

Table 5.4.13.1-C: History for each Patient for who Rupture was Suspected and/or Confirmed

Pt. ID	Patient Information	History (Hx)	Local Reader	Central Reviewer	Final Determination of Rupture Status	Method of Determination	Adverse Events
[]	<p>Cohort: Revision DOS: 11/17/00 Implant Type: textured round gel Placement: subglandular MRI Substudy: YES MRI Scan Dates: 2/27/03, 3/20/02, 12/17/03 Investigator: Paul Silverstein (# 404)</p>	Previous ruptured right implant, MRI reported Ruptures	Bilateral ruptures	Bilateral Ruptures	Bilateral Ruptures	Explanted Ruptures confirmed by Product Evaluation. Patient had implants replaced.	Bilateral ruptures onset date unknown Concomittant surgeries: Catherization and thrombectomy L hand for blood clots 10/1/01. Amputation L hand 10/30/01 for blood clots
[]	<p>Cohort: Augmentation DOS: 4/27/0 Implant Type: smooth round gel Placement: subglandular MRI Substudy: YES MRI Scan Dates: 5/28/02, 4/30/03 Investigator: Garland Porterfield (# 405)</p>	Possible rupture on right per local MRI reader	Possible rupture on right	No rupture	No rupture	No physical findings of rupture. Plastic surgeon felt area of concern was buckle in the implant.	Wrinkling
[]	<p>Cohort: Revision DOS: 6/8/01 Implant Type: textured round gel Placement: subpectoral MRI Substudy: YES MRI Scan Dates: 11/13/02, 8/29/03 Investigator: Gloria Duda (# 421)</p>	Previously ruptured implants & silicone granulomas possible extracapsular silicone on right per MRI	indeterminate for extracapsular rupture on right, correlate with hx of previous implants, current implants intact	Indeterminate for extracapsular rupture on right, correlate with hx of previous implants, current implants intact	No rupture, indeterminate for extracapsular silicone Hx of ruptured gel implant in 1985	Patient had ultrasound 5/12/04 No rupture. No mention of extracapsular silicone in the report Radiologist recommended repeat MRI	R breast trauma sustained in car accident 2/12/02. Note: no adverse event submitted as occurrence was not device or procedure related
[]	<p>Cohort: Revision DOS: 4/18/01 Implant Type: smooth round gel Placement: subglandular MRI Substudy: YES MRI Scan Dates: 3/11/03 Investigator: Robert Mirabile (#409)</p>	Closed capsulotomy, possible rupture on the left per local MRI reader	Rupture on left side	No rupture	No rupture	Mentor recommended repeat scan. Patient has yet to return for re-scan.	L - Hematoma 4/24/01 R - Nipple Unacceptably Low Sensitivity 4/18/01 L - Nipple Unacceptably Low Sensitivity 4/18/01 L - Baker III Capsular Contracture 1/17/02 L - Breast Unacceptably Low Sensitivity 2/24/03

Pt. ID	Patient Information	History (Hx)	Local Reader	Central Reviewer	Final Determination of Rupture Status	Method of Determination	Adverse Events
[]	Cohort: Reconstruction DOS: 10/11/0 Implant Type: textured round gel Placement: submuscular MRI Substudy: YES MRI Scan Dates: 11/13/02, 8/29/03 Investigator: Mark Migliori (# 448)	Possible extracapsular silicone per local MRI reader	Hyperintense spot, possibly extracapsular rupture Motion artifact on scan	No rupture or extracapsular silicone	No rupture or extracapsular silicone	Repeat scan was suggested. Dr. Migliori said he didn't believe she had a rupture. Given her health status, it was not important to confirm his diagnosis. Patient died of breast cancer January 2004	No Adverse Events submitted
[]	Cohort: Revision DOS: 11/10/00 Implant Type: smooth round gel Placement: subpectoral MRI Substudy: YES MRI Scan Dates: 10/30/02 Investigator: Thomas DeWire (#418)	Previously ruptured bilateral implants	Small amount of intracapsular silicone, but no evidence of collapse or rupture	"Extra-capsular silicone, most likely residual from previous implants, no evidence of rupture of current implant"	No rupture	MRI	Bilateral: Low nipple sensitivity 5/1/01, resolved

Suspected Rupture Patient Summary

Study ID: []

Cohort: Augmentation

DOS: 4/27/01

Implant Type: smooth round gel filled breast implant

Placement: subglandular

MRI Substudy: YES

MRI scan dates: 5/28/02, 4/30/03

Investigator []

This patient was entered in the Core Gel study on 4/27/01 for general breast enlargement. No significant past medical history related to the breast is reported.

On 5/28/02 she underwent her Year 1 study MRI scan. The Local Reader reported findings suspicious of rupture on the right, with no extracapsular silicone. The Central Reader reported no evidence of rupture or extracapsular silicone bilaterally.

On 4/30/03 the patient underwent her Year 2 study MRI scan. The Local Reader reported findings suspicious for intracapsular rupture on the right side and an intact left breast implant. The Central Reader notes no rupture or extracapsular silicone. The Central Reader notes specifically no evidence of rupture on the right.

[] was consulted after reviewing both the [] reports as well as those from the Central Reader. He wrote a letter stating that had examined the patient and felt that the area noted on the MRI scan was associated with a buckle in the implant and that he doesn't feel any problem exists.

No further action is [] on this patient. She continues to be followed in the Core Gel Study by [] She will have her Year 4 MRI scan in 2005 in accordance with the MRI protocol.

[Handwritten signature]

[Handwritten: MD, FACS]

November 14, 2003

Attn: Carolyn Offutt
Mentor Corporation
201 Mentor Drive
Santa Barbara, CA 93111

Re:

Dear Carolyn,

[REDACTED] underwent MRI Scans on April 30, 2003 and May 28, 2002. Both of these scans showed a possible intracapsular rupture associated with the right breast implant. I have examined this patient and feel like this is associated with a buckle in the implant. I have assured this patient that I don't feel any problem exist and that I have reviewed the reports from **[REDACTED]** as well as Mentor Corporations reviewer.

If you should have any questions, please feel free to contact my office.

