="text"/> cm Bra Size (i.e. 32A) <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="checkbox"/> N/A (breast absent)

NIPPLE/BREAST SENSITIVITY - How would patient describe the feeling in nipple(s) and/or breast(s) now?	
RIGHT <input type="checkbox"/> Not to be Implanted with Study Device Nipple Sensation is: 1 <input type="checkbox"/> Unacceptably low 2 <input type="checkbox"/> Acceptable 3 <input type="checkbox"/> Unacceptably high 4 <input type="checkbox"/> N/A, nipple absent Breast sensation is: 1 <input type="checkbox"/> Unacceptably low 2 <input type="checkbox"/> Acceptable 3 <input type="checkbox"/> Unacceptably high 4 <input type="checkbox"/> N/A, breast absent	LEFT <input type="checkbox"/> Not to be Implanted with Study Device Nipple Sensation is: 1 <input type="checkbox"/> Unacceptably low 2 <input type="checkbox"/> Acceptable 3 <input type="checkbox"/> Unacceptably high 4 <input type="checkbox"/> N/A, nipple absent Breast sensation is: 1 <input type="checkbox"/> Unacceptably low 2 <input type="checkbox"/> Acceptable 3 <input type="checkbox"/> Unacceptably high 4 <input type="checkbox"/> N/A, breast absent

MAMMOGRAPHY RESULTS	
Date of Most Recent Mammogram: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="checkbox"/> Not Done <small>month year</small>	
RIGHT 1 <input type="checkbox"/> Birads 0 <i>Needs additional imaging evaluation</i> 2 <input type="checkbox"/> Birads 1 <i>Negative</i> 3 <input type="checkbox"/> Birads 2 <i>Benign finding</i> 4 <input type="checkbox"/> Birads 3 <i>Probable benign finding—short interval follow-up is suggested</i> 5 <input type="checkbox"/> Birads 4 <i>Suspicious abnormality—biopsy should be considered</i> 6 <input type="checkbox"/> Birads 5 <i>Highly suggestive of malignancy—appropriate action should be taken</i> List abnormality: _____	LEFT 1 <input type="checkbox"/> Birads 0 <i>Needs additional imaging evaluation</i> 2 <input type="checkbox"/> Birads 1 <i>Negative</i> 3 <input type="checkbox"/> Birads 2 <i>Benign finding</i> 4 <input type="checkbox"/> Birads 3 <i>Probable benign finding—short interval follow-up is suggested</i> 5 <input type="checkbox"/> Birads 4 <i>Suspicious abnormality—biopsy should be considered</i> 6 <input type="checkbox"/> Birads 5 <i>Highly suggestive of malignancy—appropriate action should be taken</i> List abnormality: _____

INVESTIGATOR SIGNATURE
I have reviewed the Baseline Case Report Forms and have verified that all data are accurate.
_____ Investigator's Signature
<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <small>month day year</small>

 MENTOR	Core Gel Breast IDE Clinical Trial			BASELINE			
	<small>TRIAL NO.</small> 10-009	<small>COUNTRY NO.</small> 0 0 1		<small>SITE NO.</small>		<small>PATIENT NO.</small>	

ROSENBERG SELF-ESTEEM SCALE (Page 1 of 1)

TO THE PATIENT: Below are some statements with which some people agree and disagree. Please read each statement and check **one** response to each statement.

	Strongly Agree 1	Agree 2	Disagree 3	Strongly Disagree 4
1. I feel that I am a person of worth, at least on an equal basis with others.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. I feel that I have a number of good qualities.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. All in all, I am inclined to feel that I am a failure.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. I am able to do things as well as most people.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. I feel I do not have much of which to be proud.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. I take a positive attitude towards myself.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. On the whole, I am satisfied with myself.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. I wish I could have more respect for myself.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. I certainly feel useless at times.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. At times I think I am no good at all.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

 MENTOR	Core Gel Breast IDE Clinical Trial			BASELINE				
	PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO.	PATIENT NO.	PATIENT INITIALS first middle last		

TENNESSEE SELF-CONCEPT SCALE (Page 1 of 4)

TO THE PATIENT: The statements below are to help you describe yourself as you see yourself. Please respond to them as if you were describing yourself **to yourself**. Do not omit any item. Read each statement carefully, then select one of the five responses listed below. On the test, put a **circle** around the response you chose. If you want to change an answer after you have circled it, do not erase it but put an X mark through the response and then circle the response you want.

<i>Remember, put a circle around the response number you have chosen for each statement.</i>	Completely False	Mostly False	Partly True and Partly False	Mostly True	Completely True
1. I have a healthy body.	1	2	3	4	5
2. I am an attractive person.	1	2	3	4	5
3. I consider myself a sloppy person.	1	2	3	4	5
4. I am a decent sort of person.	1	2	3	4	5
5. I am an honest person.	1	2	3	4	5
6. I am a bad person.	1	2	3	4	5
7. I am a cheerful person.	1	2	3	4	5
8. I am a calm and easygoing person.	1	2	3	4	5
9. I am a nobody.	1	2	3	4	5
10. I have a family that would always help me in any kind of trouble.	1	2	3	4	5
11. I am a member of a happy family.	1	2	3	4	5
12. My friends have no confidence in me.	1	2	3	4	5
13. I am a friendly person.	1	2	3	4	5
14. I am popular with men.	1	2	3	4	5
15. I am not interested in what other people do.	1	2	3	4	5
16. I do not always tell the truth.	1	2	3	4	5
17. I get angry sometimes.	1	2	3	4	5
18. I like to look nice and neat all the time.	1	2	3	4	5
19. I am full of aches and pains.	1	2	3	4	5
20. I am a sick person.	1	2	3	4	5
21. I am a religious person.	1	2	3	4	5
22. I am a moral failure.	1	2	3	4	5
23. I am a morally weak person.	1	2	3	4	5

 MENTOR	Core Gel Breast IDE Clinical Trial			BASELINE						
	TRIAL NO. 10-009	COUNTRY NO. 0 0 1			SITE NO.		PATIENT NO.		PATIENT INITIALS first middle last	

TENNESSEE SELF-CONCEPT SCALE (Page 2 of 4)

<i>Remember, put a circle around the response number you have chosen for each statement.</i>	Completely False	Mostly False	Partly True and Partly False	Mostly True	Completely True
24. I have a lot of self-control.	1	2	3	4	5
25. I am a hateful person.	1	2	3	4	5
26. I am losing my mind.	1	2	3	4	5
27. I am an important person to my friends and family.	1	2	3	4	5
28. I am not loved by my family.	1	2	3	4	5
29. I feel that my family doesn't trust me.	1	2	3	4	5
30. I am popular with women.	1	2	3	4	5
31. I am mad at the whole world.	1	2	3	4	5
32. I am hard to be friendly with.	1	2	3	4	5
33. Once in a while I think of things too bad to talk about.	1	2	3	4	5
34. Sometimes when I am not feeling well, I am cross.	1	2	3	4	5
35. I am neither too fat nor too thin.	1	2	3	4	5
36. I like my looks just the way they are.	1	2	3	4	5
37. I would like to change some parts of my body.	1	2	3	4	5
38. I am satisfied with my moral behavior.	1	2	3	4	5
39. I am satisfied with my relationship to God.	1	2	3	4	5
40. I ought to go to church more.	1	2	3	4	5
41. I am satisfied to be just what I am.	1	2	3	4	5
42. I am just as nice as I should be.	1	2	3	4	5
43. I despise myself.	1	2	3	4	5
44. I am satisfied with my family relationships.	1	2	3	4	5
45. I understand my family as well as I should.	1	2	3	4	5
46. I should trust my family more.	1	2	3	4	5
47. I am as sociable as I want to be.	1	2	3	4	5
48. I try to please others, but I don't overdo it.	1	2	3	4	5
49. I am no good at all from a social standpoint.	1	2	3	4	5

 MENTOR	Core Gel Breast IDE Clinical Trial			BASELINE						
	TRIAL NO. 10-009	COUNTRY NO. 0 0 1			SITE NO.		PATIENT NO.		PATIENT INITIALS first middle last	

TENNESSEE SELF-CONCEPT SCALE (Page 3 of 4)

<i>Remember, put a circle around the response number you have chosen for each statement.</i>	Completely False	Mostly False	Partly True and Partly False	Mostly True	Completely True
50. I do not like everyone I know.	1	2	3	4	5
51. Once in a while, I laugh at a dirty joke.	1	2	3	4	5
52. I am neither too tall nor too short.	1	2	3	4	5
53. I don't feel as well as I should.	1	2	3	4	5
54. I should have more sex appeal.	1	2	3	4	5
55. I am as religious as I want to be.	1	2	3	4	5
56. I wish I could be more trustworthy.	1	2	3	4	5
57. I shouldn't tell so many lies.	1	2	3	4	5
58. I am as smart as I want to be.	1	2	3	4	5
59. I am not the person I would like to be.	1	2	3	4	5
60. I wish I didn't give up as easily as I do.	1	2	3	4	5
61. I treat my parents as well as I should. <i>(Use past tense if parents are not living.)</i>	1	2	3	4	5
62. I am too sensitive to things my family says.	1	2	3	4	5
63. I should love my family more.	1	2	3	4	5
64. I am satisfied with the way I treat other people.	1	2	3	4	5
65. I should be more polite to others.	1	2	3	4	5
66. I ought to get along better with other people.	1	2	3	4	5
67. I gossip a little at times.	1	2	3	4	5
68. At times I feel like swearing.	1	2	3	4	5
69. I take good care of myself physically.	1	2	3	4	5
70. I try to be careful about my appearance.	1	2	3	4	5
71. I often act like I am "all thumbs".	1	2	3	4	5
72. I am true to my religion in my everyday life.	1	2	3	4	5
73. I try to change when I know I'm doing things that are wrong.	1	2	3	4	5
74. I sometimes do very bad things.	1	2	3	4	5
75. I can always take care of myself in any situation.	1	2	3	4	5

 MENTOR	Core Gel Breast IDE Clinical Trial			BASELINE						
	TRIAL NO. 10-009	COUNTRY NO. 0 0 1			SITE NO.		PATIENT NO.		PATIENT INITIALS first middle last	

TENNESSEE SELF-CONCEPT SCALE (Page 4 of 4)					
<i>Remember, put a circle around the response number you have chosen for each statement.</i>	Completely False	Mostly False	Partly True and Partly False	Mostly True	Completely True
76. I take the blame for things without getting mad.	1	2	3	4	5
77. I do things without thinking about them first.	1	2	3	4	5
78. I try to play fair with my friends and family.	1	2	3	4	5
79. I take a real interest in my family.	1	2	3	4	5
80. I give in to my parents. <i>(Use past tense if parents are not living.)</i>	1	2	3	4	5
81. I try to understand the other fellow's point of view.	1	2	3	4	5
82. I get along well with other people.	1	2	3	4	5
83. I do not forgive others easily.	1	2	3	4	5
84. I would rather win than lose in a game.	1	2	3	4	5
85. I feel good most of the time.	1	2	3	4	5
86. I do poorly in sports and games.	1	2	3	4	5
87. I am a poor sleeper.	1	2	3	4	5
88. I do what is right most of the time.	1	2	3	4	5
89. I sometimes use unfair means to get ahead.	1	2	3	4	5
90. I have trouble doing the things that are right.	1	2	3	4	5
91. I solve my problems quite easily.	1	2	3	4	5
92. I change my mind a lot.	1	2	3	4	5
93. I try to run away from my problems.	1	2	3	4	5
94. I do my share of work at home.	1	2	3	4	5
95. I quarrel with my family.	1	2	3	4	5
96. I do not act like my family thinks I should.	1	2	3	4	5
97. I see good points in all the people I meet.	1	2	3	4	5
98. I do not feel at ease with other people.	1	2	3	4	5
99. I find it hard to talk with strangers.	1	2	3	4	5
100. Once in a while I put off until tomorrow what I ought to do today.	1	2	3	4	5

 MENTOR	Core Gel Breast IDE Clinical Trial			BASELINE						
	TRIAL NO. 10-009	COUNTRY NO. 0 0 1			SITE NO.		PATIENT NO.		PATIENT INITIALS first middle last	

SF-36 (Page 1 of 3)

TO THE PATIENT: This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Answer each question by circling **one** number. If you are unsure about how to answer a question, please give the best answer you can.

1. In general, would you say your health is: (Circle one number)	Excellent	Very Good	Good	Fair	Poor
	1	2	3	4	5

2. Compared to one year ago, how would you rate your health in general now ? (Circle one number)	Much Better Now	Somewhat Better Now	About the Same	Somewhat Worse Now	Much Worse Now
	1	2	3	4	5

3. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much? (Circle one number for each question.)	Yes, Limited a Lot	Yes, Limited a Little	No, Not Limited at All
Vigorous activities , such as running, lifting heavy objects, participating in strenuous sports.	1	2	3
Moderate activities , such as moving a table, pushing a vacuum cleaner, bowling or playing golf	1	2	3
Lifting or carrying groceries	1	2	3
Climbing several flights of stairs	1	2	3
Climbing one flight of stairs	1	2	3
Bending, kneeling, or stooping	1	2	3
Walking more than a mile	1	2	3
Walking several blocks	1	2	3
Walking one block	1	2	3
Bathing or dressing yourself	1	2	3

 MENTOR	Core Gel Breast IDE Clinical Trial			BASELINE							
	PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1			SITE NO.		PATIENT NO.		PATIENT INITIALS first middle last	

SF-36 (Page 2 of 3)

4. During the past 4 weeks , have you had any of the following problems with your work or other regular daily activities as a result of your physical health? (Circle one number for each question.)	YES	NO
Cut down on the amount of time you spent on work or other activities	1	2
Accomplished less than you would like	1	2
Were limited in the kind of work or other activities	1	2
Had difficulty performing the work or other activities (for example, it took extra effort)	1	2

5. During the past 4 weeks , have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)? (Circle one number for each question.)	YES	NO
Cut down on the amount of time you spent on work or other activities	1	2
Accomplished less than you would like	1	2
Didn't do work or other activities as carefully as usual	1	2

6. During the past 4 weeks , to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups? (Circle one number)	Not at All	Slightly	Moderately	Quite a Bit	Extremely
	1	2	3	4	5

7. How much bodily pain have you had during the past 4 weeks? (Circle one number)	None	Very Mild	Mild	Moderate	Severe	Very Severe
	1	2	3	4	5	6

8. During the past 4 weeks , how much did pain interfere with your normal work (including both work outside the home and housework)? (Circle one number)	Not at All	A Little Bit	Moderately	Quite a Bit	Extremely
	1	2	3	4	5

 MENTOR	Core Gel Breast IDE Clinical Trial			BASELINE				
	PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO.	PATIENT NO.	PATIENT INITIALS first middle last		

SF-36 (Page 3 of 3)

9. These questions are about how you feel and how things have been with you **during the past 4 weeks**. For each question, please indicate the one answer that comes closest to the way you have been feeling. (Circle **one** number for each question.)

How much of the time during the past 4 weeks ...	All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	None of the Time
Did you feel full of pep?	1	2	3	4	5	6
Have you been a very nervous person?	1	2	3	4	5	6
Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
Have you felt calm and peaceful?	1	2	3	4	5	6
Did you have a lot of energy?	1	2	3	4	5	6
Have you felt downhearted and blue?	1	2	3	4	5	6
Did you feel worn out?	1	2	3	4	5	6
Have you been a happy person?	1	2	3	4	5	6
Did you feel tired?	1	2	3	4	5	6

10. During the past 4 weeks , how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)? (Circle one number.)	All of the Time	Most of the Time	Some of the Time	A Little of the Time	None of the Time
	1	2	3	4	5

11. How TRUE or FALSE is each of the following statements for you? (Circle one number for each question.)	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
I seem to get sick a little easier than other people	1	2	3	4	5
I am as healthy as anybody I know	1	2	3	4	5
I expect my health to get worse	1	2	3	4	5
My health is excellent	1	2	3	4	5



MENTOR

**Core Gel Breast
IDE Clinical Trial**

BASELINE

PATIENT STUDY ID:

TRIAL NO.
10-009

COUNTRY NO.
0 | 0 | 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last

BODY ESTEEM SCALE (Page 1 of 1)

TO THE PATIENT: On this page are listed a number of body parts and functions. Please read each item and indicate how you feel about this part or function of ***your own body***, using the following scale:

- 1 = Have strong negative feelings
- 2 = Have moderate negative feelings
- 3 = Have no feeling one way or the other
- 4 = Have moderate positive feelings
- 5 = Have strong positive feelings

- | | |
|--|--|
| <input type="checkbox"/> 1. Body Scent | <input type="checkbox"/> 19. Arms |
| <input type="checkbox"/> 2. Appetite | <input type="checkbox"/> 20. Chest |
| <input type="checkbox"/> 3. Nose | <input type="checkbox"/> 21. Appearance of Eyes |
| <input type="checkbox"/> 4. Physical Stamina | <input type="checkbox"/> 22. Cheeks/Cheekbones |
| <input type="checkbox"/> 5. Reflexes | <input type="checkbox"/> 23. Hips |
| <input type="checkbox"/> 6. Lips | <input type="checkbox"/> 24. Legs |
| <input type="checkbox"/> 7. Muscular Strength | <input type="checkbox"/> 25. Physique |
| <input type="checkbox"/> 8. Waist | <input type="checkbox"/> 26. Sex Drive |
| <input type="checkbox"/> 9. Energy Level | <input type="checkbox"/> 27. Feet |
| <input type="checkbox"/> 10. Thighs | <input type="checkbox"/> 28. Sex Organs |
| <input type="checkbox"/> 11. Ears | <input type="checkbox"/> 29. Appearance of Stomach |
| <input type="checkbox"/> 12. Biceps | <input type="checkbox"/> 30. Health |
| <input type="checkbox"/> 13. Chin | <input type="checkbox"/> 31. Sex Activities |
| <input type="checkbox"/> 14. Body Build | <input type="checkbox"/> 32. Body Hair |
| <input type="checkbox"/> 15. Physical Coordination | <input type="checkbox"/> 33. Physical Condition |
| <input type="checkbox"/> 16. Buttocks | <input type="checkbox"/> 34. Face |
| <input type="checkbox"/> 17. Agility | <input type="checkbox"/> 35. Weight |
| <input type="checkbox"/> 18. Width of Shoulders | |



MENTOR

**Core Gel Breast
IDE Clinical Trial**

BASELINE

PATIENT STUDY ID:

TRIAL NO.
10-009

COUNTRY NO.
0 | 0 | 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last

MANITOBA CANCER TREATMENT & RESEARCH FOUNDATION FUNCTIONAL LIVING INDEX: CANCER (FLIC)

Page 1 of 3

N/A (not a cancer patient)

TO THE PATIENT: Please indicate your rating by drawing a vertical line (|).

1. Most people experience some feelings of depression at times. Rate how often you feel these feelings.

1	2	3	4	5	6	7
Never						Continually

2. How well are you coping with your everyday stress?

1	2	3	4	5	6	7
Not Well						Very Well

3. How much time do you spend thinking about your illness?

1	2	3	4	5	6	7
Constantly						Never

4. Rate your ability to maintain your usual recreation or leisure activities.

1	2	3	4	5	6	7
Able						Unable

5. Has nausea affected your daily functioning?

1	2	3	4	5	6	7
Not At All						A Great Deal

6. How well do you feel today?

1	2	3	4	5	6	7
Extremely Poor						Extremely Well

7. Do you feel well enough to make a meal or do minor household repairs today?

1	2	3	4	5	6	7
Very Able						Not Able



MENTOR

**Core Gel Breast
IDE Clinical Trial**

BASELINE

PATIENT STUDY ID:

TRIAL NO.
10-009

COUNTRY NO.
0 | 0 | 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last

MANITOBA CANCER TREATMENT & RESEARCH FOUNDATION FUNCTIONAL LIVING INDEX: CANCER (FLIC)

Page 2 of 3

N/A (not a cancer patient)

8. Rate the degree to which your cancer has imposed a hardship on those closest to you in the past 2 months.

| | | | | | |

1 2 3 4 5 6 7

No Hardship Tremendous Hardship

9. Rate how often you feel discouraged about your life.

| | | | | | |

1 2 3 4 5 6 7

Always Never

10. Rate your satisfaction with your work and your jobs around the house in the past month.

| | | | | | |

1 2 3 4 5 6 7

Very Dissatisfied Very Satisfied

11. How uncomfortable do you feel today?

| | | | | | |

1 2 3 4 5 6 7

Not at All Very Uncomfortable

12. Rate in your opinion, how disruptive your cancer has been to those closest to you in the past 2 weeks.

| | | | | | |

1 2 3 4 5 6 7

Totally Disruptive No Disruption

13. How much is pain or discomfort interfering with your daily activities?

| | | | | | |

1 2 3 4 5 6 7

Not at All A Great Deal

14. Rate the degree to which your cancer has imposed a hardship on you (personally) in the past 2 weeks.

| | | | | | |

1 2 3 4 5 6 7

Tremendous Hardship No Hardship



MENTOR

**Core Gel Breast
IDE Clinical Trial**

BASELINE

PATIENT STUDY ID:

TRIAL NO.
10-009

COUNTRY NO.
0 0 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last

MANITOBA CANCER TREATMENT & RESEARCH FOUNDATION FUNCTIONAL LIVING INDEX: CANCER (FLIC)

Page 3 of 3

N/A (not a cancer patient)

15. How much of your usual household tasks are you able to complete?

1	2	3	4	5	6	7
All						None

16. Rate how willing you were to see and spend time with those closest to you, in the past 2 weeks.

1	2	3	4	5	6	7
Unwilling						Very Willing

17. How much nausea have you had in the past 2 weeks?

1	2	3	4	5	6	7
None						A Great Deal

18. Rate the degree to which you are frightened of the future.

1	2	3	4	5	6	7
Constantly Terrified						Not Afraid

19. Rate how willing you were to see and spend time with friends, in the past 2 weeks.

1	2	3	4	5	6	7
Unwilling						Very Willing

20. How much of your pain or discomfort over the past 2 weeks was related to your cancer?

1	2	3	4	5	6	7
None						All

21. Rate your confidence in your prescribed course of treatment.

1	2	3	4	5	6	7
No Confidence						Very Confident

22. How well do you appear today?

1	2	3	4	5	6	7
Extremely Poor						Extremely Well



MENTOR

**Core Gel Breast
IDE Clinical Trial**

OPERATIVE REPORT

PATIENT STUDY ID:

TRIAL NO.
10-009

COUNTRY NO.
0 0 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last

SURGICAL INFORMATION

Date of Surgery: month day year

Institution at which surgery took place: _____

Anesthesia Type (check all that apply):

- General
- Local
- Local with Sedation
- Other, specify: _____

Were any other surgical procedures performed at this time?

- 1 No
- 2 Yes, specify: _____

	RIGHT <input type="checkbox"/> Not Implanted With Study Device	LEFT <input type="checkbox"/> Not Implanted With Study Device
Device Placement:	1 <input type="checkbox"/> Submuscular 2 <input type="checkbox"/> Subglandular 3 <input type="checkbox"/> Subpectoral 4 <input type="checkbox"/> Other: _____	1 <input type="checkbox"/> Submuscular 2 <input type="checkbox"/> Subglandular 3 <input type="checkbox"/> Subpectoral 4 <input type="checkbox"/> Other: _____
Incision Size:	<input type="text"/> cm	<input type="text"/> cm
Implant Information:	1 <input type="checkbox"/> Smooth Surface 2 <input type="checkbox"/> Textured Surface Device Volume: <input type="text"/> cc	1 <input type="checkbox"/> Smooth Surface 2 <input type="checkbox"/> Textured Surface Device Volume: <input type="text"/> cc
Catalog Number:		
Lot Number:		
Surgical Approach:	1 <input type="checkbox"/> Periareolar 2 <input type="checkbox"/> Inframammary 3 <input type="checkbox"/> Transaxillary 4 <input type="checkbox"/> Mastectomy Scar 5 <input type="checkbox"/> Other: _____	1 <input type="checkbox"/> Periareolar 2 <input type="checkbox"/> Inframammary 3 <input type="checkbox"/> Transaxillary 4 <input type="checkbox"/> Mastectomy Scar 5 <input type="checkbox"/> Other: _____
Pocket Irrigation (check all that apply):	<input type="checkbox"/> Saline Only <input type="checkbox"/> Steroid: _____ Dose: _____ <input type="checkbox"/> Antibiotic: _____ <input type="checkbox"/> Drug: _____ <input type="checkbox"/> Other: _____	<input type="checkbox"/> Saline Only <input type="checkbox"/> Steroid: _____ Dose: _____ <input type="checkbox"/> Antibiotic: _____ <input type="checkbox"/> Drug: _____ <input type="checkbox"/> Other: _____
Post-Operative Recommendations (check all that apply):	<input type="checkbox"/> Antibiotic: _____ <input type="checkbox"/> Restricted Activities <input type="checkbox"/> Recommend Massage <input type="checkbox"/> Other: _____	<input type="checkbox"/> Antibiotic: _____ <input type="checkbox"/> Restricted Activities <input type="checkbox"/> Recommend Massage <input type="checkbox"/> Other: _____

Complete Adverse Events Report if the patient experienced any operative complications or adverse events.



MENTOR

**Core Gel Breast
IDE Clinical Trial**

PATIENT REGISTRY FORM
Please type or legibly print all requested information.

PATIENT STUDY ID:

TRIAL NO.
10-009

COUNTRY NO.
0 0 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last

I. DEVICE INFORMATION

Implantation Date:
month day year

RIGHT SIDE

Product Name: _____

Cat. No.: _____

Lot No.: _____

LEFT SIDE

Product Name: _____

Cat. No.: _____

Lot No.: _____

II. PATIENT INFORMATION

Patient Name: _____ Phone No.: (_____) _____
Last First MI Area Code

Address: _____
Street Address City State Zip Code Country

Date of Birth: Social Security No.: - -
month day year

III. IMPLANTING SURGEON INFORMATION

Name: _____ Phone No.: (_____) _____
Last First MI Area Code

Address: _____
Street Address City State Zip Code Country

Name of facility where surgery was performed: _____



MENTOR

**Core Gel Breast
IDE Clinical Trial**

6 MONTH VISIT

PATIENT STUDY ID:

TRIAL NO.
10-009

COUNTRY NO.
0 0 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last

Visit Date:

month day year

Missed Visit

BREAST MEASUREMENTS

RIGHT Not Implanted with Study Device

Circumferential Breast Measurement cm

Bra Size (i.e. 32A) N/A (breast absent)

LEFT Not Implanted with Study Device

Circumferential Breast Measurement cm

Bra Size (i.e. 32A) N/A (breast absent)

MAMMOGRAPHY RESULTS

Date of Mammogram:

month year

Not Done

RIGHT

- 1 Birads 0 *Needs additional imaging evaluation*
 - 2 Birads 1 *Negative*
 - 3 Birads 2 *Benign finding*
 - 4 Birads 3 *Probable benign finding—short interval follow-up is suggested*
 - 5 Birads 4 *Suspicious abnormality—biopsy should be considered*
 - 6 Birads 5 *Highly suggestive of malignancy—appropriate action should be taken*
- List abnormality: _____

LEFT

- 1 Birads 0 *Needs additional imaging evaluation*
 - 2 Birads 1 *Negative*
 - 3 Birads 2 *Benign finding*
 - 4 Birads 3 *Probable benign finding—short interval follow-up is suggested*
 - 5 Birads 4 *Suspicious abnormality—biopsy should be considered*
 - 6 Birads 5 *Highly suggestive of malignancy—appropriate action should be taken*
- List abnormality: _____

VISIT REPORT

1. Has the patient become pregnant since the last visit?

- 1 No
- 2 Yes, without complications
- 3 Yes, with complications

Complete Adverse Events Report

2. Has the patient attempted to breastfeed since the last visit?

- 1 No
- 2 Yes, was there adequate milk?
 - 1 No *(Enter code 30 on Adverse Events Report)*
 - 2 Yes

3. Would the patient have this breast surgery again?

- 1 No, reason: _____
- 2 Yes

4. **Breast Cancer Reconstruction Patients only:**

N/A (augmentation patient)

Has the patient received any adjuvant therapies since the last visit?

- 1 No
- 2 Yes, check all that apply:
 - Radiation Therapy
 - Chemotherapy
 - Other, specify: _____

Treating Oncologist

Name: _____

Phone: (_____) _____

	Core Gel Breast IDE Clinical Trial		6 MONTH VISIT			
	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO.	PATIENT NO.	PATIENT INITIALS <small>first middle last</small>	

CAPSULAR CONTRACTURE ASSESSMENT OF PROSTHESIS	
Right Prosthesis is: <input type="radio"/> Not Implanted with Study Device 1 <input type="checkbox"/> Baker Class I (normally soft and natural appearance) 2 <input type="checkbox"/> Baker Class II (a natural appearance despite palpable firmness) 3 <input type="checkbox"/> Baker Class III (firm with visible distortion) 4 <input type="checkbox"/> Baker Class IV (obvious spherical distortion)	Left Prosthesis is: <input type="radio"/> Not Implanted with Study Device 1 <input type="checkbox"/> Baker Class I (normally soft and natural appearance) 2 <input type="checkbox"/> Baker Class II (a natural appearance despite palpable firmness) 3 <input type="checkbox"/> Baker Class III (firm with visible distortion) 4 <input type="checkbox"/> Baker Class IV (obvious spherical distortion)
Complete Adverse Events Report for Baker III or IV.	

NIPPLE/BREAST SENSITIVITY	
<p style="text-align: center;">How would patient describe the feeling in nipple(s) and/or breast(s) now?</p> <p style="text-align: center;"><i>If unacceptably high or low at baseline, and sensation remains the same post-operatively, do not complete an Adverse Events Report.</i></p> <p style="text-align: center;"><i>If acceptable at baseline and has become unacceptable post-operatively, complete an Adverse Events Report.</i></p>	
RIGHT <input type="radio"/> Not Implanted with Study Device Nipple Sensation is: 1 <input type="checkbox"/> Unacceptably low 2 <input type="checkbox"/> Acceptable 3 <input type="checkbox"/> Unacceptably high 4 <input type="checkbox"/> N/A, nipple absent Breast sensation is: 1 <input type="checkbox"/> Unacceptably low 2 <input type="checkbox"/> Acceptable 3 <input type="checkbox"/> Unacceptably high 4 <input type="checkbox"/> N/A, breast absent	LEFT <input type="radio"/> Not Implanted with Study Device Nipple Sensation is: 1 <input type="checkbox"/> Unacceptably low 2 <input type="checkbox"/> Acceptable 3 <input type="checkbox"/> Unacceptably high 4 <input type="checkbox"/> N/A, nipple absent Breast sensation is: 1 <input type="checkbox"/> Unacceptably low 2 <input type="checkbox"/> Acceptable 3 <input type="checkbox"/> Unacceptably high 4 <input type="checkbox"/> N/A, breast absent
Complete Adverse Events Report for any complications or adverse events noted at this visit.	



Core Gel Breast IDE Clinical Trial

ADVERSE EVENTS

6 MONTH VISIT

PATIENT STUDY ID: TRIAL NO. 10-009 COUNTRY NO. 0 0 1 SITE NO. PATIENT NO. PATIENT INITIALS first middle last No Adverse Events

Enter one adverse event per line. If the event was experienced at more than one body site, enter each body site on a separate line.

AE CODE* (See Below)	CAUSALITY 1 = Procedure related 2 = Device related 3 = Unknown 4 = Other	EVENT SIDE 0 = N/A 1 = Right 2 = Left	ASSOCIATED BREAST PAIN 0 = None 1 = Mild 2 = Moderate 3 = Severe	ONSET DATE month day year	SEVERITY 1 = Mild 2 = Moderate 3 = Severe	TREATMENT REQUIRED (check all that apply) 1 = No Treatment 2 = Medication (specify) 3 = Secondary Procedure (enter Procedure Type Code and date below, and complete Secondary Procedures Report for all procedures performed for this date)** 4 = Hospitalization (specify # of days and admission date) 5 = Other (specify)	OUTCOME 1 = Resolved 2 = Ongoing 3 = Death 4 = Unknown	RESOLUTION DATE month day year
<input type="checkbox"/> 1	<input type="checkbox"/> 3	<input type="checkbox"/> 0	<input type="checkbox"/> 0 <input type="checkbox"/> 3	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 4 days, Date: ___/___/___	<input type="checkbox"/> 1 <input type="checkbox"/> 4	
<input type="checkbox"/> 2	<input type="checkbox"/> 4	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 5 Procedure Date: ___/___/___	<input type="checkbox"/> 2	
<input type="checkbox"/> 1	<input type="checkbox"/> 3	<input type="checkbox"/> 0	<input type="checkbox"/> 0 <input type="checkbox"/> 3	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 4 days, Date: ___/___/___	<input type="checkbox"/> 1 <input type="checkbox"/> 4	
<input type="checkbox"/> 2	<input type="checkbox"/> 4	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 5 Procedure Date: ___/___/___	<input type="checkbox"/> 2	
<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 3	Procedure Date: ___/___/___	<input type="checkbox"/> 3	

**Complete Secondary Procedures Report. If new study device is implanted, complete Re-implantation Report.

Investigator's Signature _____ month _____ day _____ year

*ADVERSE EVENT CODES	+SECONDARY PROCEDURE TYPE CODES
1 = Asymmetry 2 = Baker II Capsular Contracture with Surgical Intervention 3 = Baker III Capsular Contracture 4 = Baker IV Capsular Contracture 5 = Breast pain not associated with any other complication 6 = Breast—Unacceptably Low Sensitivity 7 = Breast—Unacceptably High Sensitivity 8 = Calcification 9 = Delayed Wound Healing 10 = Extrusion 11 = Granuloma 12 = Hematoma 13 = Hypertrophic Scarring 14 = Infection 15 = Lymphadenopathy 16 = Necrosis 17 = New Diagnosis of Breast Cancer 18 = New Diagnosis of Rheumatic Disease, specify: 19 = Nipple—Unacceptably Low Sensitivity 20 = Nipple—Unacceptably High Sensitivity 21 = Position Change 22 = Ptosis 23 = Rupture 24 = Seroma 25 = Size Change—Patient Request 26 = Size Change—Physician Assessment only 27 = Wrinkling	81 = Biopsy 82 = Capsulectomy 83 = Explanation with Replacement** 84 = Explanation without Replacement 85 = Incision and Drainage 86 = Mastopexy 87 = Open Capsulotomy 88 = Position Change 89 = Scar Revision 90 = Skin Adjustment 91 = Other, specify: _____ 92 = Other, specify: _____ 28 = Lactation Difficulties, specify: _____ 29 = Other, specify: _____ 30 = Other, specify: _____



MENTOR

**Core Gel Breast
IDE Clinical Trial**

1 YEAR VISIT

PATIENT STUDY ID:

TRIAL NO.
10-009

COUNTRY NO.
0 0 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last

Visit Date:

month day year

Missed Visit

BREAST MEASUREMENTS

RIGHT Not Implanted with Study Device

Circumferential Breast Measurement cm

Bra Size (i.e. 32A) N/A (breast absent)

LEFT Not Implanted with Study Device

Circumferential Breast Measurement cm

Bra Size (i.e. 32A) N/A (breast absent)

MAMMOGRAPHY RESULTS

Date of Mammogram:

month year

Not Done

RIGHT

- Birads 0 Needs additional imaging evaluation
 - Birads 1 Negative
 - Birads 2 Benign finding
 - Birads 3 Probable benign finding—short interval follow-up is suggested
 - Birads 4 Suspicious abnormality—biopsy should be considered
 - Birads 5 Highly suggestive of malignancy—appropriate action should be taken
- List abnormality: _____

LEFT

- Birads 0 Needs additional imaging evaluation
 - Birads 1 Negative
 - Birads 2 Benign finding
 - Birads 3 Probable benign finding—short interval follow-up is suggested
 - Birads 4 Suspicious abnormality—biopsy should be considered
 - Birads 5 Highly suggestive of malignancy—appropriate action should be taken
- List abnormality: _____

VISIT REPORT

1. Has the patient become pregnant since the last visit?

- No
- Yes, without complications
- Yes, with complications

Complete Adverse Events Report

2. Has the patient attempted to breastfeed since the last visit?

- No
- Yes, was there adequate milk?
 - No (Enter code 30 on Adverse Events Report)
 - Yes

3. Would the patient have this breast surgery again?

- No, reason: _____
- Yes

4. **Breast Cancer Reconstruction Patients only:**

N/A (augmentation patient)

Has the patient received any adjuvant therapies since the last visit?

- No
- Yes, check all that apply:
 - Radiation Therapy
 - Chemotherapy
 - Other, specify: _____

Treating Oncologist

Name: _____

Phone: (_____) _____

 MENTOR	Core Gel Breast IDE Clinical Trial		1 YEAR VISIT			
	PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO.	PATIENT NO.	PATIENT INITIALS first middle last

CAPSULAR CONTRACTURE ASSESSMENT OF PROSTHESIS	
Right Prosthesis is: <input type="radio"/> <input type="checkbox"/> Not Implanted with Study Device 1 <input type="checkbox"/> Baker Class I (normally soft and natural appearance) 2 <input type="checkbox"/> Baker Class II (a natural appearance despite palpable firmness) 3 <input type="checkbox"/> Baker Class III (firm with visible distortion) 4 <input type="checkbox"/> Baker Class IV (obvious spherical distortion)	Left Prosthesis is: <input type="radio"/> <input type="checkbox"/> Not Implanted with Study Device 1 <input type="checkbox"/> Baker Class I (normally soft and natural appearance) 2 <input type="checkbox"/> Baker Class II (a natural appearance despite palpable firmness) 3 <input type="checkbox"/> Baker Class III (firm with visible distortion) 4 <input type="checkbox"/> Baker Class IV (obvious spherical distortion)
Complete Adverse Events Report for Baker III or IV.	

NIPPLE/BREAST SENSITIVITY	
<p>How would patient describe the feeling in nipple(s) and/or breast(s) now?</p> <p><i>If unacceptably high or low at baseline, and sensation remains the same post-operatively, do not complete an Adverse Events Report.</i></p> <p><i>If acceptable at baseline and has become unacceptable post-operatively, complete an Adverse Events Report.</i></p>	
RIGHT <input type="radio"/> <input type="checkbox"/> Not Implanted with Study Device Nipple Sensation is: 1 <input type="checkbox"/> Unacceptably low 2 <input type="checkbox"/> Acceptable 3 <input type="checkbox"/> Unacceptably high 4 <input type="checkbox"/> N/A, nipple absent Breast sensation is: 1 <input type="checkbox"/> Unacceptably low 2 <input type="checkbox"/> Acceptable 3 <input type="checkbox"/> Unacceptably high 4 <input type="checkbox"/> N/A, breast absent	LEFT <input type="radio"/> <input type="checkbox"/> Not Implanted with Study Device Nipple Sensation is: 1 <input type="checkbox"/> Unacceptably low 2 <input type="checkbox"/> Acceptable 3 <input type="checkbox"/> Unacceptably high 4 <input type="checkbox"/> N/A, nipple absent Breast sensation is: 1 <input type="checkbox"/> Unacceptably low 2 <input type="checkbox"/> Acceptable 3 <input type="checkbox"/> Unacceptably high 4 <input type="checkbox"/> N/A, breast absent
Complete Adverse Events Report for any complications or adverse events noted at this visit.	



MENTOR

**Core Gel Breast
IDE Clinical Trial**

1 YEAR VISIT

PATIENT STUDY ID:

TRIAL NO.
10-009

COUNTRY NO.
0 | 0 | 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last

INVESTIGATOR-COMPLETED RHEUMATIC DISEASE DIAGNOSIS QUESTIONNAIRE

No diagnosis made

Has the patient been diagnosed by a RHEUMATOLOGIST for any of the following **since the last visit?**

If YES, complete Adverse Event Report.

RHEUMATIC DISEASE	NO YES		DATE OF ONSET (if known)	
			month	year
Connective Tissue Disorders: SLE	<input type="checkbox"/>	<input type="checkbox"/>		
Sjogren's Syndrome	<input type="checkbox"/>	<input type="checkbox"/>		
Scleroderma	<input type="checkbox"/>	<input type="checkbox"/>		
Polymyositis	<input type="checkbox"/>	<input type="checkbox"/>		
Other Connective Tissue Disorders	<input type="checkbox"/>	<input type="checkbox"/>		
Inflammatory Arthritis: Rheumatoid Arthritis	<input type="checkbox"/>	<input type="checkbox"/>		
Crystalline Arthritis	<input type="checkbox"/>	<input type="checkbox"/>		
Infectious Arthritis	<input type="checkbox"/>	<input type="checkbox"/>		
Spondyarthropathies	<input type="checkbox"/>	<input type="checkbox"/>		
Other Inflammatory Arthritis	<input type="checkbox"/>	<input type="checkbox"/>		
Non-Inflammatory Rheumatic Conditions: Osteoarthritis	<input type="checkbox"/>	<input type="checkbox"/>		
Fibromyalgia	<input type="checkbox"/>	<input type="checkbox"/>		
Chronic Fatigue	<input type="checkbox"/>	<input type="checkbox"/>		
Other Mechanical or Degenerative	<input type="checkbox"/>	<input type="checkbox"/>		
Other, specify: _____	<input type="checkbox"/>	<input type="checkbox"/>		
Other, specify: _____	<input type="checkbox"/>	<input type="checkbox"/>		

Disease must be diagnosed by a rheumatologist.

Rheumatologist who made diagnosis:

Name: _____

Address: _____

Phone: (_____) _____

**MENTOR****Core Gel Breast
IDE Clinical Trial****1 YEAR VISIT****PATIENT STUDY ID:**TRIAL NO.
10-009COUNTRY NO.
0 0 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last**RHEUMATOLOGY SYMPTOMS (Page 1 of 2)**1 No symptoms; patient not referred to rheumatologistPlease check any **current** symptoms which:

1. The patient experiences on a regular basis
2. The cause is unknown and cannot be attributed to any patient activity.

RHEUMATOLOGY SYMPTOM	STATUS SINCE LAST VISIT		DATE OF ONSET (only if new since last visit)		STATUS AS OF THIS VISIT	
	CONTINUING	NEW	month	year	RESOLVED	CONTINUING
Loss of weight without dieting	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Insomnia	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Weakness	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Exhaustion	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Joint swelling	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Heel pain	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Frequent muscle cramps	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Numbness of feet	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Ringing in ears	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Pain/grittiness in eyes	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Dryness of eyes, nose	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Pain on swallowing or chewing	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Neck pain/stiffness	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Pain on breathing	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Heart murmurs	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Loss of appetite	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Persistent fever	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Night sweats	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Generalized aching	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Loss of height	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Joint pain	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Frequent muscle pain	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>



**Core Gel Breast
IDE Clinical Trial**

1 YEAR VISIT

PATIENT STUDY ID:	TRIAL NO.	COUNTRY NO.			SITE NO.	PATIENT NO.	PATIENT INITIALS		
	10-009	0	0	1			first	middle	last

RHEUMATOLOGY SYMPTOMS (Page 2 of 2)

Please check any **current** symptoms which:

1. The patient experiences on a regular basis
2. The cause is unknown and cannot be attributed to any patient activity.

RHEUMATOLOGY SYMPTOM	STATUS SINCE LAST VISIT		DATE OF ONSET (only if new since last visit)		STATUS AS OF THIS VISIT	
	CONTINUING	NEW	month	year	RESOLVED	CONTINUING
Numbness of hands	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Jaw pain	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Open sores	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Redness of eyes	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Dryness of mouth	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Back pain/stiffness	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Severe chest pains	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Chronic cough	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Difficulty swallowing	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Frequent, severe or persistent diarrhea or constipation	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Severe rashes	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Frequent muscle cramps	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Severe dryness of skin	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Tender lumps/bumps	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Excessive sensitivity to sun	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Color changes on hands or feet with cold exposure	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Joint pain	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Frequent hives	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Numbness of hands	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Tightness of skin	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Unusual hair loss	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Tenderness of scalp	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Severe bruising with little or no injury	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>



**Core Gel Breast
IDE Clinical Trial**

1 YEAR VISIT

PATIENT STUDY ID:	TRIAL NO.	COUNTRY NO.			SITE NO.	PATIENT NO.	PATIENT INITIALS		
	10-009	0	0	1			first	middle	last

RHEUMATOLOGICAL PHYSICAL EXAMINATION (Page 1 of 2)

No symptoms present

Check the box for each physical finding noted to be present and outside normal limits.

PHYSICAL FINDING	STATUS SINCE LAST VISIT		DATE OF ONSET (only if new since last visit)		STATUS AS OF THIS VISIT	
	CONTINUING	NEW	month	year	RESOLVED	CONTINUING
Muscle weakness: Headlift from supine position against gravity	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Inability to raise arms	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Inability to get out of chair	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Joint swellings: Wrists	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Digits	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Elbows	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Knees	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Ankles	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Joint deformities and flexion contracture: Boutonnière ¹	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Ulnar drift ²	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Swan neck ³	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Trigger fingers	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Joint tenderness	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Grip strength and motion-finger to palm crease (normal = 0 cm)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Neck motion—chin to chest or sternum (normal = 0 cm)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Chest expansion (normal = at least 5 cm)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Occiput to wall (normal = 0 cm)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Jaw motion (normally upper-lower incisors 3 cm)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Back motion—measure 10 cm above posterior supine iliac spines— with forward bending motion at least 5 cm from first point (total distance at least 15 cm)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>

¹**Boutonnière** - Contractures of hand musculature characterized by proximal interphalangeal joint flexion and distal interphalangeal joint hyperextension.

³**Swan Neck** - Finger deformity characterized by flexion of distal interphalangeal joints and hyperflexion of the proximal interphalangeal joints due to hypermobility.

²**Ulnar Drift** - Joint change at the metacarpophalangeal joints. Long axis of fingers deviate in an ulnar direction.

**MENTOR****Core Gel Breast
IDE Clinical Trial****1 YEAR VISIT****PATIENT STUDY ID:**TRIAL NO.
10-009COUNTRY NO.
0 0 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last**RHEUMATOLOGICAL PHYSICAL EXAMINATION (Page 2 of 2)**

Check the box for each physical finding noted to be present and outside normal limits.

PHYSICAL FINDING	POSSIBLE INDICATION	STATUS SINCE LAST VISIT		DATE OF ONSET (only if new since last visit)		STATUS AS OF THIS VISIT	
		CONTINUING	NEW	month	year	RESOLVED	CONTINUING
Hair loss	<i>Lupus, Scleroderma</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Skin tightness, especially face and hands	<i>Scleroderma</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Raynaud's phenomenon	<i>Lupus, Scleroderma</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Calcinosis over tibia, ulna, elbows	<i>Scleroderma, Dermatomyositis</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Swollen digits	<i>Juvenile RA, Reiter's syndrome, Psoriatic arthritis, Early scleroderma, Reflex sympathetic dystrophy</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Erythema over knuckles	<i>Dermatomyositis</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Bluish hue color on eyelids	<i>Dermatomyositis</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Non-tender lumps or nodules on elbows	<i>Rheumatoid gout</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Tender lumps-tibia	<i>Erythema nodosum</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Painless eye redness	<i>Conjunctivitis</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Painful eye redness with decreased vision, small pupils	<i>Uveitis</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Tenderness—insertion of deltoids	<i>Polymyalgia rheumatica</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Muscle tenderness	<i>Polymyositis</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Nail pittings	<i>Psoriatic arthritis, Reiter's syndrome</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Tinels or Phalen's signs	<i>Carpal tunnel syndrome</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Skin rashes	<i>Discoid lupus</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>

Does the patient require an examination by a rheumatologist?

 No Yes, record rheumatologist's findings:

 MENTOR	Core Gel Breast IDE Clinical Trial			1 YEAR VISIT			
	PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO.	PATIENT NO.	PATIENT INITIALS first middle last	

ROSENBERG SELF-ESTEEM SCALE (Page 1 of 1)

TO THE PATIENT: Below are some statements with which some people agree and disagree. Please read each statement and check **one** response to each statement.

	Strongly Agree 1	Agree 2	Disagree 3	Strongly Disagree 4
1. I feel that I am a person of worth, at least on an equal basis with others.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. I feel that I have a number of good qualities.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. All in all, I am inclined to feel that I am a failure.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. I am able to do things as well as most people.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. I feel I do not have much of which to be proud.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. I take a positive attitude towards myself.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. On the whole, I am satisfied with myself.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. I wish I could have more respect for myself.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. I certainly feel useless at times.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. At times I think I am no good at all.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

 MENTOR	Core Gel Breast IDE Clinical Trial			1 YEAR VISIT		
	PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO.	PATIENT NO.	PATIENT INITIALS first middle last

TENNESSEE SELF-CONCEPT SCALE (Page 1 of 4)

TO THE PATIENT: The statements below are to help you describe yourself as you see yourself. Please respond to them as if you were describing yourself **to yourself**. Do not omit any item. Read each statement carefully, then select one of the five responses listed below. On the test, put a **circle** around the response you chose. If you want to change an answer after you have circled it, do not erase it but put an X mark through the response and then circle the response you want.

<i>Remember, put a circle around the response number you have chosen for each statement.</i>	Completely False	Mostly False	Partly True and Partly False	Mostly True	Completely True
1. I have a healthy body.	1	2	3	4	5
2. I am an attractive person.	1	2	3	4	5
3. I consider myself a sloppy person.	1	2	3	4	5
4. I am a decent sort of person.	1	2	3	4	5
5. I am an honest person.	1	2	3	4	5
6. I am a bad person.	1	2	3	4	5
7. I am a cheerful person.	1	2	3	4	5
8. I am a calm and easygoing person.	1	2	3	4	5
9. I am a nobody.	1	2	3	4	5
10. I have a family that would always help me in any kind of trouble.	1	2	3	4	5
11. I am a member of a happy family.	1	2	3	4	5
12. My friends have no confidence in me.	1	2	3	4	5
13. I am a friendly person.	1	2	3	4	5
14. I am popular with men.	1	2	3	4	5
15. I am not interested in what other people do.	1	2	3	4	5
16. I do not always tell the truth.	1	2	3	4	5
17. I get angry sometimes.	1	2	3	4	5
18. I like to look nice and neat all the time.	1	2	3	4	5
19. I am full of aches and pains.	1	2	3	4	5
20. I am a sick person.	1	2	3	4	5
21. I am a religious person.	1	2	3	4	5
22. I am a moral failure.	1	2	3	4	5
23. I am a morally weak person.	1	2	3	4	5

 MENTOR	Core Gel Breast IDE Clinical Trial			1 YEAR VISIT				
	PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO.	PATIENT NO.	PATIENT INITIALS first middle last		

TENNESSEE SELF-CONCEPT SCALE (Page 2 of 4)

<i>Remember, put a circle around the response number you have chosen for each statement.</i>	Completely False	Mostly False	Partly True and Partly False	Mostly True	Completely True
24. I have a lot of self-control.	1	2	3	4	5
25. I am a hateful person.	1	2	3	4	5
26. I am losing my mind.	1	2	3	4	5
27. I am an important person to my friends and family.	1	2	3	4	5
28. I am not loved by my family.	1	2	3	4	5
29. I feel that my family doesn't trust me.	1	2	3	4	5
30. I am popular with women.	1	2	3	4	5
31. I am mad at the whole world.	1	2	3	4	5
32. I am hard to be friendly with.	1	2	3	4	5
33. Once in a while I think of things too bad to talk about.	1	2	3	4	5
34. Sometimes when I am not feeling well, I am cross.	1	2	3	4	5
35. I am neither too fat nor too thin.	1	2	3	4	5
36. I like my looks just the way they are.	1	2	3	4	5
37. I would like to change some parts of my body.	1	2	3	4	5
38. I am satisfied with my moral behavior.	1	2	3	4	5
39. I am satisfied with my relationship to God.	1	2	3	4	5
40. I ought to go to church more.	1	2	3	4	5
41. I am satisfied to be just what I am.	1	2	3	4	5
42. I am just as nice as I should be.	1	2	3	4	5
43. I despise myself.	1	2	3	4	5
44. I am satisfied with my family relationships.	1	2	3	4	5
45. I understand my family as well as I should.	1	2	3	4	5
46. I should trust my family more.	1	2	3	4	5
47. I am as sociable as I want to be.	1	2	3	4	5
48. I try to please others, but I don't overdo it.	1	2	3	4	5
49. I am no good at all from a social standpoint.	1	2	3	4	5

 MENTOR	Core Gel Breast IDE Clinical Trial			1 YEAR VISIT				
	PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO.	PATIENT NO.	PATIENT INITIALS first middle last		

TENNESSEE SELF-CONCEPT SCALE (Page 3 of 4)					
<i>Remember, put a circle around the response number you have chosen for each statement.</i>	Completely False	Mostly False	Partly True and Partly False	Mostly True	Completely True
50. I do not like everyone I know.	1	2	3	4	5
51. Once in a while, I laugh at a dirty joke.	1	2	3	4	5
52. I am neither too tall nor too short.	1	2	3	4	5
53. I don't feel as well as I should.	1	2	3	4	5
54. I should have more sex appeal.	1	2	3	4	5
55. I am as religious as I want to be.	1	2	3	4	5
56. I wish I could be more trustworthy.	1	2	3	4	5
57. I shouldn't tell so many lies.	1	2	3	4	5
58. I am as smart as I want to be.	1	2	3	4	5
59. I am not the person I would like to be.	1	2	3	4	5
60. I wish I didn't give up as easily as I do.	1	2	3	4	5
61. I treat my parents as well as I should. <i>(Use past tense if parents are not living.)</i>	1	2	3	4	5
62. I am too sensitive to things my family says.	1	2	3	4	5
63. I should love my family more.	1	2	3	4	5
64. I am satisfied with the way I treat other people.	1	2	3	4	5
65. I should be more polite to others.	1	2	3	4	5
66. I ought to get along better with other people.	1	2	3	4	5
67. I gossip a little at times.	1	2	3	4	5
68. At times I feel like swearing.	1	2	3	4	5
69. I take good care of myself physically.	1	2	3	4	5
70. I try to be careful about my appearance.	1	2	3	4	5
71. I often act like I am "all thumbs".	1	2	3	4	5
72. I am true to my religion in my everyday life.	1	2	3	4	5
73. I try to change when I know I'm doing things that are wrong.	1	2	3	4	5
74. I sometimes do very bad things.	1	2	3	4	5
75. I can always take care of myself in any situation.	1	2	3	4	5

 MENTOR	Core Gel Breast IDE Clinical Trial			1 YEAR VISIT				
	PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO.	PATIENT NO.	PATIENT INITIALS first middle last		

TENNESSEE SELF-CONCEPT SCALE (Page 4 of 4)					
<i>Remember, put a circle around the response number you have chosen for each statement.</i>	Completely False	Mostly False	Partly True and Partly False	Mostly True	Completely True
76. I take the blame for things without getting mad.	1	2	3	4	5
77. I do things without thinking about them first.	1	2	3	4	5
78. I try to play fair with my friends and family.	1	2	3	4	5
79. I take a real interest in my family.	1	2	3	4	5
80. I give in to my parents. <i>(Use past tense if parents are not living.)</i>	1	2	3	4	5
81. I try to understand the other fellow's point of view.	1	2	3	4	5
82. I get along well with other people.	1	2	3	4	5
83. I do not forgive others easily.	1	2	3	4	5
84. I would rather win than lose in a game.	1	2	3	4	5
85. I feel good most of the time.	1	2	3	4	5
86. I do poorly in sports and games.	1	2	3	4	5
87. I am a poor sleeper.	1	2	3	4	5
88. I do what is right most of the time.	1	2	3	4	5
89. I sometimes use unfair means to get ahead.	1	2	3	4	5
90. I have trouble doing the things that are right.	1	2	3	4	5
91. I solve my problems quite easily.	1	2	3	4	5
92. I change my mind a lot.	1	2	3	4	5
93. I try to run away from my problems.	1	2	3	4	5
94. I do my share of work at home.	1	2	3	4	5
95. I quarrel with my family.	1	2	3	4	5
96. I do not act like my family thinks I should.	1	2	3	4	5
97. I see good points in all the people I meet.	1	2	3	4	5
98. I do not feel at ease with other people.	1	2	3	4	5
99. I find it hard to talk with strangers.	1	2	3	4	5
100. Once in a while I put off until tomorrow what I ought to do today.	1	2	3	4	5

 MENTOR	Core Gel Breast IDE Clinical Trial			1 YEAR VISIT				
	PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO.	PATIENT NO.	PATIENT INITIALS first middle last		

SF-36 (Page 1 of 3)

TO THE PATIENT: This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Answer each question by circling **one** number. If you are unsure about how to answer a question, please give the best answer you can.

1. In general, would you say your health is: (Circle one number)	Excellent	Very Good	Good	Fair	Poor
	1	2	3	4	5

2. Compared to one year ago, how would you rate your health in general now? (Circle one number)	Much Better Now	Somewhat Better Now	About the Same	Somewhat Worse Now	Much Worse Now
	1	2	3	4	5

3. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much? (Circle one number for each question.)	Yes, Limited a Lot	Yes, Limited a Little	No, Not Limited at All
Vigorous activities , such as running, lifting heavy objects, participating in strenuous sports.	1	2	3
Moderate activities , such as moving a table, pushing a vacuum cleaner, bowling or playing golf	1	2	3
Lifting or carrying groceries	1	2	3
Climbing several flights of stairs	1	2	3
Climbing one flight of stairs	1	2	3
Bending, kneeling, or stooping	1	2	3
Walking more than a mile	1	2	3
Walking several blocks	1	2	3
Walking one block	1	2	3
Bathing or dressing yourself	1	2	3

 MENTOR	Core Gel Breast IDE Clinical Trial			1 YEAR VISIT				
	PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO.	PATIENT NO.	PATIENT INITIALS first middle last		

SF-36 (Page 2 of 3)

4. During the past 4 weeks , have you had any of the following problems with your work or other regular daily activities as a result of your physical health? (Circle one number for each question.)	YES	NO
Cut down on the amount of time you spent on work or other activities	1	2
Accomplished less than you would like	1	2
Were limited in the kind of work or other activities	1	2
Had difficulty performing the work or other activities (for example, it took extra effort)	1	2

5. During the past 4 weeks , have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)? (Circle one number for each question.)	YES	NO
Cut down on the amount of time you spent on work or other activities	1	2
Accomplished less than you would like	1	2
Didn't do work or other activities as carefully as usual	1	2

6. During the past 4 weeks , to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups? (Circle one number)	Not at All	Slightly	Moderately	Quite a Bit	Extremely
	1	2	3	4	5

7. How much bodily pain have you had during the past 4 weeks? (Circle one number)	None	Very Mild	Mild	Moderate	Severe	Very Severe
	1	2	3	4	5	6

8. During the past 4 weeks , how much did pain interfere with your normal work (including both work outside the home and housework)? (Circle one number)	Not at All	A Little Bit	Moderately	Quite a Bit	Extremely
	1	2	3	4	5

 MENTOR	Core Gel Breast IDE Clinical Trial			1 YEAR VISIT				
	PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO.	PATIENT NO.	PATIENT INITIALS first middle last		

SF-36 (Page 3 of 3)

9. These questions are about how you feel and how things have been with you **during the past 4 weeks**. For each question, please indicate the one answer that comes closest to the way you have been feeling. (Circle **one** number for each question.)

How much of the time during the past 4 weeks ...	All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	None of the Time
Did you feel full of pep?	1	2	3	4	5	6
Have you been a very nervous person?	1	2	3	4	5	6
Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
Have you felt calm and peaceful?	1	2	3	4	5	6
Did you have a lot of energy?	1	2	3	4	5	6
Have you felt downhearted and blue?	1	2	3	4	5	6
Did you feel worn out?	1	2	3	4	5	6
Have you been a happy person?	1	2	3	4	5	6
Did you feel tired?	1	2	3	4	5	6

10. During the past 4 weeks , how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)? (Circle one number.)	All of the Time	Most of the Time	Some of the Time	A Little of the Time	None of the Time
	1	2	3	4	5

11. How TRUE or FALSE is each of the following statements for you? (Circle one number for each question.)	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
I seem to get sick a little easier than other people	1	2	3	4	5
I am as healthy as anybody I know	1	2	3	4	5
I expect my health to get worse	1	2	3	4	5
My health is excellent	1	2	3	4	5



MENTOR

**Core Gel Breast
IDE Clinical Trial**

1 YEAR VISIT

PATIENT STUDY ID:

TRIAL NO.
10-009

COUNTRY NO.
0 | 0 | 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last

BODY ESTEEM SCALE (Page 1 of 1)

TO THE PATIENT: On this page are listed a number of body parts and functions. Please read each item and indicate how you feel about this part or function of ***your own body***, using the following scale:

- 1 = Have strong negative feelings
- 2 = Have moderate negative feelings
- 3 = Have no feeling one way or the other
- 4 = Have moderate positive feelings
- 5 = Have strong positive feelings

- | | |
|--|--|
| <input type="checkbox"/> 1. Body Scent | <input type="checkbox"/> 19. Arms |
| <input type="checkbox"/> 2. Appetite | <input type="checkbox"/> 20. Chest |
| <input type="checkbox"/> 3. Nose | <input type="checkbox"/> 21. Appearance of Eyes |
| <input type="checkbox"/> 4. Physical Stamina | <input type="checkbox"/> 22. Cheeks/Cheekbones |
| <input type="checkbox"/> 5. Reflexes | <input type="checkbox"/> 23. Hips |
| <input type="checkbox"/> 6. Lips | <input type="checkbox"/> 24. Legs |
| <input type="checkbox"/> 7. Muscular Strength | <input type="checkbox"/> 25. Physique |
| <input type="checkbox"/> 8. Waist | <input type="checkbox"/> 26. Sex Drive |
| <input type="checkbox"/> 9. Energy Level | <input type="checkbox"/> 27. Feet |
| <input type="checkbox"/> 10. Thighs | <input type="checkbox"/> 28. Sex Organs |
| <input type="checkbox"/> 11. Ears | <input type="checkbox"/> 29. Appearance of Stomach |
| <input type="checkbox"/> 12. Biceps | <input type="checkbox"/> 30. Health |
| <input type="checkbox"/> 13. Chin | <input type="checkbox"/> 31. Sex Activities |
| <input type="checkbox"/> 14. Body Build | <input type="checkbox"/> 32. Body Hair |
| <input type="checkbox"/> 15. Physical Coordination | <input type="checkbox"/> 33. Physical Condition |
| <input type="checkbox"/> 16. Buttocks | <input type="checkbox"/> 34. Face |
| <input type="checkbox"/> 17. Agility | <input type="checkbox"/> 35. Weight |
| <input type="checkbox"/> 18. Width of Shoulders | |



MENTOR

**Core Gel Breast
IDE Clinical Trial**

1 YEAR VISIT

PATIENT STUDY ID:

TRIAL NO.
10-009

COUNTRY NO.
0 | 0 | 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last

MANITOBA CANCER TREATMENT & RESEARCH FOUNDATION FUNCTIONAL LIVING INDEX: CANCER (FLIC)

Page 1 of 3

N/A (not a cancer patient)

TO THE PATIENT: Please indicate your rating by drawing a vertical line (|).

1. Most people experience some feelings of depression at times. Rate how often you feel these feelings.

1	2	3	4	5	6	7
Never						Continually

2. How well are you coping with your everyday stress?

1	2	3	4	5	6	7
Not Well						Very Well

3. How much time do you spend thinking about your illness?

1	2	3	4	5	6	7
Constantly						Never

4. Rate your ability to maintain your usual recreation or leisure activities.

1	2	3	4	5	6	7
Able						Unable

5. Has nausea affected your daily functioning?

1	2	3	4	5	6	7
Not At All						A Great Deal

6. How well do you feel today?

1	2	3	4	5	6	7
Extremely Poor						Extremely Well

7. Do you feel well enough to make a meal or do minor household repairs today?

1	2	3	4	5	6	7
Very Able						Not Able



MENTOR

**Core Gel Breast
IDE Clinical Trial**

1 YEAR VISIT

PATIENT STUDY ID:

TRIAL NO.
10-009

COUNTRY NO.
0 0 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last

MANITOBA CANCER TREATMENT & RESEARCH FOUNDATION FUNCTIONAL LIVING INDEX: CANCER (FLIC)
Page 2 of 3 N/A (not a cancer patient)

8. Rate the degree to which your cancer has imposed a hardship on those closest to you in the past 2 months.
| | | | | | |
1 2 3 4 5 6 7
No Hardship Tremendous Hardship

9. Rate how often you feel discouraged about your life.
| | | | | | |
1 2 3 4 5 6 7
Always Never

10. Rate your satisfaction with your work and your jobs around the house in the past month.
| | | | | | |
1 2 3 4 5 6 7
Very Dissatisfied Very Satisfied

11. How uncomfortable do you feel today?
| | | | | | |
1 2 3 4 5 6 7
Not at All Very Uncomfortable

12. Rate in your opinion, how disruptive your cancer has been to those closest to you in the past 2 weeks.
| | | | | | |
1 2 3 4 5 6 7
Totally Disruptive No Disruption

13. How much is pain or discomfort interfering with your daily activities?
| | | | | | |
1 2 3 4 5 6 7
Not at All A Great Deal

14. Rate the degree to which your cancer has imposed a hardship on you (personally) in the past 2 weeks.
| | | | | | |
1 2 3 4 5 6 7
Tremendous Hardship No Hardship



MENTOR

**Core Gel Breast
IDE Clinical Trial**

1 YEAR VISIT

PATIENT STUDY ID:

TRIAL NO.
10-009

COUNTRY NO.
0 0 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last

MANITOBA CANCER TREATMENT & RESEARCH FOUNDATION FUNCTIONAL LIVING INDEX: CANCER (FLIC)

Page 3 of 3

N/A (not a cancer patient)

15. How much of your usual household tasks are you able to complete?

1	2	3	4	5	6	7
All						None

16. Rate how willing you were to see and spend time with those closest to you, in the past 2 weeks.

1	2	3	4	5	6	7
Unwilling						Very Willing

17. How much nausea have you had in the past 2 weeks?

1	2	3	4	5	6	7
None						A Great Deal

18. Rate the degree to which you are frightened of the future.

1	2	3	4	5	6	7
Constantly Terrified						Not Afraid

19. Rate how willing you were to see and spend time with friends, in the past 2 weeks.

1	2	3	4	5	6	7
Unwilling						Very Willing

20. How much of your pain or discomfort over the past 2 weeks was related to your cancer?

1	2	3	4	5	6	7
None						All

21. Rate your confidence in your prescribed course of treatment.

1	2	3	4	5	6	7
No Confidence						Very Confident

22. How well do you appear today?

1	2	3	4	5	6	7
Extremely Poor						Extremely Well



**Core Gel Breast
IDE Clinical Trial**

ADVERSE EVENTS

1 YEAR VISIT

PATIENT STUDY ID: TRIAL NO. **10-009** COUNTRY NO. **0 0 1** SITE NO. PATIENT NO. PATIENT INITIALS first middle last No Adverse Events

Enter one adverse event per line. If the event was experienced at more than one body site, enter each body site on a separate line.

AE CODE* (See Below)	CAUSALITY 1 = Procedure related 2 = Device related 3 = Unknown 4 = Other	EVENT SIDE 0 = N/A 1 = Right 2 = Left	ASSOCIATED BREAST PAIN 0 = None 1 = Mild 2 = Moderate 3 = Severe	ONSET DATE month day year	SEVERITY 1 = Mild 2 = Moderate 3 = Severe	TREATMENT REQUIRED (check all that apply) 1 = No Treatment 2 = Medication (specify) 3 = Secondary Procedure (enter Procedure Type Code and date below, and complete Secondary Procedures Report for all procedures performed for this date)** 4 = Hospitalization (specify # of days and admission date) 5 = Other (specify)	OUTCOME 1 = Resolved 2 = Ongoing 3 = Death 4 = Unknown	RESOLUTION DATE month day year
<input type="checkbox"/> 1	<input type="checkbox"/> 3	<input type="checkbox"/> 0	<input type="checkbox"/> 0 <input type="checkbox"/> 3	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 4 days, Date: ___/___/___	<input type="checkbox"/> 1 <input type="checkbox"/> 4	
<input type="checkbox"/> 2	<input type="checkbox"/> 4	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 5 Procedure Date: ___/___/___	<input type="checkbox"/> 2	
<input type="checkbox"/> 1	<input type="checkbox"/> 3	<input type="checkbox"/> 0	<input type="checkbox"/> 0 <input type="checkbox"/> 3	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 4 days, Date: ___/___/___	<input type="checkbox"/> 1 <input type="checkbox"/> 4	
<input type="checkbox"/> 2	<input type="checkbox"/> 4	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 5 Procedure Date: ___/___/___	<input type="checkbox"/> 2	
<input type="checkbox"/> 1	<input type="checkbox"/> 3	<input type="checkbox"/> 0	<input type="checkbox"/> 0 <input type="checkbox"/> 3	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 4 days, Date: ___/___/___	<input type="checkbox"/> 1 <input type="checkbox"/> 4	
<input type="checkbox"/> 2	<input type="checkbox"/> 4	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 5 Procedure Date: ___/___/___	<input type="checkbox"/> 2	
<input type="checkbox"/> 1	<input type="checkbox"/> 3	<input type="checkbox"/> 0	<input type="checkbox"/> 0 <input type="checkbox"/> 3	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 4 days, Date: ___/___/___	<input type="checkbox"/> 1 <input type="checkbox"/> 4	
<input type="checkbox"/> 2	<input type="checkbox"/> 4	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 5 Procedure Date: ___/___/___	<input type="checkbox"/> 2	
<input type="checkbox"/> 1	<input type="checkbox"/> 3	<input type="checkbox"/> 0	<input type="checkbox"/> 0 <input type="checkbox"/> 3	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 4 days, Date: ___/___/___	<input type="checkbox"/> 1 <input type="checkbox"/> 4	
<input type="checkbox"/> 2	<input type="checkbox"/> 4	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 5 Procedure Date: ___/___/___	<input type="checkbox"/> 2	
<input type="checkbox"/> 1	<input type="checkbox"/> 3	<input type="checkbox"/> 0	<input type="checkbox"/> 0 <input type="checkbox"/> 3	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 4 days, Date: ___/___/___	<input type="checkbox"/> 1 <input type="checkbox"/> 4	
<input type="checkbox"/> 2	<input type="checkbox"/> 4	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 5 Procedure Date: ___/___/___	<input type="checkbox"/> 2	

****Complete Secondary Procedures Report. If new study device is implanted, complete Re-implantation Report.**

Investigator's Signature

month day year

***ADVERSE EVENT CODES**

15 = Lymphadenopathy
16 = Necrosis
17 = New Diagnosis of Breast Cancer
18 = New Diagnosis of Rheumatic Disease, specify:
19 = Nipple—Unacceptably Low Sensitivity
20 = Nipple—Unacceptably High Sensitivity
21 = Position Change
22 = Ptosis
23 = Rupture
24 = Seroma
25 = Size Change—Patient Request
26 = Size Change—Physician Assessment only
27 = Wrinkling

+SECONDARY PROCEDURE TYPE CODES

81 = Biopsy
82 = Capsulectomy
83 = Explanation with Replacement**
84 = Explanation without Replacement
85 = Incision and Drainage
86 = Mastopexy
87 = Open Capsulotomy
88 = Position Change
89 = Scar Revision
90 = Skin Adjustment
91 = Other, specify: _____
92 = Other, specify: _____

28 = Lactation Difficulties, specify: _____
29 = Other, specify: _____
30 = Other, specify: _____



MENTOR

**Core Gel Breast
IDE Clinical Trial**

2 YEAR VISIT

PATIENT STUDY ID:

TRIAL NO.
10-009

COUNTRY NO.
0 0 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last

Visit Date:

month day year

Missed Visit

BREAST MEASUREMENTS

RIGHT Not Implanted with Study Device

Circumferential Breast Measurement cm

Bra Size (i.e. 32A) N/A (breast absent)

LEFT Not Implanted with Study Device

Circumferential Breast Measurement cm

Bra Size (i.e. 32A) N/A (breast absent)

MAMMOGRAPHY RESULTS

Date of Mammogram:

month year

Not Done

RIGHT

- 1 Birads 0 *Needs additional imaging evaluation*
 - 2 Birads 1 *Negative*
 - 3 Birads 2 *Benign finding*
 - 4 Birads 3 *Probable benign finding—short interval follow-up is suggested*
 - 5 Birads 4 *Suspicious abnormality—biopsy should be considered*
 - 6 Birads 5 *Highly suggestive of malignancy—appropriate action should be taken*
- List abnormality: _____

LEFT

- 1 Birads 0 *Needs additional imaging evaluation*
 - 2 Birads 1 *Negative*
 - 3 Birads 2 *Benign finding*
 - 4 Birads 3 *Probable benign finding—short interval follow-up is suggested*
 - 5 Birads 4 *Suspicious abnormality—biopsy should be considered*
 - 6 Birads 5 *Highly suggestive of malignancy—appropriate action should be taken*
- List abnormality: _____

VISIT REPORT

1. Has the patient become pregnant since the last visit?

- 1 No
- 2 Yes, without complications
- 3 Yes, with complications

Complete Adverse Events Report

2. Has the patient attempted to breastfeed since the last visit?

- 1 No
- 2 Yes, was there adequate milk?
 - 1 No **(Enter code 30 on Adverse Events Report)**
 - 2 Yes

3. Would the patient have this breast surgery again?

- 1 No, reason: _____
- 2 Yes

4. **Breast Cancer Reconstruction Patients only:**

N/A (augmentation patient)

Has the patient received any adjuvant therapies since the last visit?

- 1 No
- 2 Yes, check all that apply:
 - Radiation Therapy
 - Chemotherapy
 - Other, specify: _____

Treating Oncologist

Name: _____

Phone: (_____) _____

 MENTOR	Core Gel Breast IDE Clinical Trial		2 YEAR VISIT			
	PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO.	PATIENT NO.	PATIENT INITIALS first middle last

CAPSULAR CONTRACTURE ASSESSMENT OF PROSTHESIS	
Right Prosthesis is: <input type="radio"/> <input type="checkbox"/> Not Implanted with Study Device 1 <input type="checkbox"/> Baker Class I (normally soft and natural appearance) 2 <input type="checkbox"/> Baker Class II (a natural appearance despite palpable firmness) 3 <input type="checkbox"/> Baker Class III (firm with visible distortion) 4 <input type="checkbox"/> Baker Class IV (obvious spherical distortion)	Left Prosthesis is: <input type="radio"/> <input type="checkbox"/> Not Implanted with Study Device 1 <input type="checkbox"/> Baker Class I (normally soft and natural appearance) 2 <input type="checkbox"/> Baker Class II (a natural appearance despite palpable firmness) 3 <input type="checkbox"/> Baker Class III (firm with visible distortion) 4 <input type="checkbox"/> Baker Class IV (obvious spherical distortion)
Complete Adverse Events Report for Baker III or IV.	

NIPPLE/BREAST SENSITIVITY	
<p>How would patient describe the feeling in nipple(s) and/or breast(s) now?</p> <p><i>If unacceptably high or low at baseline, and sensation remains the same post-operatively, do not complete an Adverse Events Report.</i></p> <p><i>If acceptable at baseline and has become unacceptable post-operatively, complete an Adverse Events Report.</i></p>	
RIGHT <input type="radio"/> <input type="checkbox"/> Not Implanted with Study Device Nipple Sensation is: 1 <input type="checkbox"/> Unacceptably low 2 <input type="checkbox"/> Acceptable 3 <input type="checkbox"/> Unacceptably high 4 <input type="checkbox"/> N/A, nipple absent Breast sensation is: 1 <input type="checkbox"/> Unacceptably low 2 <input type="checkbox"/> Acceptable 3 <input type="checkbox"/> Unacceptably high 4 <input type="checkbox"/> N/A, breast absent	LEFT <input type="radio"/> <input type="checkbox"/> Not Implanted with Study Device Nipple Sensation is: 1 <input type="checkbox"/> Unacceptably low 2 <input type="checkbox"/> Acceptable 3 <input type="checkbox"/> Unacceptably high 4 <input type="checkbox"/> N/A, nipple absent Breast sensation is: 1 <input type="checkbox"/> Unacceptably low 2 <input type="checkbox"/> Acceptable 3 <input type="checkbox"/> Unacceptably high 4 <input type="checkbox"/> N/A, breast absent
Complete Adverse Events Report for any complications or adverse events noted at this visit.	



MENTOR

**Core Gel Breast
IDE Clinical Trial**

2 YEAR VISIT

PATIENT STUDY ID:

TRIAL NO.
10-009

COUNTRY NO.
0 | 0 | 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last

INVESTIGATOR-COMPLETED RHEUMATIC DISEASE DIAGNOSIS QUESTIONNAIRE

No diagnosis made

Has the patient been diagnosed by a RHEUMATOLOGIST for any of the following **since the last visit?**

If YES, complete Adverse Event Report.

RHEUMATIC DISEASE	NO YES		DATE OF ONSET (if known)	
			month	year
Connective Tissue Disorders: SLE	<input type="checkbox"/>	<input type="checkbox"/>		
Sjogren's Syndrome	<input type="checkbox"/>	<input type="checkbox"/>		
Scleroderma	<input type="checkbox"/>	<input type="checkbox"/>		
Polymyositis	<input type="checkbox"/>	<input type="checkbox"/>		
Other Connective Tissue Disorders	<input type="checkbox"/>	<input type="checkbox"/>		
Inflammatory Arthritis: Rheumatoid Arthritis	<input type="checkbox"/>	<input type="checkbox"/>		
Crystalline Arthritis	<input type="checkbox"/>	<input type="checkbox"/>		
Infectious Arthritis	<input type="checkbox"/>	<input type="checkbox"/>		
Spondyarthropathies	<input type="checkbox"/>	<input type="checkbox"/>		
Other Inflammatory Arthritis	<input type="checkbox"/>	<input type="checkbox"/>		
Non-Inflammatory Rheumatic Conditions: Osteoarthritis	<input type="checkbox"/>	<input type="checkbox"/>		
Fibromyalgia	<input type="checkbox"/>	<input type="checkbox"/>		
Chronic Fatigue	<input type="checkbox"/>	<input type="checkbox"/>		
Other Mechanical or Degenerative	<input type="checkbox"/>	<input type="checkbox"/>		
Other, specify: _____	<input type="checkbox"/>	<input type="checkbox"/>		
Other, specify: _____	<input type="checkbox"/>	<input type="checkbox"/>		

Disease must be diagnosed by a rheumatologist.

Rheumatologist who made diagnosis:

Name: _____

Address: _____

Phone: (_____) _____

**MENTOR****Core Gel Breast
IDE Clinical Trial****2 YEAR VISIT****PATIENT STUDY ID:**TRIAL NO.
10-009COUNTRY NO.
0 0 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last**RHEUMATOLOGY SYMPTOMS (Page 1 of 2)**1 No symptoms; patient not referred to rheumatologistPlease check any **current** symptoms which:

1. The patient experiences on a regular basis
2. The cause is unknown and cannot be attributed to any patient activity.

RHEUMATOLOGY SYMPTOM	STATUS SINCE LAST VISIT		DATE OF ONSET (only if new since last visit)		STATUS AS OF THIS VISIT	
	CONTINUING	NEW	month	year	RESOLVED	CONTINUING
Loss of weight without dieting	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Insomnia	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Weakness	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Exhaustion	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Joint swelling	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Heel pain	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Frequent muscle cramps	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Numbness of feet	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Ringing in ears	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Pain/grittiness in eyes	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Dryness of eyes, nose	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Pain on swallowing or chewing	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Neck pain/stiffness	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Pain on breathing	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Heart murmurs	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Loss of appetite	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Persistent fever	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Night sweats	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Generalized aching	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Loss of height	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Joint pain	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Frequent muscle pain	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>



**Core Gel Breast
IDE Clinical Trial**

2 YEAR VISIT

PATIENT STUDY ID:	TRIAL NO.	COUNTRY NO.			SITE NO.	PATIENT NO.	PATIENT INITIALS		
	10-009	0	0	1			first	middle	last

RHEUMATOLOGY SYMPTOMS (Page 2 of 2)

Please check any **current** symptoms which:

1. The patient experiences on a regular basis
2. The cause is unknown and cannot be attributed to any patient activity.

RHEUMATOLOGY SYMPTOM	STATUS SINCE LAST VISIT		DATE OF ONSET (only if new since last visit)		STATUS AS OF THIS VISIT	
	CONTINUING	NEW	month	year	RESOLVED	CONTINUING
Numbness of hands	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Jaw pain	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Open sores	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Redness of eyes	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Dryness of mouth	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Back pain/stiffness	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Severe chest pains	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Chronic cough	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Difficulty swallowing	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Frequent, severe or persistent diarrhea or constipation	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Severe rashes	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Frequent muscle cramps	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Severe dryness of skin	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Tender lumps/bumps	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Excessive sensitivity to sun	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Color changes on hands or feet with cold exposure	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Joint pain	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Frequent hives	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Numbness of hands	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Tightness of skin	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Unusual hair loss	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Tenderness of scalp	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Severe bruising with little or no injury	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>



**Core Gel Breast
IDE Clinical Trial**

2 YEAR VISIT

PATIENT STUDY ID:	TRIAL NO.	COUNTRY NO.			SITE NO.	PATIENT NO.	PATIENT INITIALS		
	10-009	0	0	1			first	middle	last

RHEUMATOLOGICAL PHYSICAL EXAMINATION (Page 1 of 2)

No symptoms present

Check the box for each physical finding noted to be present and outside normal limits.

PHYSICAL FINDING	STATUS SINCE LAST VISIT		DATE OF ONSET (only if new since last visit)		STATUS AS OF THIS VISIT	
	CONTINUING	NEW	month	year	RESOLVED	CONTINUING
Muscle weakness: Headlift from supine position against gravity	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Inability to raise arms	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Inability to get out of chair	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Joint swellings: Wrists	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Digits	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Elbows	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Knees	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Ankles	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Joint deformities and flexion contracture: Boutonnière ¹	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Ulnar drift ²	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Swan neck ³	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Trigger fingers	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Joint tenderness	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Grip strength and motion-finger to palm crease (normal = 0 cm)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Neck motion—chin to chest or sternum (normal = 0 cm)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Chest expansion (normal = at least 5 cm)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Occiput to wall (normal = 0 cm)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Jaw motion (normally upper-lower incisors 3 cm)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Back motion—measure 10 cm above posterior supine iliac spines— with forward bending motion at least 5 cm from first point (total distance at least 15 cm)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>

¹**Boutonnière** - Contractures of hand musculature characterized by proximal interphalangeal joint flexion and distal interphalangeal joint hyperextension.

³**Swan Neck** - Finger deformity characterized by flexion of distal interphalangeal joints and hyperflexion of the proximal interphalangeal joints due to hypermobility.

²**Ulnar Drift** - Joint change at the metacarpophalangeal joints. Long axis of fingers deviate in an ulnar direction.

**MENTOR****Core Gel Breast
IDE Clinical Trial****2 YEAR VISIT****PATIENT STUDY ID:**TRIAL NO.
10-009COUNTRY NO.
0 0 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last**RHEUMATOLOGICAL PHYSICAL EXAMINATION (Page 2 of 2)**

Check the box for each physical finding noted to be present and outside normal limits.

PHYSICAL FINDING	POSSIBLE INDICATION	STATUS SINCE LAST VISIT		DATE OF ONSET (only if new since last visit)		STATUS AS OF THIS VISIT	
		CONTINUING	NEW	month	year	RESOLVED	CONTINUING
Hair loss	<i>Lupus, Scleroderma</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Skin tightness, especially face and hands	<i>Scleroderma</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Raynaud's phenomenon	<i>Lupus, Scleroderma</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Calcinosis over tibia, ulna, elbows	<i>Scleroderma, Dermatomyositis</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Swollen digits	<i>Juvenile RA, Reiter's syndrome, Psoriatic arthritis, Early scleroderma, Reflex sympathetic dystrophy</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Erythema over knuckles	<i>Dermatomyositis</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Bluish hue color on eyelids	<i>Dermatomyositis</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Non-tender lumps or nodules on elbows	<i>Rheumatoid gout</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Tender lumps-tibia	<i>Erythema nodosum</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Painless eye redness	<i>Conjunctivitis</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Painful eye redness with decreased vision, small pupils	<i>Uveitis</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Tenderness—insertion of deltoids	<i>Polymyalgia rheumatica</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Muscle tenderness	<i>Polymyositis</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Nail pittings	<i>Psoriatic arthritis, Reiter's syndrome</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Tinels or Phalen's signs	<i>Carpal tunnel syndrome</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Skin rashes	<i>Discoid lupus</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>

Does the patient require an examination by a rheumatologist?

 No Yes, record rheumatologist's findings:

**MENTOR****Core Gel Breast
IDE Clinical Trial****2 YEAR VISIT****PATIENT STUDY ID:**TRIAL NO.
10-009COUNTRY NO.
0 | 0 | 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last**ROSENBERG SELF-ESTEEM SCALE (Page 1 of 1)****TO THE PATIENT:** Below are some statements with which some people agree and disagree. Please read each statement and check **one** response to each statement.

	Strongly Agree 1	Agree 2	Disagree 3	Strongly Disagree 4
1. I feel that I am a person of worth, at least on an equal basis with others.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. I feel that I have a number of good qualities.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. All in all, I am inclined to feel that I am a failure.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. I am able to do things as well as most people.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. I feel I do not have much of which to be proud.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. I take a positive attitude towards myself.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. On the whole, I am satisfied with myself.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. I wish I could have more respect for myself.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. I certainly feel useless at times.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. At times I think I am no good at all.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

 MENTOR	Core Gel Breast IDE Clinical Trial			2 YEAR VISIT			
	PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO.	PATIENT NO.	PATIENT INITIALS first middle last	

TENNESSEE SELF-CONCEPT SCALE (Page 1 of 4)

TO THE PATIENT: The statements below are to help you describe yourself as you see yourself. Please respond to them as if you were describing yourself **to yourself**. Do not omit any item. Read each statement carefully, then select one of the five responses listed below. On the test, put a **circle** around the response you chose. If you want to change an answer after you have circled it, do not erase it but put an X mark through the response and then circle the response you want.

<i>Remember, put a circle around the response number you have chosen for each statement.</i>	Completely False	Mostly False	Partly True and Partly False	Mostly True	Completely True
1. I have a healthy body.	1	2	3	4	5
2. I am an attractive person.	1	2	3	4	5
3. I consider myself a sloppy person.	1	2	3	4	5
4. I am a decent sort of person.	1	2	3	4	5
5. I am an honest person.	1	2	3	4	5
6. I am a bad person.	1	2	3	4	5
7. I am a cheerful person.	1	2	3	4	5
8. I am a calm and easygoing person.	1	2	3	4	5
9. I am a nobody.	1	2	3	4	5
10. I have a family that would always help me in any kind of trouble.	1	2	3	4	5
11. I am a member of a happy family.	1	2	3	4	5
12. My friends have no confidence in me.	1	2	3	4	5
13. I am a friendly person.	1	2	3	4	5
14. I am popular with men.	1	2	3	4	5
15. I am not interested in what other people do.	1	2	3	4	5
16. I do not always tell the truth.	1	2	3	4	5
17. I get angry sometimes.	1	2	3	4	5
18. I like to look nice and neat all the time.	1	2	3	4	5
19. I am full of aches and pains.	1	2	3	4	5
20. I am a sick person.	1	2	3	4	5
21. I am a religious person.	1	2	3	4	5
22. I am a moral failure.	1	2	3	4	5
23. I am a morally weak person.	1	2	3	4	5

 MENTOR	Core Gel Breast IDE Clinical Trial			2 YEAR VISIT				
	PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO.	PATIENT NO.	PATIENT INITIALS first middle last		

TENNESSEE SELF-CONCEPT SCALE (Page 2 of 4)

<i>Remember, put a circle around the response number you have chosen for each statement.</i>	Completely False	Mostly False	Partly True and Partly False	Mostly True	Completely True
24. I have a lot of self-control.	1	2	3	4	5
25. I am a hateful person.	1	2	3	4	5
26. I am losing my mind.	1	2	3	4	5
27. I am an important person to my friends and family.	1	2	3	4	5
28. I am not loved by my family.	1	2	3	4	5
29. I feel that my family doesn't trust me.	1	2	3	4	5
30. I am popular with women.	1	2	3	4	5
31. I am mad at the whole world.	1	2	3	4	5
32. I am hard to be friendly with.	1	2	3	4	5
33. Once in a while I think of things too bad to talk about.	1	2	3	4	5
34. Sometimes when I am not feeling well, I am cross.	1	2	3	4	5
35. I am neither too fat nor too thin.	1	2	3	4	5
36. I like my looks just the way they are.	1	2	3	4	5
37. I would like to change some parts of my body.	1	2	3	4	5
38. I am satisfied with my moral behavior.	1	2	3	4	5
39. I am satisfied with my relationship to God.	1	2	3	4	5
40. I ought to go to church more.	1	2	3	4	5
41. I am satisfied to be just what I am.	1	2	3	4	5
42. I am just as nice as I should be.	1	2	3	4	5
43. I despise myself.	1	2	3	4	5
44. I am satisfied with my family relationships.	1	2	3	4	5
45. I understand my family as well as I should.	1	2	3	4	5
46. I should trust my family more.	1	2	3	4	5
47. I am as sociable as I want to be.	1	2	3	4	5
48. I try to please others, but I don't overdo it.	1	2	3	4	5
49. I am no good at all from a social standpoint.	1	2	3	4	5

 MENTOR	Core Gel Breast IDE Clinical Trial			2 YEAR VISIT				
	PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO.	PATIENT NO.	PATIENT INITIALS first middle last		

TENNESSEE SELF-CONCEPT SCALE (Page 3 of 4)

<i>Remember, put a circle around the response number you have chosen for each statement.</i>	Completely False	Mostly False	Partly True and Partly False	Mostly True	Completely True
50. I do not like everyone I know.	1	2	3	4	5
51. Once in a while, I laugh at a dirty joke.	1	2	3	4	5
52. I am neither too tall nor too short.	1	2	3	4	5
53. I don't feel as well as I should.	1	2	3	4	5
54. I should have more sex appeal.	1	2	3	4	5
55. I am as religious as I want to be.	1	2	3	4	5
56. I wish I could be more trustworthy.	1	2	3	4	5
57. I shouldn't tell so many lies.	1	2	3	4	5
58. I am as smart as I want to be.	1	2	3	4	5
59. I am not the person I would like to be.	1	2	3	4	5
60. I wish I didn't give up as easily as I do.	1	2	3	4	5
61. I treat my parents as well as I should. <i>(Use past tense if parents are not living.)</i>	1	2	3	4	5
62. I am too sensitive to things my family says.	1	2	3	4	5
63. I should love my family more.	1	2	3	4	5
64. I am satisfied with the way I treat other people.	1	2	3	4	5
65. I should be more polite to others.	1	2	3	4	5
66. I ought to get along better with other people.	1	2	3	4	5
67. I gossip a little at times.	1	2	3	4	5
68. At times I feel like swearing.	1	2	3	4	5
69. I take good care of myself physically.	1	2	3	4	5
70. I try to be careful about my appearance.	1	2	3	4	5
71. I often act like I am "all thumbs".	1	2	3	4	5
72. I am true to my religion in my everyday life.	1	2	3	4	5
73. I try to change when I know I'm doing things that are wrong.	1	2	3	4	5
74. I sometimes do very bad things.	1	2	3	4	5
75. I can always take care of myself in any situation.	1	2	3	4	5

 MENTOR	Core Gel Breast IDE Clinical Trial			2 YEAR VISIT				
	PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO.	PATIENT NO.	PATIENT INITIALS first middle last		

TENNESSEE SELF-CONCEPT SCALE (Page 4 of 4)

<i>Remember, put a circle around the response number you have chosen for each statement.</i>	Completely False	Mostly False	Partly True and Partly False	Mostly True	Completely True
76. I take the blame for things without getting mad.	1	2	3	4	5
77. I do things without thinking about them first.	1	2	3	4	5
78. I try to play fair with my friends and family.	1	2	3	4	5
79. I take a real interest in my family.	1	2	3	4	5
80. I give in to my parents. <i>(Use past tense if parents are not living.)</i>	1	2	3	4	5
81. I try to understand the other fellow's point of view.	1	2	3	4	5
82. I get along well with other people.	1	2	3	4	5
83. I do not forgive others easily.	1	2	3	4	5
84. I would rather win than lose in a game.	1	2	3	4	5
85. I feel good most of the time.	1	2	3	4	5
86. I do poorly in sports and games.	1	2	3	4	5
87. I am a poor sleeper.	1	2	3	4	5
88. I do what is right most of the time.	1	2	3	4	5
89. I sometimes use unfair means to get ahead.	1	2	3	4	5
90. I have trouble doing the things that are right.	1	2	3	4	5
91. I solve my problems quite easily.	1	2	3	4	5
92. I change my mind a lot.	1	2	3	4	5
93. I try to run away from my problems.	1	2	3	4	5
94. I do my share of work at home.	1	2	3	4	5
95. I quarrel with my family.	1	2	3	4	5
96. I do not act like my family thinks I should.	1	2	3	4	5
97. I see good points in all the people I meet.	1	2	3	4	5
98. I do not feel at ease with other people.	1	2	3	4	5
99. I find it hard to talk with strangers.	1	2	3	4	5
100. Once in a while I put off until tomorrow what I ought to do today.	1	2	3	4	5

 MENTOR	Core Gel Breast IDE Clinical Trial			2 YEAR VISIT				
	PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO.	PATIENT NO.	PATIENT INITIALS first middle last		

SF-36 (Page 1 of 3)

TO THE PATIENT: This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Answer each question by circling **one** number. If you are unsure about how to answer a question, please give the best answer you can.

1. In general, would you say your health is: (Circle one number)	Excellent	Very Good	Good	Fair	Poor
	1	2	3	4	5

2. Compared to one year ago, how would you rate your health in general now? (Circle one number)	Much Better Now	Somewhat Better Now	About the Same	Somewhat Worse Now	Much Worse Now
	1	2	3	4	5

3. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much? (Circle one number for each question.)	Yes, Limited a Lot	Yes, Limited a Little	No, Not Limited at All
Vigorous activities , such as running, lifting heavy objects, participating in strenuous sports.	1	2	3
Moderate activities , such as moving a table, pushing a vacuum cleaner, bowling or playing golf	1	2	3
Lifting or carrying groceries	1	2	3
Climbing several flights of stairs	1	2	3
Climbing one flight of stairs	1	2	3
Bending, kneeling, or stooping	1	2	3
Walking more than a mile	1	2	3
Walking several blocks	1	2	3
Walking one block	1	2	3
Bathing or dressing yourself	1	2	3

 MENTOR	Core Gel Breast IDE Clinical Trial			2 YEAR VISIT							
	PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1			SITE NO.		PATIENT NO.		PATIENT INITIALS first middle last	

SF-36 (Page 2 of 3)

4. During the past 4 weeks , have you had any of the following problems with your work or other regular daily activities as a result of your physical health? (Circle one number for each question.)	YES	NO
Cut down on the amount of time you spent on work or other activities	1	2
Accomplished less than you would like	1	2
Were limited in the kind of work or other activities	1	2
Had difficulty performing the work or other activities (for example, it took extra effort)	1	2

5. During the past 4 weeks , have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)? (Circle one number for each question.)	YES	NO
Cut down on the amount of time you spent on work or other activities	1	2
Accomplished less than you would like	1	2
Didn't do work or other activities as carefully as usual	1	2

6. During the past 4 weeks , to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups? (Circle one number)	Not at All	Slightly	Moderately	Quite a Bit	Extremely
	1	2	3	4	5

7. How much bodily pain have you had during the past 4 weeks? (Circle one number)	None	Very Mild	Mild	Moderate	Severe	Very Severe
	1	2	3	4	5	6

8. During the past 4 weeks , how much did pain interfere with your normal work (including both work outside the home and housework)? (Circle one number)	Not at All	A Little Bit	Moderately	Quite a Bit	Extremely
	1	2	3	4	5

 MENTOR	Core Gel Breast IDE Clinical Trial			2 YEAR VISIT				
	PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO.	PATIENT NO.	PATIENT INITIALS first middle last		

SF-36 (Page 3 of 3)

9. These questions are about how you feel and how things have been with you **during the past 4 weeks**. For each question, please indicate the one answer that comes closest to the way you have been feeling. (Circle **one** number for each question.)