Sincerely,



MENTOR

89

MRI Silicone Breast Implant Evaluation Data Sheet

6/17/03

PATIENT STUDY ID:

TRIAL NO.
10-009

COUNTRY NO
0 | 0 | 1

PATIENT INITIALS

PATIENT SOCIAL SECURITY NO

MRI EVALUATION

Patient's Date of Birth:

[REDACTED]

MRI Reviewer:

[REDACTED]

Scan Quality (check one):

- 1 Good
- 2 Adequate
- 3 Inadequate

Date of MRI Evaluation:

04 | 30 | 2003
month day year

	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 checked="" type="checkbox"/> Subglandular	1 <input type="checkbox"/> Submuscular 2 <input checked="" type="checkbox"/> Subglandular
Implant Type:	1 <input checked="" type="checkbox"/> Smooth 2 <input type="checkbox"/> Siltex	1 <input checked="" type="checkbox"/> Smooth 2 <input type="checkbox"/> Siltex
Implant Evaluation:	1 <input checked="" type="checkbox"/> No Evidence of Rupture 2 <input type="checkbox"/> Indeterminate Evidence of Rupture 3 <input type="checkbox"/> Rupture: Check one Type: 1 <input type="checkbox"/> Intracapsular 2 <input type="checkbox"/> Extracapsular Check one Condition: 1 <input type="checkbox"/> Uncollapsed 2 <input type="checkbox"/> Partially Collapsed 3 <input type="checkbox"/> Fully Collapsed (linguini sign)	1 <input checked="" type="checkbox"/> No Evidence of Rupture 2 <input type="checkbox"/> Indeterminate Evidence of Rupture 3 <input type="checkbox"/> Rupture: Check one Type: 1 <input type="checkbox"/> Intracapsular 2 <input type="checkbox"/> Extracapsular Check one Condition: 1 <input type="checkbox"/> Uncollapsed 2 <input type="checkbox"/> Partially Collapsed 3 <input type="checkbox"/> Fully Collapsed (linguini sign)
Soft Tissue Evaluation:	1 <input checked="" type="checkbox"/> No Evidence of Extracapsular Silicone 2 <input type="checkbox"/> Indeterminate for Extracapsular Silicone 3 <input type="checkbox"/> Definite Extracapsular Silicone	1 <input checked="" type="checkbox"/> No Evidence of Extracapsular Silicone 2 <input type="checkbox"/> Indeterminate for Extracapsular Silicone 3 <input type="checkbox"/> Definite Extracapsular Silicone

Notes:

Specifically NO evidence of rupture on the right. Prominent folds
2yr Scan.

Reviewer's Signature

[REDACTED]

07 | 02 | 2003
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.

Name: [REDACTED]
Phys: [REDACTED]
Dob: [REDACTED] Sex: F
Acct: [REDACTED]
Exam Date: 04/30/2003 Status: REG REF
Radiology No:
Unit No: [REDACTED]
Patient Phone No: [REDACTED]

EXAMS: 001135213 MRI BREAST BILAT WITHOUT CONTR
Clinical Data: MENTOR STUDY

MRI BREAST BILATERAL WITHOUT CONTRAST.

MRI SEQUENCES: Axial T2 and fat-suppressed T2 as well as sagittal T2 with water-suppressed pulsing sequences were performed of both breasts using a Siemens 1.5 Tesla magnet and a bilateral breast coil.

RIGHT BREAST: There is a subpectoral silicone implant demonstrated on the right. There is a peculiar complex fold pattern involving the lower inner quadrant of the right implant. This appears to have silicone on both sides of this fold and it is confluent from anterior to posterior. I really cannot totally explain this appearance just on the basis of complex folds and am concerned that there may be a small intracapsular rupture in this location. There is no evidence of extracapsular silicone. The remainder of the implant appears to be intact.

LEFT BREAST: On the left the implant appears to be intact and silicone in nature and lies in a subpectoral location. There is no definite evidence of intra- or extracapsular rupture at this time.

IMPRESSION:

1. Findings suspicious for an intracapsular rupture of the right implant in the lower inner aspect.
2. There is no definite evidence of abnormality involving the left implant which appears to be intact.

Report was stat faxed to [REDACTED] on 05/12/03 at 1630 hours at

Name: [REDACTED]
Phys: Porterfield MD, Garland
Dob: [REDACTED] Age: 45 Sex: F
Acct: M25778937 Loc: MORAD
Exam Date: 04/30/2003 Status: REG REF
Radiology No:
Unit No: J0604436
Patient Phone No: [REDACTED]

EXAMS: 001135213 MRI BREAST BILAT WITHOUT CONTR
Clinical Data: MENTOR STUDY
<Continued>

848-7297.

** REPORT SIGNATURE ON FILE 05/14/2003 **
Reported By: [REDACTED]
Signed By: [REDACTED]

Cc: [REDACTED]

Dictated Date/Time: 04/30/2003 (1459)
Transcribed Date/Time: 05/12/2003 (1625)
Transcriptionist: MER GSS
Printed Date/Time: 06/06/2003 (0833)



MENTOR

16-17 MRI Silicone Breast Implant Evaluation Data Sheet

PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0101	SITE NO.	PATIENT NO.	PATIENT INITIALS first middle last	PATIENT SOCIAL SECURITY NO.
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MRI EVALUATION

Patient's Date of Birth: [REDACTED]

MRI Reviewer: [REDACTED]

Date of MRI Evaluation: 05/28/2002
month day year

Scan Quality (check one):
 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 checked="" type="checkbox"/> Subglandular	1 <input type="checkbox"/> Submuscular 2 <input checked="" 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 checked="" type="checkbox"/> No Evidence of Rupture 2 <input type="checkbox"/> Indeterminate Evidence of Rupture 3 <input type="checkbox"/> Rupture: Check one Type: 1 <input type="checkbox"/> Intracapsular 2 <input type="checkbox"/> Extracapsular Check one Condition: 1 <input type="checkbox"/> Uncollapsed 2 <input type="checkbox"/> Partially Collapsed 3 <input type="checkbox"/> Fully Collapsed (linguini sign)	1 <input checked="" type="checkbox"/> No Evidence of Rupture 2 <input type="checkbox"/> Indeterminate Evidence of Rupture 3 <input type="checkbox"/> Rupture: Check one Type: 1 <input type="checkbox"/> Intracapsular 2 <input type="checkbox"/> Extracapsular Check one Condition: 1 <input type="checkbox"/> Uncollapsed 2 <input type="checkbox"/> Partially Collapsed 3 <input type="checkbox"/> Fully Collapsed (linguini sign)
Soft Tissue Evaluation:	1 <input checked="" type="checkbox"/> No Evidence of Extracapsular Silicone 2 <input type="checkbox"/> Indeterminate for Extracapsular Silicone 3 <input type="checkbox"/> Definite Extracapsular Silicone	1 <input checked="" type="checkbox"/> No Evidence of Extracapsular Silicone 2 <input type="checkbox"/> Indeterminate for Extracapsular Silicone 3 <input type="checkbox"/> Definite Extracapsular Silicone

Notes: Speculally (R) medial aspect intact
1 yr

Reviewer's Signature: [REDACTED]

Date: 07/09/2003
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.