How much of the time during the past 4 weeks ...	All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	None of the Time
Did you feel full of pep?	1	2	3	4	5	6
Have you been a very nervous person?	1	2	3	4	5	6
Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
Have you felt calm and peaceful?	1	2	3	4	5	6
Did you have a lot of energy?	1	2	3	4	5	6
Have you felt downhearted and blue?	1	2	3	4	5	6
Did you feel worn out?	1	2	3	4	5	6
Have you been a happy person?	1	2	3	4	5	6
Did you feel tired?	1	2	3	4	5	6

10. During the past 4 weeks , how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)? (Circle one number.)	All of the Time	Most of the Time	Some of the Time	A Little of the Time	None of the Time
	1	2	3	4	5

11. How TRUE or FALSE is each of the following statements for you? (Circle one number for each question.)	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
I seem to get sick a little easier than other people	1	2	3	4	5
I am as healthy as anybody I know	1	2	3	4	5
I expect my health to get worse	1	2	3	4	5
My health is excellent	1	2	3	4	5



Core Gel Breast
IDE Clinical Trial

2 YEAR VISIT

PATIENT STUDY ID:

TRIAL NO.
10-009

COUNTRY NO.
0 | 0 | 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last

BODY ESTEEM SCALE (Page 1 of 1)

TO THE PATIENT: On this page are listed a number of body parts and functions. Please read each item and indicate how you feel about this part or function of ***your own body***, using the following scale:

- 1 = Have strong negative feelings
- 2 = Have moderate negative feelings
- 3 = Have no feeling one way or the other
- 4 = Have moderate positive feelings
- 5 = Have strong positive feelings

- | | |
|--|--|
| <input type="checkbox"/> 1. Body Scent | <input type="checkbox"/> 19. Arms |
| <input type="checkbox"/> 2. Appetite | <input type="checkbox"/> 20. Chest |
| <input type="checkbox"/> 3. Nose | <input type="checkbox"/> 21. Appearance of Eyes |
| <input type="checkbox"/> 4. Physical Stamina | <input type="checkbox"/> 22. Cheeks/Cheekbones |
| <input type="checkbox"/> 5. Reflexes | <input type="checkbox"/> 23. Hips |
| <input type="checkbox"/> 6. Lips | <input type="checkbox"/> 24. Legs |
| <input type="checkbox"/> 7. Muscular Strength | <input type="checkbox"/> 25. Physique |
| <input type="checkbox"/> 8. Waist | <input type="checkbox"/> 26. Sex Drive |
| <input type="checkbox"/> 9. Energy Level | <input type="checkbox"/> 27. Feet |
| <input type="checkbox"/> 10. Thighs | <input type="checkbox"/> 28. Sex Organs |
| <input type="checkbox"/> 11. Ears | <input type="checkbox"/> 29. Appearance of Stomach |
| <input type="checkbox"/> 12. Biceps | <input type="checkbox"/> 30. Health |
| <input type="checkbox"/> 13. Chin | <input type="checkbox"/> 31. Sex Activities |
| <input type="checkbox"/> 14. Body Build | <input type="checkbox"/> 32. Body Hair |
| <input type="checkbox"/> 15. Physical Coordination | <input type="checkbox"/> 33. Physical Condition |
| <input type="checkbox"/> 16. Buttocks | <input type="checkbox"/> 34. Face |
| <input type="checkbox"/> 17. Agility | <input type="checkbox"/> 35. Weight |
| <input type="checkbox"/> 18. Width of Shoulders | |



MENTOR

**Core Gel Breast
IDE Clinical Trial**

2 YEAR VISIT

PATIENT STUDY ID:

TRIAL NO.
10-009

COUNTRY NO.
0 | 0 | 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last

MANITOBA CANCER TREATMENT & RESEARCH FOUNDATION FUNCTIONAL LIVING INDEX: CANCER (FLIC)

Page 1 of 3

N/A (not a cancer patient)

TO THE PATIENT: Please indicate your rating by drawing a vertical line (|).

1. Most people experience some feelings of depression at times. Rate how often you feel these feelings.

1	2	3	4	5	6	7
Never						Continually

2. How well are you coping with your everyday stress?

1	2	3	4	5	6	7
Not Well						Very Well

3. How much time do you spend thinking about your illness?

1	2	3	4	5	6	7
Constantly						Never

4. Rate your ability to maintain your usual recreation or leisure activities.

1	2	3	4	5	6	7
Able						Unable

5. Has nausea affected your daily functioning?

1	2	3	4	5	6	7
Not At All						A Great Deal

6. How well do you feel today?

1	2	3	4	5	6	7
Extremely Poor						Extremely Well

7. Do you feel well enough to make a meal or do minor household repairs today?

1	2	3	4	5	6	7
Very Able						Not Able



MENTOR

**Core Gel Breast
IDE Clinical Trial**

2 YEAR VISIT

PATIENT STUDY ID:

TRIAL NO.
10-009

COUNTRY NO.
0 0 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last

MANITOBA CANCER TREATMENT & RESEARCH FOUNDATION FUNCTIONAL LIVING INDEX: CANCER (FLIC)

Page 2 of 3

N/A (not a cancer patient)

8. Rate the degree to which your cancer has imposed a hardship on those closest to you in the past 2 months.

| | | | | | |

1 2 3 4 5 6 7

No Hardship Tremendous Hardship

9. Rate how often you feel discouraged about your life.

| | | | | | |

1 2 3 4 5 6 7

Always Never

10. Rate your satisfaction with your work and your jobs around the house in the past month.

| | | | | | |

1 2 3 4 5 6 7

Very Dissatisfied Very Satisfied

11. How uncomfortable do you feel today?

| | | | | | |

1 2 3 4 5 6 7

Not at All Very Uncomfortable

12. Rate in your opinion, how disruptive your cancer has been to those closest to you in the past 2 weeks.

| | | | | | |

1 2 3 4 5 6 7

Totally Disruptive No Disruption

13. How much is pain or discomfort interfering with your daily activities?

| | | | | | |

1 2 3 4 5 6 7

Not at All A Great Deal

14. Rate the degree to which your cancer has imposed a hardship on you (personally) in the past 2 weeks.

| | | | | | |

1 2 3 4 5 6 7

Tremendous Hardship No Hardship



MENTOR

**Core Gel Breast
IDE Clinical Trial**

2 YEAR VISIT

PATIENT STUDY ID:

TRIAL NO.
10-009

COUNTRY NO.
0 0 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last

MANITOBA CANCER TREATMENT & RESEARCH FOUNDATION FUNCTIONAL LIVING INDEX: CANCER (FLIC)

Page 3 of 3

N/A (not a cancer patient)

15. How much of your usual household tasks are you able to complete?

1	2	3	4	5	6	7
All						None

16. Rate how willing you were to see and spend time with those closest to you, in the past 2 weeks.

1	2	3	4	5	6	7
Unwilling						Very Willing

17. How much nausea have you had in the past 2 weeks?

1	2	3	4	5	6	7
None						A Great Deal

18. Rate the degree to which you are frightened of the future.

1	2	3	4	5	6	7
Constantly Terrified						Not Afraid

19. Rate how willing you were to see and spend time with friends, in the past 2 weeks.

1	2	3	4	5	6	7
Unwilling						Very Willing

20. How much of your pain or discomfort over the past 2 weeks was related to your cancer?

1	2	3	4	5	6	7
None						All

21. Rate your confidence in your prescribed course of treatment.

1	2	3	4	5	6	7
No Confidence						Very Confident

22. How well do you appear today?

1	2	3	4	5	6	7
Extremely Poor						Extremely Well



**Core Gel Breast
IDE Clinical Trial**

ADVERSE EVENTS

2 YEAR VISIT

PATIENT STUDY ID: TRIAL NO. **10-009** COUNTRY NO. **0 0 1** SITE NO. PATIENT NO. PATIENT INITIALS first middle last No Adverse Events

Enter one adverse event per line. If the event was experienced at more than one body site, enter each body site on a separate line.

AE CODE* (See Below)	CAUSALITY 1 = Procedure related 2 = Device related 3 = Unknown 4 = Other	EVENT SIDE 0 = N/A 1 = Right 2 = Left	ASSOCIATED BREAST PAIN 0 = None 1 = Mild 2 = Moderate 3 = Severe	ONSET DATE month day year	SEVERITY 1 = Mild 2 = Moderate 3 = Severe	TREATMENT REQUIRED (check all that apply) 1 = No Treatment 2 = Medication (specify) 3 = Secondary Procedure (enter Procedure Type Code and date below, and complete Secondary Procedures Report for all procedures performed for this date)** 4 = Hospitalization (specify # of days and admission date) 5 = Other (specify)	OUTCOME 1 = Resolved 2 = Ongoing 3 = Death 4 = Unknown	RESOLUTION DATE month day year
<input type="checkbox"/> 1	<input type="checkbox"/> 3	<input type="checkbox"/> 0	<input type="checkbox"/> 0 <input type="checkbox"/> 3	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 4 days, Date: ___/___/___	<input type="checkbox"/> 1 <input type="checkbox"/> 4	
<input type="checkbox"/> 2	<input type="checkbox"/> 4	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 5 Procedure Date: ___/___/___	<input type="checkbox"/> 2	
<input type="checkbox"/> 1	<input type="checkbox"/> 3	<input type="checkbox"/> 0	<input type="checkbox"/> 0 <input type="checkbox"/> 3	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 4 days, Date: ___/___/___	<input type="checkbox"/> 1 <input type="checkbox"/> 4	
<input type="checkbox"/> 2	<input type="checkbox"/> 4	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 5 Procedure Date: ___/___/___	<input type="checkbox"/> 2	
<input type="checkbox"/> 1	<input type="checkbox"/> 3	<input type="checkbox"/> 0	<input type="checkbox"/> 0 <input type="checkbox"/> 3	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 4 days, Date: ___/___/___	<input type="checkbox"/> 1 <input type="checkbox"/> 4	
<input type="checkbox"/> 2	<input type="checkbox"/> 4	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 5 Procedure Date: ___/___/___	<input type="checkbox"/> 2	
<input type="checkbox"/> 1	<input type="checkbox"/> 3	<input type="checkbox"/> 0	<input type="checkbox"/> 0 <input type="checkbox"/> 3	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 4 days, Date: ___/___/___	<input type="checkbox"/> 1 <input type="checkbox"/> 4	
<input type="checkbox"/> 2	<input type="checkbox"/> 4	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 5 Procedure Date: ___/___/___	<input type="checkbox"/> 2	
<input type="checkbox"/> 1	<input type="checkbox"/> 3	<input type="checkbox"/> 0	<input type="checkbox"/> 0 <input type="checkbox"/> 3	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 4 days, Date: ___/___/___	<input type="checkbox"/> 1 <input type="checkbox"/> 4	
<input type="checkbox"/> 2	<input type="checkbox"/> 4	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 5 Procedure Date: ___/___/___	<input type="checkbox"/> 2	
<input type="checkbox"/> 1	<input type="checkbox"/> 3	<input type="checkbox"/> 0	<input type="checkbox"/> 0 <input type="checkbox"/> 3	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 4 days, Date: ___/___/___	<input type="checkbox"/> 1 <input type="checkbox"/> 4	
<input type="checkbox"/> 2	<input type="checkbox"/> 4	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 5 Procedure Date: ___/___/___	<input type="checkbox"/> 2	

****Complete Secondary Procedures Report. If new study device is implanted, complete Re-implantation Report.**

Investigator's Signature _____ month _____ day _____ year

*ADVERSE EVENT CODES	+SECONDARY PROCEDURE TYPE CODES
1 = Asymmetry 2 = Baker II Capsular Contracture with Surgical Intervention 3 = Baker III Capsular Contracture 4 = Baker IV Capsular Contracture 5 = Breast pain not associated with any other complication 6 = Breast—Unacceptably Low Sensitivity 7 = Breast—Unacceptably High Sensitivity 8 = Calcification 9 = Delayed Wound Healing 10 = Extrusion 11 = Granuloma 12 = Hematoma 13 = Hypertrophic Scarring 14 = Infection 15 = Lymphadenopathy 16 = Necrosis 17 = New Diagnosis of Breast Cancer 18 = New Diagnosis of Rheumatic Disease, specify: 19 = Nipple—Unacceptably Low Sensitivity 20 = Nipple—Unacceptably High Sensitivity 21 = Position Change 22 = Ptosis 23 = Rupture 24 = Seroma 25 = Size Change—Patient Request 26 = Size Change—Physician Assessment only 27 = Wrinkling 28 = Lactation Difficulties, specify: 29 = Other, specify: 30 = Other, specify:	81 = Biopsy 82 = Capsulectomy 83 = Explanation with Replacement** 84 = Explanation without Replacement 85 = Incision and Drainage 86 = Mastopexy 87 = Open Capsulotomy 88 = Position Change 89 = Scar Revision 90 = Skin Adjustment 91 = Other, specify: 92 = Other, specify:



MENTOR

**Core Gel Breast
IDE Clinical Trial**

3 YEAR VISIT

PATIENT STUDY ID:

TRIAL NO.
10-009

COUNTRY NO.
0 0 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last

Visit Date:

month day year

Missed Visit

BREAST MEASUREMENTS

RIGHT Not Implanted with Study Device

Circumferential Breast Measurement cm

Bra Size (i.e. 32A) N/A (breast absent)

LEFT Not Implanted with Study Device

Circumferential Breast Measurement cm

Bra Size (i.e. 32A) N/A (breast absent)

MAMMOGRAPHY RESULTS

Date of Mammogram:

month year

Not Done

RIGHT

- 1 Birads 0 *Needs additional imaging evaluation*
 - 2 Birads 1 *Negative*
 - 3 Birads 2 *Benign finding*
 - 4 Birads 3 *Probable benign finding—short interval follow-up is suggested*
 - 5 Birads 4 *Suspicious abnormality—biopsy should be considered*
 - 6 Birads 5 *Highly suggestive of malignancy—appropriate action should be taken*
- List abnormality: _____

LEFT

- 1 Birads 0 *Needs additional imaging evaluation*
 - 2 Birads 1 *Negative*
 - 3 Birads 2 *Benign finding*
 - 4 Birads 3 *Probable benign finding—short interval follow-up is suggested*
 - 5 Birads 4 *Suspicious abnormality—biopsy should be considered*
 - 6 Birads 5 *Highly suggestive of malignancy—appropriate action should be taken*
- List abnormality: _____

VISIT REPORT

1. Has the patient become pregnant since the last visit?

- 1 No
- 2 Yes, without complications
- 3 Yes, with complications

Complete Adverse Events Report

2. Has the patient attempted to breastfeed since the last visit?

- 1 No
- 2 Yes, was there adequate milk?
 - 1 No **(Enter code 30 on Adverse Events Report)**
 - 2 Yes

3. Would the patient have this breast surgery again?

- 1 No, reason: _____
- 2 Yes

4. **Breast Cancer Reconstruction Patients only:**

N/A (augmentation patient)

Has the patient received any adjuvant therapies since the last visit?

- 1 No
- 2 Yes, check all that apply:
 - Radiation Therapy
 - Chemotherapy
 - Other, specify: _____

Treating Oncologist

Name: _____

Phone: (_____) _____

	Core Gel Breast IDE Clinical Trial		3 YEAR VISIT			
	PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO.	PATIENT NO.	PATIENT INITIALS first middle last

CAPSULAR CONTRACTURE ASSESSMENT OF PROSTHESIS	
Right Prosthesis is: <input type="radio"/> <input type="checkbox"/> Not Implanted with Study Device 1 <input type="checkbox"/> Baker Class I (normally soft and natural appearance) 2 <input type="checkbox"/> Baker Class II (a natural appearance despite palpable firmness) 3 <input type="checkbox"/> Baker Class III (firm with visible distortion) 4 <input type="checkbox"/> Baker Class IV (obvious spherical distortion)	Left Prosthesis is: <input type="radio"/> <input type="checkbox"/> Not Implanted with Study Device 1 <input type="checkbox"/> Baker Class I (normally soft and natural appearance) 2 <input type="checkbox"/> Baker Class II (a natural appearance despite palpable firmness) 3 <input type="checkbox"/> Baker Class III (firm with visible distortion) 4 <input type="checkbox"/> Baker Class IV (obvious spherical distortion)
Complete Adverse Events Report for Baker III or IV.	

NIPPLE/BREAST SENSITIVITY	
<p>How would patient describe the feeling in nipple(s) and/or breast(s) now?</p> <p><i>If unacceptably high or low at baseline, and sensation remains the same post-operatively, do not complete an Adverse Events Report.</i></p> <p><i>If acceptable at baseline and has become unacceptable post-operatively, complete an Adverse Events Report.</i></p>	
RIGHT <input type="radio"/> <input type="checkbox"/> Not Implanted with Study Device Nipple Sensation is: 1 <input type="checkbox"/> Unacceptably low 2 <input type="checkbox"/> Acceptable 3 <input type="checkbox"/> Unacceptably high 4 <input type="checkbox"/> N/A, nipple absent Breast sensation is: 1 <input type="checkbox"/> Unacceptably low 2 <input type="checkbox"/> Acceptable 3 <input type="checkbox"/> Unacceptably high 4 <input type="checkbox"/> N/A, breast absent	LEFT <input type="radio"/> <input type="checkbox"/> Not Implanted with Study Device Nipple Sensation is: 1 <input type="checkbox"/> Unacceptably low 2 <input type="checkbox"/> Acceptable 3 <input type="checkbox"/> Unacceptably high 4 <input type="checkbox"/> N/A, nipple absent Breast sensation is: 1 <input type="checkbox"/> Unacceptably low 2 <input type="checkbox"/> Acceptable 3 <input type="checkbox"/> Unacceptably high 4 <input type="checkbox"/> N/A, breast absent
Complete Adverse Events Report for any complications or adverse events noted at this visit.	



MENTOR

**Core Gel Breast
IDE Clinical Trial**

3 YEAR VISIT

PATIENT STUDY ID:

TRIAL NO.
10-009

COUNTRY NO.
0 | 0 | 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last

INVESTIGATOR-COMPLETED RHEUMATIC DISEASE DIAGNOSIS QUESTIONNAIRE

No diagnosis made

Has the patient been diagnosed by a RHEUMATOLOGIST for any of the following **since the last visit?**

If YES, complete Adverse Event Report.

RHEUMATIC DISEASE	NO YES		DATE OF ONSET (if known)	
			month	year
Connective Tissue Disorders: SLE	<input type="checkbox"/>	<input type="checkbox"/>		
Sjogren's Syndrome	<input type="checkbox"/>	<input type="checkbox"/>		
Scleroderma	<input type="checkbox"/>	<input type="checkbox"/>		
Polymyositis	<input type="checkbox"/>	<input type="checkbox"/>		
Other Connective Tissue Disorders	<input type="checkbox"/>	<input type="checkbox"/>		
Inflammatory Arthritis: Rheumatoid Arthritis	<input type="checkbox"/>	<input type="checkbox"/>		
Crystalline Arthritis	<input type="checkbox"/>	<input type="checkbox"/>		
Infectious Arthritis	<input type="checkbox"/>	<input type="checkbox"/>		
Spondyarthropathies	<input type="checkbox"/>	<input type="checkbox"/>		
Other Inflammatory Arthritis	<input type="checkbox"/>	<input type="checkbox"/>		
Non-Inflammatory Rheumatic Conditions: Osteoarthritis	<input type="checkbox"/>	<input type="checkbox"/>		
Fibromyalgia	<input type="checkbox"/>	<input type="checkbox"/>		
Chronic Fatigue	<input type="checkbox"/>	<input type="checkbox"/>		
Other Mechanical or Degenerative	<input type="checkbox"/>	<input type="checkbox"/>		
Other, specify: _____	<input type="checkbox"/>	<input type="checkbox"/>		
Other, specify: _____	<input type="checkbox"/>	<input type="checkbox"/>		

Disease must be diagnosed by a rheumatologist.

Rheumatologist who made diagnosis:

Name: _____

Address: _____

Phone: (_____) _____

**MENTOR****Core Gel Breast
IDE Clinical Trial****3 YEAR VISIT****PATIENT STUDY ID:**TRIAL NO.
10-009COUNTRY NO.
0 0 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last**RHEUMATOLOGY SYMPTOMS (Page 1 of 2)**1 No symptoms; patient not referred to rheumatologistPlease check any **current** symptoms which:

1. The patient experiences on a regular basis
2. The cause is unknown and cannot be attributed to any patient activity.

RHEUMATOLOGY SYMPTOM	STATUS SINCE LAST VISIT		DATE OF ONSET (only if new since last visit)		STATUS AS OF THIS VISIT	
	CONTINUING	NEW	month	year	RESOLVED	CONTINUING
Loss of weight without dieting	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Insomnia	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Weakness	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Exhaustion	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Joint swelling	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Heel pain	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Frequent muscle cramps	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Numbness of feet	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Ringing in ears	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Pain/grittiness in eyes	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Dryness of eyes, nose	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Pain on swallowing or chewing	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Neck pain/stiffness	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Pain on breathing	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Heart murmurs	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Loss of appetite	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Persistent fever	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Night sweats	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Generalized aching	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Loss of height	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Joint pain	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Frequent muscle pain	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>



**Core Gel Breast
IDE Clinical Trial**

3 YEAR VISIT

PATIENT STUDY ID:	TRIAL NO.	COUNTRY NO.			SITE NO.	PATIENT NO.	PATIENT INITIALS		
	10-009	0	0	1			first	middle	last

RHEUMATOLOGY SYMPTOMS (Page 2 of 2)

Please check any **current** symptoms which:

1. The patient experiences on a regular basis
2. The cause is unknown and cannot be attributed to any patient activity.

RHEUMATOLOGY SYMPTOM	STATUS SINCE LAST VISIT		DATE OF ONSET (only if new since last visit)		STATUS AS OF THIS VISIT	
	CONTINUING	NEW	month	year	RESOLVED	CONTINUING
Numbness of hands	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Jaw pain	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Open sores	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Redness of eyes	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Dryness of mouth	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Back pain/stiffness	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Severe chest pains	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Chronic cough	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Difficulty swallowing	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Frequent, severe or persistent diarrhea or constipation	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Severe rashes	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Frequent muscle cramps	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Severe dryness of skin	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Tender lumps/bumps	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Excessive sensitivity to sun	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Color changes on hands or feet with cold exposure	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Joint pain	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Frequent hives	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Numbness of hands	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Tightness of skin	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Unusual hair loss	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Tenderness of scalp	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Severe bruising with little or no injury	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>



**Core Gel Breast
IDE Clinical Trial**

3 YEAR VISIT

PATIENT STUDY ID:	TRIAL NO.	COUNTRY NO.			SITE NO.	PATIENT NO.	PATIENT INITIALS		
	10-009	0	0	1			first	middle	last

RHEUMATOLOGICAL PHYSICAL EXAMINATION (Page 1 of 2)

No symptoms present

Check the box for each physical finding noted to be present and outside normal limits.

PHYSICAL FINDING	STATUS SINCE LAST VISIT		DATE OF ONSET (only if new since last visit)		STATUS AS OF THIS VISIT	
	CONTINUING	NEW	month	year	RESOLVED	CONTINUING
Muscle weakness: Headlift from supine position against gravity	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Inability to raise arms	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Inability to get out of chair	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Joint swellings: Wrists	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Digits	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Elbows	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Knees	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Ankles	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Joint deformities and flexion contracture: Boutonnière ¹	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Ulnar drift ²	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Swan neck ³	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Trigger fingers	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Joint tenderness	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Grip strength and motion-finger to palm crease (normal = 0 cm)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Neck motion—chin to chest or sternum (normal = 0 cm)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Chest expansion (normal = at least 5 cm)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Occiput to wall (normal = 0 cm)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Jaw motion (normally upper-lower incisors 3 cm)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Back motion—measure 10 cm above posterior supine iliac spines— with forward bending motion at least 5 cm from first point (total distance at least 15 cm)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>

¹**Boutonnière** - Contractures of hand musculature characterized by proximal interphalangeal joint flexion and distal interphalangeal joint hyperextension.

³**Swan Neck** - Finger deformity characterized by flexion of distal interphalangeal joints and hyperflexion of the proximal interphalangeal joints due to hypermobility.

²**Ulnar Drift** - Joint change at the metacarpophalangeal joints. Long axis of fingers deviate in an ulnar direction.

**MENTOR****Core Gel Breast
IDE Clinical Trial****3 YEAR VISIT****PATIENT STUDY ID:**TRIAL NO.
10-009COUNTRY NO.
0 0 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last**RHEUMATOLOGICAL PHYSICAL EXAMINATION (Page 2 of 2)**

Check the box for each physical finding noted to be present and outside normal limits.

PHYSICAL FINDING	POSSIBLE INDICATION	STATUS SINCE LAST VISIT		DATE OF ONSET (only if new since last visit)		STATUS AS OF THIS VISIT	
		CONTINUING	NEW	month	year	RESOLVED	CONTINUING
Hair loss	<i>Lupus, Scleroderma</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Skin tightness, especially face and hands	<i>Scleroderma</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Raynaud's phenomenon	<i>Lupus, Scleroderma</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Calcinosis over tibia, ulna, elbows	<i>Scleroderma, Dermatomyositis</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Swollen digits	<i>Juvenile RA, Reiter's syndrome, Psoriatic arthritis, Early scleroderma, Reflex sympathetic dystrophy</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Erythema over knuckles	<i>Dermatomyositis</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Bluish hue color on eyelids	<i>Dermatomyositis</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Non-tender lumps or nodules on elbows	<i>Rheumatoid gout</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Tender lumps-tibia	<i>Erythema nodosum</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Painless eye redness	<i>Conjunctivitis</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Painful eye redness with decreased vision, small pupils	<i>Uveitis</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Tenderness—insertion of deltoids	<i>Polymyalgia rheumatica</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Muscle tenderness	<i>Polymyositis</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Nail pittings	<i>Psoriatic arthritis, Reiter's syndrome</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Tinels or Phalen's signs	<i>Carpal tunnel syndrome</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Skin rashes	<i>Discoid lupus</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>

Does the patient require an examination by a rheumatologist?

 No Yes, record rheumatologist's findings:



Core Gel Breast IDE Clinical Trial

ADVERSE EVENTS

3 YEAR VISIT

PATIENT STUDY ID: TRIAL NO. 10-009 COUNTRY NO. 0 0 1 SITE NO. PATIENT NO. PATIENT INITIALS first middle last No Adverse Events

Enter one adverse event per line. If the event was experienced at more than one body site, enter each body site on a separate line.

AE CODE* (See Below)	CAUSALITY 1 = Procedure related 2 = Device related 3 = Unknown 4 = Other	EVENT SIDE 0 = N/A 1 = Right 2 = Left	ASSOCIATED BREAST PAIN 0 = None 1 = Mild 2 = Moderate 3 = Severe	ONSET DATE month day year	SEVERITY 1 = Mild 2 = Moderate 3 = Severe	TREATMENT REQUIRED (check all that apply) 1 = No Treatment 2 = Medication (specify) 3 = Secondary Procedure (enter Procedure Type Code and date below, and complete Secondary Procedures Report for all procedures performed for this date)** 4 = Hospitalization (specify # of days and admission date) 5 = Other (specify)	OUTCOME 1 = Resolved 2 = Ongoing 3 = Death 4 = Unknown	RESOLUTION DATE month day year
<input type="checkbox"/> 1	<input type="checkbox"/> 3	<input type="checkbox"/> 0	<input type="checkbox"/> 0 <input type="checkbox"/> 3	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 4 days, Date: ___/___/___	<input type="checkbox"/> 1 <input type="checkbox"/> 4	
<input type="checkbox"/> 2	<input type="checkbox"/> 4	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 5 Procedure Date: ___/___/___	<input type="checkbox"/> 2	
<input type="checkbox"/> 1	<input type="checkbox"/> 3	<input type="checkbox"/> 0	<input type="checkbox"/> 0 <input type="checkbox"/> 3	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 4 days, Date: ___/___/___	<input type="checkbox"/> 1 <input type="checkbox"/> 4	
<input type="checkbox"/> 2	<input type="checkbox"/> 4	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 5 Procedure Date: ___/___/___	<input type="checkbox"/> 2	
<input type="checkbox"/> 1	<input type="checkbox"/> 3	<input type="checkbox"/> 0	<input type="checkbox"/> 0 <input type="checkbox"/> 3	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 4 days, Date: ___/___/___	<input type="checkbox"/> 1 <input type="checkbox"/> 4	
<input type="checkbox"/> 2	<input type="checkbox"/> 4	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 5 Procedure Date: ___/___/___	<input type="checkbox"/> 2	
<input type="checkbox"/> 1	<input type="checkbox"/> 3	<input type="checkbox"/> 0	<input type="checkbox"/> 0 <input type="checkbox"/> 3	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 4 days, Date: ___/___/___	<input type="checkbox"/> 1 <input type="checkbox"/> 4	
<input type="checkbox"/> 2	<input type="checkbox"/> 4	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 5 Procedure Date: ___/___/___	<input type="checkbox"/> 2	
<input type="checkbox"/> 1	<input type="checkbox"/> 3	<input type="checkbox"/> 0	<input type="checkbox"/> 0 <input type="checkbox"/> 3	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 4 days, Date: ___/___/___	<input type="checkbox"/> 1 <input type="checkbox"/> 4	
<input type="checkbox"/> 2	<input type="checkbox"/> 4	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 5 Procedure Date: ___/___/___	<input type="checkbox"/> 2	
<input type="checkbox"/> 1	<input type="checkbox"/> 3	<input type="checkbox"/> 0	<input type="checkbox"/> 0 <input type="checkbox"/> 3	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 4 days, Date: ___/___/___	<input type="checkbox"/> 1 <input type="checkbox"/> 4	
<input type="checkbox"/> 2	<input type="checkbox"/> 4	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 5 Procedure Date: ___/___/___	<input type="checkbox"/> 2	

**Complete Secondary Procedures Report. If new study device is implanted, complete Re-implantation Report.

Investigator's Signature _____ month _____ day _____ year

*ADVERSE EVENT CODES	+SECONDARY PROCEDURE TYPE CODES
1 = Asymmetry 2 = Baker II Capsular Contracture with Surgical Intervention 3 = Baker III Capsular Contracture 4 = Baker IV Capsular Contracture 5 = Breast pain not associated with any other complication 6 = Breast—Unacceptably Low Sensitivity 7 = Breast—Unacceptably High Sensitivity 8 = Calcification 9 = Delayed Wound Healing 10 = Extrusion 11 = Granuloma 12 = Hematoma 13 = Hypertrophic Scarring 14 = Infection 15 = Lymphadenopathy 16 = Necrosis 17 = New Diagnosis of Breast Cancer 18 = New Diagnosis of Rheumatic Disease, specify: 19 = Nipple—Unacceptably Low Sensitivity 20 = Nipple—Unacceptably High Sensitivity 21 = Position Change 22 = Ptosis 23 = Rupture 24 = Seroma 25 = Size Change—Patient Request 26 = Size Change—Physician Assessment only 27 = Wrinkling 28 = Lactation Difficulties, specify: 29 = Other, specify: 30 = Other, specify:	81 = Biopsy 82 = Capsulectomy 83 = Explanation with Replacement** 84 = Explanation without Replacement 85 = Incision and Drainage 86 = Mastopexy 87 = Open Capsulotomy 88 = Position Change 89 = Scar Revision 90 = Skin Adjustment 91 = Other, specify: 92 = Other, specify:



MENTOR

**Core Gel Breast
IDE Clinical Trial**

4 YEAR VISIT

PATIENT STUDY ID:

TRIAL NO.
10-009

COUNTRY NO.
0 0 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last

Visit Date:

month day year

Missed Visit

BREAST MEASUREMENTS

RIGHT Not Implanted with Study Device

Circumferential Breast Measurement cm

Bra Size (i.e. 32A) N/A (breast absent)

LEFT Not Implanted with Study Device

Circumferential Breast Measurement cm

Bra Size (i.e. 32A) N/A (breast absent)

MAMMOGRAPHY RESULTS

Date of Mammogram:

month year

Not Done

RIGHT

- Birads 0 Needs additional imaging evaluation
 - Birads 1 Negative
 - Birads 2 Benign finding
 - Birads 3 Probable benign finding—short interval follow-up is suggested
 - Birads 4 Suspicious abnormality—biopsy should be considered
 - Birads 5 Highly suggestive of malignancy—appropriate action should be taken
- List abnormality: _____

LEFT

- Birads 0 Needs additional imaging evaluation
 - Birads 1 Negative
 - Birads 2 Benign finding
 - Birads 3 Probable benign finding—short interval follow-up is suggested
 - Birads 4 Suspicious abnormality—biopsy should be considered
 - Birads 5 Highly suggestive of malignancy—appropriate action should be taken
- List abnormality: _____

VISIT REPORT

1. Has the patient become pregnant since the last visit?

- No
- Yes, without complications
- Yes, with complications

Complete Adverse Events Report

2. Has the patient attempted to breastfeed since the last visit?

- No
- Yes, was there adequate milk?
 - No (Enter code 30 on Adverse Events Report)
 - Yes

3. Would the patient have this breast surgery again?

- No, reason: _____
- Yes

4. **Breast Cancer Reconstruction Patients only:**

N/A (augmentation patient)

Has the patient received any adjuvant therapies since the last visit?

- No
- Yes, check all that apply:
 - Radiation Therapy
 - Chemotherapy
 - Other, specify: _____

Treating Oncologist

Name: _____

Phone: (_____) _____

 MENTOR	Core Gel Breast IDE Clinical Trial		4 YEAR VISIT			
	PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO.	PATIENT NO.	PATIENT INITIALS first middle last

CAPSULAR CONTRACTURE ASSESSMENT OF PROSTHESIS	
Right Prosthesis is: o <input type="checkbox"/> Not Implanted with Study Device 1 <input type="checkbox"/> Baker Class I (normally soft and natural appearance) 2 <input type="checkbox"/> Baker Class II (a natural appearance despite palpable firmness) 3 <input type="checkbox"/> Baker Class III (firm with visible distortion) 4 <input type="checkbox"/> Baker Class IV (obvious spherical distortion)	Left Prosthesis is: o <input type="checkbox"/> Not Implanted with Study Device 1 <input type="checkbox"/> Baker Class I (normally soft and natural appearance) 2 <input type="checkbox"/> Baker Class II (a natural appearance despite palpable firmness) 3 <input type="checkbox"/> Baker Class III (firm with visible distortion) 4 <input type="checkbox"/> Baker Class IV (obvious spherical distortion)
Complete Adverse Events Report for Baker III or IV.	

NIPPLE/BREAST SENSITIVITY	
<p>How would patient describe the feeling in nipple(s) and/or breast(s) now?</p> <p><i>If unacceptably high or low at baseline, and sensation remains the same post-operatively, do not complete an Adverse Events Report.</i></p> <p><i>If acceptable at baseline and has become unacceptable post-operatively, complete an Adverse Events Report.</i></p>	
RIGHT o <input type="checkbox"/> Not Implanted with Study Device Nipple Sensation is: 1 <input type="checkbox"/> Unacceptably low 2 <input type="checkbox"/> Acceptable 3 <input type="checkbox"/> Unacceptably high 4 <input type="checkbox"/> N/A, nipple absent Breast sensation is: 1 <input type="checkbox"/> Unacceptably low 2 <input type="checkbox"/> Acceptable 3 <input type="checkbox"/> Unacceptably high 4 <input type="checkbox"/> N/A, breast absent	LEFT o <input type="checkbox"/> Not Implanted with Study Device Nipple Sensation is: 1 <input type="checkbox"/> Unacceptably low 2 <input type="checkbox"/> Acceptable 3 <input type="checkbox"/> Unacceptably high 4 <input type="checkbox"/> N/A, nipple absent Breast sensation is: 1 <input type="checkbox"/> Unacceptably low 2 <input type="checkbox"/> Acceptable 3 <input type="checkbox"/> Unacceptably high 4 <input type="checkbox"/> N/A, breast absent
Complete Adverse Events Report for any complications or adverse events noted at this visit.	



MENTOR

**Core Gel Breast
IDE Clinical Trial**

4 YEAR VISIT

PATIENT STUDY ID:

TRIAL NO.
10-009

COUNTRY NO.
0 | 0 | 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last

INVESTIGATOR-COMPLETED RHEUMATIC DISEASE DIAGNOSIS QUESTIONNAIRE

No diagnosis made

Has the patient been diagnosed by a RHEUMATOLOGIST for any of the following **since the last visit?**

If YES, complete Adverse Event Report.

RHEUMATIC DISEASE	NO YES		DATE OF ONSET (if known)	
			month	year
Connective Tissue Disorders: SLE	<input type="checkbox"/>	<input type="checkbox"/>		
Sjogren's Syndrome	<input type="checkbox"/>	<input type="checkbox"/>		
Scleroderma	<input type="checkbox"/>	<input type="checkbox"/>		
Polymyositis	<input type="checkbox"/>	<input type="checkbox"/>		
Other Connective Tissue Disorders	<input type="checkbox"/>	<input type="checkbox"/>		
Inflammatory Arthritis: Rheumatoid Arthritis	<input type="checkbox"/>	<input type="checkbox"/>		
Crystalline Arthritis	<input type="checkbox"/>	<input type="checkbox"/>		
Infectious Arthritis	<input type="checkbox"/>	<input type="checkbox"/>		
Spondyarthropathies	<input type="checkbox"/>	<input type="checkbox"/>		
Other Inflammatory Arthritis	<input type="checkbox"/>	<input type="checkbox"/>		
Non-Inflammatory Rheumatic Conditions: Osteoarthritis	<input type="checkbox"/>	<input type="checkbox"/>		
Fibromyalgia	<input type="checkbox"/>	<input type="checkbox"/>		
Chronic Fatigue	<input type="checkbox"/>	<input type="checkbox"/>		
Other Mechanical or Degenerative	<input type="checkbox"/>	<input type="checkbox"/>		
Other, specify: _____	<input type="checkbox"/>	<input type="checkbox"/>		
Other, specify: _____	<input type="checkbox"/>	<input type="checkbox"/>		

Disease must be diagnosed by a rheumatologist.

Rheumatologist who made diagnosis:

Name: _____

Address: _____

Phone: (_____) _____

**MENTOR****Core Gel Breast
IDE Clinical Trial****4 YEAR VISIT****PATIENT STUDY ID:**TRIAL NO.
10-009COUNTRY NO.
0 0 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last**RHEUMATOLOGY SYMPTOMS (Page 1 of 2)**1 No symptoms; patient not referred to rheumatologistPlease check any **current** symptoms which:

1. The patient experiences on a regular basis
2. The cause is unknown and cannot be attributed to any patient activity.

RHEUMATOLOGY SYMPTOM	STATUS SINCE LAST VISIT		DATE OF ONSET (only if new since last visit)		STATUS AS OF THIS VISIT	
	CONTINUING	NEW	month	year	RESOLVED	CONTINUING
Loss of weight without dieting	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Insomnia	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Weakness	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Exhaustion	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Joint swelling	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Heel pain	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Frequent muscle cramps	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Numbness of feet	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Ringing in ears	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Pain/grittiness in eyes	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Dryness of eyes, nose	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Pain on swallowing or chewing	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Neck pain/stiffness	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Pain on breathing	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Heart murmurs	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Loss of appetite	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Persistent fever	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Night sweats	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Generalized aching	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Loss of height	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Joint pain	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Frequent muscle pain	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>



**Core Gel Breast
IDE Clinical Trial**

4 YEAR VISIT

PATIENT STUDY ID:	TRIAL NO.	COUNTRY NO.			SITE NO.	PATIENT NO.	PATIENT INITIALS		
	10-009	0	0	1			first	middle	last

RHEUMATOLOGY SYMPTOMS (Page 2 of 2)

Please check any **current** symptoms which:

1. The patient experiences on a regular basis
2. The cause is unknown and cannot be attributed to any patient activity.

RHEUMATOLOGY SYMPTOM	STATUS SINCE LAST VISIT		DATE OF ONSET (only if new since last visit)		STATUS AS OF THIS VISIT	
	CONTINUING	NEW	month	year	RESOLVED	CONTINUING
Numbness of hands	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Jaw pain	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Open sores	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Redness of eyes	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Dryness of mouth	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Back pain/stiffness	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Severe chest pains	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Chronic cough	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Difficulty swallowing	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Frequent, severe or persistent diarrhea or constipation	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Severe rashes	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Frequent muscle cramps	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Severe dryness of skin	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Tender lumps/bumps	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Excessive sensitivity to sun	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Color changes on hands or feet with cold exposure	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Joint pain	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Frequent hives	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Numbness of hands	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Tightness of skin	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Unusual hair loss	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Tenderness of scalp	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Severe bruising with little or no injury	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>



**Core Gel Breast
IDE Clinical Trial**

4 YEAR VISIT

PATIENT STUDY ID:	TRIAL NO.	COUNTRY NO.			SITE NO.	PATIENT NO.	PATIENT INITIALS		
	10-009	0	0	1			first	middle	last

RHEUMATOLOGICAL PHYSICAL EXAMINATION (Page 1 of 2)

No symptoms present

Check the box for each physical finding noted to be present and outside normal limits.

PHYSICAL FINDING	STATUS SINCE LAST VISIT		DATE OF ONSET (only if new since last visit)		STATUS AS OF THIS VISIT	
	CONTINUING	NEW	month	year	RESOLVED	CONTINUING
Muscle weakness: Headlift from supine position against gravity	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Inability to raise arms	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Inability to get out of chair	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Joint swellings: Wrists	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Digits	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Elbows	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Knees	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Ankles	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Joint deformities and flexion contracture: Boutonnière ¹	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Ulnar drift ²	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Swan neck ³	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Trigger fingers	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Joint tenderness	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Grip strength and motion-finger to palm crease (normal = 0 cm)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Neck motion—chin to chest or sternum (normal = 0 cm)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Chest expansion (normal = at least 5 cm)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Occiput to wall (normal = 0 cm)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Jaw motion (normally upper-lower incisors 3 cm)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Back motion—measure 10 cm above posterior supine iliac spines— with forward bending motion at least 5 cm from first point (total distance at least 15 cm)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>

¹**Boutonnière** - Contractures of hand musculature characterized by proximal interphalangeal joint flexion and distal interphalangeal joint hyperextension.

³**Swan Neck** - Finger deformity characterized by flexion of distal interphalangeal joints and hyperflexion of the proximal interphalangeal joints due to hypermobility.

²**Ulnar Drift** - Joint change at the metacarpophalangeal joints. Long axis of fingers deviate in an ulnar direction.

**MENTOR****Core Gel Breast
IDE Clinical Trial****4 YEAR VISIT****PATIENT STUDY ID:**TRIAL NO.
10-009COUNTRY NO.
0 0 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last**RHEUMATOLOGICAL PHYSICAL EXAMINATION (Page 2 of 2)**

Check the box for each physical finding noted to be present and outside normal limits.

PHYSICAL FINDING	POSSIBLE INDICATION	STATUS SINCE LAST VISIT		DATE OF ONSET (only if new since last visit)		STATUS AS OF THIS VISIT	
		CONTINUING	NEW	month	year	RESOLVED	CONTINUING
Hair loss	<i>Lupus, Scleroderma</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Skin tightness, especially face and hands	<i>Scleroderma</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Raynaud's phenomenon	<i>Lupus, Scleroderma</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Calcinosis over tibia, ulna, elbows	<i>Scleroderma, Dermatomyositis</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Swollen digits	<i>Juvenile RA, Reiter's syndrome, Psoriatic arthritis, Early scleroderma, Reflex sympathetic dystrophy</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Erythema over knuckles	<i>Dermatomyositis</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Bluish hue color on eyelids	<i>Dermatomyositis</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Non-tender lumps or nodules on elbows	<i>Rheumatoid gout</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Tender lumps-tibia	<i>Erythema nodosum</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Painless eye redness	<i>Conjunctivitis</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Painful eye redness with decreased vision, small pupils	<i>Uveitis</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Tenderness—insertion of deltoids	<i>Polymyalgia rheumatica</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Muscle tenderness	<i>Polymyositis</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Nail pittings	<i>Psoriatic arthritis, Reiter's syndrome</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Tinels or Phalen's signs	<i>Carpal tunnel syndrome</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Skin rashes	<i>Discoid lupus</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>

Does the patient require an examination by a rheumatologist?

 No Yes, record rheumatologist's findings:

 MENTOR	Core Gel Breast IDE Clinical Trial		4 YEAR VISIT			
	PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO.	PATIENT NO.	PATIENT INITIALS first middle last

ROSENBERG SELF-ESTEEM SCALE (Page 1 of 1)

TO THE PATIENT: Below are some statements with which some people agree and disagree. Please read each statement and check **one** response to each statement.

	Strongly Agree 1	Agree 2	Disagree 3	Strongly Disagree 4
1. I feel that I am a person of worth, at least on an equal basis with others.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. I feel that I have a number of good qualities.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. All in all, I am inclined to feel that I am a failure.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. I am able to do things as well as most people.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. I feel I do not have much of which to be proud.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. I take a positive attitude towards myself.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. On the whole, I am satisfied with myself.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. I wish I could have more respect for myself.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. I certainly feel useless at times.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. At times I think I am no good at all.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



Core Gel Breast
IDE Clinical Trial

4 YEAR VISIT

PATIENT STUDY ID:

TRIAL NO.
10-009

COUNTRY NO.
0 | 0 | 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last

TENNESSEE SELF-CONCEPT SCALE (Page 1 of 4)

TO THE PATIENT: The statements below are to help you describe yourself as you see yourself. Please respond to them as if you were describing yourself **to yourself**. Do not omit any item. Read each statement carefully, then select one of the five responses listed below. On the test, put a **circle** around the response you chose. If you want to change an answer after you have circled it, do not erase it but put an X mark through the response and then circle the response you want.

*Remember, put a **circle** around the response number you have chosen for each statement.*

	Completely False	Mostly False	Partly True and Partly False	Mostly True	Completely True
1. I have a healthy body.	1	2	3	4	5
2. I am an attractive person.	1	2	3	4	5
3. I consider myself a sloppy person.	1	2	3	4	5
4. I am a decent sort of person.	1	2	3	4	5
5. I am an honest person.	1	2	3	4	5
6. I am a bad person.	1	2	3	4	5
7. I am a cheerful person.	1	2	3	4	5
8. I am a calm and easygoing person.	1	2	3	4	5
9. I am a nobody.	1	2	3	4	5
10. I have a family that would always help me in any kind of trouble.	1	2	3	4	5
11. I am a member of a happy family.	1	2	3	4	5
12. My friends have no confidence in me.	1	2	3	4	5
13. I am a friendly person.	1	2	3	4	5
14. I am popular with men.	1	2	3	4	5
15. I am not interested in what other people do.	1	2	3	4	5
16. I do not always tell the truth.	1	2	3	4	5
17. I get angry sometimes.	1	2	3	4	5
18. I like to look nice and neat all the time.	1	2	3	4	5
19. I am full of aches and pains.	1	2	3	4	5
20. I am a sick person.	1	2	3	4	5
21. I am a religious person.	1	2	3	4	5
22. I am a moral failure.	1	2	3	4	5
23. I am a morally weak person.	1	2	3	4	5

 MENTOR	Core Gel Breast IDE Clinical Trial			4 YEAR VISIT							
	PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1			SITE NO.		PATIENT NO.		PATIENT INITIALS first middle last	

TENNESSEE SELF-CONCEPT SCALE (Page 2 of 4)

<i>Remember, put a circle around the response number you have chosen for each statement.</i>	Completely False	Mostly False	Partly True and Partly False	Mostly True	Completely True
24. I have a lot of self-control.	1	2	3	4	5
25. I am a hateful person.	1	2	3	4	5
26. I am losing my mind.	1	2	3	4	5
27. I am an important person to my friends and family.	1	2	3	4	5
28. I am not loved by my family.	1	2	3	4	5
29. I feel that my family doesn't trust me.	1	2	3	4	5
30. I am popular with women.	1	2	3	4	5
31. I am mad at the whole world.	1	2	3	4	5
32. I am hard to be friendly with.	1	2	3	4	5
33. Once in a while I think of things too bad to talk about.	1	2	3	4	5
34. Sometimes when I am not feeling well, I am cross.	1	2	3	4	5
35. I am neither too fat nor too thin.	1	2	3	4	5
36. I like my looks just the way they are.	1	2	3	4	5
37. I would like to change some parts of my body.	1	2	3	4	5
38. I am satisfied with my moral behavior.	1	2	3	4	5
39. I am satisfied with my relationship to God.	1	2	3	4	5
40. I ought to go to church more.	1	2	3	4	5
41. I am satisfied to be just what I am.	1	2	3	4	5
42. I am just as nice as I should be.	1	2	3	4	5
43. I despise myself.	1	2	3	4	5
44. I am satisfied with my family relationships.	1	2	3	4	5
45. I understand my family as well as I should.	1	2	3	4	5
46. I should trust my family more.	1	2	3	4	5
47. I am as sociable as I want to be.	1	2	3	4	5
48. I try to please others, but I don't overdo it.	1	2	3	4	5
49. I am no good at all from a social standpoint.	1	2	3	4	5



Core Gel Breast
IDE Clinical Trial

4 YEAR VISIT

PATIENT STUDY ID:

TRIAL NO.
10-009

COUNTRY NO.
0 0 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last

TENNESSEE SELF-CONCEPT SCALE (Page 3 of 4)

Remember, put a **circle** around the response number you have chosen for each statement.

Completely
False

Mostly
False

Partly True
and
Partly False

Mostly
True

Completely
True

50. I do not like everyone I know.

1

2

3

4

5

51. Once in a while, I laugh at a dirty joke.

1

2

3

4

5

52. I am neither too tall nor too short.

1

2

3

4

5

53. I don't feel as well as I should.

1

2

3

4

5

54. I should have more sex appeal.

1

2

3

4

5

55. I am as religious as I want to be.

1

2

3

4

5

56. I wish I could be more trustworthy.

1

2

3

4

5

57. I shouldn't tell so many lies.

1

2

3

4

5

58. I am as smart as I want to be.

1

2

3

4

5

59. I am not the person I would like to be.

1

2

3

4

5

60. I wish I didn't give up as easily as I do.

1

2

3

4

5

61. I treat my parents as well as I should. *(Use past tense if parents are not living.)*

1

2

3

4

5

62. I am too sensitive to things my family says.

1

2

3

4

5

63. I should love my family more.

1

2

3

4

5

64. I am satisfied with the way I treat other people.

1

2

3

4

5

65. I should be more polite to others.

1

2

3

4

5

66. I ought to get along better with other people.

1

2

3

4

5

67. I gossip a little at times.

1

2

3

4

5

68. At times I feel like swearing.

1

2

3

4

5

69. I take good care of myself physically.

1

2

3

4

5

70. I try to be careful about my appearance.

1

2

3

4

5

71. I often act like I am "all thumbs".

1

2

3

4

5

72. I am true to my religion in my everyday life.

1

2

3

4

5

73. I try to change when I know I'm doing things that are wrong.

1

2

3

4

5

74. I sometimes do very bad things.

1

2

3

4

5

75. I can always take care of myself in any situation.

1

2

3

4

5

 MENTOR	Core Gel Breast IDE Clinical Trial			4 YEAR VISIT				
	PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO.	PATIENT NO.	PATIENT INITIALS first middle last		

TENNESSEE SELF-CONCEPT SCALE (Page 4 of 4)

<i>Remember, put a circle around the response number you have chosen for each statement.</i>	Completely False	Mostly False	Partly True and Partly False	Mostly True	Completely True
76. I take the blame for things without getting mad.	1	2	3	4	5
77. I do things without thinking about them first.	1	2	3	4	5
78. I try to play fair with my friends and family.	1	2	3	4	5
79. I take a real interest in my family.	1	2	3	4	5
80. I give in to my parents. <i>(Use past tense if parents are not living.)</i>	1	2	3	4	5
81. I try to understand the other fellow's point of view.	1	2	3	4	5
82. I get along well with other people.	1	2	3	4	5
83. I do not forgive others easily.	1	2	3	4	5
84. I would rather win than lose in a game.	1	2	3	4	5
85. I feel good most of the time.	1	2	3	4	5
86. I do poorly in sports and games.	1	2	3	4	5
87. I am a poor sleeper.	1	2	3	4	5
88. I do what is right most of the time.	1	2	3	4	5
89. I sometimes use unfair means to get ahead.	1	2	3	4	5
90. I have trouble doing the things that are right.	1	2	3	4	5
91. I solve my problems quite easily.	1	2	3	4	5
92. I change my mind a lot.	1	2	3	4	5
93. I try to run away from my problems.	1	2	3	4	5
94. I do my share of work at home.	1	2	3	4	5
95. I quarrel with my family.	1	2	3	4	5
96. I do not act like my family thinks I should.	1	2	3	4	5
97. I see good points in all the people I meet.	1	2	3	4	5
98. I do not feel at ease with other people.	1	2	3	4	5
99. I find it hard to talk with strangers.	1	2	3	4	5
100. Once in a while I put off until tomorrow what I ought to do today.	1	2	3	4	5

 MENTOR	Core Gel Breast IDE Clinical Trial			4 YEAR VISIT				
	PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO.	PATIENT NO.	PATIENT INITIALS first middle last		

SF-36 (Page 1 of 3)

TO THE PATIENT: This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Answer each question by circling **one** number. If you are unsure about how to answer a question, please give the best answer you can.

1. In general, would you say your health is: (Circle one number)	Excellent	Very Good	Good	Fair	Poor
	1	2	3	4	5

2. Compared to one year ago, how would you rate your health in general now? (Circle one number)	Much Better Now	Somewhat Better Now	About the Same	Somewhat Worse Now	Much Worse Now
	1	2	3	4	5

3. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much? (Circle one number for each question.)	Yes, Limited a Lot	Yes, Limited a Little	No, Not Limited at All
Vigorous activities , such as running, lifting heavy objects, participating in strenuous sports.	1	2	3
Moderate activities , such as moving a table, pushing a vacuum cleaner, bowling or playing golf	1	2	3
Lifting or carrying groceries	1	2	3
Climbing several flights of stairs	1	2	3
Climbing one flight of stairs	1	2	3
Bending, kneeling, or stooping	1	2	3
Walking more than a mile	1	2	3
Walking several blocks	1	2	3
Walking one block	1	2	3
Bathing or dressing yourself	1	2	3

 MENTOR	Core Gel Breast IDE Clinical Trial			4 YEAR VISIT				
	PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO.	PATIENT NO.	PATIENT INITIALS first middle last		

SF-36 (Page 2 of 3)

4. During the past 4 weeks , have you had any of the following problems with your work or other regular daily activities as a result of your physical health? (Circle one number for each question.)	YES	NO
Cut down on the amount of time you spent on work or other activities	1	2
Accomplished less than you would like	1	2
Were limited in the kind of work or other activities	1	2
Had difficulty performing the work or other activities (for example, it took extra effort)	1	2

5. During the past 4 weeks , have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)? (Circle one number for each question.)	YES	NO
Cut down on the amount of time you spent on work or other activities	1	2
Accomplished less than you would like	1	2
Didn't do work or other activities as carefully as usual	1	2

6. During the past 4 weeks , to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups? (Circle one number)	Not at All	Slightly	Moderately	Quite a Bit	Extremely
	1	2	3	4	5

7. How much bodily pain have you had during the past 4 weeks? (Circle one number)	None	Very Mild	Mild	Moderate	Severe	Very Severe
	1	2	3	4	5	6

8. During the past 4 weeks , how much did pain interfere with your normal work (including both work outside the home and housework)? (Circle one number)	Not at All	A Little Bit	Moderately	Quite a Bit	Extremely
	1	2	3	4	5

 MENTOR	Core Gel Breast IDE Clinical Trial			4 YEAR VISIT				
	PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO.	PATIENT NO.	PATIENT INITIALS first middle last		

SF-36 (Page 3 of 3)

9. These questions are about how you feel and how things have been with you **during the past 4 weeks**. For each question, please indicate the one answer that comes closest to the way you have been feeling. (Circle **one** number for each question.)

How much of the time during the past 4 weeks ...	All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	None of the Time
Did you feel full of pep?	1	2	3	4	5	6
Have you been a very nervous person?	1	2	3	4	5	6
Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
Have you felt calm and peaceful?	1	2	3	4	5	6
Did you have a lot of energy?	1	2	3	4	5	6
Have you felt downhearted and blue?	1	2	3	4	5	6
Did you feel worn out?	1	2	3	4	5	6
Have you been a happy person?	1	2	3	4	5	6
Did you feel tired?	1	2	3	4	5	6

10. During the past 4 weeks , how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)? (Circle one number.)	All of the Time	Most of the Time	Some of the Time	A Little of the Time	None of the Time
	1	2	3	4	5

11. How TRUE or FALSE is each of the following statements for you? (Circle one number for each question.)	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
I seem to get sick a little easier than other people	1	2	3	4	5
I am as healthy as anybody I know	1	2	3	4	5
I expect my health to get worse	1	2	3	4	5
My health is excellent	1	2	3	4	5



MENTOR

**Core Gel Breast
IDE Clinical Trial**

4 YEAR VISIT

PATIENT STUDY ID:

TRIAL NO.
10-009

COUNTRY NO.
0 | 0 | 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last

BODY ESTEEM SCALE (Page 1 of 1)

TO THE PATIENT: On this page are listed a number of body parts and functions. Please read each item and indicate how you feel about this part or function of ***your own body***, using the following scale:

- 1 = Have strong negative feelings
- 2 = Have moderate negative feelings
- 3 = Have no feeling one way or the other
- 4 = Have moderate positive feelings
- 5 = Have strong positive feelings

- | | |
|--|--|
| <input type="checkbox"/> 1. Body Scent | <input type="checkbox"/> 19. Arms |
| <input type="checkbox"/> 2. Appetite | <input type="checkbox"/> 20. Chest |
| <input type="checkbox"/> 3. Nose | <input type="checkbox"/> 21. Appearance of Eyes |
| <input type="checkbox"/> 4. Physical Stamina | <input type="checkbox"/> 22. Cheeks/Cheekbones |
| <input type="checkbox"/> 5. Reflexes | <input type="checkbox"/> 23. Hips |
| <input type="checkbox"/> 6. Lips | <input type="checkbox"/> 24. Legs |
| <input type="checkbox"/> 7. Muscular Strength | <input type="checkbox"/> 25. Physique |
| <input type="checkbox"/> 8. Waist | <input type="checkbox"/> 26. Sex Drive |
| <input type="checkbox"/> 9. Energy Level | <input type="checkbox"/> 27. Feet |
| <input type="checkbox"/> 10. Thighs | <input type="checkbox"/> 28. Sex Organs |
| <input type="checkbox"/> 11. Ears | <input type="checkbox"/> 29. Appearance of Stomach |
| <input type="checkbox"/> 12. Biceps | <input type="checkbox"/> 30. Health |
| <input type="checkbox"/> 13. Chin | <input type="checkbox"/> 31. Sex Activities |
| <input type="checkbox"/> 14. Body Build | <input type="checkbox"/> 32. Body Hair |
| <input type="checkbox"/> 15. Physical Coordination | <input type="checkbox"/> 33. Physical Condition |
| <input type="checkbox"/> 16. Buttocks | <input type="checkbox"/> 34. Face |
| <input type="checkbox"/> 17. Agility | <input type="checkbox"/> 35. Weight |
| <input type="checkbox"/> 18. Width of Shoulders | |



MENTOR

**Core Gel Breast
IDE Clinical Trial**

4 YEAR VISIT

PATIENT STUDY ID:

TRIAL NO.
10-009

COUNTRY NO.
0 | 0 | 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last

MANITOBA CANCER TREATMENT & RESEARCH FOUNDATION FUNCTIONAL LIVING INDEX: CANCER (FLIC)

Page 1 of 3

N/A (not a cancer patient)

TO THE PATIENT: Please indicate your rating by drawing a vertical line (|).

1. Most people experience some feelings of depression at times. Rate how often you feel these feelings.

1	2	3	4	5	6	7
Never						Continually

2. How well are you coping with your everyday stress?

1	2	3	4	5	6	7
Not Well						Very Well

3. How much time do you spend thinking about your illness?

1	2	3	4	5	6	7
Constantly						Never

4. Rate your ability to maintain your usual recreation or leisure activities.

1	2	3	4	5	6	7
Able						Unable

5. Has nausea affected your daily functioning?

1	2	3	4	5	6	7
Not At All						A Great Deal

6. How well do you feel today?

1	2	3	4	5	6	7
Extremely Poor						Extremely Well

7. Do you feel well enough to make a meal or do minor household repairs today?

1	2	3	4	5	6	7
Very Able						Not Able



MENTOR

**Core Gel Breast
IDE Clinical Trial**

4 YEAR VISIT

PATIENT STUDY ID:

TRIAL NO.
10-009

COUNTRY NO.
0 0 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last

MANITOBA CANCER TREATMENT & RESEARCH FOUNDATION FUNCTIONAL LIVING INDEX: CANCER (FLIC)

Page 2 of 3

N/A (not a cancer patient)

8. Rate the degree to which your cancer has imposed a hardship on those closest to you in the past 2 months.

| | | | | | |

1 2 3 4 5 6 7

No Hardship Tremendous Hardship

9. Rate how often you feel discouraged about your life.

| | | | | | |

1 2 3 4 5 6 7

Always Never

10. Rate your satisfaction with your work and your jobs around the house in the past month.

| | | | | | |

1 2 3 4 5 6 7

Very Dissatisfied Very Satisfied

11. How uncomfortable do you feel today?

| | | | | | |

1 2 3 4 5 6 7

Not at All Very Uncomfortable

12. Rate in your opinion, how disruptive your cancer has been to those closest to you in the past 2 weeks.

| | | | | | |

1 2 3 4 5 6 7

Totally Disruptive No Disruption

13. How much is pain or discomfort interfering with your daily activities?

| | | | | | |

1 2 3 4 5 6 7

Not at All A Great Deal

14. Rate the degree to which your cancer has imposed a hardship on you (personally) in the past 2 weeks.

| | | | | | |

1 2 3 4 5 6 7

Tremendous Hardship No Hardship



MENTOR

**Core Gel Breast
IDE Clinical Trial**

4 YEAR VISIT

PATIENT STUDY ID:

TRIAL NO.
10-009

COUNTRY NO.
0 0 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last

MANITOBA CANCER TREATMENT & RESEARCH FOUNDATION FUNCTIONAL LIVING INDEX: CANCER (FLIC)

Page 3 of 3

N/A (not a cancer patient)

15. How much of your usual household tasks are you able to complete?

1	2	3	4	5	6	7
All						None

16. Rate how willing you were to see and spend time with those closest to you, in the past 2 weeks.

1	2	3	4	5	6	7
Unwilling						Very Willing

17. How much nausea have you had in the past 2 weeks?

1	2	3	4	5	6	7
None						A Great Deal

18. Rate the degree to which you are frightened of the future.

1	2	3	4	5	6	7
Constantly Terrified						Not Afraid

19. Rate how willing you were to see and spend time with friends, in the past 2 weeks.

1	2	3	4	5	6	7
Unwilling						Very Willing

20. How much of your pain or discomfort over the past 2 weeks was related to your cancer?

1	2	3	4	5	6	7
None						All

21. Rate your confidence in your prescribed course of treatment.

1	2	3	4	5	6	7
No Confidence						Very Confident

22. How well do you appear today?

1	2	3	4	5	6	7
Extremely Poor						Extremely Well

	Core Gel Breast IDE Clinical Trial	ADVERSE EVENTS				4 YEAR VISIT
PATIENT STUDY ID:	TRIAL NO.	COUNTRY NO.	SITE NO.	PATIENT NO.	PATIENT INITIALS	<input type="checkbox"/> No Adverse Events
10-009	0 0 1				first middle last	

Enter one adverse event per line. If the event was experienced at more than one body site, enter each body site on a separate line.

AE CODE* (See Below)	CAUSALITY 1 = Procedure related 2 = Device related 3 = Unknown 4 = Other	EVENT SIDE 0 = N/A 1 = Right 2 = Left	ASSOCIATED BREAST PAIN 0 = None 1 = Mild 2 = Moderate 3 = Severe	ONSET DATE month day year	SEVERITY 1 = Mild 2 = Moderate 3 = Severe	TREATMENT REQUIRED (check all that apply) 1 = No Treatment 2 = Medication (specify) 3 = Secondary Procedure (enter Procedure Type Code and date below, and complete Secondary Procedures Report for all procedures performed for this date)** 4 = Hospitalization (specify # of days and admission date) 5 = Other (specify)	OUTCOME 1 = Resolved 2 = Ongoing 3 = Death 4 = Unknown	RESOLUTION DATE month day year
<input type="checkbox"/> 1	<input type="checkbox"/> 3	<input type="checkbox"/> 0	<input type="checkbox"/> 0 <input type="checkbox"/> 3		<input type="checkbox"/> 1	<input type="checkbox"/> 1 No Treatment <input type="checkbox"/> 4 ___ days, Date: ___/___/___	<input type="checkbox"/> 1 <input type="checkbox"/> 4	
<input type="checkbox"/> 2	<input type="checkbox"/> 4	<input type="checkbox"/> 1	<input type="checkbox"/> 1		<input type="checkbox"/> 2	<input type="checkbox"/> 2 ___ <input type="checkbox"/> 5 ___	<input type="checkbox"/> 2	
<input type="checkbox"/> 2	<input type="checkbox"/> 4	<input type="checkbox"/> 1	<input type="checkbox"/> 1		<input type="checkbox"/> 3	Procedure Date: ___/___/___ <input type="checkbox"/> 3 Procedure Type Code: ___	<input type="checkbox"/> 3	
<input type="checkbox"/> 1	<input type="checkbox"/> 3	<input type="checkbox"/> 0	<input type="checkbox"/> 0 <input type="checkbox"/> 3		<input type="checkbox"/> 1	<input type="checkbox"/> 1 No Treatment <input type="checkbox"/> 4 ___ days, Date: ___/___/___	<input type="checkbox"/> 1 <input type="checkbox"/> 4	
<input type="checkbox"/> 2	<input type="checkbox"/> 4	<input type="checkbox"/> 1	<input type="checkbox"/> 1		<input type="checkbox"/> 2	<input type="checkbox"/> 2 ___ <input type="checkbox"/> 5 ___	<input type="checkbox"/> 2	
<input type="checkbox"/> 2	<input type="checkbox"/> 4	<input type="checkbox"/> 1	<input type="checkbox"/> 1		<input type="checkbox"/> 3	Procedure Date: ___/___/___ <input type="checkbox"/> 3 Procedure Type Code: ___	<input type="checkbox"/> 3	

****Complete Secondary Procedures Report. If new study device is implanted, complete Re-implantation Report.**

Investigator's Signature _____ month _____ day _____ year

*ADVERSE EVENT CODES	†SECONDARY PROCEDURE TYPE CODES
1 = Asymmetry 2 = Baker II Capsular Contracture with Surgical Intervention 3 = Baker III Capsular Contracture 4 = Baker IV Capsular Contracture 5 = Breast pain not associated with any other complication 6 = Breast—Unacceptably Low Sensitivity 7 = Breast—Unacceptably High Sensitivity 8 = Calcification 9 = Delayed Wound Healing 10 = Extrusion 11 = Granuloma 12 = Hematoma 13 = Hypertrophic Scarring 14 = Infection 15 = Lymphadenopathy 16 = Necrosis 17 = New Diagnosis of Breast Cancer 18 = New Diagnosis of Rheumatic Disease, specify: 19 = Nipple—Unacceptably Low Sensitivity 20 = Nipple—Unacceptably High Sensitivity 21 = Position Change 22 = Ptosis 23 = Rupture 24 = Seroma 25 = Size Change—Patient Request 26 = Size Change—Physician Assessment only 27 = Wrinkling	81 = Biopsy 82 = Capsulectomy 83 = Explanation with Replacement** 84 = Explanation without Replacement 85 = Incision and Drainage 86 = Mastopexy 87 = Open Capsulotomy 88 = Position Change 89 = Scar Revision 90 = Skin Adjustment 91 = Other, specify: _____ 92 = Other, specify: _____ 28 = Lactation Difficulties, specify: _____ 29 = Other, specify: _____ 30 = Other, specify: _____



MENTOR

**Core Gel Breast
IDE Clinical Trial**

5 YEAR VISIT

PATIENT STUDY ID:

TRIAL NO.
10-009

COUNTRY NO.
0 0 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last

Visit Date:

month day year

Missed Visit

BREAST MEASUREMENTS

RIGHT Not Implanted with Study Device

Circumferential Breast Measurement cm

Bra Size (i.e. 32A) N/A (breast absent)

LEFT Not Implanted with Study Device

Circumferential Breast Measurement cm

Bra Size (i.e. 32A) N/A (breast absent)

MAMMOGRAPHY RESULTS

Date of Mammogram:

month year

Not Done

RIGHT

- 1 Birads 0 *Needs additional imaging evaluation*
 - 2 Birads 1 *Negative*
 - 3 Birads 2 *Benign finding*
 - 4 Birads 3 *Probable benign finding—short interval follow-up is suggested*
 - 5 Birads 4 *Suspicious abnormality—biopsy should be considered*
 - 6 Birads 5 *Highly suggestive of malignancy—appropriate action should be taken*
- List abnormality: _____

LEFT

- 1 Birads 0 *Needs additional imaging evaluation*
 - 2 Birads 1 *Negative*
 - 3 Birads 2 *Benign finding*
 - 4 Birads 3 *Probable benign finding—short interval follow-up is suggested*
 - 5 Birads 4 *Suspicious abnormality—biopsy should be considered*
 - 6 Birads 5 *Highly suggestive of malignancy—appropriate action should be taken*
- List abnormality: _____

VISIT REPORT

1. Has the patient become pregnant since the last visit?

- 1 No
- 2 Yes, without complications
- 3 Yes, with complications

Complete Adverse Events Report

2. Has the patient attempted to breastfeed since the last visit?

- 1 No
- 2 Yes, was there adequate milk?
 - 1 No **(Enter code 30 on Adverse Events Report)**
 - 2 Yes

3. Would the patient have this breast surgery again?

- 1 No, reason: _____
- 2 Yes

4. **Breast Cancer Reconstruction Patients only:**

N/A (augmentation patient)

Has the patient received any adjuvant therapies since the last visit?

- 1 No
- 2 Yes, check all that apply:
 - Radiation Therapy
 - Chemotherapy
 - Other, specify: _____

Treating Oncologist

Name: _____

Phone: (_____) _____

 MENTOR	Core Gel Breast IDE Clinical Trial		5 YEAR VISIT			
	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO.	PATIENT NO.	PATIENT INITIALS <small>first middle last</small>	

CAPSULAR CONTRACTURE ASSESSMENT OF PROSTHESIS	
Right Prosthesis is: <input type="radio"/> <input type="checkbox"/> Not Implanted with Study Device 1 <input type="checkbox"/> Baker Class I (normally soft and natural appearance) 2 <input type="checkbox"/> Baker Class II (a natural appearance despite palpable firmness) 3 <input type="checkbox"/> Baker Class III (firm with visible distortion) 4 <input type="checkbox"/> Baker Class IV (obvious spherical distortion)	Left Prosthesis is: <input type="radio"/> <input type="checkbox"/> Not Implanted with Study Device 1 <input type="checkbox"/> Baker Class I (normally soft and natural appearance) 2 <input type="checkbox"/> Baker Class II (a natural appearance despite palpable firmness) 3 <input type="checkbox"/> Baker Class III (firm with visible distortion) 4 <input type="checkbox"/> Baker Class IV (obvious spherical distortion)
Complete Adverse Events Report for Baker III or IV.	

NIPPLE/BREAST SENSITIVITY	
<p>How would patient describe the feeling in nipple(s) and/or breast(s) now?</p> <p><i>If unacceptably high or low at baseline, and sensation remains the same post-operatively, do not complete an Adverse Events Report.</i></p> <p><i>If acceptable at baseline and has become unacceptable post-operatively, complete an Adverse Events Report.</i></p>	
RIGHT <input type="radio"/> <input type="checkbox"/> Not Implanted with Study Device Nipple Sensation is: 1 <input type="checkbox"/> Unacceptably low 2 <input type="checkbox"/> Acceptable 3 <input type="checkbox"/> Unacceptably high 4 <input type="checkbox"/> N/A, nipple absent Breast sensation is: 1 <input type="checkbox"/> Unacceptably low 2 <input type="checkbox"/> Acceptable 3 <input type="checkbox"/> Unacceptably high 4 <input type="checkbox"/> N/A, breast absent	LEFT <input type="radio"/> <input type="checkbox"/> Not Implanted with Study Device Nipple Sensation is: 1 <input type="checkbox"/> Unacceptably low 2 <input type="checkbox"/> Acceptable 3 <input type="checkbox"/> Unacceptably high 4 <input type="checkbox"/> N/A, nipple absent Breast sensation is: 1 <input type="checkbox"/> Unacceptably low 2 <input type="checkbox"/> Acceptable 3 <input type="checkbox"/> Unacceptably high 4 <input type="checkbox"/> N/A, breast absent
Complete Adverse Events Report for any complications or adverse events noted at this visit.	

	Core Gel Breast IDE Clinical Trial			5 YEAR VISIT		
	PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO.	PATIENT NO.	PATIENT INITIALS first middle last

INVESTIGATOR-COMPLETED RHEUMATIC DISEASE DIAGNOSIS QUESTIONNAIRE No diagnosis made

Has the patient been diagnosed by a RHEUMATOLOGIST for any of the following **since the last visit**?
If YES, complete Adverse Event Report.

RHEUMATIC DISEASE	NO YES		DATE OF ONSET (if known)	
			month	year
Connective Tissue Disorders: SLE	<input type="checkbox"/>	<input type="checkbox"/>		
Sjogren's Syndrome	<input type="checkbox"/>	<input type="checkbox"/>		
Scleroderma	<input type="checkbox"/>	<input type="checkbox"/>		
Polymyositis	<input type="checkbox"/>	<input type="checkbox"/>		
Other Connective Tissue Disorders	<input type="checkbox"/>	<input type="checkbox"/>		
Inflammatory Arthritis: Rheumatoid Arthritis	<input type="checkbox"/>	<input type="checkbox"/>		
Crystalline Arthritis	<input type="checkbox"/>	<input type="checkbox"/>		
Infectious Arthritis	<input type="checkbox"/>	<input type="checkbox"/>		
Spondyarthropathies	<input type="checkbox"/>	<input type="checkbox"/>		
Other Inflammatory Arthritis	<input type="checkbox"/>	<input type="checkbox"/>		
Non-Inflammatory Rheumatic Conditions: Osteoarthritis	<input type="checkbox"/>	<input type="checkbox"/>		
Fibromyalgia	<input type="checkbox"/>	<input type="checkbox"/>		
Chronic Fatigue	<input type="checkbox"/>	<input type="checkbox"/>		
Other Mechanical or Degenerative	<input type="checkbox"/>	<input type="checkbox"/>		
Other, specify: _____	<input type="checkbox"/>	<input type="checkbox"/>		
Other, specify: _____	<input type="checkbox"/>	<input type="checkbox"/>		

Disease must be diagnosed by a rheumatologist.

Rheumatologist who made diagnosis:

Name: _____

Address: _____

Phone: (_____) _____

**MENTOR****Core Gel Breast
IDE Clinical Trial****5 YEAR VISIT****PATIENT STUDY ID:**TRIAL NO.
10-009COUNTRY NO.
0 0 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last**RHEUMATOLOGY SYMPTOMS (Page 1 of 2)**1 No symptoms; patient not referred to rheumatologistPlease check any **current** symptoms which:

1. The patient experiences on a regular basis
2. The cause is unknown and cannot be attributed to any patient activity.

RHEUMATOLOGY SYMPTOM	STATUS SINCE LAST VISIT		DATE OF ONSET (only if new since last visit)		STATUS AS OF THIS VISIT	
	CONTINUING	NEW	month	year	RESOLVED	CONTINUING
Loss of weight without dieting	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Insomnia	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Weakness	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Exhaustion	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Joint swelling	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Heel pain	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Frequent muscle cramps	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Numbness of feet	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Ringing in ears	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Pain/grittiness in eyes	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Dryness of eyes, nose	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Pain on swallowing or chewing	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Neck pain/stiffness	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Pain on breathing	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Heart murmurs	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Loss of appetite	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Persistent fever	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Night sweats	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Generalized aching	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Loss of height	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Joint pain	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Frequent muscle pain	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>

**MENTOR****Core Gel Breast
IDE Clinical Trial****5 YEAR VISIT****PATIENT STUDY ID:**TRIAL NO.
10-009COUNTRY NO.
0 0 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last**RHEUMATOLOGY SYMPTOMS (Page 2 of 2)**Please check any **current** symptoms which:

1. The patient experiences on a regular basis
2. The cause is unknown and cannot be attributed to any patient activity.

RHEUMATOLOGY SYMPTOM	STATUS SINCE LAST VISIT		DATE OF ONSET (only if new since last visit)		STATUS AS OF THIS VISIT	
	CONTINUING	NEW	month	year	RESOLVED	CONTINUING
Numbness of hands	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Jaw pain	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Open sores	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Redness of eyes	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Dryness of mouth	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Back pain/stiffness	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Severe chest pains	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Chronic cough	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Difficulty swallowing	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Frequent, severe or persistent diarrhea or constipation	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Severe rashes	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Frequent muscle cramps	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Severe dryness of skin	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Tender lumps/bumps	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Excessive sensitivity to sun	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Color changes on hands or feet with cold exposure	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Joint pain	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Frequent hives	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Numbness of hands	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Tightness of skin	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Unusual hair loss	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Tenderness of scalp	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Severe bruising with little or no injury	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>



**Core Gel Breast
IDE Clinical Trial**

5 YEAR VISIT

PATIENT STUDY ID:	TRIAL NO.	COUNTRY NO.			SITE NO.	PATIENT NO.	PATIENT INITIALS		
	10-009	0	0	1			first	middle	last

RHEUMATOLOGICAL PHYSICAL EXAMINATION (Page 1 of 2)

No symptoms present

Check the box for each physical finding noted to be present and outside normal limits.

PHYSICAL FINDING	STATUS SINCE LAST VISIT		DATE OF ONSET (only if new since last visit)		STATUS AS OF THIS VISIT	
	CONTINUING	NEW	month	year	RESOLVED	CONTINUING
Muscle weakness: Headlift from supine position against gravity	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Inability to raise arms	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Inability to get out of chair	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Joint swellings: Wrists	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Digits	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Elbows	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Knees	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Ankles	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Joint deformities and flexion contracture: Boutonnière ¹	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Ulnar drift ²	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Swan neck ³	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Trigger fingers	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Joint tenderness	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Grip strength and motion-finger to palm crease (normal = 0 cm)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Neck motion—chin to chest or sternum (normal = 0 cm)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Chest expansion (normal = at least 5 cm)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Occiput to wall (normal = 0 cm)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Jaw motion (normally upper-lower incisors 3 cm)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Back motion—measure 10 cm above posterior supine iliac spines— with forward bending motion at least 5 cm from first point (total distance at least 15 cm)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>

¹**Boutonnière** - Contractures of hand musculature characterized by proximal interphalangeal joint flexion and distal interphalangeal joint hyperextension.

³**Swan Neck** - Finger deformity characterized by flexion of distal interphalangeal joints and hyperflexion of the proximal interphalangeal joints due to hypermobility.

²**Ulnar Drift** - Joint change at the metacarpophalangeal joints. Long axis of fingers deviate in an ulnar direction.

**MENTOR****Core Gel Breast
IDE Clinical Trial****5 YEAR VISIT****PATIENT STUDY ID:**TRIAL NO.
10-009COUNTRY NO.
0 | 0 | 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last**RHEUMATOLOGICAL PHYSICAL EXAMINATION (Page 2 of 2)**

Check the box for each physical finding noted to be present and outside normal limits.

PHYSICAL FINDING	POSSIBLE INDICATION	STATUS SINCE LAST VISIT		DATE OF ONSET (only if new since last visit)		STATUS AS OF THIS VISIT	
		CONTINUING	NEW	month	year	RESOLVED	CONTINUING
Hair loss	<i>Lupus, Scleroderma</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Skin tightness, especially face and hands	<i>Scleroderma</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Raynaud's phenomenon	<i>Lupus, Scleroderma</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Calcinosis over tibia, ulna, elbows	<i>Scleroderma, Dermatomyositis</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Swollen digits	<i>Juvenile RA, Reiter's syndrome, Psoriatic arthritis, Early scleroderma, Reflex sympathetic dystrophy</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Erythema over knuckles	<i>Dermatomyositis</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Bluish hue color on eyelids	<i>Dermatomyositis</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Non-tender lumps or nodules on elbows	<i>Rheumatoid gout</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Tender lumps-tibia	<i>Erythema nodosum</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Painless eye redness	<i>Conjunctivitis</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Painful eye redness with decreased vision, small pupils	<i>Uveitis</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Tenderness—insertion of deltoids	<i>Polymyalgia rheumatica</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Muscle tenderness	<i>Polymyositis</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Nail pittings	<i>Psoriatic arthritis, Reiter's syndrome</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Tinels or Phalen's signs	<i>Carpal tunnel syndrome</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Skin rashes	<i>Discoid lupus</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>

Does the patient require an examination by a rheumatologist?

 No Yes, record rheumatologist's findings:



Core Gel Breast IDE Clinical Trial

ADVERSE EVENTS

5 YEAR VISIT

PATIENT STUDY ID: TRIAL NO. **10-009** COUNTRY NO. **0 0 1** SITE NO. PATIENT NO. PATIENT INITIALS first middle last No Adverse Events

Enter one adverse event per line. If the event was experienced at more than one body site, enter each body site on a separate line.

AE CODE* (See Below)	CAUSALITY 1 = Procedure related 2 = Device related 3 = Unknown 4 = Other	EVENT SIDE 0 = N/A 1 = Right 2 = Left	ASSOCIATED BREAST PAIN 0 = None 1 = Mild 2 = Moderate 3 = Severe	ONSET DATE month day year	SEVERITY 1 = Mild 2 = Moderate 3 = Severe	TREATMENT REQUIRED (check all that apply) 1 = No Treatment 2 = Medication (specify) 3 = Secondary Procedure (enter Procedure Type Code and date below, and complete Secondary Procedures Report for all procedures performed for this date)** 4 = Hospitalization (specify # of days and admission date) 5 = Other (specify)	OUTCOME 1 = Resolved 2 = Ongoing 3 = Death 4 = Unknown	RESOLUTION DATE month day year
<input type="checkbox"/> 1	<input type="checkbox"/> 3	<input type="checkbox"/> 0	<input type="checkbox"/> 0 <input type="checkbox"/> 3	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 4 days, Date: ___/___/___	<input type="checkbox"/> 1 <input type="checkbox"/> 4	
<input type="checkbox"/> 2	<input type="checkbox"/> 4	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 5 Procedure Date: ___/___/___	<input type="checkbox"/> 2	
<input type="checkbox"/> 1	<input type="checkbox"/> 3	<input type="checkbox"/> 0	<input type="checkbox"/> 0 <input type="checkbox"/> 3	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 4 days, Date: ___/___/___	<input type="checkbox"/> 1 <input type="checkbox"/> 4	
<input type="checkbox"/> 2	<input type="checkbox"/> 4	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 5 Procedure Date: ___/___/___	<input type="checkbox"/> 2	
<input type="checkbox"/> 1	<input type="checkbox"/> 3	<input type="checkbox"/> 0	<input type="checkbox"/> 0 <input type="checkbox"/> 3	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 4 days, Date: ___/___/___	<input type="checkbox"/> 1 <input type="checkbox"/> 4	
<input type="checkbox"/> 2	<input type="checkbox"/> 4	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 5 Procedure Date: ___/___/___	<input type="checkbox"/> 2	
<input type="checkbox"/> 1	<input type="checkbox"/> 3	<input type="checkbox"/> 0	<input type="checkbox"/> 0 <input type="checkbox"/> 3	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 4 days, Date: ___/___/___	<input type="checkbox"/> 1 <input type="checkbox"/> 4	
<input type="checkbox"/> 2	<input type="checkbox"/> 4	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 5 Procedure Date: ___/___/___	<input type="checkbox"/> 2	
<input type="checkbox"/> 1	<input type="checkbox"/> 3	<input type="checkbox"/> 0	<input type="checkbox"/> 0 <input type="checkbox"/> 3	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 4 days, Date: ___/___/___	<input type="checkbox"/> 1 <input type="checkbox"/> 4	
<input type="checkbox"/> 2	<input type="checkbox"/> 4	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 5 Procedure Date: ___/___/___	<input type="checkbox"/> 2	
<input type="checkbox"/> 1	<input type="checkbox"/> 3	<input type="checkbox"/> 0	<input type="checkbox"/> 0 <input type="checkbox"/> 3	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 4 days, Date: ___/___/___	<input type="checkbox"/> 1 <input type="checkbox"/> 4	
<input type="checkbox"/> 2	<input type="checkbox"/> 4	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 5 Procedure Date: ___/___/___	<input type="checkbox"/> 2	
<input type="checkbox"/> 1	<input type="checkbox"/> 3	<input type="checkbox"/> 0	<input type="checkbox"/> 0 <input type="checkbox"/> 3	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 4 days, Date: ___/___/___	<input type="checkbox"/> 1 <input type="checkbox"/> 4	
<input type="checkbox"/> 2	<input type="checkbox"/> 4	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 5 Procedure Date: ___/___/___	<input type="checkbox"/> 2	

**Complete Secondary Procedures Report. If new study device is implanted, complete Re-implantation Report.

Investigator's Signature _____ month _____ day _____ year

*ADVERSE EVENT CODES	+SECONDARY PROCEDURE TYPE CODES
1 = Asymmetry 2 = Baker II Capsular Contracture with Surgical Intervention 3 = Baker III Capsular Contracture 4 = Baker IV Capsular Contracture 5 = Breast pain not associated with any other complication 6 = Breast—Unacceptably Low Sensitivity 7 = Breast—Unacceptably High Sensitivity 8 = Calcification 9 = Delayed Wound Healing 10 = Extrusion 11 = Granuloma 12 = Hematoma 13 = Hypertrophic Scarring 14 = Infection 15 = Lymphadenopathy 16 = Necrosis 17 = New Diagnosis of Breast Cancer 18 = New Diagnosis of Rheumatic Disease, specify: 19 = Nipple—Unacceptably Low Sensitivity 20 = Nipple—Unacceptably High Sensitivity 21 = Position Change 22 = Ptosis 23 = Rupture 24 = Seroma 25 = Size Change—Patient Request 26 = Size Change—Physician Assessment only 27 = Wrinkling 28 = Lactation Difficulties, specify: 29 = Other, specify: 30 = Other, specify:	81 = Biopsy 82 = Capsulectomy 83 = Explanation with Replacement** 84 = Explanation without Replacement 85 = Incision and Drainage 86 = Mastopexy 87 = Open Capsulotomy 88 = Position Change 89 = Scar Revision 90 = Skin Adjustment 91 = Other, specify: 92 = Other, specify:



MENTOR

**Core Gel Breast
IDE Clinical Trial**

6 YEAR VISIT

PATIENT STUDY ID:

TRIAL NO.
10-009

COUNTRY NO.
0 0 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last

Visit Date:

month day year

Missed Visit

BREAST MEASUREMENTS

RIGHT Not Implanted with Study Device

Circumferential Breast Measurement cm

Bra Size (i.e. 32A) N/A (breast absent)

LEFT Not Implanted with Study Device

Circumferential Breast Measurement cm

Bra Size (i.e. 32A) N/A (breast absent)

MAMMOGRAPHY RESULTS

Date of Mammogram:

month year

Not Done

RIGHT

- Birads 0 Needs additional imaging evaluation
 - Birads 1 Negative
 - Birads 2 Benign finding
 - Birads 3 Probable benign finding—short interval follow-up is suggested
 - Birads 4 Suspicious abnormality—biopsy should be considered
 - Birads 5 Highly suggestive of malignancy—appropriate action should be taken
- List abnormality: _____

LEFT

- Birads 0 Needs additional imaging evaluation
 - Birads 1 Negative
 - Birads 2 Benign finding
 - Birads 3 Probable benign finding—short interval follow-up is suggested
 - Birads 4 Suspicious abnormality—biopsy should be considered
 - Birads 5 Highly suggestive of malignancy—appropriate action should be taken
- List abnormality: _____

VISIT REPORT

1. Has the patient become pregnant since the last visit?

- No
- Yes, without complications
- Yes, with complications

Complete Adverse Events Report

2. Has the patient attempted to breastfeed since the last visit?

- No
- Yes, was there adequate milk?
 - No (Enter code 30 on Adverse Events Report)
 - Yes

3. Would the patient have this breast surgery again?

- No, reason: _____
- Yes

4. **Breast Cancer Reconstruction Patients only:**

N/A (augmentation patient)

Has the patient received any adjuvant therapies since the last visit?

- No
- Yes, check all that apply:
 - Radiation Therapy
 - Chemotherapy
 - Other, specify: _____

Treating Oncologist

Name: _____

Phone: (_____) _____

	Core Gel Breast IDE Clinical Trial		6 YEAR VISIT			
	PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO.	PATIENT NO.	PATIENT INITIALS first middle last

CAPSULAR CONTRACTURE ASSESSMENT OF PROSTHESIS	
Right Prosthesis is: <input type="radio"/> <input type="checkbox"/> Not Implanted with Study Device 1 <input type="checkbox"/> Baker Class I (normally soft and natural appearance) 2 <input type="checkbox"/> Baker Class II (a natural appearance despite palpable firmness) 3 <input type="checkbox"/> Baker Class III (firm with visible distortion) 4 <input type="checkbox"/> Baker Class IV (obvious spherical distortion)	Left Prosthesis is: <input type="radio"/> <input type="checkbox"/> Not Implanted with Study Device 1 <input type="checkbox"/> Baker Class I (normally soft and natural appearance) 2 <input type="checkbox"/> Baker Class II (a natural appearance despite palpable firmness) 3 <input type="checkbox"/> Baker Class III (firm with visible distortion) 4 <input type="checkbox"/> Baker Class IV (obvious spherical distortion)
Complete Adverse Events Report for Baker III or IV.	

NIPPLE/BREAST SENSITIVITY	
<p style="text-align: center;">How would patient describe the feeling in nipple(s) and/or breast(s) now?</p> <p style="text-align: center;"><i>If unacceptably high or low at baseline, and sensation remains the same post-operatively, do not complete an Adverse Events Report.</i></p> <p style="text-align: center;"><i>If acceptable at baseline and has become unacceptable post-operatively, complete an Adverse Events Report.</i></p>	
RIGHT <input type="radio"/> <input type="checkbox"/> Not Implanted with Study Device Nipple Sensation is: 1 <input type="checkbox"/> Unacceptably low 2 <input type="checkbox"/> Acceptable 3 <input type="checkbox"/> Unacceptably high 4 <input type="checkbox"/> N/A, nipple absent Breast sensation is: 1 <input type="checkbox"/> Unacceptably low 2 <input type="checkbox"/> Acceptable 3 <input type="checkbox"/> Unacceptably high 4 <input type="checkbox"/> N/A, breast absent	LEFT <input type="radio"/> <input type="checkbox"/> Not Implanted with Study Device Nipple Sensation is: 1 <input type="checkbox"/> Unacceptably low 2 <input type="checkbox"/> Acceptable 3 <input type="checkbox"/> Unacceptably high 4 <input type="checkbox"/> N/A, nipple absent Breast sensation is: 1 <input type="checkbox"/> Unacceptably low 2 <input type="checkbox"/> Acceptable 3 <input type="checkbox"/> Unacceptably high 4 <input type="checkbox"/> N/A, breast absent
Complete Adverse Events Report for any complications or adverse events noted at this visit.	

**MENTOR****Core Gel Breast
IDE Clinical Trial****6 YEAR VISIT****PATIENT STUDY ID:**TRIAL NO.
10-009COUNTRY NO.
0 | 0 | 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last**INVESTIGATOR-COMPLETED RHEUMATIC DISEASE DIAGNOSIS QUESTIONNAIRE** No diagnosis madeHas the patient been diagnosed by a RHEUMATOLOGIST for any of the following **since the last visit?****If YES, complete Adverse Event Report.**

RHEUMATIC DISEASE	NO YES		DATE OF ONSET (if known)	
			month	year
Connective Tissue Disorders: SLE	<input type="checkbox"/>	<input type="checkbox"/>		
Sjogren's Syndrome	<input type="checkbox"/>	<input type="checkbox"/>		
Scleroderma	<input type="checkbox"/>	<input type="checkbox"/>		
Polymyositis	<input type="checkbox"/>	<input type="checkbox"/>		
Other Connective Tissue Disorders	<input type="checkbox"/>	<input type="checkbox"/>		
Inflammatory Arthritis: Rheumatoid Arthritis	<input type="checkbox"/>	<input type="checkbox"/>		
Crystalline Arthritis	<input type="checkbox"/>	<input type="checkbox"/>		
Infectious Arthritis	<input type="checkbox"/>	<input type="checkbox"/>		
Spondyarthropathies	<input type="checkbox"/>	<input type="checkbox"/>		
Other Inflammatory Arthritis	<input type="checkbox"/>	<input type="checkbox"/>		
Non-Inflammatory Rheumatic Conditions: Osteoarthritis	<input type="checkbox"/>	<input type="checkbox"/>		
Fibromyalgia	<input type="checkbox"/>	<input type="checkbox"/>		
Chronic Fatigue	<input type="checkbox"/>	<input type="checkbox"/>		
Other Mechanical or Degenerative	<input type="checkbox"/>	<input type="checkbox"/>		
Other, specify: _____	<input type="checkbox"/>	<input type="checkbox"/>		
Other, specify: _____	<input type="checkbox"/>	<input type="checkbox"/>		

Disease must be diagnosed by a rheumatologist.

Rheumatologist who made diagnosis:

Name: _____

Address: _____

Phone: (_____) _____

**MENTOR****Core Gel Breast
IDE Clinical Trial****6 YEAR VISIT****PATIENT STUDY ID:**TRIAL NO.
10-009COUNTRY NO.
0 0 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last**RHEUMATOLOGY SYMPTOMS (Page 1 of 2)**1 No symptoms; patient not referred to rheumatologistPlease check any **current** symptoms which:

1. The patient experiences on a regular basis
2. The cause is unknown and cannot be attributed to any patient activity.

RHEUMATOLOGY SYMPTOM	STATUS SINCE LAST VISIT		DATE OF ONSET (only if new since last visit)		STATUS AS OF THIS VISIT	
	CONTINUING	NEW	month	year	RESOLVED	CONTINUING
Loss of weight without dieting	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Insomnia	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Weakness	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Exhaustion	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Joint swelling	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Heel pain	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Frequent muscle cramps	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Numbness of feet	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Ringing in ears	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Pain/grittiness in eyes	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Dryness of eyes, nose	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Pain on swallowing or chewing	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Neck pain/stiffness	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Pain on breathing	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Heart murmurs	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Loss of appetite	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Persistent fever	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Night sweats	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Generalized aching	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Loss of height	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Joint pain	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Frequent muscle pain	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>



**Core Gel Breast
IDE Clinical Trial**

6 YEAR VISIT

PATIENT STUDY ID:	TRIAL NO.	COUNTRY NO.			SITE NO.	PATIENT NO.	PATIENT INITIALS		
	10-009	0	0	1			first	middle	last

RHEUMATOLOGY SYMPTOMS (Page 2 of 2)

Please check any **current** symptoms which:

1. The patient experiences on a regular basis
2. The cause is unknown and cannot be attributed to any patient activity.

RHEUMATOLOGY SYMPTOM	STATUS SINCE LAST VISIT		DATE OF ONSET (only if new since last visit)		STATUS AS OF THIS VISIT	
	CONTINUING	NEW	month	year	RESOLVED	CONTINUING
Numbness of hands	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Jaw pain	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Open sores	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Redness of eyes	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Dryness of mouth	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Back pain/stiffness	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Severe chest pains	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Chronic cough	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Difficulty swallowing	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Frequent, severe or persistent diarrhea or constipation	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Severe rashes	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Frequent muscle cramps	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Severe dryness of skin	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Tender lumps/bumps	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Excessive sensitivity to sun	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Color changes on hands or feet with cold exposure	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Joint pain	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Frequent hives	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Numbness of hands	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Tightness of skin	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Unusual hair loss	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Tenderness of scalp	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Severe bruising with little or no injury	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>



**Core Gel Breast
IDE Clinical Trial**

6 YEAR VISIT

PATIENT STUDY ID:	TRIAL NO.	COUNTRY NO.			SITE NO.	PATIENT NO.	PATIENT INITIALS		
	10-009	0	0	1			first	middle	last

RHEUMATOLOGICAL PHYSICAL EXAMINATION (Page 1 of 2)

No symptoms present

Check the box for each physical finding noted to be present and outside normal limits.

PHYSICAL FINDING	STATUS SINCE LAST VISIT		DATE OF ONSET (only if new since last visit)		STATUS AS OF THIS VISIT	
	CONTINUING	NEW	month	year	RESOLVED	CONTINUING
Muscle weakness: Headlift from supine position against gravity	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Inability to raise arms	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Inability to get out of chair	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Joint swellings: Wrists	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Digits	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Elbows	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Knees	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Ankles	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Joint deformities and flexion contracture: Boutonnière ¹	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Ulnar drift ²	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Swan neck ³	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Trigger fingers	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Joint tenderness	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Grip strength and motion-finger to palm crease (normal = 0 cm)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Neck motion—chin to chest or sternum (normal = 0 cm)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Chest expansion (normal = at least 5 cm)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Occiput to wall (normal = 0 cm)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Jaw motion (normally upper-lower incisors 3 cm)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Back motion—measure 10 cm above posterior supine iliac spines— with forward bending motion at least 5 cm from first point (total distance at least 15 cm)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>

¹**Boutonnière** - Contractures of hand musculature characterized by proximal interphalangeal joint flexion and distal interphalangeal joint hyperextension.