Local Radiologist Assessment

MENTOR		MRI Silicone Breast Implant Evaluation Data Sheet			
PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO.	PATIENT NO.	PATIENT SOCIAL SECURITY NO.

MRI EVALUATION

Patient's Date of Birth: [REDACTED]

LOCAL MRI Reviewer: [Signature]

Date of MRI Evaluation: 04/30/2003
month day year

Scan Quality (check one):
 1 Good *n/a*
 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 checked="" type="checkbox"/> Rupture: Check one Type: - 1 <input checked="" type="checkbox"/> Intracapsular 2 <input type="checkbox"/> Extracapsular Check one Condition: <i>na</i> 1 <input type="checkbox"/> Uncollapsed 2 <input type="checkbox"/> Partially Collapsed 3 <input type="checkbox"/> Fully Collapsed (linguini sign)	1 <input checked="" type="checkbox"/> No Evidence of Rupture 2 <input type="checkbox"/> Indeterminate Evidence of Rupture 3 <input type="checkbox"/> Rupture: Check one Type: 1 <input type="checkbox"/> Intracapsular 2 <input type="checkbox"/> Extracapsular Check one Condition: <i>na</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 checked="" type="checkbox"/> No Evidence of Extracapsular Silicone 2 <input type="checkbox"/> Indeterminate for Extracapsular Silicone 3 <input type="checkbox"/> Definite Extracapsular Silicone	1 <input checked="" type="checkbox"/> No Evidence of Extracapsular Silicone 2 <input type="checkbox"/> Indeterminate for Extracapsular Silicone 3 <input type="checkbox"/> Definite Extracapsular Silicone

Notes: *this form was completed by Carolyn Offutt using information from the Mercy Hospital radiology report 4/21/04*

2 yr scan

Reviewer's Signature: *n/a* 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.

 MENTOR	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.		<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			SEVERITY 1 = Mild 2 = Moderate 3 = Severe	TREATMENT REQUIRED (check all that apply)			OUTCOME 1 = Resolved 2 = Ongoing 3 = Death 4 = Unknown	RESOLUTION DATE		
				month	day	year		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)	4 ___ days, Date: ___/___/___	5 _____		Procedure Type Code: _____	Procedure Date: ___/___/___	month
27	<input type="checkbox"/> 1 <input checked="" type="checkbox"/> 3 <input type="checkbox"/> 2 <input type="checkbox"/> 4	<input type="checkbox"/> 0 <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2	<input checked="" type="checkbox"/> 0 <input type="checkbox"/> 3 <input type="checkbox"/> 1 <input type="checkbox"/> 2		04	30	2003	<input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3	<input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 Procedure Type Code: _____	<input type="checkbox"/> 4 ___ days, Date: ___/___/___ <input type="checkbox"/> 5 _____ Procedure Date: ___/___/___	<input type="checkbox"/> 1 <input type="checkbox"/> 4 <input checked="" 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 Procedure Type Code: _____	<input type="checkbox"/> 4 ___ days, Date: ___/___/___ <input type="checkbox"/> 5 _____ Procedure Date: ___/___/___	<input type="checkbox"/> 1 <input type="checkbox"/> 4 <input type="checkbox"/> 2 <input type="checkbox"/> 3				

Investigator's Signature: [Signature] 06 08 2004
month day year

****Complete Secondary Procedures Report. If new study device is implanted, complete Re-implantation Report.**

*ADVERSE EVENT CODES			†SECONDARY PROCEDURE TYPE CODES
1 = Asymmetry	15 = Lymphadenopathy	25 = Lactation Difficulties, specify: _____	81 = Bopsy
2 = Baker II Capsular Contracture with Surgical Intervention	16 = Necrosis	_____	82 = Capsulectomy
3 = Baker III Capsular Contracture	17 = New Diagnosis of Breast Cancer	_____	83 = Explantation with Replacement**
4 = Baker IV Capsular Contracture	18 = New Diagnosis of Rheumatic Disease, specify: _____	29 = Other, specify: _____	84 = Explantation without Replacement
5 = Breast pain not associated with any other complication	19 = Nipple—Unacceptably Low Sensitivity	_____	85 = Incision and Drainage
6 = Breast—Unacceptably Low Sensitivity	20 = Nipple—Unacceptably High Sensitivity	30 = Other, specify: _____	86 = Mastopexy
7 = Breast—Unacceptably High Sensitivity	21 = Position Change		87 = Open Capsulectomy
8 = Calcification	22 = Ptsis		88 = Position Change
9 = Delayed Wound Healing	23 = Rupture		89 = Scar Revision
10 = Extrusion	24 = Seroma		90 = Skin Adjustment
11 = Granuloma	25 = Size Change—Patient Request		91 = Other, specify: _____
12 = Hematoma	26 = Size Change—Physician Assessment only		
13 = Hypertrophic Scarring	27 = Wrinkling		92 = Other, specify: _____
14 = Infection			

4817

Suspected Rupture Patient Summary

Study ID:

Cohort: Revision

DOS: 6/8/01

Implant Type: textured round gel filled breast implant

Placement: subpectoral

MRI Substudy: YES

MRI scan dates: 11/13/02, 8/29/03

Investigator: []

This patient was originally implanted with gel implants from an unknown manufacturer in 1985. In 1995, the right implant ruptured and both implants were replaced with saline implants. In 2001, the right saline implanted ruptured. On 6/8/01 she was entered in the Core Gel study and both saline implants were replaced with Core Gel implants.