³**Swan Neck** - Finger deformity characterized by flexion of distal interphalangeal joints and hyperflexion of the proximal interphalangeal joints due to hypermobility.

²**Ulnar Drift** - Joint change at the metacarpophalangeal joints. Long axis of fingers deviate in an ulnar direction.

**MENTOR****Core Gel Breast
IDE Clinical Trial****6 YEAR VISIT****PATIENT STUDY ID:**TRIAL NO.
10-009COUNTRY NO.
0 0 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last**RHEUMATOLOGICAL PHYSICAL EXAMINATION (Page 2 of 2)**

Check the box for each physical finding noted to be present and outside normal limits.

PHYSICAL FINDING	POSSIBLE INDICATION	STATUS SINCE LAST VISIT		DATE OF ONSET (only if new since last visit)		STATUS AS OF THIS VISIT	
		CONTINUING	NEW	month	year	RESOLVED	CONTINUING
Hair loss	<i>Lupus, Scleroderma</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Skin tightness, especially face and hands	<i>Scleroderma</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Raynaud's phenomenon	<i>Lupus, Scleroderma</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Calcinosis over tibia, ulna, elbows	<i>Scleroderma, Dermatomyositis</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Swollen digits	<i>Juvenile RA, Reiter's syndrome, Psoriatic arthritis, Early scleroderma, Reflex sympathetic dystrophy</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Erythema over knuckles	<i>Dermatomyositis</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Bluish hue color on eyelids	<i>Dermatomyositis</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Non-tender lumps or nodules on elbows	<i>Rheumatoid gout</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Tender lumps-tibia	<i>Erythema nodosum</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Painless eye redness	<i>Conjunctivitis</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Painful eye redness with decreased vision, small pupils	<i>Uveitis</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Tenderness—insertion of deltoids	<i>Polymyalgia rheumatica</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Muscle tenderness	<i>Polymyositis</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Nail pittings	<i>Psoriatic arthritis, Reiter's syndrome</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Tinels or Phalen's signs	<i>Carpal tunnel syndrome</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Skin rashes	<i>Discoid lupus</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>

Does the patient require an examination by a rheumatologist?

 No Yes, record rheumatologist's findings:

 MENTOR	Core Gel Breast IDE Clinical Trial			6 YEAR VISIT			
	PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO.	PATIENT NO.	PATIENT INITIALS first middle last	

ROSENBERG SELF-ESTEEM SCALE (Page 1 of 1)

TO THE PATIENT: Below are some statements with which some people agree and disagree. Please read each statement and check **one** response to each statement.

	Strongly Agree 1	Agree 2	Disagree 3	Strongly Disagree 4
1. I feel that I am a person of worth, at least on an equal basis with others.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. I feel that I have a number of good qualities.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. All in all, I am inclined to feel that I am a failure.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. I am able to do things as well as most people.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. I feel I do not have much of which to be proud.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. I take a positive attitude towards myself.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. On the whole, I am satisfied with myself.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. I wish I could have more respect for myself.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. I certainly feel useless at times.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. At times I think I am no good at all.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

 MENTOR	Core Gel Breast IDE Clinical Trial			6 YEAR VISIT		
	PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO.	PATIENT NO.	PATIENT INITIALS first middle last

TENNESSEE SELF-CONCEPT SCALE (Page 1 of 4)

TO THE PATIENT: The statements below are to help you describe yourself as you see yourself. Please respond to them as if you were describing yourself **to yourself**. Do not omit any item. Read each statement carefully, then select one of the five responses listed below. On the test, put a **circle** around the response you chose. If you want to change an answer after you have circled it, do not erase it but put an X mark through the response and then circle the response you want.

<i>Remember, put a circle around the response number you have chosen for each statement.</i>	Completely False	Mostly False	Partly True and Partly False	Mostly True	Completely True
1. I have a healthy body.	1	2	3	4	5
2. I am an attractive person.	1	2	3	4	5
3. I consider myself a sloppy person.	1	2	3	4	5
4. I am a decent sort of person.	1	2	3	4	5
5. I am an honest person.	1	2	3	4	5
6. I am a bad person.	1	2	3	4	5
7. I am a cheerful person.	1	2	3	4	5
8. I am a calm and easygoing person.	1	2	3	4	5
9. I am a nobody.	1	2	3	4	5
10. I have a family that would always help me in any kind of trouble.	1	2	3	4	5
11. I am a member of a happy family.	1	2	3	4	5
12. My friends have no confidence in me.	1	2	3	4	5
13. I am a friendly person.	1	2	3	4	5
14. I am popular with men.	1	2	3	4	5
15. I am not interested in what other people do.	1	2	3	4	5
16. I do not always tell the truth.	1	2	3	4	5
17. I get angry sometimes.	1	2	3	4	5
18. I like to look nice and neat all the time.	1	2	3	4	5
19. I am full of aches and pains.	1	2	3	4	5
20. I am a sick person.	1	2	3	4	5
21. I am a religious person.	1	2	3	4	5
22. I am a moral failure.	1	2	3	4	5
23. I am a morally weak person.	1	2	3	4	5

 MENTOR	Core Gel Breast IDE Clinical Trial			6 YEAR VISIT				
	PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO.	PATIENT NO.	PATIENT INITIALS first middle last		

TENNESSEE SELF-CONCEPT SCALE (Page 2 of 4)

<i>Remember, put a circle around the response number you have chosen for each statement.</i>	Completely False	Mostly False	Partly True and Partly False	Mostly True	Completely True
24. I have a lot of self-control.	1	2	3	4	5
25. I am a hateful person.	1	2	3	4	5
26. I am losing my mind.	1	2	3	4	5
27. I am an important person to my friends and family.	1	2	3	4	5
28. I am not loved by my family.	1	2	3	4	5
29. I feel that my family doesn't trust me.	1	2	3	4	5
30. I am popular with women.	1	2	3	4	5
31. I am mad at the whole world.	1	2	3	4	5
32. I am hard to be friendly with.	1	2	3	4	5
33. Once in a while I think of things too bad to talk about.	1	2	3	4	5
34. Sometimes when I am not feeling well, I am cross.	1	2	3	4	5
35. I am neither too fat nor too thin.	1	2	3	4	5
36. I like my looks just the way they are.	1	2	3	4	5
37. I would like to change some parts of my body.	1	2	3	4	5
38. I am satisfied with my moral behavior.	1	2	3	4	5
39. I am satisfied with my relationship to God.	1	2	3	4	5
40. I ought to go to church more.	1	2	3	4	5
41. I am satisfied to be just what I am.	1	2	3	4	5
42. I am just as nice as I should be.	1	2	3	4	5
43. I despise myself.	1	2	3	4	5
44. I am satisfied with my family relationships.	1	2	3	4	5
45. I understand my family as well as I should.	1	2	3	4	5
46. I should trust my family more.	1	2	3	4	5
47. I am as sociable as I want to be.	1	2	3	4	5
48. I try to please others, but I don't overdo it.	1	2	3	4	5
49. I am no good at all from a social standpoint.	1	2	3	4	5

 MENTOR	Core Gel Breast IDE Clinical Trial			6 YEAR VISIT				
	PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO.	PATIENT NO.	PATIENT INITIALS first middle last		

TENNESSEE SELF-CONCEPT SCALE (Page 3 of 4)

<i>Remember, put a circle around the response number you have chosen for each statement.</i>	Completely False	Mostly False	Partly True and Partly False	Mostly True	Completely True
50. I do not like everyone I know.	1	2	3	4	5
51. Once in a while, I laugh at a dirty joke.	1	2	3	4	5
52. I am neither too tall nor too short.	1	2	3	4	5
53. I don't feel as well as I should.	1	2	3	4	5
54. I should have more sex appeal.	1	2	3	4	5
55. I am as religious as I want to be.	1	2	3	4	5
56. I wish I could be more trustworthy.	1	2	3	4	5
57. I shouldn't tell so many lies.	1	2	3	4	5
58. I am as smart as I want to be.	1	2	3	4	5
59. I am not the person I would like to be.	1	2	3	4	5
60. I wish I didn't give up as easily as I do.	1	2	3	4	5
61. I treat my parents as well as I should. <i>(Use past tense if parents are not living.)</i>	1	2	3	4	5
62. I am too sensitive to things my family says.	1	2	3	4	5
63. I should love my family more.	1	2	3	4	5
64. I am satisfied with the way I treat other people.	1	2	3	4	5
65. I should be more polite to others.	1	2	3	4	5
66. I ought to get along better with other people.	1	2	3	4	5
67. I gossip a little at times.	1	2	3	4	5
68. At times I feel like swearing.	1	2	3	4	5
69. I take good care of myself physically.	1	2	3	4	5
70. I try to be careful about my appearance.	1	2	3	4	5
71. I often act like I am "all thumbs".	1	2	3	4	5
72. I am true to my religion in my everyday life.	1	2	3	4	5
73. I try to change when I know I'm doing things that are wrong.	1	2	3	4	5
74. I sometimes do very bad things.	1	2	3	4	5
75. I can always take care of myself in any situation.	1	2	3	4	5

 MENTOR	Core Gel Breast IDE Clinical Trial			6 YEAR VISIT				
	PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO.	PATIENT NO.	PATIENT INITIALS first middle last		

TENNESSEE SELF-CONCEPT SCALE (Page 4 of 4)

<i>Remember, put a circle around the response number you have chosen for each statement.</i>	Completely False	Mostly False	Partly True and Partly False	Mostly True	Completely True
76. I take the blame for things without getting mad.	1	2	3	4	5
77. I do things without thinking about them first.	1	2	3	4	5
78. I try to play fair with my friends and family.	1	2	3	4	5
79. I take a real interest in my family.	1	2	3	4	5
80. I give in to my parents. <i>(Use past tense if parents are not living.)</i>	1	2	3	4	5
81. I try to understand the other fellow's point of view.	1	2	3	4	5
82. I get along well with other people.	1	2	3	4	5
83. I do not forgive others easily.	1	2	3	4	5
84. I would rather win than lose in a game.	1	2	3	4	5
85. I feel good most of the time.	1	2	3	4	5
86. I do poorly in sports and games.	1	2	3	4	5
87. I am a poor sleeper.	1	2	3	4	5
88. I do what is right most of the time.	1	2	3	4	5
89. I sometimes use unfair means to get ahead.	1	2	3	4	5
90. I have trouble doing the things that are right.	1	2	3	4	5
91. I solve my problems quite easily.	1	2	3	4	5
92. I change my mind a lot.	1	2	3	4	5
93. I try to run away from my problems.	1	2	3	4	5
94. I do my share of work at home.	1	2	3	4	5
95. I quarrel with my family.	1	2	3	4	5
96. I do not act like my family thinks I should.	1	2	3	4	5
97. I see good points in all the people I meet.	1	2	3	4	5
98. I do not feel at ease with other people.	1	2	3	4	5
99. I find it hard to talk with strangers.	1	2	3	4	5
100. Once in a while I put off until tomorrow what I ought to do today.	1	2	3	4	5

 MENTOR	Core Gel Breast IDE Clinical Trial			6 YEAR VISIT				
	PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO.	PATIENT NO.	PATIENT INITIALS first middle last		

SF-36 (Page 1 of 3)

TO THE PATIENT: This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Answer each question by circling **one** number. If you are unsure about how to answer a question, please give the best answer you can.

1. In general, would you say your health is: (Circle one number)	Excellent	Very Good	Good	Fair	Poor
	1	2	3	4	5

2. Compared to one year ago, how would you rate your health in general now ? (Circle one number)	Much Better Now	Somewhat Better Now	About the Same	Somewhat Worse Now	Much Worse Now
	1	2	3	4	5

3. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much? (Circle one number for each question.)	Yes, Limited a Lot	Yes, Limited a Little	No, Not Limited at All
Vigorous activities , such as running, lifting heavy objects, participating in strenuous sports.	1	2	3
Moderate activities , such as moving a table, pushing a vacuum cleaner, bowling or playing golf	1	2	3
Lifting or carrying groceries	1	2	3
Climbing several flights of stairs	1	2	3
Climbing one flight of stairs	1	2	3
Bending, kneeling, or stooping	1	2	3
Walking more than a mile	1	2	3
Walking several blocks	1	2	3
Walking one block	1	2	3
Bathing or dressing yourself	1	2	3

 MENTOR	Core Gel Breast IDE Clinical Trial			6 YEAR VISIT							
	PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1			SITE NO.		PATIENT NO.		PATIENT INITIALS first middle last	

SF-36 (Page 2 of 3)

4. During the past 4 weeks , have you had any of the following problems with your work or other regular daily activities as a result of your physical health? (Circle one number for each question.)	YES	NO
Cut down on the amount of time you spent on work or other activities	1	2
Accomplished less than you would like	1	2
Were limited in the kind of work or other activities	1	2
Had difficulty performing the work or other activities (for example, it took extra effort)	1	2

5. During the past 4 weeks , have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)? (Circle one number for each question.)	YES	NO
Cut down on the amount of time you spent on work or other activities	1	2
Accomplished less than you would like	1	2
Didn't do work or other activities as carefully as usual	1	2

6. During the past 4 weeks , to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups? (Circle one number)	Not at All	Slightly	Moderately	Quite a Bit	Extremely
	1	2	3	4	5

7. How much bodily pain have you had during the past 4 weeks? (Circle one number)	None	Very Mild	Mild	Moderate	Severe	Very Severe
	1	2	3	4	5	6

8. During the past 4 weeks , how much did pain interfere with your normal work (including both work outside the home and housework)? (Circle one number)	Not at All	A Little Bit	Moderately	Quite a Bit	Extremely
	1	2	3	4	5

 MENTOR	Core Gel Breast IDE Clinical Trial			6 YEAR VISIT				
	PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO.	PATIENT NO.	PATIENT INITIALS first middle last		

SF-36 (Page 3 of 3)

9. These questions are about how you feel and how things have been with you **during the past 4 weeks**. For each question, please indicate the one answer that comes closest to the way you have been feeling. (Circle **one** number for each question.)

How much of the time during the past 4 weeks ...	All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	None of the Time
Did you feel full of pep?	1	2	3	4	5	6
Have you been a very nervous person?	1	2	3	4	5	6
Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
Have you felt calm and peaceful?	1	2	3	4	5	6
Did you have a lot of energy?	1	2	3	4	5	6
Have you felt downhearted and blue?	1	2	3	4	5	6
Did you feel worn out?	1	2	3	4	5	6
Have you been a happy person?	1	2	3	4	5	6
Did you feel tired?	1	2	3	4	5	6

10. During the past 4 weeks , how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)? (Circle one number.)	All of the Time	Most of the Time	Some of the Time	A Little of the Time	None of the Time
	1	2	3	4	5

11. How TRUE or FALSE is each of the following statements for you? (Circle one number for each question.)	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
I seem to get sick a little easier than other people	1	2	3	4	5
I am as healthy as anybody I know	1	2	3	4	5
I expect my health to get worse	1	2	3	4	5
My health is excellent	1	2	3	4	5



MENTOR

**Core Gel Breast
IDE Clinical Trial**

6 YEAR VISIT

PATIENT STUDY ID:

TRIAL NO.
10-009

COUNTRY NO.
0 | 0 | 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last

BODY ESTEEM SCALE (Page 1 of 1)

TO THE PATIENT: On this page are listed a number of body parts and functions. Please read each item and indicate how you feel about this part or function of ***your own body***, using the following scale:

- 1 = Have strong negative feelings
- 2 = Have moderate negative feelings
- 3 = Have no feeling one way or the other
- 4 = Have moderate positive feelings
- 5 = Have strong positive feelings

- | | |
|--|--|
| <input type="checkbox"/> 1. Body Scent | <input type="checkbox"/> 19. Arms |
| <input type="checkbox"/> 2. Appetite | <input type="checkbox"/> 20. Chest |
| <input type="checkbox"/> 3. Nose | <input type="checkbox"/> 21. Appearance of Eyes |
| <input type="checkbox"/> 4. Physical Stamina | <input type="checkbox"/> 22. Cheeks/Cheekbones |
| <input type="checkbox"/> 5. Reflexes | <input type="checkbox"/> 23. Hips |
| <input type="checkbox"/> 6. Lips | <input type="checkbox"/> 24. Legs |
| <input type="checkbox"/> 7. Muscular Strength | <input type="checkbox"/> 25. Physique |
| <input type="checkbox"/> 8. Waist | <input type="checkbox"/> 26. Sex Drive |
| <input type="checkbox"/> 9. Energy Level | <input type="checkbox"/> 27. Feet |
| <input type="checkbox"/> 10. Thighs | <input type="checkbox"/> 28. Sex Organs |
| <input type="checkbox"/> 11. Ears | <input type="checkbox"/> 29. Appearance of Stomach |
| <input type="checkbox"/> 12. Biceps | <input type="checkbox"/> 30. Health |
| <input type="checkbox"/> 13. Chin | <input type="checkbox"/> 31. Sex Activities |
| <input type="checkbox"/> 14. Body Build | <input type="checkbox"/> 32. Body Hair |
| <input type="checkbox"/> 15. Physical Coordination | <input type="checkbox"/> 33. Physical Condition |
| <input type="checkbox"/> 16. Buttocks | <input type="checkbox"/> 34. Face |
| <input type="checkbox"/> 17. Agility | <input type="checkbox"/> 35. Weight |
| <input type="checkbox"/> 18. Width of Shoulders | |



MENTOR

**Core Gel Breast
IDE Clinical Trial**

6 YEAR VISIT

PATIENT STUDY ID:

TRIAL NO.
10-009

COUNTRY NO.
0 | 0 | 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last

MANITOBA CANCER TREATMENT & RESEARCH FOUNDATION FUNCTIONAL LIVING INDEX: CANCER (FLIC)

Page 1 of 3

N/A (not a cancer patient)

TO THE PATIENT: Please indicate your rating by drawing a vertical line (|).

1. Most people experience some feelings of depression at times. Rate how often you feel these feelings.

1	2	3	4	5	6	7
Never						Continually

2. How well are you coping with your everyday stress?

1	2	3	4	5	6	7
Not Well						Very Well

3. How much time do you spend thinking about your illness?

1	2	3	4	5	6	7
Constantly						Never

4. Rate your ability to maintain your usual recreation or leisure activities.

1	2	3	4	5	6	7
Able						Unable

5. Has nausea affected your daily functioning?

1	2	3	4	5	6	7
Not At All						A Great Deal

6. How well do you feel today?

1	2	3	4	5	6	7
Extremely Poor						Extremely Well

7. Do you feel well enough to make a meal or do minor household repairs today?

1	2	3	4	5	6	7
Very Able						Not Able



MENTOR

**Core Gel Breast
IDE Clinical Trial**

6 YEAR VISIT

PATIENT STUDY ID:

TRIAL NO.
10-009

COUNTRY NO.
0 0 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last

MANITOBA CANCER TREATMENT & RESEARCH FOUNDATION FUNCTIONAL LIVING INDEX: CANCER (FLIC)

Page 2 of 3

N/A (not a cancer patient)

8. Rate the degree to which your cancer has imposed a hardship on those closest to you in the past 2 months.

| | | | | | |

1 2 3 4 5 6 7

No Hardship Tremendous Hardship

9. Rate how often you feel discouraged about your life.

| | | | | | |

1 2 3 4 5 6 7

Always Never

10. Rate your satisfaction with your work and your jobs around the house in the past month.

| | | | | | |

1 2 3 4 5 6 7

Very Dissatisfied Very Satisfied

11. How uncomfortable do you feel today?

| | | | | | |

1 2 3 4 5 6 7

Not at All Very Uncomfortable

12. Rate in your opinion, how disruptive your cancer has been to those closest to you in the past 2 weeks.

| | | | | | |

1 2 3 4 5 6 7

Totally Disruptive No Disruption

13. How much is pain or discomfort interfering with your daily activities?

| | | | | | |

1 2 3 4 5 6 7

Not at All A Great Deal

14. Rate the degree to which your cancer has imposed a hardship on you (personally) in the past 2 weeks.

| | | | | | |

1 2 3 4 5 6 7

Tremendous Hardship No Hardship



MENTOR

**Core Gel Breast
IDE Clinical Trial**

6 YEAR VISIT

PATIENT STUDY ID:

TRIAL NO.
10-009

COUNTRY NO.
0 0 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last

MANITOBA CANCER TREATMENT & RESEARCH FOUNDATION FUNCTIONAL LIVING INDEX: CANCER (FLIC)

Page 3 of 3

N/A (not a cancer patient)

15. How much of your usual household tasks are you able to complete?

1	2	3	4	5	6	7
All						None

16. Rate how willing you were to see and spend time with those closest to you, in the past 2 weeks.

1	2	3	4	5	6	7
Unwilling						Very Willing

17. How much nausea have you had in the past 2 weeks?

1	2	3	4	5	6	7
None						A Great Deal

18. Rate the degree to which you are frightened of the future.

1	2	3	4	5	6	7
Constantly Terrified						Not Afraid

19. Rate how willing you were to see and spend time with friends, in the past 2 weeks.

1	2	3	4	5	6	7
Unwilling						Very Willing

20. How much of your pain or discomfort over the past 2 weeks was related to your cancer?

1	2	3	4	5	6	7
None						All

21. Rate your confidence in your prescribed course of treatment.

1	2	3	4	5	6	7
No Confidence						Very Confident

22. How well do you appear today?

1	2	3	4	5	6	7
Extremely Poor						Extremely Well



Core Gel Breast IDE Clinical Trial

ADVERSE EVENTS

6 YEAR VISIT

PATIENT STUDY ID: TRIAL NO. 10-009 COUNTRY NO. 0 0 1 SITE NO. PATIENT NO. PATIENT INITIALS first middle last No Adverse Events

Enter one adverse event per line. If the event was experienced at more than one body site, enter each body site on a separate line.

AE CODE* (See Below)	CAUSALITY 1 = Procedure related 2 = Device related 3 = Unknown 4 = Other	EVENT SIDE 0 = N/A 1 = Right 2 = Left	ASSOCIATED BREAST PAIN 0 = None 1 = Mild 2 = Moderate 3 = Severe	ONSET DATE month day year	SEVERITY 1 = Mild 2 = Moderate 3 = Severe	TREATMENT REQUIRED (check all that apply) 1 = No Treatment 2 = Medication (specify) 3 = Secondary Procedure (enter Procedure Type Code and date below, and complete Secondary Procedures Report for all procedures performed for this date)** 4 = Hospitalization (specify # of days and admission date) 5 = Other (specify)	OUTCOME 1 = Resolved 2 = Ongoing 3 = Death 4 = Unknown	RESOLUTION DATE month day year
<input type="checkbox"/> 1	<input type="checkbox"/> 3	<input type="checkbox"/> 0	<input type="checkbox"/> 0 <input type="checkbox"/> 3	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 4 days, Date: ___/___/___	<input type="checkbox"/> 1 <input type="checkbox"/> 4	
<input type="checkbox"/> 2	<input type="checkbox"/> 4	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 5 Procedure Date: ___/___/___	<input type="checkbox"/> 2	
<input type="checkbox"/> 1	<input type="checkbox"/> 3	<input type="checkbox"/> 0	<input type="checkbox"/> 0 <input type="checkbox"/> 3	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 4 days, Date: ___/___/___	<input type="checkbox"/> 1 <input type="checkbox"/> 4	
<input type="checkbox"/> 2	<input type="checkbox"/> 4	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 5 Procedure Date: ___/___/___	<input type="checkbox"/> 2	
<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 3	Procedure Date: ___/___/___	<input type="checkbox"/> 3	

**Complete Secondary Procedures Report. If new study device is implanted, complete Re-implantation Report.

Investigator's Signature _____ month _____ day _____ year

***ADVERSE EVENT CODES**

15 = Lymphadenopathy
16 = Necrosis
17 = New Diagnosis of Breast Cancer
18 = New Diagnosis of Rheumatic Disease, specify:
19 = Nipple—Unacceptably Low Sensitivity
20 = Nipple—Unacceptably High Sensitivity
21 = Position Change
22 = Ptosis
23 = Rupture
24 = Seroma
25 = Size Change—Patient Request
26 = Size Change—Physician Assessment only
27 = Wrinkling

+SECONDARY PROCEDURE TYPE CODES

81 = Biopsy
82 = Capsulectomy
83 = Explanation with Replacement**
84 = Explanation without Replacement
85 = Incision and Drainage
86 = Mastopexy
87 = Open Capsulotomy
88 = Position Change
89 = Scar Revision
90 = Skin Adjustment
91 = Other, specify: _____
92 = Other, specify: _____

28 = Lactation Difficulties, specify: _____
29 = Other, specify: _____
30 = Other, specify: _____



MENTOR

**Core Gel Breast
IDE Clinical Trial**

7 YEAR VISIT

PATIENT STUDY ID:

TRIAL NO.
10-009

COUNTRY NO.
0 0 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last

Visit Date:

month day year

Missed Visit

BREAST MEASUREMENTS

RIGHT Not Implanted with Study Device

Circumferential Breast Measurement cm

Bra Size (i.e. 32A) N/A (breast absent)

LEFT Not Implanted with Study Device

Circumferential Breast Measurement cm

Bra Size (i.e. 32A) N/A (breast absent)

MAMMOGRAPHY RESULTS

Date of Mammogram:

month year

Not Done

RIGHT

- Birads 0 Needs additional imaging evaluation
 - Birads 1 Negative
 - Birads 2 Benign finding
 - Birads 3 Probable benign finding—short interval follow-up is suggested
 - Birads 4 Suspicious abnormality—biopsy should be considered
 - Birads 5 Highly suggestive of malignancy—appropriate action should be taken
- List abnormality: _____

LEFT

- Birads 0 Needs additional imaging evaluation
 - Birads 1 Negative
 - Birads 2 Benign finding
 - Birads 3 Probable benign finding—short interval follow-up is suggested
 - Birads 4 Suspicious abnormality—biopsy should be considered
 - Birads 5 Highly suggestive of malignancy—appropriate action should be taken
- List abnormality: _____

VISIT REPORT

1. Has the patient become pregnant since the last visit?

- No
- Yes, without complications
- Yes, with complications

Complete Adverse Events Report

2. Has the patient attempted to breastfeed since the last visit?

- No
- Yes, was there adequate milk?
 - No (Enter code 30 on Adverse Events Report)
 - Yes

3. Would the patient have this breast surgery again?

- No, reason: _____
- Yes

4. **Breast Cancer Reconstruction Patients only:**

N/A (augmentation patient)

Has the patient received any adjuvant therapies since the last visit?

- No
- Yes, check all that apply:
 - Radiation Therapy
 - Chemotherapy
 - Other, specify: _____

Treating Oncologist

Name: _____

Phone: (_____) _____

	Core Gel Breast IDE Clinical Trial		7 YEAR VISIT		
	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO.	PATIENT NO.	PATIENT INITIALS first middle last

CAPSULAR CONTRACTURE ASSESSMENT OF PROSTHESIS	
Right Prosthesis is: <input type="radio"/> <input type="checkbox"/> Not Implanted with Study Device 1 <input type="checkbox"/> Baker Class I (normally soft and natural appearance) 2 <input type="checkbox"/> Baker Class II (a natural appearance despite palpable firmness) 3 <input type="checkbox"/> Baker Class III (firm with visible distortion) 4 <input type="checkbox"/> Baker Class IV (obvious spherical distortion)	Left Prosthesis is: <input type="radio"/> <input type="checkbox"/> Not Implanted with Study Device 1 <input type="checkbox"/> Baker Class I (normally soft and natural appearance) 2 <input type="checkbox"/> Baker Class II (a natural appearance despite palpable firmness) 3 <input type="checkbox"/> Baker Class III (firm with visible distortion) 4 <input type="checkbox"/> Baker Class IV (obvious spherical distortion)
Complete Adverse Events Report for Baker III or IV.	

NIPPLE/BREAST SENSITIVITY	
<p style="text-align: center;">How would patient describe the feeling in nipple(s) and/or breast(s) now?</p> <p style="text-align: center;"><i>If unacceptably high or low at baseline, and sensation remains the same post-operatively, do not complete an Adverse Events Report.</i></p> <p style="text-align: center;"><i>If acceptable at baseline and has become unacceptable post-operatively, complete an Adverse Events Report.</i></p>	
RIGHT <input type="radio"/> <input type="checkbox"/> Not Implanted with Study Device Nipple Sensation is: 1 <input type="checkbox"/> Unacceptably low 2 <input type="checkbox"/> Acceptable 3 <input type="checkbox"/> Unacceptably high 4 <input type="checkbox"/> N/A, nipple absent Breast sensation is: 1 <input type="checkbox"/> Unacceptably low 2 <input type="checkbox"/> Acceptable 3 <input type="checkbox"/> Unacceptably high 4 <input type="checkbox"/> N/A, breast absent	LEFT <input type="radio"/> <input type="checkbox"/> Not Implanted with Study Device Nipple Sensation is: 1 <input type="checkbox"/> Unacceptably low 2 <input type="checkbox"/> Acceptable 3 <input type="checkbox"/> Unacceptably high 4 <input type="checkbox"/> N/A, nipple absent Breast sensation is: 1 <input type="checkbox"/> Unacceptably low 2 <input type="checkbox"/> Acceptable 3 <input type="checkbox"/> Unacceptably high 4 <input type="checkbox"/> N/A, breast absent
Complete Adverse Events Report for any complications or adverse events noted at this visit.	



MENTOR

**Core Gel Breast
IDE Clinical Trial**

7 YEAR VISIT

PATIENT STUDY ID:

TRIAL NO.
10-009

COUNTRY NO.
0 | 0 | 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last

INVESTIGATOR-COMPLETED RHEUMATIC DISEASE DIAGNOSIS QUESTIONNAIRE

No diagnosis made

Has the patient been diagnosed by a RHEUMATOLOGIST for any of the following **since the last visit?**

If YES, complete Adverse Event Report.

RHEUMATIC DISEASE	NO YES		DATE OF ONSET (if known)	
			month	year
Connective Tissue Disorders: SLE	<input type="checkbox"/>	<input type="checkbox"/>		
Sjogren's Syndrome	<input type="checkbox"/>	<input type="checkbox"/>		
Scleroderma	<input type="checkbox"/>	<input type="checkbox"/>		
Polymyositis	<input type="checkbox"/>	<input type="checkbox"/>		
Other Connective Tissue Disorders	<input type="checkbox"/>	<input type="checkbox"/>		
Inflammatory Arthritis: Rheumatoid Arthritis	<input type="checkbox"/>	<input type="checkbox"/>		
Crystalline Arthritis	<input type="checkbox"/>	<input type="checkbox"/>		
Infectious Arthritis	<input type="checkbox"/>	<input type="checkbox"/>		
Spondyarthropathies	<input type="checkbox"/>	<input type="checkbox"/>		
Other Inflammatory Arthritis	<input type="checkbox"/>	<input type="checkbox"/>		
Non-Inflammatory Rheumatic Conditions: Osteoarthritis	<input type="checkbox"/>	<input type="checkbox"/>		
Fibromyalgia	<input type="checkbox"/>	<input type="checkbox"/>		
Chronic Fatigue	<input type="checkbox"/>	<input type="checkbox"/>		
Other Mechanical or Degenerative	<input type="checkbox"/>	<input type="checkbox"/>		
Other, specify: _____	<input type="checkbox"/>	<input type="checkbox"/>		
Other, specify: _____	<input type="checkbox"/>	<input type="checkbox"/>		

Disease must be diagnosed by a rheumatologist.

Rheumatologist who made diagnosis:

Name: _____

Address: _____

Phone: (_____) _____



**Core Gel Breast
IDE Clinical Trial**

7 YEAR VISIT

PATIENT STUDY ID:	TRIAL NO.	COUNTRY NO.			SITE NO.	PATIENT NO.	PATIENT INITIALS		
	10-009	0	0	1			first	middle	last

RHEUMATOLOGY SYMPTOMS (Page 1 of 2)

No symptoms; patient not referred to rheumatologist

Please check any **current** symptoms which:

1. The patient experiences on a regular basis
2. The cause is unknown and cannot be attributed to any patient activity.

RHEUMATOLOGY SYMPTOM	STATUS SINCE LAST VISIT		DATE OF ONSET (only if new since last visit)		STATUS AS OF THIS VISIT	
	CONTINUING	NEW	month	year	RESOLVED	CONTINUING
Loss of weight without dieting	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Insomnia	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Weakness	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Exhaustion	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Joint swelling	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Heel pain	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Frequent muscle cramps	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Numbness of feet	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Ringing in ears	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Pain/grittiness in eyes	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Dryness of eyes, nose	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Pain on swallowing or chewing	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Neck pain/stiffness	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Pain on breathing	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Heart murmurs	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Loss of appetite	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Persistent fever	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Night sweats	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Generalized aching	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Loss of height	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Joint pain	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Frequent muscle pain	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>



**Core Gel Breast
IDE Clinical Trial**

7 YEAR VISIT

PATIENT STUDY ID:	TRIAL NO.	COUNTRY NO.			SITE NO.	PATIENT NO.	PATIENT INITIALS		
	10-009	0	0	1			first	middle	last

RHEUMATOLOGY SYMPTOMS (Page 2 of 2)

Please check any **current** symptoms which:

1. The patient experiences on a regular basis
2. The cause is unknown and cannot be attributed to any patient activity.

RHEUMATOLOGY SYMPTOM	STATUS SINCE LAST VISIT		DATE OF ONSET (only if new since last visit)		STATUS AS OF THIS VISIT	
	CONTINUING	NEW	month	year	RESOLVED	CONTINUING
Numbness of hands	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Jaw pain	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Open sores	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Redness of eyes	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Dryness of mouth	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Back pain/stiffness	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Severe chest pains	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Chronic cough	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Difficulty swallowing	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Frequent, severe or persistent diarrhea or constipation	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Severe rashes	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Frequent muscle cramps	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Severe dryness of skin	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Tender lumps/bumps	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Excessive sensitivity to sun	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Color changes on hands or feet with cold exposure	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Joint pain	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Frequent hives	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Numbness of hands	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Tightness of skin	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Unusual hair loss	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Tenderness of scalp	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Severe bruising with little or no injury	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>



**Core Gel Breast
IDE Clinical Trial**

7 YEAR VISIT

PATIENT STUDY ID:	TRIAL NO.	COUNTRY NO.			SITE NO.	PATIENT NO.	PATIENT INITIALS		
	10-009	0	0	1			first	middle	last

RHEUMATOLOGICAL PHYSICAL EXAMINATION (Page 1 of 2)

No symptoms present

Check the box for each physical finding noted to be present and outside normal limits.

PHYSICAL FINDING	STATUS SINCE LAST VISIT		DATE OF ONSET (only if new since last visit)		STATUS AS OF THIS VISIT	
	CONTINUING	NEW	month	year	RESOLVED	CONTINUING
Muscle weakness: Headlift from supine position against gravity	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Inability to raise arms	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Inability to get out of chair	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Joint swellings: Wrists	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Digits	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Elbows	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Knees	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Ankles	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Joint deformities and flexion contracture: Boutonnière ¹	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Ulnar drift ²	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Swan neck ³	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Trigger fingers	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Joint tenderness	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Grip strength and motion-finger to palm crease (normal = 0 cm)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Neck motion—chin to chest or sternum (normal = 0 cm)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Chest expansion (normal = at least 5 cm)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Occiput to wall (normal = 0 cm)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Jaw motion (normally upper-lower incisors 3 cm)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Back motion—measure 10 cm above posterior supine iliac spines— with forward bending motion at least 5 cm from first point (total distance at least 15 cm)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>

¹**Boutonnière** - Contractures of hand musculature characterized by proximal interphalangeal joint flexion and distal interphalangeal joint hyperextension.

³**Swan Neck** - Finger deformity characterized by flexion of distal interphalangeal joints and hyperflexion of the proximal interphalangeal joints due to hypermobility.

²**Ulnar Drift** - Joint change at the metacarpophalangeal joints. Long axis of fingers deviate in an ulnar direction.

**MENTOR****Core Gel Breast
IDE Clinical Trial****7 YEAR VISIT****PATIENT STUDY ID:**TRIAL NO.
10-009COUNTRY NO.
0 | 0 | 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last**RHEUMATOLOGICAL PHYSICAL EXAMINATION (Page 2 of 2)**

Check the box for each physical finding noted to be present and outside normal limits.

PHYSICAL FINDING	POSSIBLE INDICATION	STATUS SINCE LAST VISIT		DATE OF ONSET (only if new since last visit)		STATUS AS OF THIS VISIT	
		CONTINUING	NEW	month	year	RESOLVED	CONTINUING
Hair loss	<i>Lupus, Scleroderma</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Skin tightness, especially face and hands	<i>Scleroderma</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Raynaud's phenomenon	<i>Lupus, Scleroderma</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Calcinosis over tibia, ulna, elbows	<i>Scleroderma, Dermatomyositis</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Swollen digits	<i>Juvenile RA, Reiter's syndrome, Psoriatic arthritis, Early scleroderma, Reflex sympathetic dystrophy</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Erythema over knuckles	<i>Dermatomyositis</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Bluish hue color on eyelids	<i>Dermatomyositis</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Non-tender lumps or nodules on elbows	<i>Rheumatoid gout</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Tender lumps-tibia	<i>Erythema nodosum</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Painless eye redness	<i>Conjunctivitis</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Painful eye redness with decreased vision, small pupils	<i>Uveitis</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Tenderness—insertion of deltoids	<i>Polymyalgia rheumatica</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Muscle tenderness	<i>Polymyositis</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Nail pittings	<i>Psoriatic arthritis, Reiter's syndrome</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Tinels or Phalen's signs	<i>Carpal tunnel syndrome</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Skin rashes	<i>Discoid lupus</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>

Does the patient require an examination by a rheumatologist?

 No Yes, record rheumatologist's findings:



Core Gel Breast IDE Clinical Trial

ADVERSE EVENTS

7 YEAR VISIT

PATIENT STUDY ID: TRIAL NO. 10-009 COUNTRY NO. 0 0 1 SITE NO. PATIENT NO. PATIENT INITIALS first middle last No Adverse Events

Enter one adverse event per line. If the event was experienced at more than one body site, enter each body site on a separate line.

AE CODE* (See Below)	CAUSALITY 1 = Procedure related 2 = Device related 3 = Unknown 4 = Other	EVENT SIDE 0 = N/A 1 = Right 2 = Left	ASSOCIATED BREAST PAIN 0 = None 1 = Mild 2 = Moderate 3 = Severe	ONSET DATE month day year	SEVERITY 1 = Mild 2 = Moderate 3 = Severe	TREATMENT REQUIRED (check all that apply) 1 = No Treatment 2 = Medication (specify) 3 = Secondary Procedure (enter Procedure Type Code and date below, and complete Secondary Procedures Report for all procedures performed for this date)** 4 = Hospitalization (specify # of days and admission date) 5 = Other (specify)	OUTCOME 1 = Resolved 2 = Ongoing 3 = Death 4 = Unknown	RESOLUTION DATE month day year
<input type="checkbox"/> 1	<input type="checkbox"/> 3	<input type="checkbox"/> 0	<input type="checkbox"/> 0 <input type="checkbox"/> 3	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 4 days, Date: ___/___/___	<input type="checkbox"/> 1 <input type="checkbox"/> 4	
<input type="checkbox"/> 2	<input type="checkbox"/> 4	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 5 Procedure Date: ___/___/___	<input type="checkbox"/> 2	
<input type="checkbox"/> 1	<input type="checkbox"/> 3	<input type="checkbox"/> 0	<input type="checkbox"/> 0 <input type="checkbox"/> 3	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 4 days, Date: ___/___/___	<input type="checkbox"/> 1 <input type="checkbox"/> 4	
<input type="checkbox"/> 2	<input type="checkbox"/> 4	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 5 Procedure Date: ___/___/___	<input type="checkbox"/> 2	
<input type="checkbox"/> 1	<input type="checkbox"/> 3	<input type="checkbox"/> 0	<input type="checkbox"/> 0 <input type="checkbox"/> 3	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 4 days, Date: ___/___/___	<input type="checkbox"/> 1 <input type="checkbox"/> 4	
<input type="checkbox"/> 2	<input type="checkbox"/> 4	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 5 Procedure Date: ___/___/___	<input type="checkbox"/> 2	
<input type="checkbox"/> 1	<input type="checkbox"/> 3	<input type="checkbox"/> 0	<input type="checkbox"/> 0 <input type="checkbox"/> 3	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 4 days, Date: ___/___/___	<input type="checkbox"/> 1 <input type="checkbox"/> 4	
<input type="checkbox"/> 2	<input type="checkbox"/> 4	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 5 Procedure Date: ___/___/___	<input type="checkbox"/> 2	
<input type="checkbox"/> 1	<input type="checkbox"/> 3	<input type="checkbox"/> 0	<input type="checkbox"/> 0 <input type="checkbox"/> 3	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 4 days, Date: ___/___/___	<input type="checkbox"/> 1 <input type="checkbox"/> 4	
<input type="checkbox"/> 2	<input type="checkbox"/> 4	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 5 Procedure Date: ___/___/___	<input type="checkbox"/> 2	
<input type="checkbox"/> 1	<input type="checkbox"/> 3	<input type="checkbox"/> 0	<input type="checkbox"/> 0 <input type="checkbox"/> 3	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 4 days, Date: ___/___/___	<input type="checkbox"/> 1 <input type="checkbox"/> 4	
<input type="checkbox"/> 2	<input type="checkbox"/> 4	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 5 Procedure Date: ___/___/___	<input type="checkbox"/> 2	

**Complete Secondary Procedures Report. If new study device is implanted, complete Re-implantation Report.

Investigator's Signature _____ month _____ day _____ year

*ADVERSE EVENT CODES	+SECONDARY PROCEDURE TYPE CODES
1 = Asymmetry 2 = Baker II Capsular Contracture with Surgical Intervention 3 = Baker III Capsular Contracture 4 = Baker IV Capsular Contracture 5 = Breast pain not associated with any other complication 6 = Breast—Unacceptably Low Sensitivity 7 = Breast—Unacceptably High Sensitivity 8 = Calcification 9 = Delayed Wound Healing 10 = Extrusion 11 = Granuloma 12 = Hematoma 13 = Hypertrophic Scarring 14 = Infection 15 = Lymphadenopathy 16 = Necrosis 17 = New Diagnosis of Breast Cancer 18 = New Diagnosis of Rheumatic Disease, specify: 19 = Nipple—Unacceptably Low Sensitivity 20 = Nipple—Unacceptably High Sensitivity 21 = Position Change 22 = Ptosis 23 = Rupture 24 = Seroma 25 = Size Change—Patient Request 26 = Size Change—Physician Assessment only 27 = Wrinkling 28 = Lactation Difficulties, specify: 29 = Other, specify: 30 = Other, specify:	81 = Biopsy 82 = Capsulectomy 83 = Explanation with Replacement** 84 = Explanation without Replacement 85 = Incision and Drainage 86 = Mastopexy 87 = Open Capsulotomy 88 = Position Change 89 = Scar Revision 90 = Skin Adjustment 91 = Other, specify: 92 = Other, specify:



MENTOR

**Core Gel Breast
IDE Clinical Trial**

8 YEAR VISIT

PATIENT STUDY ID:

TRIAL NO.
10-009

COUNTRY NO.
0 0 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last

Visit Date:

month day year

Missed Visit

BREAST MEASUREMENTS

RIGHT Not Implanted with Study Device

Circumferential Breast Measurement cm

Bra Size (i.e. 32A) N/A (breast absent)

LEFT Not Implanted with Study Device

Circumferential Breast Measurement cm

Bra Size (i.e. 32A) N/A (breast absent)

MAMMOGRAPHY RESULTS

Date of Mammogram:

month year

Not Done

RIGHT

- Birads 0 Needs additional imaging evaluation
 - Birads 1 Negative
 - Birads 2 Benign finding
 - Birads 3 Probable benign finding—short interval follow-up is suggested
 - Birads 4 Suspicious abnormality—biopsy should be considered
 - Birads 5 Highly suggestive of malignancy—appropriate action should be taken
- List abnormality: _____

LEFT

- Birads 0 Needs additional imaging evaluation
 - Birads 1 Negative
 - Birads 2 Benign finding
 - Birads 3 Probable benign finding—short interval follow-up is suggested
 - Birads 4 Suspicious abnormality—biopsy should be considered
 - Birads 5 Highly suggestive of malignancy—appropriate action should be taken
- List abnormality: _____

VISIT REPORT

1. Has the patient become pregnant since the last visit?

- No
- Yes, without complications
- Yes, with complications

Complete Adverse Events Report

2. Has the patient attempted to breastfeed since the last visit?

- No
- Yes, was there adequate milk?
 - No (Enter code 30 on Adverse Events Report)
 - Yes

3. Would the patient have this breast surgery again?

- No, reason: _____
- Yes

4. **Breast Cancer Reconstruction Patients only:**

N/A (augmentation patient)

Has the patient received any adjuvant therapies since the last visit?

- No
- Yes, check all that apply:
 - Radiation Therapy
 - Chemotherapy
 - Other, specify: _____

Treating Oncologist

Name: _____

Phone: (_____) _____

	Core Gel Breast IDE Clinical Trial		8 YEAR VISIT			
	PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO.	PATIENT NO.	PATIENT INITIALS first middle last

CAPSULAR CONTRACTURE ASSESSMENT OF PROSTHESIS	
Right Prosthesis is: o <input type="checkbox"/> Not Implanted with Study Device 1 <input type="checkbox"/> Baker Class I (normally soft and natural appearance) 2 <input type="checkbox"/> Baker Class II (a natural appearance despite palpable firmness) 3 <input type="checkbox"/> Baker Class III (firm with visible distortion) 4 <input type="checkbox"/> Baker Class IV (obvious spherical distortion)	Left Prosthesis is: o <input type="checkbox"/> Not Implanted with Study Device 1 <input type="checkbox"/> Baker Class I (normally soft and natural appearance) 2 <input type="checkbox"/> Baker Class II (a natural appearance despite palpable firmness) 3 <input type="checkbox"/> Baker Class III (firm with visible distortion) 4 <input type="checkbox"/> Baker Class IV (obvious spherical distortion)
Complete Adverse Events Report for Baker III or IV.	

NIPPLE/BREAST SENSITIVITY	
<p>How would patient describe the feeling in nipple(s) and/or breast(s) now?</p> <p><i>If unacceptably high or low at baseline, and sensation remains the same post-operatively, do not complete an Adverse Events Report.</i></p> <p><i>If acceptable at baseline and has become unacceptable post-operatively, complete an Adverse Events Report.</i></p>	
RIGHT o <input type="checkbox"/> Not Implanted with Study Device Nipple Sensation is: 1 <input type="checkbox"/> Unacceptably low 2 <input type="checkbox"/> Acceptable 3 <input type="checkbox"/> Unacceptably high 4 <input type="checkbox"/> N/A, nipple absent Breast sensation is: 1 <input type="checkbox"/> Unacceptably low 2 <input type="checkbox"/> Acceptable 3 <input type="checkbox"/> Unacceptably high 4 <input type="checkbox"/> N/A, breast absent	LEFT o <input type="checkbox"/> Not Implanted with Study Device Nipple Sensation is: 1 <input type="checkbox"/> Unacceptably low 2 <input type="checkbox"/> Acceptable 3 <input type="checkbox"/> Unacceptably high 4 <input type="checkbox"/> N/A, nipple absent Breast sensation is: 1 <input type="checkbox"/> Unacceptably low 2 <input type="checkbox"/> Acceptable 3 <input type="checkbox"/> Unacceptably high 4 <input type="checkbox"/> N/A, breast absent
Complete Adverse Events Report for any complications or adverse events noted at this visit.	

**MENTOR****Core Gel Breast
IDE Clinical Trial****8 YEAR VISIT****PATIENT STUDY ID:**TRIAL NO.
10-009COUNTRY NO.
0 | 0 | 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last**INVESTIGATOR-COMPLETED RHEUMATIC DISEASE DIAGNOSIS QUESTIONNAIRE** No diagnosis madeHas the patient been diagnosed by a RHEUMATOLOGIST for any of the following **since the last visit?****If YES, complete Adverse Event Report.**

RHEUMATIC DISEASE	NO YES		DATE OF ONSET (if known)	
			month	year
Connective Tissue Disorders: SLE	<input type="checkbox"/>	<input type="checkbox"/>		
Sjogren's Syndrome	<input type="checkbox"/>	<input type="checkbox"/>		
Scleroderma	<input type="checkbox"/>	<input type="checkbox"/>		
Polymyositis	<input type="checkbox"/>	<input type="checkbox"/>		
Other Connective Tissue Disorders	<input type="checkbox"/>	<input type="checkbox"/>		
Inflammatory Arthritis: Rheumatoid Arthritis	<input type="checkbox"/>	<input type="checkbox"/>		
Crystalline Arthritis	<input type="checkbox"/>	<input type="checkbox"/>		
Infectious Arthritis	<input type="checkbox"/>	<input type="checkbox"/>		
Spondyarthropathies	<input type="checkbox"/>	<input type="checkbox"/>		
Other Inflammatory Arthritis	<input type="checkbox"/>	<input type="checkbox"/>		
Non-Inflammatory Rheumatic Conditions: Osteoarthritis	<input type="checkbox"/>	<input type="checkbox"/>		
Fibromyalgia	<input type="checkbox"/>	<input type="checkbox"/>		
Chronic Fatigue	<input type="checkbox"/>	<input type="checkbox"/>		
Other Mechanical or Degenerative	<input type="checkbox"/>	<input type="checkbox"/>		
Other, specify: _____	<input type="checkbox"/>	<input type="checkbox"/>		
Other, specify: _____	<input type="checkbox"/>	<input type="checkbox"/>		

Disease must be diagnosed by a rheumatologist.

Rheumatologist who made diagnosis:

Name: _____

Address: _____

Phone: (_____) _____

**MENTOR****Core Gel Breast
IDE Clinical Trial****8 YEAR VISIT****PATIENT STUDY ID:**TRIAL NO.
10-009COUNTRY NO.
0 0 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last**RHEUMATOLOGY SYMPTOMS (Page 1 of 2)**1 No symptoms; patient not referred to rheumatologistPlease check any **current** symptoms which:

1. The patient experiences on a regular basis
2. The cause is unknown and cannot be attributed to any patient activity.

RHEUMATOLOGY SYMPTOM	STATUS SINCE LAST VISIT		DATE OF ONSET (only if new since last visit)		STATUS AS OF THIS VISIT	
	CONTINUING	NEW	month	year	RESOLVED	CONTINUING
Loss of weight without dieting	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Insomnia	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Weakness	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Exhaustion	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Joint swelling	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Heel pain	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Frequent muscle cramps	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Numbness of feet	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Ringing in ears	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Pain/grittiness in eyes	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Dryness of eyes, nose	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Pain on swallowing or chewing	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Neck pain/stiffness	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Pain on breathing	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Heart murmurs	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Loss of appetite	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Persistent fever	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Night sweats	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Generalized aching	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Loss of height	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Joint pain	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Frequent muscle pain	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>



**Core Gel Breast
IDE Clinical Trial**

8 YEAR VISIT

PATIENT STUDY ID:	TRIAL NO.	COUNTRY NO.			SITE NO.	PATIENT NO.	PATIENT INITIALS		
	10-009	0	0	1			first	middle	last

RHEUMATOLOGY SYMPTOMS (Page 2 of 2)

Please check any **current** symptoms which:

1. The patient experiences on a regular basis
2. The cause is unknown and cannot be attributed to any patient activity.

RHEUMATOLOGY SYMPTOM	STATUS SINCE LAST VISIT		DATE OF ONSET (only if new since last visit)		STATUS AS OF THIS VISIT	
	CONTINUING	NEW	month	year	RESOLVED	CONTINUING
Numbness of hands	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Jaw pain	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Open sores	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Redness of eyes	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Dryness of mouth	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Back pain/stiffness	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Severe chest pains	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Chronic cough	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Difficulty swallowing	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Frequent, severe or persistent diarrhea or constipation	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Severe rashes	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Frequent muscle cramps	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Severe dryness of skin	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Tender lumps/bumps	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Excessive sensitivity to sun	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Color changes on hands or feet with cold exposure	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Joint pain	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Frequent hives	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Numbness of hands	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Tightness of skin	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Unusual hair loss	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Tenderness of scalp	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Severe bruising with little or no injury	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>



**Core Gel Breast
IDE Clinical Trial**

8 YEAR VISIT

PATIENT STUDY ID:	TRIAL NO.	COUNTRY NO.			SITE NO.	PATIENT NO.	PATIENT INITIALS		
	10-009	0	0	1			first	middle	last

RHEUMATOLOGICAL PHYSICAL EXAMINATION (Page 1 of 2)

No symptoms present

Check the box for each physical finding noted to be present and outside normal limits.

PHYSICAL FINDING	STATUS SINCE LAST VISIT		DATE OF ONSET (only if new since last visit)		STATUS AS OF THIS VISIT	
	CONTINUING	NEW	month	year	RESOLVED	CONTINUING
Muscle weakness: Headlift from supine position against gravity	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Inability to raise arms	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Inability to get out of chair	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Joint swellings: Wrists	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Digits	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Elbows	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Knees	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Ankles	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Joint deformities and flexion contracture: Boutonnière ¹	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Ulnar drift ²	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Swan neck ³	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Trigger fingers	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Joint tenderness	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Grip strength and motion-finger to palm crease (normal = 0 cm)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Neck motion—chin to chest or sternum (normal = 0 cm)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Chest expansion (normal = at least 5 cm)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Occiput to wall (normal = 0 cm)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Jaw motion (normally upper-lower incisors 3 cm)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Back motion—measure 10 cm above posterior supine iliac spines— with forward bending motion at least 5 cm from first point (total distance at least 15 cm)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>

¹**Boutonnière** - Contractures of hand musculature characterized by proximal interphalangeal joint flexion and distal interphalangeal joint hyperextension.

³**Swan Neck** - Finger deformity characterized by flexion of distal interphalangeal joints and hyperflexion of the proximal interphalangeal joints due to hypermobility.

²**Ulnar Drift** - Joint change at the metacarpophalangeal joints. Long axis of fingers deviate in an ulnar direction.

**MENTOR****Core Gel Breast
IDE Clinical Trial****8 YEAR VISIT****PATIENT STUDY ID:**TRIAL NO.
10-009COUNTRY NO.
0 0 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last**RHEUMATOLOGICAL PHYSICAL EXAMINATION (Page 2 of 2)**

Check the box for each physical finding noted to be present and outside normal limits.

PHYSICAL FINDING	POSSIBLE INDICATION	STATUS SINCE LAST VISIT		DATE OF ONSET (only if new since last visit)		STATUS AS OF THIS VISIT	
		CONTINUING	NEW	month	year	RESOLVED	CONTINUING
Hair loss	<i>Lupus, Scleroderma</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Skin tightness, especially face and hands	<i>Scleroderma</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Raynaud's phenomenon	<i>Lupus, Scleroderma</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Calcinosis over tibia, ulna, elbows	<i>Scleroderma, Dermatomyositis</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Swollen digits	<i>Juvenile RA, Reiter's syndrome, Psoriatic arthritis, Early scleroderma, Reflex sympathetic dystrophy</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Erythema over knuckles	<i>Dermatomyositis</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Bluish hue color on eyelids	<i>Dermatomyositis</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Non-tender lumps or nodules on elbows	<i>Rheumatoid gout</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Tender lumps-tibia	<i>Erythema nodosum</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Painless eye redness	<i>Conjunctivitis</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Painful eye redness with decreased vision, small pupils	<i>Uveitis</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Tenderness—insertion of deltoids	<i>Polymyalgia rheumatica</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Muscle tenderness	<i>Polymyositis</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Nail pittings	<i>Psoriatic arthritis, Reiter's syndrome</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Tinels or Phalen's signs	<i>Carpal tunnel syndrome</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Skin rashes	<i>Discoid lupus</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>

Does the patient require an examination by a rheumatologist?

 No Yes, record rheumatologist's findings:



Core Gel Breast
IDE Clinical Trial

8 YEAR VISIT

PATIENT STUDY ID:

TRIAL NO.
10-009

COUNTRY NO.
0 | 0 | 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last

ROSENBERG SELF-ESTEEM SCALE (Page 1 of 1)

TO THE PATIENT: Below are some statements with which some people agree and disagree. Please read each statement and check **one** response to each statement.

	Strongly Agree 1	Agree 2	Disagree 3	Strongly Disagree 4
1. I feel that I am a person of worth, at least on an equal basis with others.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. I feel that I have a number of good qualities.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. All in all, I am inclined to feel that I am a failure.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. I am able to do things as well as most people.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. I feel I do not have much of which to be proud.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. I take a positive attitude towards myself.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. On the whole, I am satisfied with myself.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. I wish I could have more respect for myself.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. I certainly feel useless at times.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. At times I think I am no good at all.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

 MENTOR	Core Gel Breast IDE Clinical Trial			8 YEAR VISIT			
	PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO.	PATIENT NO.	PATIENT INITIALS first middle last	

TENNESSEE SELF-CONCEPT SCALE (Page 1 of 4)

TO THE PATIENT: The statements below are to help you describe yourself as you see yourself. Please respond to them as if you were describing yourself **to yourself**. Do not omit any item. Read each statement carefully, then select one of the five responses listed below. On the test, put a **circle** around the response you chose. If you want to change an answer after you have circled it, do not erase it but put an X mark through the response and then circle the response you want.

<i>Remember, put a circle around the response number you have chosen for each statement.</i>	Completely False	Mostly False	Partly True and Partly False	Mostly True	Completely True
1. I have a healthy body.	1	2	3	4	5
2. I am an attractive person.	1	2	3	4	5
3. I consider myself a sloppy person.	1	2	3	4	5
4. I am a decent sort of person.	1	2	3	4	5
5. I am an honest person.	1	2	3	4	5
6. I am a bad person.	1	2	3	4	5
7. I am a cheerful person.	1	2	3	4	5
8. I am a calm and easygoing person.	1	2	3	4	5
9. I am a nobody.	1	2	3	4	5
10. I have a family that would always help me in any kind of trouble.	1	2	3	4	5
11. I am a member of a happy family.	1	2	3	4	5
12. My friends have no confidence in me.	1	2	3	4	5
13. I am a friendly person.	1	2	3	4	5
14. I am popular with men.	1	2	3	4	5
15. I am not interested in what other people do.	1	2	3	4	5
16. I do not always tell the truth.	1	2	3	4	5
17. I get angry sometimes.	1	2	3	4	5
18. I like to look nice and neat all the time.	1	2	3	4	5
19. I am full of aches and pains.	1	2	3	4	5
20. I am a sick person.	1	2	3	4	5
21. I am a religious person.	1	2	3	4	5
22. I am a moral failure.	1	2	3	4	5
23. I am a morally weak person.	1	2	3	4	5

 MENTOR	Core Gel Breast IDE Clinical Trial			8 YEAR VISIT							
	PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1			SITE NO.		PATIENT NO.		PATIENT INITIALS first middle last	

TENNESSEE SELF-CONCEPT SCALE (Page 2 of 4)

<i>Remember, put a circle around the response number you have chosen for each statement.</i>	Completely False	Mostly False	Partly True and Partly False	Mostly True	Completely True
24. I have a lot of self-control.	1	2	3	4	5
25. I am a hateful person.	1	2	3	4	5
26. I am losing my mind.	1	2	3	4	5
27. I am an important person to my friends and family.	1	2	3	4	5
28. I am not loved by my family.	1	2	3	4	5
29. I feel that my family doesn't trust me.	1	2	3	4	5
30. I am popular with women.	1	2	3	4	5
31. I am mad at the whole world.	1	2	3	4	5
32. I am hard to be friendly with.	1	2	3	4	5
33. Once in a while I think of things too bad to talk about.	1	2	3	4	5
34. Sometimes when I am not feeling well, I am cross.	1	2	3	4	5
35. I am neither too fat nor too thin.	1	2	3	4	5
36. I like my looks just the way they are.	1	2	3	4	5
37. I would like to change some parts of my body.	1	2	3	4	5
38. I am satisfied with my moral behavior.	1	2	3	4	5
39. I am satisfied with my relationship to God.	1	2	3	4	5
40. I ought to go to church more.	1	2	3	4	5
41. I am satisfied to be just what I am.	1	2	3	4	5
42. I am just as nice as I should be.	1	2	3	4	5
43. I despise myself.	1	2	3	4	5
44. I am satisfied with my family relationships.	1	2	3	4	5
45. I understand my family as well as I should.	1	2	3	4	5
46. I should trust my family more.	1	2	3	4	5
47. I am as sociable as I want to be.	1	2	3	4	5
48. I try to please others, but I don't overdo it.	1	2	3	4	5
49. I am no good at all from a social standpoint.	1	2	3	4	5



Core Gel Breast
IDE Clinical Trial

8 YEAR VISIT

PATIENT STUDY ID:	TRIAL NO.	COUNTRY NO.			SITE NO.	PATIENT NO.	PATIENT INITIALS		
	10-009	0	0	1			first	middle	last

TENNESSEE SELF-CONCEPT SCALE (Page 3 of 4)

<i>Remember, put a circle around the response number you have chosen for each statement.</i>	Completely False	Mostly False	Partly True and Partly False	Mostly True	Completely True
50. I do not like everyone I know.	1	2	3	4	5
51. Once in a while, I laugh at a dirty joke.	1	2	3	4	5
52. I am neither too tall nor too short.	1	2	3	4	5
53. I don't feel as well as I should.	1	2	3	4	5
54. I should have more sex appeal.	1	2	3	4	5
55. I am as religious as I want to be.	1	2	3	4	5
56. I wish I could be more trustworthy.	1	2	3	4	5
57. I shouldn't tell so many lies.	1	2	3	4	5
58. I am as smart as I want to be.	1	2	3	4	5
59. I am not the person I would like to be.	1	2	3	4	5
60. I wish I didn't give up as easily as I do.	1	2	3	4	5
61. I treat my parents as well as I should. <i>(Use past tense if parents are not living.)</i>	1	2	3	4	5
62. I am too sensitive to things my family says.	1	2	3	4	5
63. I should love my family more.	1	2	3	4	5
64. I am satisfied with the way I treat other people.	1	2	3	4	5
65. I should be more polite to others.	1	2	3	4	5
66. I ought to get along better with other people.	1	2	3	4	5
67. I gossip a little at times.	1	2	3	4	5
68. At times I feel like swearing.	1	2	3	4	5
69. I take good care of myself physically.	1	2	3	4	5
70. I try to be careful about my appearance.	1	2	3	4	5
71. I often act like I am "all thumbs".	1	2	3	4	5
72. I am true to my religion in my everyday life.	1	2	3	4	5
73. I try to change when I know I'm doing things that are wrong.	1	2	3	4	5
74. I sometimes do very bad things.	1	2	3	4	5
75. I can always take care of myself in any situation.	1	2	3	4	5

 MENTOR	Core Gel Breast IDE Clinical Trial			8 YEAR VISIT				
	PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO.	PATIENT NO.	PATIENT INITIALS first middle last		

TENNESSEE SELF-CONCEPT SCALE (Page 4 of 4)

<i>Remember, put a circle around the response number you have chosen for each statement.</i>	Completely False	Mostly False	Partly True and Partly False	Mostly True	Completely True
76. I take the blame for things without getting mad.	1	2	3	4	5
77. I do things without thinking about them first.	1	2	3	4	5
78. I try to play fair with my friends and family.	1	2	3	4	5
79. I take a real interest in my family.	1	2	3	4	5
80. I give in to my parents. <i>(Use past tense if parents are not living.)</i>	1	2	3	4	5
81. I try to understand the other fellow's point of view.	1	2	3	4	5
82. I get along well with other people.	1	2	3	4	5
83. I do not forgive others easily.	1	2	3	4	5
84. I would rather win than lose in a game.	1	2	3	4	5
85. I feel good most of the time.	1	2	3	4	5
86. I do poorly in sports and games.	1	2	3	4	5
87. I am a poor sleeper.	1	2	3	4	5
88. I do what is right most of the time.	1	2	3	4	5
89. I sometimes use unfair means to get ahead.	1	2	3	4	5
90. I have trouble doing the things that are right.	1	2	3	4	5
91. I solve my problems quite easily.	1	2	3	4	5
92. I change my mind a lot.	1	2	3	4	5
93. I try to run away from my problems.	1	2	3	4	5
94. I do my share of work at home.	1	2	3	4	5
95. I quarrel with my family.	1	2	3	4	5
96. I do not act like my family thinks I should.	1	2	3	4	5
97. I see good points in all the people I meet.	1	2	3	4	5
98. I do not feel at ease with other people.	1	2	3	4	5
99. I find it hard to talk with strangers.	1	2	3	4	5
100. Once in a while I put off until tomorrow what I ought to do today.	1	2	3	4	5

 MENTOR	Core Gel Breast IDE Clinical Trial			8 YEAR VISIT				
	PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO.	PATIENT NO.	PATIENT INITIALS first middle last		

SF-36 (Page 1 of 3)

TO THE PATIENT: This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Answer each question by circling **one** number. If you are unsure about how to answer a question, please give the best answer you can.

1. In general, would you say your health is: (Circle one number)	Excellent	Very Good	Good	Fair	Poor
	1	2	3	4	5

2. Compared to one year ago, how would you rate your health in general now? (Circle one number)	Much Better Now	Somewhat Better Now	About the Same	Somewhat Worse Now	Much Worse Now
	1	2	3	4	5

3. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much? (Circle one number for each question.)	Yes, Limited a Lot	Yes, Limited a Little	No, Not Limited at All
Vigorous activities , such as running, lifting heavy objects, participating in strenuous sports.	1	2	3
Moderate activities , such as moving a table, pushing a vacuum cleaner, bowling or playing golf	1	2	3
Lifting or carrying groceries	1	2	3
Climbing several flights of stairs	1	2	3
Climbing one flight of stairs	1	2	3
Bending, kneeling, or stooping	1	2	3
Walking more than a mile	1	2	3
Walking several blocks	1	2	3
Walking one block	1	2	3
Bathing or dressing yourself	1	2	3

 MENTOR	Core Gel Breast IDE Clinical Trial			8 YEAR VISIT							
	PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1			SITE NO.		PATIENT NO.		PATIENT INITIALS first middle last	

SF-36 (Page 2 of 3)

4. During the past 4 weeks , have you had any of the following problems with your work or other regular daily activities as a result of your physical health? (Circle one number for each question.)	YES	NO
Cut down on the amount of time you spent on work or other activities	1	2
Accomplished less than you would like	1	2
Were limited in the kind of work or other activities	1	2
Had difficulty performing the work or other activities (for example, it took extra effort)	1	2

5. During the past 4 weeks , have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)? (Circle one number for each question.)	YES	NO
Cut down on the amount of time you spent on work or other activities	1	2
Accomplished less than you would like	1	2
Didn't do work or other activities as carefully as usual	1	2

6. During the past 4 weeks , to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups? (Circle one number)	Not at All	Slightly	Moderately	Quite a Bit	Extremely
	1	2	3	4	5

7. How much bodily pain have you had during the past 4 weeks? (Circle one number)	None	Very Mild	Mild	Moderate	Severe	Very Severe
	1	2	3	4	5	6

8. During the past 4 weeks , how much did pain interfere with your normal work (including both work outside the home and housework)? (Circle one number)	Not at All	A Little Bit	Moderately	Quite a Bit	Extremely
	1	2	3	4	5

 MENTOR	Core Gel Breast IDE Clinical Trial			8 YEAR VISIT				
	PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO.	PATIENT NO.	PATIENT INITIALS first middle last		

SF-36 (Page 3 of 3)

9. These questions are about how you feel and how things have been with you **during the past 4 weeks**. For each question, please indicate the one answer that comes closest to the way you have been feeling. (Circle **one** number for each question.)

How much of the time during the past 4 weeks ...	All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	None of the Time
Did you feel full of pep?	1	2	3	4	5	6
Have you been a very nervous person?	1	2	3	4	5	6
Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
Have you felt calm and peaceful?	1	2	3	4	5	6
Did you have a lot of energy?	1	2	3	4	5	6
Have you felt downhearted and blue?	1	2	3	4	5	6
Did you feel worn out?	1	2	3	4	5	6
Have you been a happy person?	1	2	3	4	5	6
Did you feel tired?	1	2	3	4	5	6

10. During the past 4 weeks , how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)? (Circle one number.)	All of the Time	Most of the Time	Some of the Time	A Little of the Time	None of the Time
	1	2	3	4	5

11. How TRUE or FALSE is each of the following statements for you? (Circle one number for each question.)	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
I seem to get sick a little easier than other people	1	2	3	4	5
I am as healthy as anybody I know	1	2	3	4	5
I expect my health to get worse	1	2	3	4	5
My health is excellent	1	2	3	4	5



MENTOR

**Core Gel Breast
IDE Clinical Trial**

8 YEAR VISIT

PATIENT STUDY ID:

TRIAL NO.
10-009

COUNTRY NO.
0 | 0 | 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last

BODY ESTEEM SCALE (Page 1 of 1)

TO THE PATIENT: On this page are listed a number of body parts and functions. Please read each item and indicate how you feel about this part or function of ***your own body***, using the following scale:

- 1 = Have strong negative feelings
- 2 = Have moderate negative feelings
- 3 = Have no feeling one way or the other
- 4 = Have moderate positive feelings
- 5 = Have strong positive feelings

- | | |
|--|--|
| <input type="checkbox"/> 1. Body Scent | <input type="checkbox"/> 19. Arms |
| <input type="checkbox"/> 2. Appetite | <input type="checkbox"/> 20. Chest |
| <input type="checkbox"/> 3. Nose | <input type="checkbox"/> 21. Appearance of Eyes |
| <input type="checkbox"/> 4. Physical Stamina | <input type="checkbox"/> 22. Cheeks/Cheekbones |
| <input type="checkbox"/> 5. Reflexes | <input type="checkbox"/> 23. Hips |
| <input type="checkbox"/> 6. Lips | <input type="checkbox"/> 24. Legs |
| <input type="checkbox"/> 7. Muscular Strength | <input type="checkbox"/> 25. Physique |
| <input type="checkbox"/> 8. Waist | <input type="checkbox"/> 26. Sex Drive |
| <input type="checkbox"/> 9. Energy Level | <input type="checkbox"/> 27. Feet |
| <input type="checkbox"/> 10. Thighs | <input type="checkbox"/> 28. Sex Organs |
| <input type="checkbox"/> 11. Ears | <input type="checkbox"/> 29. Appearance of Stomach |
| <input type="checkbox"/> 12. Biceps | <input type="checkbox"/> 30. Health |
| <input type="checkbox"/> 13. Chin | <input type="checkbox"/> 31. Sex Activities |
| <input type="checkbox"/> 14. Body Build | <input type="checkbox"/> 32. Body Hair |
| <input type="checkbox"/> 15. Physical Coordination | <input type="checkbox"/> 33. Physical Condition |
| <input type="checkbox"/> 16. Buttocks | <input type="checkbox"/> 34. Face |
| <input type="checkbox"/> 17. Agility | <input type="checkbox"/> 35. Weight |
| <input type="checkbox"/> 18. Width of Shoulders | |



MENTOR

**Core Gel Breast
IDE Clinical Trial**

8 YEAR VISIT

PATIENT STUDY ID:

TRIAL NO.
10-009

COUNTRY NO.
0 | 0 | 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last

MANITOBA CANCER TREATMENT & RESEARCH FOUNDATION FUNCTIONAL LIVING INDEX: CANCER (FLIC)

Page 1 of 3

N/A (not a cancer patient)

TO THE PATIENT: Please indicate your rating by drawing a vertical line (|).

1. Most people experience some feelings of depression at times. Rate how often you feel these feelings.

1	2	3	4	5	6	7
Never						Continually

2. How well are you coping with your everyday stress?

1	2	3	4	5	6	7
Not Well						Very Well

3. How much time do you spend thinking about your illness?

1	2	3	4	5	6	7
Constantly						Never

4. Rate your ability to maintain your usual recreation or leisure activities.

1	2	3	4	5	6	7
Able						Unable

5. Has nausea affected your daily functioning?

1	2	3	4	5	6	7
Not At All						A Great Deal

6. How well do you feel today?

1	2	3	4	5	6	7
Extremely Poor						Extremely Well

7. Do you feel well enough to make a meal or do minor household repairs today?

1	2	3	4	5	6	7
Very Able						Not Able



MENTOR

**Core Gel Breast
IDE Clinical Trial**

8 YEAR VISIT

PATIENT STUDY ID:

TRIAL NO.
10-009

COUNTRY NO.
0 0 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last

MANITOBA CANCER TREATMENT & RESEARCH FOUNDATION FUNCTIONAL LIVING INDEX: CANCER (FLIC)

Page 2 of 3

N/A (not a cancer patient)

8. Rate the degree to which your cancer has imposed a hardship on those closest to you in the past 2 months.

| | | | | | |

1 2 3 4 5 6 7

No Hardship Tremendous Hardship

9. Rate how often you feel discouraged about your life.

| | | | | | |

1 2 3 4 5 6 7

Always Never

10. Rate your satisfaction with your work and your jobs around the house in the past month.

| | | | | | |

1 2 3 4 5 6 7

Very Dissatisfied Very Satisfied

11. How uncomfortable do you feel today?

| | | | | | |

1 2 3 4 5 6 7

Not at All Very Uncomfortable

12. Rate in your opinion, how disruptive your cancer has been to those closest to you in the past 2 weeks.

| | | | | | |

1 2 3 4 5 6 7

Totally Disruptive No Disruption

13. How much is pain or discomfort interfering with your daily activities?

| | | | | | |

1 2 3 4 5 6 7

Not at All A Great Deal

14. Rate the degree to which your cancer has imposed a hardship on you (personally) in the past 2 weeks.

| | | | | | |

1 2 3 4 5 6 7

Tremendous Hardship No Hardship



MENTOR

**Core Gel Breast
IDE Clinical Trial**

8 YEAR VISIT

PATIENT STUDY ID:

TRIAL NO.
10-009

COUNTRY NO.
0 0 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last

MANITOBA CANCER TREATMENT & RESEARCH FOUNDATION FUNCTIONAL LIVING INDEX: CANCER (FLIC)

Page 3 of 3

N/A (not a cancer patient)

15. How much of your usual household tasks are you able to complete?

1	2	3	4	5	6	7
All						None

16. Rate how willing you were to see and spend time with those closest to you, in the past 2 weeks.

1	2	3	4	5	6	7
Unwilling						Very Willing

17. How much nausea have you had in the past 2 weeks?

1	2	3	4	5	6	7
None						A Great Deal

18. Rate the degree to which you are frightened of the future.

1	2	3	4	5	6	7
Constantly Terrified						Not Afraid

19. Rate how willing you were to see and spend time with friends, in the past 2 weeks.

1	2	3	4	5	6	7
Unwilling						Very Willing

20. How much of your pain or discomfort over the past 2 weeks was related to your cancer?

1	2	3	4	5	6	7
None						All

21. Rate your confidence in your prescribed course of treatment.

1	2	3	4	5	6	7
No Confidence						Very Confident

22. How well do you appear today?

1	2	3	4	5	6	7
Extremely Poor						Extremely Well

	Core Gel Breast IDE Clinical Trial	ADVERSE EVENTS				8 YEAR VISIT
PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO.	PATIENT NO.	PATIENT INITIALS first middle last	<input type="checkbox"/> No Adverse Events

Enter one adverse event per line. If the event was experienced at more than one body site, enter each body site on a separate line.

AE CODE* (See Below)	CAUSALITY 1 = Procedure related 2 = Device related 3 = Unknown 4 = Other	EVENT SIDE 0 = N/A 1 = Right 2 = Left	ASSOCIATED BREAST PAIN 0 = None 1 = Mild 2 = Moderate 3 = Severe	ONSET DATE month day year	SEVERITY 1 = Mild 2 = Moderate 3 = Severe	TREATMENT REQUIRED (check all that apply) 1 = No Treatment 2 = Medication (specify) 3 = Secondary Procedure (enter Procedure Type Code and date below, and complete Secondary Procedures Report for all procedures performed for this date)** 4 = Hospitalization (specify # of days and admission date) 5 = Other (specify)	OUTCOME 1 = Resolved 2 = Ongoing 3 = Death 4 = Unknown	RESOLUTION DATE month day year
<input type="checkbox"/> 1	<input type="checkbox"/> 3	<input type="checkbox"/> 0	<input type="checkbox"/> 0 <input type="checkbox"/> 3	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 4 days, Date: ___/___/___	<input type="checkbox"/> 1 <input type="checkbox"/> 4	
<input type="checkbox"/> 2	<input type="checkbox"/> 4	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 5 Procedure Date: ___/___/___	<input type="checkbox"/> 2	
<input type="checkbox"/> 1	<input type="checkbox"/> 3	<input type="checkbox"/> 0	<input type="checkbox"/> 0 <input type="checkbox"/> 3	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 4 days, Date: ___/___/___	<input type="checkbox"/> 1 <input type="checkbox"/> 4	
<input type="checkbox"/> 2	<input type="checkbox"/> 4	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 5 Procedure Date: ___/___/___	<input type="checkbox"/> 2	
<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 3	Procedure Date: ___/___/___	<input type="checkbox"/> 3	

****Complete Secondary Procedures Report. If new study device is implanted, complete Re-implantation Report.**

Investigator's Signature _____ month _____ day _____ year

<p>*ADVERSE EVENT CODES</p> <p>15 = Lymphadenopathy 16 = Necrosis 17 = New Diagnosis of Breast Cancer 18 = New Diagnosis of Rheumatic Disease, specify: 19 = Nipple—Unacceptably Low Sensitivity 20 = Nipple—Unacceptably High Sensitivity 21 = Position Change 22 = Ptosis 23 = Rupture 24 = Seroma 25 = Size Change—Patient Request 26 = Size Change—Physician Assessment only 27 = Wrinkling</p>	<p>†SECONDARY PROCEDURE TYPE CODES</p> <p>81 = Biopsy 82 = Capsulectomy 83 = Explanation with Replacement** 84 = Explanation without Replacement 85 = Incision and Drainage 86 = Mastopexy 87 = Open Capsulotomy 88 = Position Change 89 = Scar Revision 90 = Skin Adjustment 91 = Other, specify: _____ 92 = Other, specify: _____</p>
--	--



MENTOR

**Core Gel Breast
IDE Clinical Trial**

9 YEAR VISIT

PATIENT STUDY ID:

TRIAL NO.
10-009

COUNTRY NO.
0 0 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last

Visit Date:

month day year

Missed Visit

BREAST MEASUREMENTS

RIGHT Not Implanted with Study Device

Circumferential Breast Measurement cm

Bra Size (i.e. 32A) N/A (breast absent)

LEFT Not Implanted with Study Device

Circumferential Breast Measurement cm

Bra Size (i.e. 32A) N/A (breast absent)

MAMMOGRAPHY RESULTS

Date of Mammogram:

month year

Not Done

RIGHT

- Birads 0 Needs additional imaging evaluation
 - Birads 1 Negative
 - Birads 2 Benign finding
 - Birads 3 Probable benign finding—short interval follow-up is suggested
 - Birads 4 Suspicious abnormality—biopsy should be considered
 - Birads 5 Highly suggestive of malignancy—appropriate action should be taken
- List abnormality: _____

LEFT

- Birads 0 Needs additional imaging evaluation
 - Birads 1 Negative
 - Birads 2 Benign finding
 - Birads 3 Probable benign finding—short interval follow-up is suggested
 - Birads 4 Suspicious abnormality—biopsy should be considered
 - Birads 5 Highly suggestive of malignancy—appropriate action should be taken
- List abnormality: _____

VISIT REPORT

1. Has the patient become pregnant since the last visit?

- No
- Yes, without complications
- Yes, with complications

Complete Adverse Events Report

2. Has the patient attempted to breastfeed since the last visit?

- No
- Yes, was there adequate milk?
 - No (Enter code 30 on Adverse Events Report)
 - Yes

3. Would the patient have this breast surgery again?

- No, reason: _____
- Yes

4. **Breast Cancer Reconstruction Patients only:**

N/A (augmentation patient)

Has the patient received any adjuvant therapies since the last visit?

- No
- Yes, check all that apply:
 - Radiation Therapy
 - Chemotherapy
 - Other, specify: _____

Treating Oncologist

Name: _____

Phone: (_____) _____

 MENTOR	Core Gel Breast IDE Clinical Trial		9 YEAR VISIT			
	PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO.	PATIENT NO.	PATIENT INITIALS first middle last

CAPSULAR CONTRACTURE ASSESSMENT OF PROSTHESIS	
Right Prosthesis is: <input type="radio"/> <input type="checkbox"/> Not Implanted with Study Device 1 <input type="checkbox"/> Baker Class I (normally soft and natural appearance) 2 <input type="checkbox"/> Baker Class II (a natural appearance despite palpable firmness) 3 <input type="checkbox"/> Baker Class III (firm with visible distortion) 4 <input type="checkbox"/> Baker Class IV (obvious spherical distortion)	Left Prosthesis is: <input type="radio"/> <input type="checkbox"/> Not Implanted with Study Device 1 <input type="checkbox"/> Baker Class I (normally soft and natural appearance) 2 <input type="checkbox"/> Baker Class II (a natural appearance despite palpable firmness) 3 <input type="checkbox"/> Baker Class III (firm with visible distortion) 4 <input type="checkbox"/> Baker Class IV (obvious spherical distortion)
Complete Adverse Events Report for Baker III or IV.	

NIPPLE/BREAST SENSITIVITY	
<p>How would patient describe the feeling in nipple(s) and/or breast(s) now?</p> <p><i>If unacceptably high or low at baseline, and sensation remains the same post-operatively, do not complete an Adverse Events Report.</i></p> <p><i>If acceptable at baseline and has become unacceptable post-operatively, complete an Adverse Events Report.</i></p>	
RIGHT <input type="radio"/> <input type="checkbox"/> Not Implanted with Study Device Nipple Sensation is: 1 <input type="checkbox"/> Unacceptably low 2 <input type="checkbox"/> Acceptable 3 <input type="checkbox"/> Unacceptably high 4 <input type="checkbox"/> N/A, nipple absent Breast sensation is: 1 <input type="checkbox"/> Unacceptably low 2 <input type="checkbox"/> Acceptable 3 <input type="checkbox"/> Unacceptably high 4 <input type="checkbox"/> N/A, breast absent	LEFT <input type="radio"/> <input type="checkbox"/> Not Implanted with Study Device Nipple Sensation is: 1 <input type="checkbox"/> Unacceptably low 2 <input type="checkbox"/> Acceptable 3 <input type="checkbox"/> Unacceptably high 4 <input type="checkbox"/> N/A, nipple absent Breast sensation is: 1 <input type="checkbox"/> Unacceptably low 2 <input type="checkbox"/> Acceptable 3 <input type="checkbox"/> Unacceptably high 4 <input type="checkbox"/> N/A, breast absent
Complete Adverse Events Report for any complications or adverse events noted at this visit.	



**Core Gel Breast
IDE Clinical Trial**

9 YEAR VISIT

PATIENT STUDY ID:

TRIAL NO.

10-009

COUNTRY NO.

0 | 0 | 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last

INVESTIGATOR-COMPLETED RHEUMATIC DISEASE DIAGNOSIS QUESTIONNAIRE

No diagnosis made

Has the patient been diagnosed by a RHEUMATOLOGIST for any of the following **since the last visit**?

If YES, complete Adverse Event Report.

RHEUMATIC DISEASE	NO YES		DATE OF ONSET (if known)	
			month	year
Connective Tissue Disorders: SLE	<input type="checkbox"/>	<input type="checkbox"/>		
Sjogren's Syndrome	<input type="checkbox"/>	<input type="checkbox"/>		
Scleroderma	<input type="checkbox"/>	<input type="checkbox"/>		
Polymyositis	<input type="checkbox"/>	<input type="checkbox"/>		
Other Connective Tissue Disorders	<input type="checkbox"/>	<input type="checkbox"/>		
Inflammatory Arthritis: Rheumatoid Arthritis	<input type="checkbox"/>	<input type="checkbox"/>		
Crystalline Arthritis	<input type="checkbox"/>	<input type="checkbox"/>		
Infectious Arthritis	<input type="checkbox"/>	<input type="checkbox"/>		
Spondyarthropathies	<input type="checkbox"/>	<input type="checkbox"/>		
Other Inflammatory Arthritis	<input type="checkbox"/>	<input type="checkbox"/>		
Non-Inflammatory Rheumatic Conditions: Osteoarthritis	<input type="checkbox"/>	<input type="checkbox"/>		
Fibromyalgia	<input type="checkbox"/>	<input type="checkbox"/>		
Chronic Fatigue	<input type="checkbox"/>	<input type="checkbox"/>		
Other Mechanical or Degenerative	<input type="checkbox"/>	<input type="checkbox"/>		
Other, specify: _____	<input type="checkbox"/>	<input type="checkbox"/>		
Other, specify: _____	<input type="checkbox"/>	<input type="checkbox"/>		

Disease must be diagnosed by a rheumatologist.

Rheumatologist who made diagnosis:

Name: _____

Address: _____

Phone: (_____) _____

**MENTOR****Core Gel Breast
IDE Clinical Trial****9 YEAR VISIT****PATIENT STUDY ID:**TRIAL NO.
10-009COUNTRY NO.
0 0 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last**RHEUMATOLOGY SYMPTOMS (Page 1 of 2)**1 No symptoms; patient not referred to rheumatologistPlease check any **current** symptoms which:

1. The patient experiences on a regular basis
2. The cause is unknown and cannot be attributed to any patient activity.

RHEUMATOLOGY SYMPTOM	STATUS SINCE LAST VISIT		DATE OF ONSET (only if new since last visit)		STATUS AS OF THIS VISIT	
	CONTINUING	NEW	month	year	RESOLVED	CONTINUING
Loss of weight without dieting	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Insomnia	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Weakness	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Exhaustion	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Joint swelling	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Heel pain	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Frequent muscle cramps	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Numbness of feet	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Ringing in ears	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Pain/grittiness in eyes	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Dryness of eyes, nose	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Pain on swallowing or chewing	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Neck pain/stiffness	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Pain on breathing	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Heart murmurs	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Loss of appetite	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Persistent fever	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Night sweats	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Generalized aching	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Loss of height	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Joint pain	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Frequent muscle pain	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>



**Core Gel Breast
IDE Clinical Trial**

9 YEAR VISIT

PATIENT STUDY ID:	TRIAL NO.	COUNTRY NO.			SITE NO.	PATIENT NO.	PATIENT INITIALS		
	10-009	0	0	1			first	middle	last

RHEUMATOLOGY SYMPTOMS (Page 2 of 2)

Please check any **current** symptoms which:

1. The patient experiences on a regular basis
2. The cause is unknown and cannot be attributed to any patient activity.

RHEUMATOLOGY SYMPTOM	STATUS SINCE LAST VISIT		DATE OF ONSET (only if new since last visit)		STATUS AS OF THIS VISIT	
	CONTINUING	NEW	month	year	RESOLVED	CONTINUING
Numbness of hands	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Jaw pain	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Open sores	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Redness of eyes	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Dryness of mouth	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Back pain/stiffness	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Severe chest pains	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Chronic cough	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Difficulty swallowing	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Frequent, severe or persistent diarrhea or constipation	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Severe rashes	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Frequent muscle cramps	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Severe dryness of skin	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Tender lumps/bumps	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Excessive sensitivity to sun	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Color changes on hands or feet with cold exposure	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Joint pain	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Frequent hives	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Numbness of hands	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Tightness of skin	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Unusual hair loss	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Tenderness of scalp	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Severe bruising with little or no injury	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>



**Core Gel Breast
IDE Clinical Trial**

9 YEAR VISIT

PATIENT STUDY ID:	TRIAL NO.	COUNTRY NO.			SITE NO.	PATIENT NO.	PATIENT INITIALS		
	10-009	0	0	1			first	middle	last

RHEUMATOLOGICAL PHYSICAL EXAMINATION (Page 1 of 2)

No symptoms present

Check the box for each physical finding noted to be present and outside normal limits.

PHYSICAL FINDING	STATUS SINCE LAST VISIT		DATE OF ONSET (only if new since last visit)		STATUS AS OF THIS VISIT	
	CONTINUING	NEW	month	year	RESOLVED	CONTINUING
Muscle weakness: Headlift from supine position against gravity	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Inability to raise arms	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Inability to get out of chair	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Joint swellings: Wrists	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Digits	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Elbows	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Knees	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Ankles	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Joint deformities and flexion contracture: Boutonnière ¹	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Ulnar drift ²	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Swan neck ³	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Trigger fingers	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Joint tenderness	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Grip strength and motion-finger to palm crease (normal = 0 cm)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Neck motion—chin to chest or sternum (normal = 0 cm)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Chest expansion (normal = at least 5 cm)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Occiput to wall (normal = 0 cm)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Jaw motion (normally upper-lower incisors 3 cm)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Back motion—measure 10 cm above posterior supine iliac spines— with forward bending motion at least 5 cm from first point (total distance at least 15 cm)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>

¹**Boutonnière** - Contractures of hand musculature characterized by proximal interphalangeal joint flexion and distal interphalangeal joint hyperextension.

³**Swan Neck** - Finger deformity characterized by flexion of distal interphalangeal joints and hyperflexion of the proximal interphalangeal joints due to hypermobility.

²**Ulnar Drift** - Joint change at the metacarpophalangeal joints. Long axis of fingers deviate in an ulnar direction.

**MENTOR****Core Gel Breast
IDE Clinical Trial****9 YEAR VISIT****PATIENT STUDY ID:**TRIAL NO.
10-009COUNTRY NO.
0 0 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last**RHEUMATOLOGICAL PHYSICAL EXAMINATION (Page 2 of 2)**

Check the box for each physical finding noted to be present and outside normal limits.

PHYSICAL FINDING	POSSIBLE INDICATION	STATUS SINCE LAST VISIT		DATE OF ONSET (only if new since last visit)		STATUS AS OF THIS VISIT	
		CONTINUING	NEW	month	year	RESOLVED	CONTINUING
Hair loss	<i>Lupus, Scleroderma</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Skin tightness, especially face and hands	<i>Scleroderma</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Raynaud's phenomenon	<i>Lupus, Scleroderma</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Calcinosis over tibia, ulna, elbows	<i>Scleroderma, Dermatomyositis</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Swollen digits	<i>Juvenile RA, Reiter's syndrome, Psoriatic arthritis, Early scleroderma, Reflex sympathetic dystrophy</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Erythema over knuckles	<i>Dermatomyositis</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Bluish hue color on eyelids	<i>Dermatomyositis</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Non-tender lumps or nodules on elbows	<i>Rheumatoid gout</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Tender lumps-tibia	<i>Erythema nodosum</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Painless eye redness	<i>Conjunctivitis</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Painful eye redness with decreased vision, small pupils	<i>Uveitis</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Tenderness—insertion of deltoids	<i>Polymyalgia rheumatica</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Muscle tenderness	<i>Polymyositis</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Nail pittings	<i>Psoriatic arthritis, Reiter's syndrome</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Tinels or Phalen's signs	<i>Carpal tunnel syndrome</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Skin rashes	<i>Discoid lupus</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>

Does the patient require an examination by a rheumatologist?

 No Yes, record rheumatologist's findings:



Core Gel Breast IDE Clinical Trial

ADVERSE EVENTS

9 YEAR VISIT

PATIENT STUDY ID: TRIAL NO. 10-009 COUNTRY NO. 0 0 1 SITE NO. PATIENT NO. PATIENT INITIALS first middle last

No Adverse Events

Enter one adverse event per line. If the event was experienced at more than one body site, enter each body site on a separate line.

AE CODE* (See Below)	CAUSALITY 1 = Procedure related 2 = Device related 3 = Unknown 4 = Other	EVENT SIDE 0 = N/A 1 = Right 2 = Left	ASSOCIATED BREAST PAIN 0 = None 1 = Mild 2 = Moderate 3 = Severe	ONSET DATE month day year	SEVERITY 1 = Mild 2 = Moderate 3 = Severe	TREATMENT REQUIRED (check all that apply) 1 = No Treatment 2 = Medication (specify) 3 = Secondary Procedure (enter Procedure Type Code and date below, and complete Secondary Procedures Report for all procedures performed for this date)** 4 = Hospitalization (specify # of days and admission date) 5 = Other (specify)	OUTCOME 1 = Resolved 2 = Ongoing 3 = Death 4 = Unknown	RESOLUTION DATE month day year
<input type="checkbox"/> 1	<input type="checkbox"/> 3	<input type="checkbox"/> 0	<input type="checkbox"/> 0 <input type="checkbox"/> 3	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 4 days, Date: ___/___/___	<input type="checkbox"/> 1 <input type="checkbox"/> 4	
<input type="checkbox"/> 2	<input type="checkbox"/> 4	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 5 Procedure Date: ___/___/___	<input type="checkbox"/> 2	
<input type="checkbox"/> 1	<input type="checkbox"/> 3	<input type="checkbox"/> 0	<input type="checkbox"/> 0 <input type="checkbox"/> 3	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 4 days, Date: ___/___/___	<input type="checkbox"/> 1 <input type="checkbox"/> 4	
<input type="checkbox"/> 2	<input type="checkbox"/> 4	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 5 Procedure Date: ___/___/___	<input type="checkbox"/> 2	
<input type="checkbox"/> 1	<input type="checkbox"/> 3	<input type="checkbox"/> 0	<input type="checkbox"/> 0 <input type="checkbox"/> 3	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 4 days, Date: ___/___/___	<input type="checkbox"/> 1 <input type="checkbox"/> 4	
<input type="checkbox"/> 2	<input type="checkbox"/> 4	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 5 Procedure Date: ___/___/___	<input type="checkbox"/> 2	
<input type="checkbox"/> 1	<input type="checkbox"/> 3	<input type="checkbox"/> 0	<input type="checkbox"/> 0 <input type="checkbox"/> 3	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 4 days, Date: ___/___/___	<input type="checkbox"/> 1 <input type="checkbox"/> 4	
<input type="checkbox"/> 2	<input type="checkbox"/> 4	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 5 Procedure Date: ___/___/___	<input type="checkbox"/> 2	
<input type="checkbox"/> 1	<input type="checkbox"/> 3	<input type="checkbox"/> 0	<input type="checkbox"/> 0 <input type="checkbox"/> 3	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 4 days, Date: ___/___/___	<input type="checkbox"/> 1 <input type="checkbox"/> 4	
<input type="checkbox"/> 2	<input type="checkbox"/> 4	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 5 Procedure Date: ___/___/___	<input type="checkbox"/> 2	
<input type="checkbox"/> 1	<input type="checkbox"/> 3	<input type="checkbox"/> 0	<input type="checkbox"/> 0 <input type="checkbox"/> 3	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 4 days, Date: ___/___/___	<input type="checkbox"/> 1 <input type="checkbox"/> 4	
<input type="checkbox"/> 2	<input type="checkbox"/> 4	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 5 Procedure Date: ___/___/___	<input type="checkbox"/> 2	

**Complete Secondary Procedures Report. If new study device is implanted, complete Re-implantation Report.

Investigator's Signature _____ month _____ day _____ year

*ADVERSE EVENT CODES	†SECONDARY PROCEDURE TYPE CODES
1 = Asymmetry 2 = Baker II Capsular Contracture with Surgical Intervention 3 = Baker III Capsular Contracture 4 = Baker IV Capsular Contracture 5 = Breast pain not associated with any other complication 6 = Breast—Unacceptably Low Sensitivity 7 = Breast—Unacceptably High Sensitivity 8 = Calcification 9 = Delayed Wound Healing 10 = Extrusion 11 = Granuloma 12 = Hematoma 13 = Hypertrophic Scarring 14 = Infection 15 = Lymphadenopathy 16 = Necrosis 17 = New Diagnosis of Breast Cancer 18 = New Diagnosis of Rheumatic Disease, specify: 19 = Nipple—Unacceptably Low Sensitivity 20 = Nipple—Unacceptably High Sensitivity 21 = Position Change 22 = Ptosis 23 = Rupture 24 = Seroma 25 = Size Change—Patient Request 26 = Size Change—Physician Assessment only 27 = Wrinkling 28 = Lactation Difficulties, specify: 29 = Other, specify: 30 = Other, specify:	81 = Biopsy 82 = Capsulectomy 83 = Explanation with Replacement** 84 = Explanation without Replacement 85 = Incision and Drainage 86 = Mastopexy 87 = Open Capsulotomy 88 = Position Change 89 = Scar Revision 90 = Skin Adjustment 91 = Other, specify: 92 = Other, specify:



MENTOR

**Core Gel Breast
IDE Clinical Trial**

10 YEAR VISIT

PATIENT STUDY ID:

TRIAL NO.
10-009

COUNTRY NO.
0 0 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last

Visit Date:

month day year

Missed Visit

BREAST MEASUREMENTS

RIGHT Not Implanted with Study Device

Circumferential Breast Measurement cm

Bra Size (i.e. 32A) N/A (breast absent)

LEFT Not Implanted with Study Device

Circumferential Breast Measurement cm

Bra Size (i.e. 32A) N/A (breast absent)

MAMMOGRAPHY RESULTS

Date of Mammogram:

month year

Not Done

RIGHT

- Birads 0 Needs additional imaging evaluation
 - Birads 1 Negative
 - Birads 2 Benign finding
 - Birads 3 Probable benign finding—short interval follow-up is suggested
 - Birads 4 Suspicious abnormality—biopsy should be considered
 - Birads 5 Highly suggestive of malignancy—appropriate action should be taken
- List abnormality: _____

LEFT

- Birads 0 Needs additional imaging evaluation
 - Birads 1 Negative
 - Birads 2 Benign finding
 - Birads 3 Probable benign finding—short interval follow-up is suggested
 - Birads 4 Suspicious abnormality—biopsy should be considered
 - Birads 5 Highly suggestive of malignancy—appropriate action should be taken
- List abnormality: _____

VISIT REPORT

1. Has the patient become pregnant since the last visit?

- No
- Yes, without complications
- Yes, with complications

Complete Adverse Events Report

2. Has the patient attempted to breastfeed since the last visit?

- No
- Yes, was there adequate milk?
 - No (Enter code 30 on Adverse Events Report)
 - Yes

3. Would the patient have this breast surgery again?

- No, reason: _____
- Yes

4. **Breast Cancer Reconstruction Patients only:**

N/A (augmentation patient)

Has the patient received any adjuvant therapies since the last visit?