On 4/17/02 she underwent her 2 Year Study MRI scan. The Local Reader notes findings suspicious for free silicone in both breasts suggestive of extracapsular rupture of an indeterminate age, possibly from a previous implant rupture. The current implants were noted to be intact. The Central Reader reported no evidence of rupture and indeterminate for extracapsular silicone bilaterally and recommends correlation with history of previously ruptured implants. It was noted that both current implants were intact. Correlation with history of prior implants and ultrasound was recommended.

The patient had a mammogram and an ultrasound, but the hospital lost the images. The patient had a breast ultrasound on 5/12/04 which demonstrated no evidence of implant rupture. The radiologist recommended repeating the breast MRI which will be offered to the patient.

The patient continues to be followed in the Core Gel Study by [] She will have her Year 4 MRI scan in 2005 in accordance with the MRI protocol.

il
5/13/04

Patient [REDACTED]

Exam Date: 12 May 2004

DOB [REDACTED]
ARA MR # [REDACTED]
SSN [REDACTED]
Exam Site:
Site Phone #:
Accession #

Referring Physician: DEFAULT, RCP

BILATERAL BREAST SONOGRAM: 05/12/2004

CLINICAL HISTORY: The patient has bilateral breast implants and has had a previous MR study dated 4/17/03 from a suburban hospital, city and state not specified with report present indicating possible implant rupture bilaterally.

No previous MR study of the breasts, mammograms, or ultrasound studies are currently available. Comparison is made with the report of the previous MR study of the breasts of 4/17/03.

Sonographically, there are enfoldings of both breast implants but the implants appear intact on a sonographic basis and no linguae sign seen.

IMPRESSION:

No definite sonographic evidence of implant rupture. However, MR study of the breast is a more sensitive test for implant rupture and given the fact that a previous MR exam of April 2003 questioned possible bilateral implant ruptures, I would recommend a follow-up bilateral breast MRI exam for re-evaluation. Comparison with the previous MR study also would be useful.

RM/II

[]
rm/pr

CONFIDENTIALITY NOTICE: This report is intended for the use of the Referring Physician or Consulting Physician. It contains information that is privileged and/or confidential. If you are not the intended recipient or that person's authorized agent, please destroy this report or return it by U.S. Mail.



MENTOR

MRI Silicone Breast Implant Evaluation Data Sheet

PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO.	PATIENT NO.	PATIENT INITIALS	PATIENT SOCIAL SECURITY NO.
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MRI EVALUATION

Patient's Date of Birth: [REDACTED]

MRI Review: []

Date of MRI Evaluation: 04/17/2003

month day year

Scan Quality (check one):

- 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:	<ul style="list-style-type: none"> 1 <input type="checkbox"/> Submuscular 2 <input type="checkbox"/> Subglandular 	<ul style="list-style-type: none"> 1 <input type="checkbox"/> Submuscular 2 <input type="checkbox"/> Subglandular
Implant Type:	<ul style="list-style-type: none"> 1 <input type="checkbox"/> Smooth 2 <input type="checkbox"/> Siliex 	<ul style="list-style-type: none"> 1 <input type="checkbox"/> Smooth 2 <input type="checkbox"/> Siliex
Implant Evaluation:	<ul style="list-style-type: none"> 1 <input checked="" type="checkbox"/> No Evidence of Rupture 2 <input type="checkbox"/> Indeterminate Evidence of Rupture 3 <input type="checkbox"/> Rupture: Check one Type: <ul style="list-style-type: none"> 1 <input type="checkbox"/> Intracapsular 2 <input type="checkbox"/> Extracapsular 	<ul style="list-style-type: none"> 1 <input checked="" type="checkbox"/> No Evidence of Rupture 2 <input type="checkbox"/> Indeterminate Evidence of Rupture 3 <input type="checkbox"/> Rupture: Check one Type: <ul style="list-style-type: none"> 1 <input type="checkbox"/> Intracapsular 2 <input type="checkbox"/> Extracapsular
Soft Tissue Evaluation:	<ul style="list-style-type: none"> 1 <input type="checkbox"/> No Evidence of Extracapsular Silicone 2 <input checked="" type="checkbox"/> Indeterminate for Extracapsular Silicone 3 <input type="checkbox"/> Definite Extracapsular Silicone 	<ul style="list-style-type: none"> 1 <input type="checkbox"/> No Evidence of Extracapsular Silicone 2 <input checked="" type="checkbox"/> Indeterminate for Extracapsular Silicone 3 <input type="checkbox"/> Definite Extracapsular Silicone

Notes:

2yr

Correlation with history of prior implants
 & evaluate with ultrasound.
 Current implants intact.

Reviewer's Signature: []

09/10/2003

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 rupture and small amounts of soft tissue silicone below our thresholds for detection may not be seen by this method.

NAME: [REDACTED]
MR # [REDACTED]
AGE: 46
EXAM DATE: 04/17/2003
LOCATION: UNK STATUS: REG CLI
DOCTOR: PRIMARY CARE/OTHER PHYSICIAN

[]

EXAM# TYPE/EXAM
000585357 MRI/BILATERAL BREAST - MENTOR
 <Continued>

RESULT

04/17/03

** REPORT SIGNATURE ON FILE 04/18/2003 **

Reported By
Signed By: [] [] []

04/17/2003
MDI/DB
RESULT CODE:

PAGE 2

Local Radiologist Assessment

MENTOR		MRI Silicone Breast Implant Evaluation Data Sheet				
PATIENT STUDY ID:	TRIAL NO 10-009	COUNTRY NO 0 0 1	SITE NO.	PATIENT NO	PATIENT INITIALS	PATIENT SOCIAL SECURITY NO.