- No
- Yes, check all that apply:
 - Radiation Therapy
 - Chemotherapy
 - Other, specify: _____

Treating Oncologist

Name: _____

Phone: (_____) _____

	Core Gel Breast IDE Clinical Trial		10 YEAR VISIT			
	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO.	PATIENT NO.	PATIENT INITIALS <small>first middle last</small>	

CAPSULAR CONTRACTURE ASSESSMENT OF PROSTHESIS	
Right Prosthesis is: <input type="radio"/> Not Implanted with Study Device 1 <input type="checkbox"/> Baker Class I (normally soft and natural appearance) 2 <input type="checkbox"/> Baker Class II (a natural appearance despite palpable firmness) 3 <input type="checkbox"/> Baker Class III (firm with visible distortion) 4 <input type="checkbox"/> Baker Class IV (obvious spherical distortion)	Left Prosthesis is: <input type="radio"/> Not Implanted with Study Device 1 <input type="checkbox"/> Baker Class I (normally soft and natural appearance) 2 <input type="checkbox"/> Baker Class II (a natural appearance despite palpable firmness) 3 <input type="checkbox"/> Baker Class III (firm with visible distortion) 4 <input type="checkbox"/> Baker Class IV (obvious spherical distortion)
Complete Adverse Events Report for Baker III or IV.	

NIPPLE/BREAST SENSITIVITY	
<p>How would patient describe the feeling in nipple(s) and/or breast(s) now?</p> <p><i>If unacceptably high or low at baseline, and sensation remains the same post-operatively, do not complete an Adverse Events Report.</i></p> <p><i>If acceptable at baseline and has become unacceptable post-operatively, complete an Adverse Events Report.</i></p>	
RIGHT <input type="radio"/> Not Implanted with Study Device Nipple Sensation is: 1 <input type="checkbox"/> Unacceptably low 2 <input type="checkbox"/> Acceptable 3 <input type="checkbox"/> Unacceptably high 4 <input type="checkbox"/> N/A, nipple absent Breast sensation is: 1 <input type="checkbox"/> Unacceptably low 2 <input type="checkbox"/> Acceptable 3 <input type="checkbox"/> Unacceptably high 4 <input type="checkbox"/> N/A, breast absent	LEFT <input type="radio"/> Not Implanted with Study Device Nipple Sensation is: 1 <input type="checkbox"/> Unacceptably low 2 <input type="checkbox"/> Acceptable 3 <input type="checkbox"/> Unacceptably high 4 <input type="checkbox"/> N/A, nipple absent Breast sensation is: 1 <input type="checkbox"/> Unacceptably low 2 <input type="checkbox"/> Acceptable 3 <input type="checkbox"/> Unacceptably high 4 <input type="checkbox"/> N/A, breast absent
Complete Adverse Events Report for any complications or adverse events noted at this visit.	

**MENTOR****Core Gel Breast
IDE Clinical Trial****10 YEAR VISIT****PATIENT STUDY ID:**TRIAL NO.
10-009COUNTRY NO.
0 | 0 | 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last**INVESTIGATOR-COMPLETED RHEUMATIC DISEASE DIAGNOSIS QUESTIONNAIRE** No diagnosis madeHas the patient been diagnosed by a RHEUMATOLOGIST for any of the following **since the last visit?****If YES, complete Adverse Event Report.**

RHEUMATIC DISEASE	NO YES		DATE OF ONSET (if known)	
			month	year
Connective Tissue Disorders: SLE	<input type="checkbox"/>	<input type="checkbox"/>		
Sjogren's Syndrome	<input type="checkbox"/>	<input type="checkbox"/>		
Scleroderma	<input type="checkbox"/>	<input type="checkbox"/>		
Polymyositis	<input type="checkbox"/>	<input type="checkbox"/>		
Other Connective Tissue Disorders	<input type="checkbox"/>	<input type="checkbox"/>		
Inflammatory Arthritis: Rheumatoid Arthritis	<input type="checkbox"/>	<input type="checkbox"/>		
Crystalline Arthritis	<input type="checkbox"/>	<input type="checkbox"/>		
Infectious Arthritis	<input type="checkbox"/>	<input type="checkbox"/>		
Spondyarthropathies	<input type="checkbox"/>	<input type="checkbox"/>		
Other Inflammatory Arthritis	<input type="checkbox"/>	<input type="checkbox"/>		
Non-Inflammatory Rheumatic Conditions: Osteoarthritis	<input type="checkbox"/>	<input type="checkbox"/>		
Fibromyalgia	<input type="checkbox"/>	<input type="checkbox"/>		
Chronic Fatigue	<input type="checkbox"/>	<input type="checkbox"/>		
Other Mechanical or Degenerative	<input type="checkbox"/>	<input type="checkbox"/>		
Other, specify: _____	<input type="checkbox"/>	<input type="checkbox"/>		
Other, specify: _____	<input type="checkbox"/>	<input type="checkbox"/>		

Disease must be diagnosed by a rheumatologist.

Rheumatologist who made diagnosis:

Name: _____

Address: _____

Phone: (_____) _____



**Core Gel Breast
IDE Clinical Trial**

10 YEAR VISIT

PATIENT STUDY ID:

TRIAL NO.
10-009

COUNTRY NO.
0 0 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last

RHEUMATOLOGY SYMPTOMS (Page 1 of 2)

No symptoms; patient not referred to rheumatologist

Please check any **current** symptoms which:

1. The patient experiences on a regular basis
2. The cause is unknown and cannot be attributed to any patient activity.

RHEUMATOLOGY SYMPTOM	STATUS SINCE LAST VISIT		DATE OF ONSET (only if new since last visit)		STATUS AS OF THIS VISIT	
	CONTINUING	NEW	month	year	RESOLVED	CONTINUING
Loss of weight without dieting	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Insomnia	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Weakness	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Exhaustion	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Joint swelling	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Heel pain	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Frequent muscle cramps	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Numbness of feet	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Ringing in ears	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Pain/grittiness in eyes	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Dryness of eyes, nose	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Pain on swallowing or chewing	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Neck pain/stiffness	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Pain on breathing	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Heart murmurs	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Loss of appetite	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Persistent fever	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Night sweats	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Generalized aching	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Loss of height	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Joint pain	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Frequent muscle pain	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>



**Core Gel Breast
IDE Clinical Trial**

10 YEAR VISIT

PATIENT STUDY ID:	TRIAL NO.	COUNTRY NO.			SITE NO.	PATIENT NO.	PATIENT INITIALS		
	10-009	0	0	1			first	middle	last

RHEUMATOLOGY SYMPTOMS (Page 2 of 2)

Please check any **current** symptoms which:

1. The patient experiences on a regular basis
2. The cause is unknown and cannot be attributed to any patient activity.

RHEUMATOLOGY SYMPTOM	STATUS SINCE LAST VISIT		DATE OF ONSET (only if new since last visit)		STATUS AS OF THIS VISIT	
	CONTINUING	NEW	month	year	RESOLVED	CONTINUING
Numbness of hands	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Jaw pain	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Open sores	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Redness of eyes	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Dryness of mouth	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Back pain/stiffness	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Severe chest pains	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Chronic cough	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Difficulty swallowing	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Frequent, severe or persistent diarrhea or constipation	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Severe rashes	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Frequent muscle cramps	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Severe dryness of skin	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Tender lumps/bumps	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Excessive sensitivity to sun	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Color changes on hands or feet with cold exposure	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Joint pain	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Frequent hives	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Numbness of hands	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Tightness of skin	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Unusual hair loss	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Tenderness of scalp	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Severe bruising with little or no injury	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>



**Core Gel Breast
IDE Clinical Trial**

10 YEAR VISIT

PATIENT STUDY ID:	TRIAL NO.	COUNTRY NO.			SITE NO.	PATIENT NO.	PATIENT INITIALS		
	10-009	0	0	1			first	middle	last

RHEUMATOLOGICAL PHYSICAL EXAMINATION (Page 1 of 2)

No symptoms present

Check the box for each physical finding noted to be present and outside normal limits.

PHYSICAL FINDING	STATUS SINCE LAST VISIT		DATE OF ONSET (only if new since last visit)		STATUS AS OF THIS VISIT	
	CONTINUING	NEW	month	year	RESOLVED	CONTINUING
Muscle weakness: Headlift from supine position against gravity	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Inability to raise arms	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Inability to get out of chair	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Joint swellings: Wrists	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Digits	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Elbows	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Knees	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Ankles	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Joint deformities and flexion contracture: Boutonnière ¹	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Ulnar drift ²	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Swan neck ³	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Trigger fingers	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Joint tenderness	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Grip strength and motion-finger to palm crease (normal = 0 cm)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Neck motion—chin to chest or sternum (normal = 0 cm)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Chest expansion (normal = at least 5 cm)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Occiput to wall (normal = 0 cm)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Jaw motion (normally upper-lower incisors 3 cm)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Back motion—measure 10 cm above posterior supine iliac spines— with forward bending motion at least 5 cm from first point (total distance at least 15 cm)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>

¹**Boutonnière** - Contractures of hand musculature characterized by proximal interphalangeal joint flexion and distal interphalangeal joint hyperextension.

³**Swan Neck** - Finger deformity characterized by flexion of distal interphalangeal joints and hyperflexion of the proximal interphalangeal joints due to hypermobility.

²**Ulnar Drift** - Joint change at the metacarpophalangeal joints. Long axis of fingers deviate in an ulnar direction.

**MENTOR****Core Gel Breast
IDE Clinical Trial****10 YEAR VISIT****PATIENT STUDY ID:**TRIAL NO.
10-009COUNTRY NO.
0 0 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last**RHEUMATOLOGICAL PHYSICAL EXAMINATION (Page 2 of 2)**

Check the box for each physical finding noted to be present and outside normal limits.

PHYSICAL FINDING	POSSIBLE INDICATION	STATUS SINCE LAST VISIT		DATE OF ONSET (only if new since last visit)		STATUS AS OF THIS VISIT	
		CONTINUING	NEW	month	year	RESOLVED	CONTINUING
Hair loss	<i>Lupus, Scleroderma</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Skin tightness, especially face and hands	<i>Scleroderma</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Raynaud's phenomenon	<i>Lupus, Scleroderma</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Calcinosis over tibia, ulna, elbows	<i>Scleroderma, Dermatomyositis</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Swollen digits	<i>Juvenile RA, Reiter's syndrome, Psoriatic arthritis, Early scleroderma, Reflex sympathetic dystrophy</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Erythema over knuckles	<i>Dermatomyositis</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Bluish hue color on eyelids	<i>Dermatomyositis</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Non-tender lumps or nodules on elbows	<i>Rheumatoid gout</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Tender lumps-tibia	<i>Erythema nodosum</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Painless eye redness	<i>Conjunctivitis</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Painful eye redness with decreased vision, small pupils	<i>Uveitis</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Tenderness—insertion of deltoids	<i>Polymyalgia rheumatica</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Muscle tenderness	<i>Polymyositis</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Nail pittings	<i>Psoriatic arthritis, Reiter's syndrome</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Tinels or Phalen's signs	<i>Carpal tunnel syndrome</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Skin rashes	<i>Discoid lupus</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>

Does the patient require an examination by a rheumatologist?

 No Yes, record rheumatologist's findings:



Core Gel Breast
IDE Clinical Trial

10 YEAR VISIT

PATIENT STUDY ID:

TRIAL NO.
10-009

COUNTRY NO.
0 | 0 | 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last

ROSENBERG SELF-ESTEEM SCALE (Page 1 of 1)

TO THE PATIENT: Below are some statements with which some people agree and disagree. Please read each statement and check **one** response to each statement.

	Strongly Agree 1	Agree 2	Disagree 3	Strongly Disagree 4
1. I feel that I am a person of worth, at least on an equal basis with others.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. I feel that I have a number of good qualities.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. All in all, I am inclined to feel that I am a failure.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. I am able to do things as well as most people.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. I feel I do not have much of which to be proud.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. I take a positive attitude towards myself.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. On the whole, I am satisfied with myself.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. I wish I could have more respect for myself.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. I certainly feel useless at times.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. At times I think I am no good at all.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

 MENTOR	Core Gel Breast IDE Clinical Trial			10 YEAR VISIT		
	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO.	PATIENT NO.	PATIENT INITIALS first middle last	

TENNESSEE SELF-CONCEPT SCALE (Page 1 of 4)

TO THE PATIENT: The statements below are to help you describe yourself as you see yourself. Please respond to them as if you were describing yourself **to yourself**. Do not omit any item. Read each statement carefully, then select one of the five responses listed below. On the test, put a **circle** around the response you chose. If you want to change an answer after you have circled it, do not erase it but put an X mark through the response and then circle the response you want.

<i>Remember, put a circle around the response number you have chosen for each statement.</i>	Completely False	Mostly False	Partly True and Partly False	Mostly True	Completely True
1. I have a healthy body.	1	2	3	4	5
2. I am an attractive person.	1	2	3	4	5
3. I consider myself a sloppy person.	1	2	3	4	5
4. I am a decent sort of person.	1	2	3	4	5
5. I am an honest person.	1	2	3	4	5
6. I am a bad person.	1	2	3	4	5
7. I am a cheerful person.	1	2	3	4	5
8. I am a calm and easygoing person.	1	2	3	4	5
9. I am a nobody.	1	2	3	4	5
10. I have a family that would always help me in any kind of trouble.	1	2	3	4	5
11. I am a member of a happy family.	1	2	3	4	5
12. My friends have no confidence in me.	1	2	3	4	5
13. I am a friendly person.	1	2	3	4	5
14. I am popular with men.	1	2	3	4	5
15. I am not interested in what other people do.	1	2	3	4	5
16. I do not always tell the truth.	1	2	3	4	5
17. I get angry sometimes.	1	2	3	4	5
18. I like to look nice and neat all the time.	1	2	3	4	5
19. I am full of aches and pains.	1	2	3	4	5
20. I am a sick person.	1	2	3	4	5
21. I am a religious person.	1	2	3	4	5
22. I am a moral failure.	1	2	3	4	5
23. I am a morally weak person.	1	2	3	4	5

 MENTOR	Core Gel Breast IDE Clinical Trial			10 YEAR VISIT							
	PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1			SITE NO.		PATIENT NO.		PATIENT INITIALS first middle last	

TENNESSEE SELF-CONCEPT SCALE (Page 2 of 4)

<i>Remember, put a circle around the response number you have chosen for each statement.</i>	Completely False	Mostly False	Partly True and Partly False	Mostly True	Completely True
24. I have a lot of self-control.	1	2	3	4	5
25. I am a hateful person.	1	2	3	4	5
26. I am losing my mind.	1	2	3	4	5
27. I am an important person to my friends and family.	1	2	3	4	5
28. I am not loved by my family.	1	2	3	4	5
29. I feel that my family doesn't trust me.	1	2	3	4	5
30. I am popular with women.	1	2	3	4	5
31. I am mad at the whole world.	1	2	3	4	5
32. I am hard to be friendly with.	1	2	3	4	5
33. Once in a while I think of things too bad to talk about.	1	2	3	4	5
34. Sometimes when I am not feeling well, I am cross.	1	2	3	4	5
35. I am neither too fat nor too thin.	1	2	3	4	5
36. I like my looks just the way they are.	1	2	3	4	5
37. I would like to change some parts of my body.	1	2	3	4	5
38. I am satisfied with my moral behavior.	1	2	3	4	5
39. I am satisfied with my relationship to God.	1	2	3	4	5
40. I ought to go to church more.	1	2	3	4	5
41. I am satisfied to be just what I am.	1	2	3	4	5
42. I am just as nice as I should be.	1	2	3	4	5
43. I despise myself.	1	2	3	4	5
44. I am satisfied with my family relationships.	1	2	3	4	5
45. I understand my family as well as I should.	1	2	3	4	5
46. I should trust my family more.	1	2	3	4	5
47. I am as sociable as I want to be.	1	2	3	4	5
48. I try to please others, but I don't overdo it.	1	2	3	4	5
49. I am no good at all from a social standpoint.	1	2	3	4	5

 MENTOR	Core Gel Breast IDE Clinical Trial			10 YEAR VISIT				
	PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO.	PATIENT NO.	PATIENT INITIALS first middle last		

TENNESSEE SELF-CONCEPT SCALE (Page 3 of 4)

<i>Remember, put a circle around the response number you have chosen for each statement.</i>	Completely False	Mostly False	Partly True and Partly False	Mostly True	Completely True
50. I do not like everyone I know.	1	2	3	4	5
51. Once in a while, I laugh at a dirty joke.	1	2	3	4	5
52. I am neither too tall nor too short.	1	2	3	4	5
53. I don't feel as well as I should.	1	2	3	4	5
54. I should have more sex appeal.	1	2	3	4	5
55. I am as religious as I want to be.	1	2	3	4	5
56. I wish I could be more trustworthy.	1	2	3	4	5
57. I shouldn't tell so many lies.	1	2	3	4	5
58. I am as smart as I want to be.	1	2	3	4	5
59. I am not the person I would like to be.	1	2	3	4	5
60. I wish I didn't give up as easily as I do.	1	2	3	4	5
61. I treat my parents as well as I should. <i>(Use past tense if parents are not living.)</i>	1	2	3	4	5
62. I am too sensitive to things my family says.	1	2	3	4	5
63. I should love my family more.	1	2	3	4	5
64. I am satisfied with the way I treat other people.	1	2	3	4	5
65. I should be more polite to others.	1	2	3	4	5
66. I ought to get along better with other people.	1	2	3	4	5
67. I gossip a little at times.	1	2	3	4	5
68. At times I feel like swearing.	1	2	3	4	5
69. I take good care of myself physically.	1	2	3	4	5
70. I try to be careful about my appearance.	1	2	3	4	5
71. I often act like I am "all thumbs".	1	2	3	4	5
72. I am true to my religion in my everyday life.	1	2	3	4	5
73. I try to change when I know I'm doing things that are wrong.	1	2	3	4	5
74. I sometimes do very bad things.	1	2	3	4	5
75. I can always take care of myself in any situation.	1	2	3	4	5

 MENTOR	Core Gel Breast IDE Clinical Trial			10 YEAR VISIT				
	PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO.	PATIENT NO.	PATIENT INITIALS first middle last		

TENNESSEE SELF-CONCEPT SCALE (Page 4 of 4)					
<i>Remember, put a circle around the response number you have chosen for each statement.</i>	Completely False	Mostly False	Partly True and Partly False	Mostly True	Completely True
76. I take the blame for things without getting mad.	1	2	3	4	5
77. I do things without thinking about them first.	1	2	3	4	5
78. I try to play fair with my friends and family.	1	2	3	4	5
79. I take a real interest in my family.	1	2	3	4	5
80. I give in to my parents. <i>(Use past tense if parents are not living.)</i>	1	2	3	4	5
81. I try to understand the other fellow's point of view.	1	2	3	4	5
82. I get along well with other people.	1	2	3	4	5
83. I do not forgive others easily.	1	2	3	4	5
84. I would rather win than lose in a game.	1	2	3	4	5
85. I feel good most of the time.	1	2	3	4	5
86. I do poorly in sports and games.	1	2	3	4	5
87. I am a poor sleeper.	1	2	3	4	5
88. I do what is right most of the time.	1	2	3	4	5
89. I sometimes use unfair means to get ahead.	1	2	3	4	5
90. I have trouble doing the things that are right.	1	2	3	4	5
91. I solve my problems quite easily.	1	2	3	4	5
92. I change my mind a lot.	1	2	3	4	5
93. I try to run away from my problems.	1	2	3	4	5
94. I do my share of work at home.	1	2	3	4	5
95. I quarrel with my family.	1	2	3	4	5
96. I do not act like my family thinks I should.	1	2	3	4	5
97. I see good points in all the people I meet.	1	2	3	4	5
98. I do not feel at ease with other people.	1	2	3	4	5
99. I find it hard to talk with strangers.	1	2	3	4	5
100. Once in a while I put off until tomorrow what I ought to do today.	1	2	3	4	5

 MENTOR	Core Gel Breast IDE Clinical Trial			10 YEAR VISIT				
	PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO.	PATIENT NO.	PATIENT INITIALS first middle last		

SF-36 (Page 1 of 3)

TO THE PATIENT: This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Answer each question by circling **one** number. If you are unsure about how to answer a question, please give the best answer you can.

1. In general, would you say your health is: (Circle one number)	Excellent	Very Good	Good	Fair	Poor
	1	2	3	4	5

2. Compared to one year ago, how would you rate your health in general now? (Circle one number)	Much Better Now	Somewhat Better Now	About the Same	Somewhat Worse Now	Much Worse Now
	1	2	3	4	5

3. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much? (Circle one number for each question.)	Yes, Limited a Lot	Yes, Limited a Little	No, Not Limited at All
Vigorous activities , such as running, lifting heavy objects, participating in strenuous sports.	1	2	3
Moderate activities , such as moving a table, pushing a vacuum cleaner, bowling or playing golf	1	2	3
Lifting or carrying groceries	1	2	3
Climbing several flights of stairs	1	2	3
Climbing one flight of stairs	1	2	3
Bending, kneeling, or stooping	1	2	3
Walking more than a mile	1	2	3
Walking several blocks	1	2	3
Walking one block	1	2	3
Bathing or dressing yourself	1	2	3

 MENTOR	Core Gel Breast IDE Clinical Trial			10 YEAR VISIT							
	PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1			SITE NO.		PATIENT NO.		PATIENT INITIALS first middle last	

SF-36 (Page 2 of 3)

4. During the past 4 weeks , have you had any of the following problems with your work or other regular daily activities as a result of your physical health? (Circle one number for each question.)	YES	NO
Cut down on the amount of time you spent on work or other activities	1	2
Accomplished less than you would like	1	2
Were limited in the kind of work or other activities	1	2
Had difficulty performing the work or other activities (for example, it took extra effort)	1	2

5. During the past 4 weeks , have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)? (Circle one number for each question.)	YES	NO
Cut down on the amount of time you spent on work or other activities	1	2
Accomplished less than you would like	1	2
Didn't do work or other activities as carefully as usual	1	2

6. During the past 4 weeks , to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups? (Circle one number)	Not at All	Slightly	Moderately	Quite a Bit	Extremely
	1	2	3	4	5

7. How much bodily pain have you had during the past 4 weeks? (Circle one number)	None	Very Mild	Mild	Moderate	Severe	Very Severe
	1	2	3	4	5	6

8. During the past 4 weeks , how much did pain interfere with your normal work (including both work outside the home and housework)? (Circle one number)	Not at All	A Little Bit	Moderately	Quite a Bit	Extremely
	1	2	3	4	5

 MENTOR	Core Gel Breast IDE Clinical Trial			10 YEAR VISIT				
	PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO.	PATIENT NO.	PATIENT INITIALS first middle last		

SF-36 (Page 3 of 3)

9. These questions are about how you feel and how things have been with you **during the past 4 weeks**. For each question, please indicate the one answer that comes closest to the way you have been feeling. (Circle **one** number for each question.)

How much of the time during the past 4 weeks ...	All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	None of the Time
Did you feel full of pep?	1	2	3	4	5	6
Have you been a very nervous person?	1	2	3	4	5	6
Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
Have you felt calm and peaceful?	1	2	3	4	5	6
Did you have a lot of energy?	1	2	3	4	5	6
Have you felt downhearted and blue?	1	2	3	4	5	6
Did you feel worn out?	1	2	3	4	5	6
Have you been a happy person?	1	2	3	4	5	6
Did you feel tired?	1	2	3	4	5	6

10. During the past 4 weeks , how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)? (Circle one number.)	All of the Time	Most of the Time	Some of the Time	A Little of the Time	None of the Time
	1	2	3	4	5

11. How TRUE or FALSE is each of the following statements for you? (Circle one number for each question.)	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
I seem to get sick a little easier than other people	1	2	3	4	5
I am as healthy as anybody I know	1	2	3	4	5
I expect my health to get worse	1	2	3	4	5
My health is excellent	1	2	3	4	5



MENTOR

**Core Gel Breast
IDE Clinical Trial**

10 YEAR VISIT

PATIENT STUDY ID:

TRIAL NO.
10-009

COUNTRY NO.
0 | 0 | 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last

BODY ESTEEM SCALE (Page 1 of 1)

TO THE PATIENT: On this page are listed a number of body parts and functions. Please read each item and indicate how you feel about this part or function of ***your own body***, using the following scale:

- 1 = Have strong negative feelings
- 2 = Have moderate negative feelings
- 3 = Have no feeling one way or the other
- 4 = Have moderate positive feelings
- 5 = Have strong positive feelings

- | | |
|--|--|
| <input type="checkbox"/> 1. Body Scent | <input type="checkbox"/> 19. Arms |
| <input type="checkbox"/> 2. Appetite | <input type="checkbox"/> 20. Chest |
| <input type="checkbox"/> 3. Nose | <input type="checkbox"/> 21. Appearance of Eyes |
| <input type="checkbox"/> 4. Physical Stamina | <input type="checkbox"/> 22. Cheeks/Cheekbones |
| <input type="checkbox"/> 5. Reflexes | <input type="checkbox"/> 23. Hips |
| <input type="checkbox"/> 6. Lips | <input type="checkbox"/> 24. Legs |
| <input type="checkbox"/> 7. Muscular Strength | <input type="checkbox"/> 25. Physique |
| <input type="checkbox"/> 8. Waist | <input type="checkbox"/> 26. Sex Drive |
| <input type="checkbox"/> 9. Energy Level | <input type="checkbox"/> 27. Feet |
| <input type="checkbox"/> 10. Thighs | <input type="checkbox"/> 28. Sex Organs |
| <input type="checkbox"/> 11. Ears | <input type="checkbox"/> 29. Appearance of Stomach |
| <input type="checkbox"/> 12. Biceps | <input type="checkbox"/> 30. Health |
| <input type="checkbox"/> 13. Chin | <input type="checkbox"/> 31. Sex Activities |
| <input type="checkbox"/> 14. Body Build | <input type="checkbox"/> 32. Body Hair |
| <input type="checkbox"/> 15. Physical Coordination | <input type="checkbox"/> 33. Physical Condition |
| <input type="checkbox"/> 16. Buttocks | <input type="checkbox"/> 34. Face |
| <input type="checkbox"/> 17. Agility | <input type="checkbox"/> 35. Weight |
| <input type="checkbox"/> 18. Width of Shoulders | |



MENTOR

**Core Gel Breast
IDE Clinical Trial**

10 YEAR VISIT

PATIENT STUDY ID:

TRIAL NO.
10-009

COUNTRY NO.
0 | 0 | 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last

MANITOBA CANCER TREATMENT & RESEARCH FOUNDATION FUNCTIONAL LIVING INDEX: CANCER (FLIC)

Page 1 of 3

N/A (not a cancer patient)

TO THE PATIENT: Please indicate your rating by drawing a vertical line (|).

1. Most people experience some feelings of depression at times. Rate how often you feel these feelings.

1	2	3	4	5	6	7
Never						Continually

2. How well are you coping with your everyday stress?

1	2	3	4	5	6	7
Not Well						Very Well

3. How much time do you spend thinking about your illness?

1	2	3	4	5	6	7
Constantly						Never

4. Rate your ability to maintain your usual recreation or leisure activities.

1	2	3	4	5	6	7
Able						Unable

5. Has nausea affected your daily functioning?

1	2	3	4	5	6	7
Not At All						A Great Deal

6. How well do you feel today?

1	2	3	4	5	6	7
Extremely Poor						Extremely Well

7. Do you feel well enough to make a meal or do minor household repairs today?

1	2	3	4	5	6	7
Very Able						Not Able



MENTOR

**Core Gel Breast
IDE Clinical Trial**

10 YEAR VISIT

PATIENT STUDY ID:

TRIAL NO.
10-009

COUNTRY NO.
0 0 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last

MANITOBA CANCER TREATMENT & RESEARCH FOUNDATION FUNCTIONAL LIVING INDEX: CANCER (FLIC)

Page 3 of 3

N/A (not a cancer patient)

15. How much of your usual household tasks are you able to complete?

1	2	3	4	5	6	7
All						None

16. Rate how willing you were to see and spend time with those closest to you, in the past 2 weeks.

1	2	3	4	5	6	7
Unwilling						Very Willing

17. How much nausea have you had in the past 2 weeks?

1	2	3	4	5	6	7
None						A Great Deal

18. Rate the degree to which you are frightened of the future.

1	2	3	4	5	6	7
Constantly Terrified						Not Afraid

19. Rate how willing you were to see and spend time with friends, in the past 2 weeks.

1	2	3	4	5	6	7
Unwilling						Very Willing

20. How much of your pain or discomfort over the past 2 weeks was related to your cancer?

1	2	3	4	5	6	7
None						All

21. Rate your confidence in your prescribed course of treatment.

1	2	3	4	5	6	7
No Confidence						Very Confident

22. How well do you appear today?

1	2	3	4	5	6	7
Extremely Poor						Extremely Well



Core Gel Breast IDE Clinical Trial

ADVERSE EVENTS

10 YEAR VISIT

PATIENT STUDY ID: TRIAL NO. 10-009 COUNTRY NO. 0 0 1 SITE NO. PATIENT NO. PATIENT INITIALS first middle last No Adverse Events

Enter one adverse event per line. If the event was experienced at more than one body site, enter each body site on a separate line.

AE CODE* (See Below)	CAUSALITY 1 = Procedure related 2 = Device related 3 = Unknown 4 = Other	EVENT SIDE 0 = N/A 1 = Right 2 = Left	ASSOCIATED BREAST PAIN 0 = None 1 = Mild 2 = Moderate 3 = Severe	ONSET DATE month day year	SEVERITY 1 = Mild 2 = Moderate 3 = Severe	TREATMENT REQUIRED (check all that apply) 1 = No Treatment 2 = Medication (specify) 3 = Secondary Procedure (enter Procedure Type Code and date below, and complete Secondary Procedures Report for all procedures performed for this date)** 4 = Hospitalization (specify # of days and admission date) 5 = Other (specify)	OUTCOME 1 = Resolved 2 = Ongoing 3 = Death 4 = Unknown	RESOLUTION DATE month day year
<input type="checkbox"/> 1	<input type="checkbox"/> 3	<input type="checkbox"/> 0	<input type="checkbox"/> 0 <input type="checkbox"/> 3	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 4 days, Date: ___/___/___	<input type="checkbox"/> 1 <input type="checkbox"/> 4	
<input type="checkbox"/> 2	<input type="checkbox"/> 4	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 5 Procedure Date: ___/___/___	<input type="checkbox"/> 2	
<input type="checkbox"/> 1	<input type="checkbox"/> 3	<input type="checkbox"/> 0	<input type="checkbox"/> 0 <input type="checkbox"/> 3	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 4 days, Date: ___/___/___	<input type="checkbox"/> 1 <input type="checkbox"/> 4	
<input type="checkbox"/> 2	<input type="checkbox"/> 4	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 5 Procedure Date: ___/___/___	<input type="checkbox"/> 2	
<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 3	Procedure Date: ___/___/___	<input type="checkbox"/> 3	

**Complete Secondary Procedures Report. If new study device is implanted, complete Re-implantation Report.

Investigator's Signature _____ month _____ day _____ year

***ADVERSE EVENT CODES**

15 = Lymphadenopathy
16 = Necrosis
17 = New Diagnosis of Breast Cancer
18 = New Diagnosis of Rheumatic Disease, specify:
19 = Nipple—Unacceptably Low Sensitivity
20 = Nipple—Unacceptably High Sensitivity
21 = Position Change
22 = Ptosis
23 = Rupture
24 = Seroma
25 = Size Change—Patient Request
26 = Size Change—Physician Assessment only
27 = Wrinkling

***SECONDARY PROCEDURE TYPE CODES**

81 = Biopsy
82 = Capsulectomy
83 = Explanation with Replacement**
84 = Explanation without Replacement
85 = Incision and Drainage
86 = Mastopexy
87 = Open Capsulotomy
88 = Position Change
89 = Scar Revision
90 = Skin Adjustment
91 = Other, specify: _____
92 = Other, specify: _____

28 = Lactation Difficulties, specify: _____
29 = Other, specify: _____
30 = Other, specify: _____



MENTOR

**Core Gel Breast
IDE Clinical Trial**

INTERIM VISIT

PATIENT STUDY ID:

TRIAL NO.
10-009

COUNTRY NO.
0 0 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last

Visit Date:

month day year

BREAST MEASUREMENTS

RIGHT Not Implanted with Study Device

Circumferential Breast Measurement cm

Bra Size (i.e. 32A) N/A (breast absent)

LEFT Not Implanted with Study Device

Circumferential Breast Measurement cm

Bra Size (i.e. 32A) N/A (breast absent)

MAMMOGRAPHY RESULTS

Date of Mammogram:

month year

Not Done

RIGHT

- Birads 0 Needs additional imaging evaluation
 - Birads 1 Negative
 - Birads 2 Benign finding
 - Birads 3 Probable benign finding—short interval follow-up is suggested
 - Birads 4 Suspicious abnormality—biopsy should be considered
 - Birads 5 Highly suggestive of malignancy—appropriate action should be taken
- List abnormality: _____

LEFT

- Birads 0 Needs additional imaging evaluation
 - Birads 1 Negative
 - Birads 2 Benign finding
 - Birads 3 Probable benign finding—short interval follow-up is suggested
 - Birads 4 Suspicious abnormality—biopsy should be considered
 - Birads 5 Highly suggestive of malignancy—appropriate action should be taken
- List abnormality: _____

VISIT REPORT

1. Has the patient become pregnant since the last visit?

- No
- Yes, without complications
- Yes, with complications

Complete Adverse Events Report

2. Has the patient attempted to breastfeed since the last visit?

- No
- Yes, was there adequate milk?
 - No (Enter code 30 on Adverse Events Report)
 - Yes

3. Would the patient have this breast surgery again?

- No, reason: _____
- Yes

4. **Breast Cancer Reconstruction Patients only:**

N/A (augmentation patient)

Has the patient received any adjuvant therapies since the last visit?

- No
- Yes, check all that apply:
 - Radiation Therapy
 - Chemotherapy
 - Other, specify: _____

Treating Oncologist

Name: _____

Phone: (_____) _____

	Core Gel Breast IDE Clinical Trial		INTERIM VISIT		
	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO.	PATIENT NO.	PATIENT INITIALS first middle last

CAPSULAR CONTRACTURE ASSESSMENT OF PROSTHESIS

Right Prosthesis is: <input type="radio"/> Not Implanted with Study Device 1 <input type="checkbox"/> Baker Class I (normally soft and natural appearance) 2 <input type="checkbox"/> Baker Class II (a natural appearance despite palpable firmness) 3 <input type="checkbox"/> Baker Class III (firm with visible distortion) 4 <input type="checkbox"/> Baker Class IV (obvious spherical distortion)	Left Prosthesis is: <input type="radio"/> Not Implanted with Study Device 1 <input type="checkbox"/> Baker Class I (normally soft and natural appearance) 2 <input type="checkbox"/> Baker Class II (a natural appearance despite palpable firmness) 3 <input type="checkbox"/> Baker Class III (firm with visible distortion) 4 <input type="checkbox"/> Baker Class IV (obvious spherical distortion)
--	---

Complete Adverse Events Report for Baker III or IV.

NIPPLE/BREAST SENSITIVITY

How would patient describe the feeling in nipple(s) and/or breast(s) now?

*If unacceptably high or low at baseline, and sensation remains the same post-operatively, do **not** complete an Adverse Events Report.*

If acceptable at baseline and has become unacceptable post-operatively, complete an Adverse Events Report.

RIGHT <input type="radio"/> Not Implanted with Study Device Nipple Sensation is: 1 <input type="checkbox"/> Unacceptably low 2 <input type="checkbox"/> Acceptable 3 <input type="checkbox"/> Unacceptably high 4 <input type="checkbox"/> N/A, nipple absent Breast sensation is: 1 <input type="checkbox"/> Unacceptably low 2 <input type="checkbox"/> Acceptable 3 <input type="checkbox"/> Unacceptably high 4 <input type="checkbox"/> N/A, breast absent	LEFT <input type="radio"/> Not Implanted with Study Device Nipple Sensation is: 1 <input type="checkbox"/> Unacceptably low 2 <input type="checkbox"/> Acceptable 3 <input type="checkbox"/> Unacceptably high 4 <input type="checkbox"/> N/A, nipple absent Breast sensation is: 1 <input type="checkbox"/> Unacceptably low 2 <input type="checkbox"/> Acceptable 3 <input type="checkbox"/> Unacceptably high 4 <input type="checkbox"/> N/A, breast absent
---	--

Complete Adverse Events Report for any complications or adverse events noted at this visit.

**MENTOR****Core Gel Breast
IDE Clinical Trial****INTERIM VISIT****PATIENT STUDY ID:**TRIAL NO.
10-009COUNTRY NO.
0 | 0 | 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last**INVESTIGATOR-COMPLETED RHEUMATIC DISEASE DIAGNOSIS QUESTIONNAIRE** No diagnosis madeHas the patient been diagnosed by a RHEUMATOLOGIST for any of the following **since the last visit?****If YES, complete Adverse Event Report.**

RHEUMATIC DISEASE	NO YES		DATE OF ONSET (if known)	
			month	year
Connective Tissue Disorders: SLE	<input type="checkbox"/>	<input type="checkbox"/>		
Sjogren's Syndrome	<input type="checkbox"/>	<input type="checkbox"/>		
Scleroderma	<input type="checkbox"/>	<input type="checkbox"/>		
Polymyositis	<input type="checkbox"/>	<input type="checkbox"/>		
Other Connective Tissue Disorders	<input type="checkbox"/>	<input type="checkbox"/>		
Inflammatory Arthritis: Rheumatoid Arthritis	<input type="checkbox"/>	<input type="checkbox"/>		
Crystalline Arthritis	<input type="checkbox"/>	<input type="checkbox"/>		
Infectious Arthritis	<input type="checkbox"/>	<input type="checkbox"/>		
Spondyarthropathies	<input type="checkbox"/>	<input type="checkbox"/>		
Other Inflammatory Arthritis	<input type="checkbox"/>	<input type="checkbox"/>		
Non-Inflammatory Rheumatic Conditions: Osteoarthritis	<input type="checkbox"/>	<input type="checkbox"/>		
Fibromyalgia	<input type="checkbox"/>	<input type="checkbox"/>		
Chronic Fatigue	<input type="checkbox"/>	<input type="checkbox"/>		
Other Mechanical or Degenerative	<input type="checkbox"/>	<input type="checkbox"/>		
Other, specify: _____	<input type="checkbox"/>	<input type="checkbox"/>		
Other, specify: _____	<input type="checkbox"/>	<input type="checkbox"/>		

Disease must be diagnosed by a rheumatologist.

Rheumatologist who made diagnosis:

Name: _____

Address: _____

Phone: (_____) _____

**MENTOR****Core Gel Breast
IDE Clinical Trial****INTERIM VISIT****PATIENT STUDY ID:**TRIAL NO.
10-009COUNTRY NO.
0 0 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last**RHEUMATOLOGY SYMPTOMS (Page 1 of 2)**1 No symptoms; patient not referred to rheumatologistPlease check any **current** symptoms which:

1. The patient experiences on a regular basis
2. The cause is unknown and cannot be attributed to any patient activity.

RHEUMATOLOGY SYMPTOM	STATUS SINCE LAST VISIT		DATE OF ONSET (only if new since last visit)		STATUS AS OF THIS VISIT	
	CONTINUING	NEW	month	year	RESOLVED	CONTINUING
Loss of weight without dieting	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Insomnia	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Weakness	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Exhaustion	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Joint swelling	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Heel pain	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Frequent muscle cramps	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Numbness of feet	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Ringing in ears	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Pain/grittiness in eyes	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Dryness of eyes, nose	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Pain on swallowing or chewing	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Neck pain/stiffness	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Pain on breathing	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Heart murmurs	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Loss of appetite	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Persistent fever	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Night sweats	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Generalized aching	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Loss of height	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Joint pain	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Frequent muscle pain	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>



**Core Gel Breast
IDE Clinical Trial**

INTERIM VISIT

PATIENT STUDY ID:	TRIAL NO.	COUNTRY NO.			SITE NO.	PATIENT NO.	PATIENT INITIALS		
	10-009	0	0	1			first	middle	last

RHEUMATOLOGY SYMPTOMS (Page 2 of 2)

Please check any **current** symptoms which:

1. The patient experiences on a regular basis
2. The cause is unknown and cannot be attributed to any patient activity.

RHEUMATOLOGY SYMPTOM	STATUS SINCE LAST VISIT		DATE OF ONSET (only if new since last visit)		STATUS AS OF THIS VISIT	
	CONTINUING	NEW	month	year	RESOLVED	CONTINUING
Numbness of hands	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Jaw pain	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Open sores	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Redness of eyes	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Dryness of mouth	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Back pain/stiffness	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Severe chest pains	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Chronic cough	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Difficulty swallowing	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Frequent, severe or persistent diarrhea or constipation	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Severe rashes	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Frequent muscle cramps	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Severe dryness of skin	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Tender lumps/bumps	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Excessive sensitivity to sun	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Color changes on hands or feet with cold exposure	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Joint pain	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Frequent hives	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Numbness of hands	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Tightness of skin	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Unusual hair loss	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Tenderness of scalp	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Severe bruising with little or no injury	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>



**Core Gel Breast
IDE Clinical Trial**

INTERIM VISIT

PATIENT STUDY ID:	TRIAL NO.	COUNTRY NO.			SITE NO.	PATIENT NO.	PATIENT INITIALS		
	10-009	0	0	1			first	middle	last

RHEUMATOLOGICAL PHYSICAL EXAMINATION (Page 1 of 2)

No symptoms present

Check the box for each physical finding noted to be present and outside normal limits.

PHYSICAL FINDING	STATUS SINCE LAST VISIT		DATE OF ONSET (only if new since last visit)		STATUS AS OF THIS VISIT	
	CONTINUING	NEW	month	year	RESOLVED	CONTINUING
Muscle weakness: Headlift from supine position against gravity	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Inability to raise arms	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Inability to get out of chair	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Joint swellings: Wrists	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Digits	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Elbows	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Knees	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Ankles	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Joint deformities and flexion contracture: Boutonnière ¹	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Ulnar drift ²	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Swan neck ³	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Trigger fingers	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Joint tenderness	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Grip strength and motion-finger to palm crease (normal = 0 cm)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Neck motion—chin to chest or sternum (normal = 0 cm)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Chest expansion (normal = at least 5 cm)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Occiput to wall (normal = 0 cm)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Jaw motion (normally upper-lower incisors 3 cm)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Back motion—measure 10 cm above posterior supine iliac spines— with forward bending motion at least 5 cm from first point (total distance at least 15 cm)	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>

¹**Boutonnière** - Contractures of hand musculature characterized by proximal interphalangeal joint flexion and distal interphalangeal joint hyperextension.

³**Swan Neck** - Finger deformity characterized by flexion of distal interphalangeal joints and hyperflexion of the proximal interphalangeal joints due to hypermobility.

²**Ulnar Drift** - Joint change at the metacarpophalangeal joints. Long axis of fingers deviate in an ulnar direction.

**MENTOR****Core Gel Breast
IDE Clinical Trial****INTERIM VISIT****PATIENT STUDY ID:**TRIAL NO.
10-009COUNTRY NO.
0 0 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last**RHEUMATOLOGICAL PHYSICAL EXAMINATION (Page 2 of 2)**

Check the box for each physical finding noted to be present and outside normal limits.

PHYSICAL FINDING	POSSIBLE INDICATION	STATUS SINCE LAST VISIT		DATE OF ONSET (only if new since last visit)		STATUS AS OF THIS VISIT	
		CONTINUING	NEW	month	year	RESOLVED	CONTINUING
Hair loss	<i>Lupus, Scleroderma</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Skin tightness, especially face and hands	<i>Scleroderma</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Raynaud's phenomenon	<i>Lupus, Scleroderma</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Calcinosis over tibia, ulna, elbows	<i>Scleroderma, Dermatomyositis</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Swollen digits	<i>Juvenile RA, Reiter's syndrome, Psoriatic arthritis, Early scleroderma, Reflex sympathetic dystrophy</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Erythema over knuckles	<i>Dermatomyositis</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Bluish hue color on eyelids	<i>Dermatomyositis</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Non-tender lumps or nodules on elbows	<i>Rheumatoid gout</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Tender lumps-tibia	<i>Erythema nodosum</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Painless eye redness	<i>Conjunctivitis</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Painful eye redness with decreased vision, small pupils	<i>Uveitis</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Tenderness—insertion of deltoids	<i>Polymyalgia rheumatica</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Muscle tenderness	<i>Polymyositis</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Nail pittings	<i>Psoriatic arthritis, Reiter's syndrome</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Tinels or Phalen's signs	<i>Carpal tunnel syndrome</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>
Skin rashes	<i>Discoid lupus</i>	<input type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>

Does the patient require an examination by a rheumatologist?

 No Yes, record rheumatologist's findings:

**MENTOR****Core Gel Breast
IDE Clinical Trial****INTERIM VISIT****PATIENT STUDY ID:**TRIAL NO.
10-009COUNTRY NO.
0 | 0 | 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last**ROSENBERG SELF-ESTEEM SCALE (Page 1 of 1)**

TO THE PATIENT: Below are some statements with which some people agree and disagree. Please read each statement and check **one** response to each statement.

	Strongly Agree 1	Agree 2	Disagree 3	Strongly Disagree 4
1. I feel that I am a person of worth, at least on an equal basis with others.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. I feel that I have a number of good qualities.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. All in all, I am inclined to feel that I am a failure.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. I am able to do things as well as most people.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. I feel I do not have much of which to be proud.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. I take a positive attitude towards myself.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. On the whole, I am satisfied with myself.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. I wish I could have more respect for myself.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. I certainly feel useless at times.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. At times I think I am no good at all.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

 MENTOR	Core Gel Breast IDE Clinical Trial			INTERIM VISIT				
	PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO.	PATIENT NO.	PATIENT INITIALS first middle last		

TENNESSEE SELF-CONCEPT SCALE (Page 1 of 4)

TO THE PATIENT: The statements below are to help you describe yourself as you see yourself. Please respond to them as if you were describing yourself **to yourself**. Do not omit any item. Read each statement carefully, then select one of the five responses listed below. On the test, put a **circle** around the response you chose. If you want to change an answer after you have circled it, do not erase it but put an X mark through the response and then circle the response you want.

<i>Remember, put a circle around the response number you have chosen for each statement.</i>	Completely False	Mostly False	Partly True and Partly False	Mostly True	Completely True
1. I have a healthy body.	1	2	3	4	5
2. I am an attractive person.	1	2	3	4	5
3. I consider myself a sloppy person.	1	2	3	4	5
4. I am a decent sort of person.	1	2	3	4	5
5. I am an honest person.	1	2	3	4	5
6. I am a bad person.	1	2	3	4	5
7. I am a cheerful person.	1	2	3	4	5
8. I am a calm and easygoing person.	1	2	3	4	5
9. I am a nobody.	1	2	3	4	5
10. I have a family that would always help me in any kind of trouble.	1	2	3	4	5
11. I am a member of a happy family.	1	2	3	4	5
12. My friends have no confidence in me.	1	2	3	4	5
13. I am a friendly person.	1	2	3	4	5
14. I am popular with men.	1	2	3	4	5
15. I am not interested in what other people do.	1	2	3	4	5
16. I do not always tell the truth.	1	2	3	4	5
17. I get angry sometimes.	1	2	3	4	5
18. I like to look nice and neat all the time.	1	2	3	4	5
19. I am full of aches and pains.	1	2	3	4	5
20. I am a sick person.	1	2	3	4	5
21. I am a religious person.	1	2	3	4	5
22. I am a moral failure.	1	2	3	4	5
23. I am a morally weak person.	1	2	3	4	5

 MENTOR	Core Gel Breast IDE Clinical Trial			INTERIM VISIT							
	PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1			SITE NO.		PATIENT NO.		PATIENT INITIALS first middle last	

TENNESSEE SELF-CONCEPT SCALE (Page 2 of 4)

<i>Remember, put a circle around the response number you have chosen for each statement.</i>	Completely False	Mostly False	Partly True and Partly False	Mostly True	Completely True
24. I have a lot of self-control.	1	2	3	4	5
25. I am a hateful person.	1	2	3	4	5
26. I am losing my mind.	1	2	3	4	5
27. I am an important person to my friends and family.	1	2	3	4	5
28. I am not loved by my family.	1	2	3	4	5
29. I feel that my family doesn't trust me.	1	2	3	4	5
30. I am popular with women.	1	2	3	4	5
31. I am mad at the whole world.	1	2	3	4	5
32. I am hard to be friendly with.	1	2	3	4	5
33. Once in a while I think of things too bad to talk about.	1	2	3	4	5
34. Sometimes when I am not feeling well, I am cross.	1	2	3	4	5
35. I am neither too fat nor too thin.	1	2	3	4	5
36. I like my looks just the way they are.	1	2	3	4	5
37. I would like to change some parts of my body.	1	2	3	4	5
38. I am satisfied with my moral behavior.	1	2	3	4	5
39. I am satisfied with my relationship to God.	1	2	3	4	5
40. I ought to go to church more.	1	2	3	4	5
41. I am satisfied to be just what I am.	1	2	3	4	5
42. I am just as nice as I should be.	1	2	3	4	5
43. I despise myself.	1	2	3	4	5
44. I am satisfied with my family relationships.	1	2	3	4	5
45. I understand my family as well as I should.	1	2	3	4	5
46. I should trust my family more.	1	2	3	4	5
47. I am as sociable as I want to be.	1	2	3	4	5
48. I try to please others, but I don't overdo it.	1	2	3	4	5
49. I am no good at all from a social standpoint.	1	2	3	4	5

 MENTOR	Core Gel Breast IDE Clinical Trial			INTERIM VISIT				
	PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO.	PATIENT NO.	PATIENT INITIALS first middle last		

TENNESSEE SELF-CONCEPT SCALE (Page 3 of 4)

<i>Remember, put a circle around the response number you have chosen for each statement.</i>	Completely False	Mostly False	Partly True and Partly False	Mostly True	Completely True
50. I do not like everyone I know.	1	2	3	4	5
51. Once in a while, I laugh at a dirty joke.	1	2	3	4	5
52. I am neither too tall nor too short.	1	2	3	4	5
53. I don't feel as well as I should.	1	2	3	4	5
54. I should have more sex appeal.	1	2	3	4	5
55. I am as religious as I want to be.	1	2	3	4	5
56. I wish I could be more trustworthy.	1	2	3	4	5
57. I shouldn't tell so many lies.	1	2	3	4	5
58. I am as smart as I want to be.	1	2	3	4	5
59. I am not the person I would like to be.	1	2	3	4	5
60. I wish I didn't give up as easily as I do.	1	2	3	4	5
61. I treat my parents as well as I should. <i>(Use past tense if parents are not living.)</i>	1	2	3	4	5
62. I am too sensitive to things my family says.	1	2	3	4	5
63. I should love my family more.	1	2	3	4	5
64. I am satisfied with the way I treat other people.	1	2	3	4	5
65. I should be more polite to others.	1	2	3	4	5
66. I ought to get along better with other people.	1	2	3	4	5
67. I gossip a little at times.	1	2	3	4	5
68. At times I feel like swearing.	1	2	3	4	5
69. I take good care of myself physically.	1	2	3	4	5
70. I try to be careful about my appearance.	1	2	3	4	5
71. I often act like I am "all thumbs".	1	2	3	4	5
72. I am true to my religion in my everyday life.	1	2	3	4	5
73. I try to change when I know I'm doing things that are wrong.	1	2	3	4	5
74. I sometimes do very bad things.	1	2	3	4	5
75. I can always take care of myself in any situation.	1	2	3	4	5

 MENTOR	Core Gel Breast IDE Clinical Trial			INTERIM VISIT				
	PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO.	PATIENT NO.	PATIENT INITIALS first middle last		

TENNESSEE SELF-CONCEPT SCALE (Page 4 of 4)

<i>Remember, put a circle around the response number you have chosen for each statement.</i>	Completely False	Mostly False	Partly True and Partly False	Mostly True	Completely True
76. I take the blame for things without getting mad.	1	2	3	4	5
77. I do things without thinking about them first.	1	2	3	4	5
78. I try to play fair with my friends and family.	1	2	3	4	5
79. I take a real interest in my family.	1	2	3	4	5
80. I give in to my parents. <i>(Use past tense if parents are not living.)</i>	1	2	3	4	5
81. I try to understand the other fellow's point of view.	1	2	3	4	5
82. I get along well with other people.	1	2	3	4	5
83. I do not forgive others easily.	1	2	3	4	5
84. I would rather win than lose in a game.	1	2	3	4	5
85. I feel good most of the time.	1	2	3	4	5
86. I do poorly in sports and games.	1	2	3	4	5
87. I am a poor sleeper.	1	2	3	4	5
88. I do what is right most of the time.	1	2	3	4	5
89. I sometimes use unfair means to get ahead.	1	2	3	4	5
90. I have trouble doing the things that are right.	1	2	3	4	5
91. I solve my problems quite easily.	1	2	3	4	5
92. I change my mind a lot.	1	2	3	4	5
93. I try to run away from my problems.	1	2	3	4	5
94. I do my share of work at home.	1	2	3	4	5
95. I quarrel with my family.	1	2	3	4	5
96. I do not act like my family thinks I should.	1	2	3	4	5
97. I see good points in all the people I meet.	1	2	3	4	5
98. I do not feel at ease with other people.	1	2	3	4	5
99. I find it hard to talk with strangers.	1	2	3	4	5
100. Once in a while I put off until tomorrow what I ought to do today.	1	2	3	4	5

 MENTOR	Core Gel Breast IDE Clinical Trial			INTERIM VISIT				
	PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO.	PATIENT NO.	PATIENT INITIALS first middle last		

SF-36 (Page 1 of 3)

TO THE PATIENT: This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Answer each question by circling **one** number. If you are unsure about how to answer a question, please give the best answer you can.

1. In general, would you say your health is: (Circle one number)	Excellent	Very Good	Good	Fair	Poor
	1	2	3	4	5

2. Compared to one year ago, how would you rate your health in general now? (Circle one number)	Much Better Now	Somewhat Better Now	About the Same	Somewhat Worse Now	Much Worse Now
	1	2	3	4	5

3. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much? (Circle one number for each question.)	Yes, Limited a Lot	Yes, Limited a Little	No, Not Limited at All
Vigorous activities , such as running, lifting heavy objects, participating in strenuous sports.	1	2	3
Moderate activities , such as moving a table, pushing a vacuum cleaner, bowling or playing golf	1	2	3
Lifting or carrying groceries	1	2	3
Climbing several flights of stairs	1	2	3
Climbing one flight of stairs	1	2	3
Bending, kneeling, or stooping	1	2	3
Walking more than a mile	1	2	3
Walking several blocks	1	2	3
Walking one block	1	2	3
Bathing or dressing yourself	1	2	3

 MENTOR	Core Gel Breast IDE Clinical Trial			INTERIM VISIT				
	PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO.	PATIENT NO.	PATIENT INITIALS first middle last		

SF-36 (Page 2 of 3)

4. During the past 4 weeks , have you had any of the following problems with your work or other regular daily activities as a result of your physical health? (Circle one number for each question.)	YES	NO
Cut down on the amount of time you spent on work or other activities	1	2
Accomplished less than you would like	1	2
Were limited in the kind of work or other activities	1	2
Had difficulty performing the work or other activities (for example, it took extra effort)	1	2

5. During the past 4 weeks , have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)? (Circle one number for each question.)	YES	NO
Cut down on the amount of time you spent on work or other activities	1	2
Accomplished less than you would like	1	2
Didn't do work or other activities as carefully as usual	1	2

6. During the past 4 weeks , to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups? (Circle one number)	Not at All	Slightly	Moderately	Quite a Bit	Extremely
	1	2	3	4	5

7. How much bodily pain have you had during the past 4 weeks? (Circle one number)	None	Very Mild	Mild	Moderate	Severe	Very Severe
	1	2	3	4	5	6

8. During the past 4 weeks , how much did pain interfere with your normal work (including both work outside the home and housework)? (Circle one number)	Not at All	A Little Bit	Moderately	Quite a Bit	Extremely
	1	2	3	4	5

 MENTOR	Core Gel Breast IDE Clinical Trial			INTERIM VISIT				
	PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO.	PATIENT NO.	PATIENT INITIALS first middle last		

SF-36 (Page 3 of 3)

9. These questions are about how you feel and how things have been with you **during the past 4 weeks**. For each question, please indicate the one answer that comes closest to the way you have been feeling. (Circle **one** number for each question.)

How much of the time during the past 4 weeks ...	All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	None of the Time
Did you feel full of pep?	1	2	3	4	5	6
Have you been a very nervous person?	1	2	3	4	5	6
Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
Have you felt calm and peaceful?	1	2	3	4	5	6
Did you have a lot of energy?	1	2	3	4	5	6
Have you felt downhearted and blue?	1	2	3	4	5	6
Did you feel worn out?	1	2	3	4	5	6
Have you been a happy person?	1	2	3	4	5	6
Did you feel tired?	1	2	3	4	5	6

10. During the past 4 weeks , how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)? (Circle one number.)	All of the Time	Most of the Time	Some of the Time	A Little of the Time	None of the Time
	1	2	3	4	5

11. How TRUE or FALSE is each of the following statements for you? (Circle one number for each question.)	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
I seem to get sick a little easier than other people	1	2	3	4	5
I am as healthy as anybody I know	1	2	3	4	5
I expect my health to get worse	1	2	3	4	5
My health is excellent	1	2	3	4	5



MENTOR

**Core Gel Breast
IDE Clinical Trial**

INTERIM VISIT

PATIENT STUDY ID:

TRIAL NO.
10-009

COUNTRY NO.
0 | 0 | 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last

BODY ESTEEM SCALE (Page 1 of 1)

TO THE PATIENT: On this page are listed a number of body parts and functions. Please read each item and indicate how you feel about this part or function of ***your own body***, using the following scale:

- 1 = Have strong negative feelings
- 2 = Have moderate negative feelings
- 3 = Have no feeling one way or the other
- 4 = Have moderate positive feelings
- 5 = Have strong positive feelings

- | | |
|--|--|
| <input type="checkbox"/> 1. Body Scent | <input type="checkbox"/> 19. Arms |
| <input type="checkbox"/> 2. Appetite | <input type="checkbox"/> 20. Chest |
| <input type="checkbox"/> 3. Nose | <input type="checkbox"/> 21. Appearance of Eyes |
| <input type="checkbox"/> 4. Physical Stamina | <input type="checkbox"/> 22. Cheeks/Cheekbones |
| <input type="checkbox"/> 5. Reflexes | <input type="checkbox"/> 23. Hips |
| <input type="checkbox"/> 6. Lips | <input type="checkbox"/> 24. Legs |
| <input type="checkbox"/> 7. Muscular Strength | <input type="checkbox"/> 25. Physique |
| <input type="checkbox"/> 8. Waist | <input type="checkbox"/> 26. Sex Drive |
| <input type="checkbox"/> 9. Energy Level | <input type="checkbox"/> 27. Feet |
| <input type="checkbox"/> 10. Thighs | <input type="checkbox"/> 28. Sex Organs |
| <input type="checkbox"/> 11. Ears | <input type="checkbox"/> 29. Appearance of Stomach |
| <input type="checkbox"/> 12. Biceps | <input type="checkbox"/> 30. Health |
| <input type="checkbox"/> 13. Chin | <input type="checkbox"/> 31. Sex Activities |
| <input type="checkbox"/> 14. Body Build | <input type="checkbox"/> 32. Body Hair |
| <input type="checkbox"/> 15. Physical Coordination | <input type="checkbox"/> 33. Physical Condition |
| <input type="checkbox"/> 16. Buttocks | <input type="checkbox"/> 34. Face |
| <input type="checkbox"/> 17. Agility | <input type="checkbox"/> 35. Weight |
| <input type="checkbox"/> 18. Width of Shoulders | |

**MENTOR****Core Gel Breast
IDE Clinical Trial****INTERIM VISIT****PATIENT STUDY ID:**TRIAL NO.
10-009COUNTRY NO.
0 | 0 | 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last**MANITOBA CANCER TREATMENT & RESEARCH FOUNDATION FUNCTIONAL LIVING INDEX: CANCER (FLIC)**

Page 1 of 3

 N/A (not a cancer patient)**TO THE PATIENT:** Please indicate your rating by drawing a vertical line (|).

1. Most people experience some feelings of depression at times. Rate how often you feel these feelings.

1	2	3	4	5	6	7
Never						Continually

2. How well are you coping with your everyday stress?

1	2	3	4	5	6	7
Not Well						Very Well

3. How much time do you spend thinking about your illness?

1	2	3	4	5	6	7
Constantly						Never

4. Rate your ability to maintain your usual recreation or leisure activities.

1	2	3	4	5	6	7
Able						Unable

5. Has nausea affected your daily functioning?

1	2	3	4	5	6	7
Not At All						A Great Deal

6. How well do you feel today?

1	2	3	4	5	6	7
Extremely Poor						Extremely Well

7. Do you feel well enough to make a meal or do minor household repairs today?

1	2	3	4	5	6	7
Very Able						Not Able



MENTOR

**Core Gel Breast
IDE Clinical Trial**

INTERIM VISIT

PATIENT STUDY ID:

TRIAL NO.
10-009

COUNTRY NO.
0 0 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last

MANITOBA CANCER TREATMENT & RESEARCH FOUNDATION FUNCTIONAL LIVING INDEX: CANCER (FLIC)

Page 3 of 3

N/A (not a cancer patient)

15. How much of your usual household tasks are you able to complete?

1	2	3	4	5	6	7
All						None

16. Rate how willing you were to see and spend time with those closest to you, in the past 2 weeks.

1	2	3	4	5	6	7
Unwilling						Very Willing

17. How much nausea have you had in the past 2 weeks?

1	2	3	4	5	6	7
None						A Great Deal

18. Rate the degree to which you are frightened of the future.

1	2	3	4	5	6	7
Constantly Terrified						Not Afraid

19. Rate how willing you were to see and spend time with friends, in the past 2 weeks.

1	2	3	4	5	6	7
Unwilling						Very Willing

20. How much of your pain or discomfort over the past 2 weeks was related to your cancer?

1	2	3	4	5	6	7
None						All

21. Rate your confidence in your prescribed course of treatment.

1	2	3	4	5	6	7
No Confidence						Very Confident

22. How well do you appear today?

1	2	3	4	5	6	7
Extremely Poor						Extremely Well



**Core Gel Breast
IDE Clinical Trial**

ADVERSE EVENTS

INTERIM VISIT

PATIENT STUDY ID: TRIAL NO. **10-009** COUNTRY NO. **0 0 1** SITE NO. PATIENT NO. PATIENT INITIALS first middle last No Adverse Events

Enter one adverse event per line. If the event was experienced at more than one body site, enter each body site on a separate line.

AE CODE* (See Below)	CAUSALITY 1 = Procedure related 2 = Device related 3 = Unknown 4 = Other	EVENT SIDE 0 = N/A 1 = Right 2 = Left	ASSOCIATED BREAST PAIN 0 = None 1 = Mild 2 = Moderate 3 = Severe	ONSET DATE month day year	SEVERITY 1 = Mild 2 = Moderate 3 = Severe	TREATMENT REQUIRED (check all that apply) 1 = No Treatment 2 = Medication (specify) 3 = Secondary Procedure (enter Procedure Type Code and date below, and complete Secondary Procedures Report for all procedures performed for this date)** 4 = Hospitalization (specify # of days and admission date) 5 = Other (specify)	OUTCOME 1 = Resolved 2 = Ongoing 3 = Death 4 = Unknown	RESOLUTION DATE month day year
<input type="checkbox"/> 1	<input type="checkbox"/> 3	<input type="checkbox"/> 0	<input type="checkbox"/> 0 <input type="checkbox"/> 3	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 4 days, Date: ___/___/___	<input type="checkbox"/> 1 <input type="checkbox"/> 4	
<input type="checkbox"/> 2	<input type="checkbox"/> 4	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 5 Procedure Date: ___/___/___	<input type="checkbox"/> 2	
<input type="checkbox"/> 1	<input type="checkbox"/> 3	<input type="checkbox"/> 0	<input type="checkbox"/> 0 <input type="checkbox"/> 3	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 4 days, Date: ___/___/___	<input type="checkbox"/> 1 <input type="checkbox"/> 4	
<input type="checkbox"/> 2	<input type="checkbox"/> 4	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 5 Procedure Date: ___/___/___	<input type="checkbox"/> 2	
<input type="checkbox"/> 1	<input type="checkbox"/> 3	<input type="checkbox"/> 0	<input type="checkbox"/> 0 <input type="checkbox"/> 3	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 4 days, Date: ___/___/___	<input type="checkbox"/> 1 <input type="checkbox"/> 4	
<input type="checkbox"/> 2	<input type="checkbox"/> 4	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 5 Procedure Date: ___/___/___	<input type="checkbox"/> 2	
<input type="checkbox"/> 1	<input type="checkbox"/> 3	<input type="checkbox"/> 0	<input type="checkbox"/> 0 <input type="checkbox"/> 3	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 4 days, Date: ___/___/___	<input type="checkbox"/> 1 <input type="checkbox"/> 4	
<input type="checkbox"/> 2	<input type="checkbox"/> 4	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 5 Procedure Date: ___/___/___	<input type="checkbox"/> 2	
<input type="checkbox"/> 1	<input type="checkbox"/> 3	<input type="checkbox"/> 0	<input type="checkbox"/> 0 <input type="checkbox"/> 3	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 4 days, Date: ___/___/___	<input type="checkbox"/> 1 <input type="checkbox"/> 4	
<input type="checkbox"/> 2	<input type="checkbox"/> 4	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 5 Procedure Date: ___/___/___	<input type="checkbox"/> 2	
<input type="checkbox"/> 1	<input type="checkbox"/> 3	<input type="checkbox"/> 0	<input type="checkbox"/> 0 <input type="checkbox"/> 3	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 4 days, Date: ___/___/___	<input type="checkbox"/> 1 <input type="checkbox"/> 4	
<input type="checkbox"/> 2	<input type="checkbox"/> 4	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 5 Procedure Date: ___/___/___	<input type="checkbox"/> 2	
<input type="checkbox"/> 1	<input type="checkbox"/> 3	<input type="checkbox"/> 0	<input type="checkbox"/> 0 <input type="checkbox"/> 3	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 4 days, Date: ___/___/___	<input type="checkbox"/> 1 <input type="checkbox"/> 4	
<input type="checkbox"/> 2	<input type="checkbox"/> 4	<input type="checkbox"/> 1	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 2	<input type="checkbox"/> 5 Procedure Date: ___/___/___	<input type="checkbox"/> 2	

**Complete Secondary Procedures Report. If new study device is implanted, complete Re-implantation Report.

Investigator's Signature _____ month _____ day _____ year

*ADVERSE EVENT CODES	+SECONDARY PROCEDURE TYPE CODES
1 = Asymmetry 2 = Baker II Capsular Contracture with Surgical Intervention 3 = Baker III Capsular Contracture 4 = Baker IV Capsular Contracture 5 = Breast pain not associated with any other complication 6 = Breast—Unacceptably Low Sensitivity 7 = Breast—Unacceptably High Sensitivity 8 = Calcification 9 = Delayed Wound Healing 10 = Extrusion 11 = Granuloma 12 = Hematoma 13 = Hypertrophic Scarring 14 = Infection 15 = Lymphadenopathy 16 = Necrosis 17 = New Diagnosis of Breast Cancer 18 = New Diagnosis of Rheumatic Disease, specify: 19 = Nipple—Unacceptably Low Sensitivity 20 = Nipple—Unacceptably High Sensitivity 21 = Position Change 22 = Ptosis 23 = Rupture 24 = Seroma 25 = Size Change—Patient Request 26 = Size Change—Physician Assessment only 27 = Wrinkling 28 = Lactation Difficulties, specify: 29 = Other, specify: 30 = Other, specify:	81 = Biopsy 82 = Capsulectomy 83 = Explanation with Replacement** 84 = Explanation without Replacement 85 = Incision and Drainage 86 = Mastopexy 87 = Open Capsulotomy 88 = Position Change 89 = Scar Revision 90 = Skin Adjustment 91 = Other, specify: 92 = Other, specify:



MENTOR

**Core Gel Breast
IDE Clinical Trial**

SECONDARY PROCEDURES REPORT

PATIENT STUDY ID:

TRIAL NO.
10-009

COUNTRY NO.
0 0 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last

SECONDARY PROCEDURES INFORMATION

Surgery Date:
month day year

Institution at which surgery took place: _____

Anesthesia Type (check all that apply):

- General
- Local
- Local with Sedation
- Other, specify: _____

Indication for Procedure (check one Primary Reason for each breast):

	RIGHT	LEFT		RIGHT	LEFT
1. Asymmetry	<input type="checkbox"/>	<input type="checkbox"/>	12. Necrosis	<input type="checkbox"/>	<input type="checkbox"/>
2. Breast Pain (Excessive)	<input type="checkbox"/>	<input type="checkbox"/>	13. Position Change	<input type="checkbox"/>	<input type="checkbox"/>
3. Capsular Contracture (Baker II)	<input type="checkbox"/>	<input type="checkbox"/>	14. Ptosis	<input type="checkbox"/>	<input type="checkbox"/>
4. Capsular Contracture (Baker III)	<input type="checkbox"/>	<input type="checkbox"/>	15. Rupture	<input type="checkbox"/>	<input type="checkbox"/>
5. Capsular Contracture (Baker IV)	<input type="checkbox"/>	<input type="checkbox"/>	16. Seroma	<input type="checkbox"/>	<input type="checkbox"/>
6. Delayed Wound Healing	<input type="checkbox"/>	<input type="checkbox"/>	17. Size Change	<input type="checkbox"/>	<input type="checkbox"/>
7. Extrusion	<input type="checkbox"/>	<input type="checkbox"/>	18. Staged Reconstruction	<input type="checkbox"/>	<input type="checkbox"/>
8. Hematoma	<input type="checkbox"/>	<input type="checkbox"/>	19. Wrinkling	<input type="checkbox"/>	<input type="checkbox"/>
9. Hypertrophic Scarring	<input type="checkbox"/>	<input type="checkbox"/>	20. Other, specify: _____	<input type="checkbox"/>	<input type="checkbox"/>
10. Infection	<input type="checkbox"/>	<input type="checkbox"/>	21. Other, specify: _____	<input type="checkbox"/>	<input type="checkbox"/>
11. Irritation/Inflammation	<input type="checkbox"/>	<input type="checkbox"/>			

Type of Secondary Procedure (check all that apply):

	RIGHT	LEFT		RIGHT	LEFT
1. Biopsy	<input type="checkbox"/>	<input type="checkbox"/>	9. Nipple Tattoo	<input type="checkbox"/>	<input type="checkbox"/>
2. Capsulectomy	<input type="checkbox"/>	<input type="checkbox"/>	10. Open Capsulotomy	<input type="checkbox"/>	<input type="checkbox"/>
3. Implant Size Change (complete Re-Implantation Report)	<input type="checkbox"/>	<input type="checkbox"/>	11. Position Change	<input type="checkbox"/>	<input type="checkbox"/>
4. Implant Removal (without replacement)	<input type="checkbox"/>	<input type="checkbox"/>	12. Scar Revision	<input type="checkbox"/>	<input type="checkbox"/>
5. Implant Removal (with replacement other than size change) (complete Re-Implantation Report)	<input type="checkbox"/>	<input type="checkbox"/>	13. Skin Adjustment	<input type="checkbox"/>	<input type="checkbox"/>
6. Incision and Drainage	<input type="checkbox"/>	<input type="checkbox"/>	14. Other, specify: _____	<input type="checkbox"/>	<input type="checkbox"/>
7. Mastopexy	<input type="checkbox"/>	<input type="checkbox"/>	_____		
8. Nipple Reconstruction	<input type="checkbox"/>	<input type="checkbox"/>	_____		

EXPLANTATION REPORT

Not Explanted

1. Explantation Site(s):

- 1 Right
- 2 Left
- 3 Both

2. Will prosthesis(es) be returned to Mentor?

- 1 No, reason: _____
- 2 Yes

Surgeon's Signature _____

month day year



MENTOR

**Core Gel Breast
IDE Clinical Trial**

RE-IMPLANTATION REPORT (Page 1 of 2)

PATIENT STUDY ID:	TRIAL NO.	COUNTRY NO.	SITE NO.	PATIENT NO.	PATIENT INITIALS	PROCEDURE DATE
	10-009	0 0 1			first middle last	month day year

RE-IMPLANTATION INFORMATION (for all patients receiving any new implant (study device or other))

Right Explant Date: <input type="checkbox"/> N/A (Not explanted)	month day year	Reason for Explant/Reimplant (check one): 1. Same as Primary Reason for Secondary Procedure 2. Iatrogenic Damage 3. Rupture Discovered 4. Pocket Size Changed 5. Other, specify: _____	RIGHT	LEFT
Left Explant Date: <input type="checkbox"/> N/A (Not explanted)	month day year		<input type="checkbox"/>	<input type="checkbox"/>

Anesthesia Type (check all that apply):
1 General 3 Local with Sedation 2 Local 4 Other, specify: _____

Institution at which surgery took place: _____

Intraoperative Parental Medications: None Given
1. _____ 3. _____
2. _____ 4. _____

	RIGHT <input type="checkbox"/> Not Re-implanted with any device	LEFT <input type="checkbox"/> Not Re-implanted with any device
New Device Type:	1 <input type="checkbox"/> Study device 2 <input type="checkbox"/> Mentor saline device 3 <input type="checkbox"/> Inamed gel device 4 <input type="checkbox"/> Inamed saline device 5 <input type="checkbox"/> Other: _____	1 <input type="checkbox"/> Study device 2 <input type="checkbox"/> Mentor saline device 3 <input type="checkbox"/> Inamed gel device 4 <input type="checkbox"/> Inamed saline device 5 <input type="checkbox"/> Other: _____
Device Placement:	1 <input type="checkbox"/> Submuscular 2 <input type="checkbox"/> Subglandular 3 <input type="checkbox"/> Subpectoral 4 <input type="checkbox"/> Other: _____	1 <input type="checkbox"/> Submuscular 2 <input type="checkbox"/> Subglandular 3 <input type="checkbox"/> Subpectoral 4 <input type="checkbox"/> Other: _____
Incision Size:	cm	cm
Implant Information:	1 <input type="checkbox"/> Smooth Surface 2 <input type="checkbox"/> Textured Surface	1 <input type="checkbox"/> Smooth Surface 2 <input type="checkbox"/> Textured Surface
Catalog Number:		
Lot Number:		
Surgical Approach:	1 <input type="checkbox"/> Periareolar 2 <input type="checkbox"/> Inframammary 3 <input type="checkbox"/> Transaxillary 4 <input type="checkbox"/> Mastectomy Scar 5 <input type="checkbox"/> Other: _____	1 <input type="checkbox"/> Periareolar 2 <input type="checkbox"/> Inframammary 3 <input type="checkbox"/> Transaxillary 4 <input type="checkbox"/> Mastectomy Scar 5 <input type="checkbox"/> Other: _____
Pocket Irrigation (check all that apply):	<input type="checkbox"/> Saline Only <input type="checkbox"/> Steroid: _____ Dose: _____ <input type="checkbox"/> Antibiotic: _____ <input type="checkbox"/> Drug: _____ <input type="checkbox"/> Other: _____	<input type="checkbox"/> Saline Only <input type="checkbox"/> Steroid: _____ Dose: _____ <input type="checkbox"/> Antibiotic: _____ <input type="checkbox"/> Drug: _____ <input type="checkbox"/> Other: _____
Post-Operative Recommendations (check all that apply):	<input type="checkbox"/> Antibiotic: _____ <input type="checkbox"/> Restricted Activities <input type="checkbox"/> Recommend Massage <input type="checkbox"/> Other: _____	<input type="checkbox"/> Antibiotic: _____ <input type="checkbox"/> Restricted Activities <input type="checkbox"/> Recommend Massage <input type="checkbox"/> Other: _____



MENTOR

**Core Gel Breast
IDE Clinical Trial**

END OF STUDY

PATIENT STUDY ID:

TRIAL NO.
10-009

COUNTRY NO.
0 0 1

SITE NO.

PATIENT NO.

PATIENT INITIALS
first middle last

1 Patient completed the 10 year study

OR

Patient did not complete study, complete below:

Date of Discontinuation:

month day year

Reason for Discontinuation (check **one** box only):

2 Protocol Violation, specify: _____

4 Consent Withdrawn by Patient, reason: _____

5 Lost to Follow-up, date of last documented contact:

month day year

(If patient is continuing in study at another site, this form should not be completed.)

List Contacts: 1. _____

2. _____

3. _____

6 Death (**Complete Adverse Events Report**)

Date of Death:

month day year

Cause: _____

7 Other, specify: _____

INVESTIGATOR SIGNATURE

I have reviewed **all** Case Report Forms for this patient and have verified that all data are accurate.

Investigator's Signature

month day year

MENTOR	Core Gel Breast IDE Clinical Trial		ADVERSE EVENTS					____ YEAR VISIT
	PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO.	PATIENT NO.	PATIENT INITIALS first middle last		

Enter **one** adverse event per line. If the event was experienced at more than one body site, enter each body site on a separate line.

AE CODE* (See Below)	CAUSALITY 1 = Procedure related 2 = Device related 3 = Unknown 4 = Other	IMPLANT SIDE 0 = N/A 1 = Right 2 = Left	ASSOCIATED BREAST PAIN 0 = None 1 = Mild 2 = Moderate 3 = Severe	ONSET DATE			SEVERITY 1 = Mild 2 = Moderate 3 = Severe	TREATMENT REQUIRED (check all that apply) 1 = No Treatment 2 = Medication (specify) 3 = Secondary Procedure (enter Procedure Type Code and date below, and complete Secondary Procedures Report for all procedures performed for this date)** 4 = Hospitalization (specify # of days and admission date) 5 = Other (specify)	OUTCOME 1 = Resolved 2 = Ongoing 3 = Death 4 = Unknown	RESOLUTION DATE		
				month	day	year				month	day	year
	<input type="checkbox"/> 1 <input type="checkbox"/> 3 <input type="checkbox"/> 2 <input type="checkbox"/> 4	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2	<input type="checkbox"/> 0 <input type="checkbox"/> 3 <input type="checkbox"/> 1 <input type="checkbox"/> 2				<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3	<input type="checkbox"/> 1 <input type="checkbox"/> 4 ___ days, Date: ___/___/___ <input type="checkbox"/> 2 _____ <input type="checkbox"/> 3 Procedure Type Code†: _____ Procedure Date: ___/___/___	<input type="checkbox"/> 1 <input type="checkbox"/> 4 <input type="checkbox"/> 2 <input type="checkbox"/> 3			
	<input type="checkbox"/> 1 <input type="checkbox"/> 3 <input type="checkbox"/> 2 <input type="checkbox"/> 4	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2	<input type="checkbox"/> 0 <input type="checkbox"/> 3 <input type="checkbox"/> 1 <input type="checkbox"/> 2				<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3	<input type="checkbox"/> 1 <input type="checkbox"/> 4 ___ days, Date: ___/___/___ <input type="checkbox"/> 2 _____ <input type="checkbox"/> 3 Procedure Type Code†: _____ Procedure Date: ___/___/___	<input type="checkbox"/> 1 <input type="checkbox"/> 4 <input type="checkbox"/> 2 <input type="checkbox"/> 3			

Investigator's Signature _____ month _____ day _____ year

****Complete Secondary Procedures Report. If new study device is implanted, complete Re-Implantation Report.**

<p style="text-align: center;">*ADVERSE EVENT CODES</p> <p>1 = Asymmetry 2 = Baker II Capsular Contracture with Surgical Intervention 3 = Baker III Capsular Contracture 4 = Baker IV Capsular Contracture 5 = Breast pain not associated with any other complication 6 = Breast—Unacceptably Low Sensitivity 7 = Breast—Unacceptably High Sensitivity 8 = Calcification 9 = Delayed Wound Healing 10 = Extrusion 11 = Granuloma 12 = Hematoma 13 = Hypertrophic Scarring 14 = Infection 15 = Lymphadenopathy 16 = Necrosis 17 = New Diagnosis of Breast Cancer 18 = New Diagnosis of Rheumatic Disease, specify: _____ 19 = Nipple—Unacceptably Low Sensitivity 20 = Nipple—Unacceptably High Sensitivity 21 = Position Change 22 = Ptosis 23 = Rupture 24 = Seroma 25 = Size Change—Patient Request 26 = Size Change—Physician Assessment only 27 = Wrinkling 28 = Lactation Difficulties, specify: _____</p>	<p style="text-align: center;">†SECONDARY PROCEDURE TYPE CODES</p> <p>29 = Other, specify: _____ 30 = Other, specify: _____ 31 = Other, specify: _____ 32 = Other, specify: _____ 33 = Other, specify: _____ 81 = Biopsy 82 = Capsulectomy 83 = Explantation with Replacement** 84 = Explantation without Replacement 85 = Incision and Drainage 86 = Mastopexy 87 = Open Capsulotomy 88 = Position Change 89 = Scar Revision 90 = Skin Adjustment 91 = Other, specify: _____ 92 = Other, specify: _____ 93 = Other, specify: _____</p>
---	--



MENTOR

MRI Silicone Breast Implant Evaluation Data Sheet

PATIENT STUDY ID:	TRIAL NO.	COUNTRY NO.	SITE NO.	PATIENT NO.	PATIENT INITIALS	PATIENT SOCIAL SECURITY NO.
	10-009	0 0 1			first middle last	

MRI EVALUATION

Patient's Date of Birth:

month day year

MRI Reviewer: _____

Scan Quality (check one):

Date of MRI Evaluation:

month day year

- 1 Good
- 2 Adequate
- 3 Inadequate

	RIGHT	LEFT
	<input type="checkbox"/> Not Implanted with Study Device	<input type="checkbox"/> Not Implanted with Study Device
Device Placement:	1 <input type="checkbox"/> Submuscular 2 <input type="checkbox"/> Subglandular	1 <input type="checkbox"/> Submuscular 2 <input type="checkbox"/> Subglandular
Implant Type:	1 <input type="checkbox"/> Smooth 2 <input type="checkbox"/> Siltex	1 <input type="checkbox"/> Smooth 2 <input type="checkbox"/> Siltex
Implant Evaluation:	1 <input type="checkbox"/> No Evidence of Rupture 2 <input type="checkbox"/> Indeterminate Evidence of Rupture 3 <input type="checkbox"/> Rupture: <i>Check one Type:</i> 1 <input type="checkbox"/> Intracapsular 2 <input type="checkbox"/> Extracapsular <i>Check one Condition:</i> 1 <input type="checkbox"/> Uncollapsed 2 <input type="checkbox"/> Partially Collapsed 3 <input type="checkbox"/> Fully Collapsed (linguini sign)	1 <input type="checkbox"/> No Evidence of Rupture 2 <input type="checkbox"/> Indeterminate Evidence of Rupture 3 <input type="checkbox"/> Rupture: <i>Check one Type:</i> 1 <input type="checkbox"/> Intracapsular 2 <input type="checkbox"/> Extracapsular <i>Check one Condition:</i> 1 <input type="checkbox"/> Uncollapsed 2 <input type="checkbox"/> Partially Collapsed 3 <input type="checkbox"/> Fully Collapsed (linguini sign)
Soft Tissue Evaluation:	1 <input type="checkbox"/> No Evidence of Extracapsular Silicone 2 <input type="checkbox"/> Indeterminate for Extracapsular Silicone 3 <input type="checkbox"/> Definite Extracapsular Silicone	1 <input type="checkbox"/> No Evidence of Extracapsular Silicone 2 <input type="checkbox"/> Indeterminate for Extracapsular Silicone 3 <input type="checkbox"/> Definite Extracapsular Silicone

Notes: _____

Reviewer's Signature _____

month day year

This study was not designed to detect breast cancer, and so the findings and impressions here should not replace routine screening mammography and clinical examination. Some implant ruptures and small amounts of soft tissue silicone below our thresholds for detection may not be seen by this method.

ATTACHMENT 11
CORE GEL RETRIEVAL PLAN

Mentor Silicone Gel-Filled Mammary Prosthesis Explanted Device Retrieval Protocol

Objective:

To evaluate explanted silicone gel-filled mammary prostheses from patients enrolled in the Core Gel clinical study and document and catalogue various failure modes. The data will be reviewed to develop test methodology to predict the clinical failure modes.

Background:

As part of the Core Gel study, any patient who reports a rupture requiring their device to be explanted and replaced will be asked permission to evaluate the explanted device. Mentor will initially evaluate the explanted devices in accordance with Complaint and MDR procedures, reference SOP-HS-112 and SOP-HS-113.

The retrieved devices will undergo a visual or “gross” evaluation as well as a microscopic visual evaluation. Photographs are taken of all returned devices. The details of the complaint handling process are specified in the procedures listed in the reference section.

The retrieval protocol outlined is an extension of the existing complaint handling process. However, this retrieval program is designed to be used for explanted devices from patients enrolled in the Core Gel clinical study. When a complaint is reported relative to the Core Gel study, the PE staff will obtain pertinent questions pertaining to the patient history, device, complaint, implant and explant procedures. The FER will be used for all reported complaints (See Attachment 1). The explanted devices will be returned to Mentor utilizing Mentor’s existing return kit and decontamination process. The explanted devices will be evaluated visually, and a description of the device failure will be documented in writing, on a diagram as well as photographed according to procedure, DOP-QA-4015.

Sample Size:

Explanted Core Gel clinical study devices that failed primarily due to rupture, and for which Mentor has received patient authorization to perform destructive testing, will be evaluated as part of the retrieval program. A maximum of 1000 patients (2000 devices) will be enrolled in the Core Gel clinical study.

Device retrieval and shipping procedure

The explanted devices will be returned to Mentor using the standard return kit and decontamination process. The PE staff will confirm the address of the complainant and send the Product Return Kit. The materials included within the Product Return Kit are as follows:

- Mailing envelope, 15" x 12" Airborne bubble pack
- Cardboard box, 8 x 8 x 4 corrugated, complies with Federal spec. PPP-B636J stamped "PE Returns"
- Packing Material, 20" x 16 ½" PIG material pad
- Three 9" x 12" self-sealing bags, Part Number 211032-3
- Airborne Express airbill, preprinted
- Envelope that includes all patient medical information and explanted device paperwork is enclosed in the envelope
- Authorization For Return and Examination of Medical Device form
- Authorization For Release of Medical Information (ROMI) form.
- Decontamination Instructions (Attachment 4)

Test Methodology:

Visual testing

Retrieved devices will be handled and evaluated according to DOP-QA-4015. The devices will be visually evaluated with the naked eye as well as microscopically. The observations will be recorded on a data sheet. The location of the tear, pinhole, cut, or other abnormality will be recorded on a diagram and maintained with the complaint file. The visual properties of the gel will also be recorded. Photographs will be taken and maintained with the complaint file.

Physical and Mechanical testing

The device catalog number, lot number, weight and dimensions will be recorded.

Explanted devices will be cut appropriately to perform the dimensional and mechanical shell property testing. Dependent upon the visual observations and conditions of the retrieved device, various tests will be performed on the device in accordance with established Test Methods.

Mechanical testing will consist of the following: tension set (TM 406), ultimate elongation (TM 019) and shell/patch joint strength (TM 401). Additional test methods may be employed to further analyze the defects.

Intact Devices and Chemical testing

Upon notification of a customer, of a bilateral replacement where one device remains intact, PE will request permission to analyze the intact device, specifically the gel filler. If permission is granted, the device will be returned to Mentor for gel cohesion testing (TM 366).

Data Collection:

The following minimum information will be recorded: patient name, physician name, device type, catalog number, lot number, date of implant, date of explant, reported complaint, fill volume at explant, patient history, concomitant medications, and other relevant information that establish the in-vivo conditions. The Field Experience Report (FER) form will be utilized to collect the pertinent medical related information. (Attachment 1)

All in-vivo conditions, visual, mechanical and chemical test results as well as any additional information will be recorded on the attached forms or other established data forms. The data will be entered in a database for analysis.

Data Analysis:

The data will be analyzed by the various test conditions, i.e., visual observations (macroscopic and microscopic), dimensional data, mechanical data, etc. The data will be reviewed for specific trends, e.g., device type, size, shape and clinical variables including years in vivo, implant placement, incision location, and Betadine or other antimicrobial usage. The data will be evaluated to determine if there is any correlation to the time of implant failure. Test data will be periodically analyzed to determine its relevance to failure modes, product design, product use, and to determine if the ongoing collection of retrieval program information is warranted. These data will also be utilized to develop test methodology to predict the clinical failure modes, if applicable.

Reporting requirements:

All data will be recorded on the attached forms or on data sheets relevant to the specific test. The data will be entered into a database and subsequently analyzed. The results will be summarized in a test report and submitted to FDA.

References:

SOP-HS-112, Rev. K	Product Complaint Handling System
SOP-HS-113, Rev. N	Medical Device Reporting (MDR)
DOP-QA-4002, Rev. E	Product Evaluation: Processing of a Complaint File

DOP-QA-4004, Rev. B	Product Evaluation Coding System
DOP-QA-4007, Rev. D	Product Complaint Handling by the Calling Coordinators
DOP-QA-4015, Rev. D	Product Evaluation Examination and Testing Procedure
TM000019, Rev. R	Determination of Tensile/Elongation Properties of Elastomeric Materials
TM000401, Rev. C	Determination of Joint Bond Strength
TM000406, Rev.	Tension Set
TM000366, Rev.	Gel Cohesion

Attachments

Attachment 1	Mentor Customer Field Experience Report (FER)
Attachment 2	Mentor Retrieval Program Data Record Form - Visual
Attachment 3	Mentor Retrieval Program Data Record Form – Physical
Attachment 4	Mentor Explanted Device Decontamination Instructions

Attachment 1

MENTOR Customer Field Experience Report (FER)

Telephone # 1-800-258-3487 Fax # 972-659-6687

Demographic Information

Patient Name _____ SS# _____
Date of Birth _____ Weight _____
Physician's Name _____ Customer# _____
Address _____
Phone # _____ Fax # _____

Complaint Information

Product Description (include size) _____
Device Left Right **Device** Left Right
Complaint _____ Complaint _____
Catalog # _____ **Lot #** _____ **Catalog #** _____ **Lot #** _____
Date Problem Observed _____ Date Problem Observed _____
Capsular Contracture Yes No Grade _____ Capsular Contracture Yes No Grade _____
Infection Yes No Infection Yes No
Culture Result _____ Culture Result _____

Implant History

Date of Implant _____ Date of Implant _____
Indication: 1°Augmentation 1°Reconstruction Indication: 1°Augmentation 1°Reconstruction
Revision Recon. Revision Augmentation Revision Recon. Revision Augmentation
Placement Submuscular Subglandular Placement Submuscular Subglandular
Incision Site _____ Incision Site _____
Incision Size _____ Incision Size _____
Final Fill Volume _____ Final Fill Volume _____
Fill Schedule _____ Fill Schedule _____
Betadine Usage Yes No Betadine Usage Yes No
Soak Yes No Concentration _____ Soak Yes No Concentration _____
Pocket irrigation Yes No Conc. _____ Pocket irrigation Yes No Conc. _____
Intraluminal Use Yes No Conc. _____ Intraluminal use Yes No Conc. _____
Pocket rinsed Yes No Pocket rinsed Yes No
Did the device come into contact with the patient? Yes No
Is patient currently involved in any clinical studies? Yes No If yes, specify _____

Explant History

Date of Explant _____ Date of Explant _____
Fill Volume _____ (see below) Fill Volume _____ (see below)
Capsular Contracture Yes No Grade _____ Capsular Contracture Yes No Grade _____
Infection Yes No Infection Yes No
Culture Result _____ Culture Result _____
Reason for Explant _____
Incision Site _____ Incision Site _____
Incision Size _____ Incision Size _____
Tissue ingrowth on shell observed Yes No Tissue ingrowth on shell observed Yes No
Tissue ingrowth in valve observed Yes No Tissue ingrowth in valve observed Yes No

Did the device(s) sustain any damage during explant? Yes No

Attachment 1 (continued)

MENTOR Customer Field Experience Report (FER)

General Patient Information

Mammograms performed since implant Yes No If yes, indicate number _____

Breast massage employed Yes No

Any history of breast trauma Yes No If yes, provide details: side (L or R), date and type of trauma _____

Any other relevant information Yes No If yes, provide details _____

Device Replacement Information

Catalog # of No Charge Replacement device(s) requested _____

Replacement device: (L) Cat # _____ Lot# _____

(R) Cat # _____ Lot # _____

Explain _____

Method of Decontamination _____ Date _____

Comments _____

Provider of Information _____ Title _____

Attachment 2

MENTOR RETRIEVAL PROGRAM
DATA RECORD FORM

VISUAL OBSERVATIONS

Date of evaluation _____ PE Reference # _____

L - Device Type _____ Catalogue Number _____ L/N _____

R - Device Type _____ Catalogue Number _____ L/N _____

Macroscopic- Left

General observations _____

Exposure conditions _____

Failure location _____

Failure dimensions _____

Color of Device _____

Failure Characteristics _____

Other _____

Macroscopic- Right

General observations _____

Exposure conditions _____

Failure location _____

Failure dimensions _____

Color of Device _____

Failure Characteristics _____

Other _____

Microscopic- Left

Surface Characteristics _____

Failure Characteristics _____

Fold Flaw Present _____

Other _____

Microscopic- Right

Surface Characteristics _____

Failure Characteristics _____

Fold Flaw Present _____

Other _____

Attachment 3

MENTOR RETRIEVAL PROGRAM
DATA RECORD FORM

PHYSICAL & MECHANICAL TESTING

Date of evaluation _____ PE Reference # _____

L - Device Type _____ Catalogue Number _____ L/N _____

R - Device Type _____ Catalogue Number _____ L/N _____

PHYSICAL ANALYSIS

Reference specification _____ Reference document _____

L- Weight _____ Diameter _____ Projection _____

R- Weight _____ Diameter _____ Projection _____

MECHANICAL ANALYSIS

Test Method	Results	Spec Range
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

OTHER ANALYSIS

Test Method	Results	Spec Range
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

If required, specify

Technician Signature/Date _____

Reviewer Signature/Date _____

Attachment 4

MENTOR EXPLANTED DEVICE DECONTAMINATION INSTRUCTIONS

Low Bleed Gel-Filled Devices:

1. Wrap the prosthesis in a suitable wrapping material intended for autoclave use. Place the unit in a clean, open autoclaving tray.
2. Autoclave by one of the following Gravity Displacement Decontamination methods:

Standard Cycle:	30 minutes at 250° F (121° C) and 15 psi
Optional Cycle:	15 minutes at 270° F (132° C) and 30 psi

Caution: Do not use a prevacuum high temperature autoclave cycle or an ethylene oxide sterilization cycle. Do not dry the implant using a vacuum Kyle.

LIQUID DISINFECTION INSTRUCTIONS

ALL Valve and Device Types:

Disinfection describes a process that eliminates many or all pathogenic microorganisms on inanimate objects, with the exception of bacterial endospores. This is generally accomplished by using a liquid chemical solution. Liquid chemical solutions may be used to achieve levels of disinfection which include sterilization, high-level disinfection, intermediate-level disinfection and low-level disinfection.¹

High-Level Disinfection is expected to destroy all microorganisms, with the exception of high numbers of bacterial spores. This is the level of disinfection recommended for devices which cannot be sterilized by autoclaving. Glutaraldehyde is a dependable high-level disinfectant, when used according to manufacturer's instructions.²

1. Immerse the device in glutaraldehyde solution (e.g. CIDEX* Activated Dialdehyde Solution) per manufacturer's instructions. Device should be soaked for a period of time sufficient to achieve *high level disinfection*.
2. Remove the device from solution, rinse thoroughly and gently blot dry.

^{1,2} Rutala WA. APIC Guideline for selection and use of disinfectants. AM J Infect Control 1990;58:100-101.
*Registered Trademark of Johnson & Johnson Medical