MRI EVALUATION

Patient's Date of Birth: [REDACTED]

MRI Reviewer: LOCA [Signature]

Date of MRI Evaluation: 04 / 17 / 2003
month day year

Scan Quality (check one):
 1 Good
 2 Adequate *Na*
 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 checked="" type="checkbox"/> No Evidence of Rupture 2 <input type="checkbox"/> Indeterminate Evidence of Rupture 3 <input type="checkbox"/> Rupture: Check one Type: 1 <input type="checkbox"/> Intracapsular 2 <input type="checkbox"/> Extracapsular Check one Condition: 1 <input type="checkbox"/> Uncollapsed <i>Na</i> 2 <input type="checkbox"/> Partially Collapsed 3 <input type="checkbox"/> Fully Collapsed (linguini sign)	1 <input checked="" type="checkbox"/> No Evidence of Rupture 2 <input type="checkbox"/> Indeterminate Evidence of Rupture 3 <input type="checkbox"/> Rupture: Check one Type: 1 <input type="checkbox"/> Intracapsular 2 <input type="checkbox"/> Extracapsular Check one Condition: 1 <input type="checkbox"/> Uncollapsed <i>Na</i> 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 checked="" type="checkbox"/> Definite Extracapsular Silicone	1 <input type="checkbox"/> No Evidence of Extracapsular Silicone 2 <input type="checkbox"/> Indeterminate for Extracapsular Silicone 3 <input checked="" type="checkbox"/> Definite Extracapsular Silicone

Notes: *This form was completed by Carolyn Offutt using information from suburban Hospital radiology report 4/22/04*

(2yr)

Reviewer's Signature: [Signature] 1 / 9 / /
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.



MRI Silicone Breast Implant Evaluation Data Sheet

PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO 0 0 1	SITE NO	PATIENT NO	PATIENT INITIALS [REDACTED]	PATIENT SOCIAL SECURITY NO [REDACTED]
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MRI EVALUATION

Patient's Date of Birth: / /

month day year

MRI Reviewer: _____

Date of MRI Evaluation: / /

month day year

Scan Quality (check one):

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: lyr

MISSED VISIT 0 00 3-15-04

 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.

OPERATIVE REPORT

[REDACTED]

ROOM TPACTP

DATE OF SURGERY

06/08/2001

SURGEON

ASSISTANT(S)

Study entry
surgery

PREOPERATIVE DIAGNOSIS FAILED LEFT BREAST IMPLANT

POSTOPERATIVE DIAGNOSIS. FAILED LEFT BREAST IMPLANT

TITLE OF SURGERY

- 1 BILATERAL OPEN CAPSULOTOMY
- 2 REPLACEMENT OF RIGHT BREAST IMPLANT
- 3 REMOVAL OF LEFT FAILED IMPLANT AND REPLACEMENT OF IMPLANT

ANESTHESIA GENERAL ENDOTRACHEAL ANESTHESIA

DESCRIPTION OF PROCEDURE: Preoperatively, the patient's chest was marked in the sitting position marking out the inframammary folds and well-healed inframammary scars. She was then brought back to the operating room and placed in the supine position on the operating table. After giving general anesthetic, her neck, chest, and the abdomen were prepped with Betadine and sterilely draped.

Work was begun on the right breast, and the well-healed inframammary scar was incised for a length of 4 cm. The incision was then carried through the subcutaneous tissue to the capsule. The capsule was entered, and the implant was removed without difficulty. The implant was intact and contained clear fluid. This was a Mentor Siltex round implant, a 325-cc implant filled to 375 cc of saline. The breast tissue was then palpated, and no abnormalities were found. The capsule was then scored along its entirety of the juncture with the chest wall, and an inferior skin flap of the capsule was then scored to allow expansion of the pocket. This was a subpectoral pocket. The pocket was then irrigated with bacitracin solution. Hemostasis was controlled with cautery. A moistened lap tape was then placed within this pocket, and a similar procedure was performed on the left side with an incision made in the well-healed inframammary scar which measured approximately 4 cm in length. The capsule was entered, and an implant was then removed which was collapsed. It contained a minimal amount of a clear yellow fluid. On examination of the implant on the posterior surface, there was an approximately 1 cm rent. The failed implant was then passed off to the back table and was prepared for return to pathology and then return to Mentor Corporation.

The pocket was irrigated with bacitracin solution. The capsule was thickened along the inferior edge. The capsule was scored along its juncture with the chest wall, and an inferior capsulectomy was performed allowing expansion of the pocket. The failure of the implant occurred on May 11, 2001. After achieving excellent hemostasis, moistened lap tape was placed. The lap tapes were removed. There was excellent hemostasis. The inframammary prostheses, reference number [REDACTED], were removed from their sterile packaging and placed in bacitracin solution. Each implant was then placed in its subpectoral pocket. The breast tissue was then reapproximated with 3-0 Vicryl, and the skin was approximated with 3-0 Vicryl and a 4-0 Monocryl subcuticular stitch.

Copy For: [REDACTED]

OPERATIVE REPORT

[REDACTED]

ROOM IPACTPA101

DATE OF SURGERY

06/08/2001

Page 2 of 2

Sten-Strips were placed at the end of the procedure. There was good symmetry of size and shape of the breasts. Sterile dressings were placed followed by a 6" Ace wrap dressing. She was then awakened and transferred to the recovery area in stable condition.

G D/mdi1WB
D. 06/11/2001 6:27 A
T
J
K

Apr 21 04 10:11a



[]

Pre-Study Surgery

PATIENT: [REDACTED]
 BIRTH: [REDACTED]
 SEX: [REDACTED]
 MED. NO: [REDACTED]
 HOME PHONE: [REDACTED]
 WORK PHONE: [REDACTED]
 RESIDENT: [REDACTED]

DATE OF OPERATION: 12/5/98
 SURGEON: [REDACTED]
 ASSISTANT: [REDACTED]

PREOPERATIVE DIAGNOSIS: Failed right breast implant.

POST-OPERATIVE DIAGNOSIS: Failed right breast implant.

DATE OF OPERATION: Bilateral capsulectomy, and removal of right implant material, left breast implant and replacement of saline breast implant submuscular.

ANESTHESIA: General.

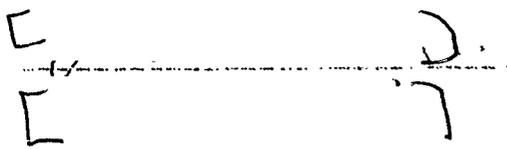
INDICATIONS FOR SURGERY: The patient is a 39-year-old white female who underwent an augmentation mammoplasty with silicone gel implants, and has noticed a change in the size and shape of her right breast. It was consistent with failed right breast implant, intracapsular rupture. The implants are glandular placement and the size and make of the implants are unknown. The procedure, risks and complications are discussed with the patient and all questions are answered. Silicone issues are discussed.

DESCRIPTION OF PROCEDURE: The patient was marked in the preoperative holding area in the sitting position marking out her axillary inframammary fold. She was then brought back to the operating room and placed in the supine position on the operating room table. After induction of general anesthesia, her neck, chest and abdomen were prepped with povidone and sterily draped. Work was begun on the right breast. A well sealed inframammary scar was infiltrated with 1% lidocaine with epinephrine mixed with 0.5% Marcaine. An intercostal block was also performed. The scar was excised leaving approximately 4 cm skin incision. The incision was carried down through the breast tissue down to the level of the capsule using Boyle cautery. The capsule was removed from the surrounding breast tissue and the pectoralis major muscle. The capsule was opened and there was a failed implant with free silicone contained within the capsule. On examination of the contents, the shell of the implant was found, and the implant was aspirated as a 7 cc saline. On further examination of the breast tissue and axilla, no abnormalities or masses were found.

The wound was irrigated with Bacitracin solution 100. A subcuticular tunnel was not raised. The lateral edge of the pectoralis major muscle was incised and using blunt dissection, the pocket was created. Hemostasis was performed with suture cautery and the medial and inferior attachments of the pectoralis muscle were released. The pocket was irrigated with Bacitracin solution, and moist lap tapes were placed. A similar procedure was performed on the left side. The implant was removed and found to be intact. The implant appeared to be a double-lumen implant, and the inner shell appeared ruptured. The outer shell was intact and there was no evidence of silicone bleed. On palpation of the breast tissue and chest wall there were no abnormalities found.

After hemostasis was completed, the empty non-filled breast implant catalog # 325 cc implant was removed from the sterile packaging and was placed in Bacitracin solution. The air was aspirated and the implant was filled with 100 cc of normal saline. There was no evidence of leak. The left breast implant was 325 cc implant filled to 375 cc of normal saline with a similar procedure was performed on the opposite side. The right breast a similar implant was placed also filled to 375 cc. The patient was placed in the sitting position and checked for symmetry. There was good symmetry of size and shape. She was then returned to supine position. The chest tubes were removed prior to placement of the implants. Jackson-Pratt drains were placed exiting through separate stab wounds in the axilla and was then secured in place with 3-0 nylon suture. The drains were put in the appropriate positions.

The breast tissue was approximated with 3-0 Vicryl and the skin approximated with 4-0 Vicryl and a 3-0 Saxon subcuticular stitch. At the end of the procedure the skin remained pink and viable. Sterna-Straps were placed followed by a sterile dressing and an Ace wrap. At the end of the procedure the instrument and lap counts were correct. The patient tolerated the procedure well and she was extubated and transferred to the recovery room in stable condition.



BD/or

01: 2/27/95

01: 198

Suspected Rupture Patient Summary

Study ID:

Cohort: Revision

DOS: 4/18/01

Implant Type: smooth round gel filled breast implant

Placement: subglandular

MRI Substudy: YES

MRI scan dates: 3/11/03

Investigator: [

]

This patient was originally implanted in 1976 with gel implants from an unknown manufacturer. Because of capsular contracture, she had these implants removed and replaced with Core gel implants on 4/18/01 at which time she was entered in the Core study. She was enrolled in the study by [] and subsequently transferred to Dr. Robert Mirabile to continue her study follow-up.

This patient had a hematoma evacuated from her left breast on 5/16/01.

The patient developed a Baker III capsular contracture on the left side in 2002. Dr. Trevisani treated this contracture by performing a closed capsulotomy in March 2002. This was a protocol deviation and it was recorded and reported in the Core PMA.

The patient transferred to [] in February 2003. He notes that her capsular contracture is still present on the left side and recommends an MRI to evaluate the left breast. The patient was part of the MRI substudy and had her 2 year scan on 3/11/03. The Local Reader reported an early extracapsular rupture of the left breast implant and intact right breast implant. The Central Reader reported no evidence of rupture or extracapsular silicone bilaterally. In order to resolve the discrepancy, Mentor recommended that the patient have her 2 year scan repeated. Dr. Mirabile's office has made several attempts to have the patient re-scanned, but she fails to make the appointments. The study coordinator states that the patient does not think it is a pressing issue.

This patient continues to be followed in the Core Gel Study by Dr. [] The study coordinator continues to try to have the patient rescanned. She is due for her Year 4 MRI scan in 2005 in accordance with the MRI study protocol.

VISIT SUMMARY

) - MMS

DATE: 2/24/03

PATIENT: 

She presents with a status post bilateral silicone breast implant placement in Florida, which was performed about 2 years ago. She did require re-operation for a hematoma on the left side. She does present with a contracture of the left side. PE reveals a scar contracture of the left side. She has previously undergone a closed capsulotomy by her doctor in Florida. I have recommended MRI evaluation of that breast.



MENTOR

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

*copy
PT chart
my files*

Fax Message

To Coeli Howarth
Company Dr. []
cc:
Fax No. 610-275-5804
Telephone No. 610-272-8821
Number of pages 2 (including this one)

Date 4 20 04
From _____
Fax No. _____
Telephone No. _____
Subject Core Gel Study

If you do not receive all pages, please call:

- Urgent
- Call to Discuss
- Confirm Receipt
- For Review

Hi Coeli,

Do you have any chart notes on [redacted] that document any physical findings surrounding the suspected rupture of her implant? [] if I recall, did not think it was ruptured - dx was made by the MRI.

Can you fax me anything you have, including mamm or ultrasound results, etc. The FDA wants us to write summaries of all the suspected ruptures.

Thanks,
Carolyn 4/22/04

Coeli talked to her this week. She is going to get MRI done. Patient doesn't think it is a pressing issue. Mentor will pay for surgery if needed.

*Did closed capsulotomy
felt hard on @
local MRI ^{per} up, our reader said normal,,
current physical findings - status quo*

Privileged and Confidential -All information here is intended only for the use of the addressee(s). If the reader of this message is not the intended recipient(s) or its employee or agent, any distribution or copying of this communication is strictly prohibited. Anyone receiving this communication in error should notify Mentor immediately by telephone and return the original message to the above address.

0001016

FAX COVER SHEET

File in Purple chart

[]

Send to:	From: []
Attention:	Date:
Office location:	Office location:
Fax number:	Phone number:

- Urgent
 Reply ASAP
 Please comment
 Please review
 For your information

Total pages, including cover: _____

Comments:

[REDACTED] has not done MRI yet. She was told again it is imperative that she have done ASAP.

The documents accompanying this telecopier contain information from the office of Robert J. Mirabile, M.D., which is confidential and/or legally privileged. The information is intended only for the use of the individual or entity named on this transmission sheet. If you are not the intended recipient, you are hereby notified that any disclosure, copying, distribution, or taking of any action in reliance on the contents of this telecopied information is strictly prohibited and that the documents should be returned to this office immediately. In this regard, if you have received this telecopy, in error, please notify this office by telephone immediately so that we can arrange for the return of these documents.

Signed: []

Data Clarification Form

SPONSOR NAME: Mentor PROTOCOL NO.: Core CRA NAME _____

PRIN./SUB-INVESTIGATOR NAME: [] SUBJECT INITIALS: [] SUBJECT NO.: _____ DATE: 2.12.04

CRF ID	QUERY	RESOLUTION
MRI Eval. Form	<p>An mri evaluation form was completed. date of mri evaluation was entered as 4/09/2003</p>	<p>Source documentation states that the mri scan was done on 3/11/03. Please change date of mri evaluation to 3/11/2003</p>

Principal/Sub-Investigator Signature _____ Date 2/12/04

Note: All signature names must be listed on the Form FDA 1572



MENTOR

MRI Silicone Breast Implant Evaluation Data Sheet

PATIENT STUDY ID:	TRIAL NO 10-009	COUNTRY NO 0 0 1	SITE NO.	PATIENT NO	PATIENT INITIALS	PATIENT SOCIAL SECURITY NO.
--------------------------	---------------------------	--------------------------------	-----------------	-------------------	-------------------------	------------------------------------

MRI EVALUATION

Patient's Date of Birth: [REDACTED]

MRI Reviewer: [Signature]

Date of MRI Evaluation:

04 | 09 | 2003
month day year

Scan Quality (check one):

- 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 checked="" type="checkbox"/> Subglandular	1 <input type="checkbox"/> Submuscular 2 <input checked="" type="checkbox"/> Subglandular
Implant Type:	1 <input checked="" type="checkbox"/> Smooth 2 <input type="checkbox"/> Siltex	1 <input checked="" type="checkbox"/> Smooth 2 <input type="checkbox"/> Siltex
Implant Evaluation:	1 <input checked="" type="checkbox"/> No Evidence of Rupture 2 <input type="checkbox"/> Indeterminate Evidence of Rupture 3 <input type="checkbox"/> Rupture: Check one Type: 1 <input type="checkbox"/> Intracapsular 2 <input type="checkbox"/> Extracapsular Check one Condition: 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: Check one Type: 1 <input type="checkbox"/> Intracapsular 2 <input type="checkbox"/> Extracapsular Check one Condition: 1 <input type="checkbox"/> Uncollapsed 2 <input type="checkbox"/> Partially Collapsed 3 <input type="checkbox"/> Fully Collapsed (linguini sign)
Soft Tissue Evaluation:	1 <input checked="" type="checkbox"/> No Evidence of Extracapsular Silicone 2 <input type="checkbox"/> Indeterminate for Extracapsular Silicone 3 <input type="checkbox"/> Definite Extracapsular Silicone	1 <input checked="" type="checkbox"/> No Evidence of Extracapsular Silicone 2 <input type="checkbox"/> Indeterminate for Extracapsular Silicone 3 <input type="checkbox"/> Definite Extracapsular Silicone

Notes:

Product false

Reviewer's Signature

04 | 09 | 2003
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.

PATIENT NAME: [REDACTED]

ACCOUNT #:

SSN: [REDACTED]

DOB: [REDACTED]

SEX: F

EXAMINATION: MRI BREAST BILAT W &/OR W/ODATE: 3/11/03

HISTORY:

RULE OUT LEFT BREAST IMPLANT RUPTURE.

COMMENT:

Axial FSE T2 weighted, sagittal water suppressed FSE T2 weighted and silicone suppressed FSE T2 weighted sequences of bilateral breasts were obtained on 1.5 Tesla MR unit.

Bilateral subglandular breast implants are present. There is early intracapsular rupture in the left breast implant in the upper inner quadrant. No intracapsular rupture of the right breast implant and no extracapsular rupture of right or left breast are demonstrated.

CONCLUSION:

EARLY INTRACAPSULAR RUPTURE OF LEFT BREAST IMPLANT AND INTACT RIGHT BREAST IMPLANT.

Thank you for referring this patient.

-, 03



MENTOR

MRI Silicone Breast Implant Evaluation Data Sheet

PATIENT STUDY ID:	TRIAL NO 10-009	COUNTRY NO. 0 0 1	SITE NO	PATIENT NO.	PATIENT INITIALS first middle last [REDACTED]	PATIENT SOCIAL SECURITY NO [REDACTED]
--------------------------	--------------------	--------------------------	---------	-------------	---	--

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:

MISSED VISIT

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.

October 24, 2003

Mentor Corporation

RE: [REDACTED]

Dear Sirs:

[REDACTED] had capsular contracture which started in early January 2002. She was placed on Pavobid for two months and underwent a closed capsulotomy with gentle squeezing of the left breast to break up the excess scar tissue which improved very nicely with this. She signed an informed consent of all the risks and benefits knowing that the only other alternative was going back to surgery which she did not want to do at this time. She knew with a gentle squeeze there is always the possibility of implant breakage and leakage. Informed consent was signed on March 18, 2002 with her shortly undergoing the procedure.

Sincerely,

[Signature]

10/31/03

JPT/bf

file MIKAVIC
phone log

MENTOR CORPORATION
CLINICAL PROGRAMS PHONE CONTACT LOG

Contact Person:	
Physician: []	Phone: _____
Date: 4-15-03	Time: _____
Subject:	Study: _____

1) has Consumer affairs been in contact

re you re: [REDACTED]

She has hardening on that side - DR. M Hunks she might have ~~rupture~~ ~~rupture~~

2) MRI reader doesn't think its Ruptured hardening
will fax Dr. [] MRI Report might have been

3) Im coming in June
Previous implants

get them in

Told her I was coming in June & to have
all pts eligible in for visits
4-30-03

Costi Told it suggested
re-scanning pt. DR. [] doesn't think
she has a rupture either

Signature: _____
vj

Local Radiologist Assessment

MENTOR	MRI Silicone Breast Implant Evaluation Data Sheet				
PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO 0 0 1		PATIENT INITIALS [redacted]	PATIENT SOCIAL SECURITY NO

MRI EVALUATION	
Patient's Date of Birth: [redacted]	
MRI Reviewer: LOCAL [initials]	Scan Quality (check one): <input type="checkbox"/> Good <input type="checkbox"/> Adequate <input checked="" type="checkbox"/> Inadequate <i>N/A</i>
Date of MRI Evaluation: 10/4/09 2003 3-11-2003 month day year <i>004/22/04</i>	

	RIGHT	LEFT
	<input type="checkbox"/> Not Implanted with Study Device	<input type="checkbox"/> Not Implanted with Study Device
Device Placement:	<input checked="" type="checkbox"/> Submuscular <input type="checkbox"/> Subglandular	<input type="checkbox"/> Submuscular <input type="checkbox"/> Subglandular
Implant Type:	<input type="checkbox"/> Smooth <input type="checkbox"/> Siltex	<input type="checkbox"/> Smooth <input type="checkbox"/> Siltex
Implant Evaluation:	1 <input checked="" type="checkbox"/> No Evidence of Rupture 2 <input type="checkbox"/> Indeterminate Evidence of Rupture 3 <input type="checkbox"/> Rupture: Check one Type: 1 <input type="checkbox"/> Intracapsular 2 <input type="checkbox"/> Extracapsular Check one Condition: <i>N/A</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 checked="" type="checkbox"/> Rupture: Check one Type: 1 <input checked="" type="checkbox"/> Intracapsular 2 <input type="checkbox"/> Extracapsular Check one Condition: <i>N/A</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 checked="" 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: *This form was completed by Corbin Offutt using information from Raytel Medical Imaging radiology report 4/22/04*

Reviewer's Signature: *N/A* 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.

Local Radiologist Assessment



MRI Silicone Breast Implant Evaluation Data Sheet

PATIENT STUDY ID:	TRIAL NO: 10-009	COUNTRY NO: 0 0 1	PATIENT INITIALS: [redacted]	PATIENT SOCIAL SECURITY NO.: [redacted]
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MRI EVALUATION

Patient's Date of Birth: [redacted]

MRI Reviewer: Local

Date of MRI Evaluation: 04 / 09 / 2003
month day year

Scan Quality (check one):
 1 Good
 2 Adequate *NA*
 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
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Implant Evaluation:	1 <input checked="" type="checkbox"/> No Evidence of Rupture 2 <input type="checkbox"/> Indeterminate Evidence of Rupture 3 <input type="checkbox"/> Rupture: Check one Type: 1 <input type="checkbox"/> Intracapsular 2 <input type="checkbox"/> Extracapsular Check one Condition: 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 checked="" type="checkbox"/> Rupture: Check one Type: 1 <input checked="" type="checkbox"/> Intracapsular 2 <input type="checkbox"/> Extracapsular Check one Condition: 1 <input type="checkbox"/> Uncollapsed 2 <input type="checkbox"/> Partially Collapsed 3 <input type="checkbox"/> Fully Collapsed (linguini sign)
Soft Tissue Evaluation:	1 <input checked="" type="checkbox"/> No Evidence of Extracapsular Silicone 2 <input type="checkbox"/> Indeterminate for Extracapsular Silicone 3 <input type="checkbox"/> Definite Extracapsular Silicone	1 <input checked="" type="checkbox"/> No Evidence of Extracapsular Silicone 2 <input type="checkbox"/> Indeterminate for Extracapsular Silicone 3 <input type="checkbox"/> Definite Extracapsular Silicone

Notes: This form was completed by Carolyn Offutt using information from the Raytel Medical Imaging radiology report

NA

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.

Core Gel 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

Still ongoing

Listing 1
Adverse Events

Center/ Patient	Outcome	AE Description	Breast	Onset			Resolution			Treatment Required #	Date
				Date	D	M	Y	Date	D		
[]	Ongoing	Nipple - Unacceptably Low Sensitivity	Right	04/18/2001						None	
		Nipple - Unacceptably Low Sensitivity	Left	04/18/2001						None	
		Baker III Capsular Contracture	Left	01/17/2002						Medication: PAVOBID X 2 MONTHS / Other: CLOSED CAPSULOTOMY	
		Breast - Unacceptably Low Sensitivity	Left	02/24/2003						None	
		Breast - Unacceptably Low Sensitivity	Left	02/24/2003						None	
	Resolved	Hematoma	Left	04/24/2001				05/16/2001		Sec Proc: 91	

Program Name: Q:\MENTOR\COREGEL\ADHOC\AE061304.SAS

Creation Date, Time: 16JUN04 17:59

Unk indicates a field that was left blank

Core Gel 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

Listing 1
Adverse Events

Center/ Patient	Outcome	AE Description	Breast	Onset			Resolution			Treatment Required #	Date
				Date	D	M	Y	Date	D		
[]	Ongoing	Nipple - Unacceptably Low Sensitivity	Right	06/16/2001						None	
[]	Ongoing	Nipple - Unacceptably Low Sensitivity	Left	05/14/2001						None	
	Ongoing	Mobax III Capsular Contracture	Left	01/17/2002						Medication: PAINOIDS X 2 MONTHS / Other: CLOSED CAPSULOTOMY	
	Ongoing	Breast - Unacceptably Low Sensitivity	Left	02/24/2003						None	
	Resolved	Mastectomy	Left	04/24/2001				03/16/2001		Sec Proc: 91	

11/7/02

Program Name: Q:\MENTOR\CONREG\LABRUC\AE.SAT

Creation Date, Time: 130003 10:42

* Unk indicates a field that was left blank

Core Gel 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

DATA CLARIFICATION FORM

PROTOCOL : NR 15766/N370
 PATIENT NUMBER :
 PATIENT INITIALS : XXXXXXXXXX
 DATE SENT : 10/22/2003

STUDY PERIOD	DESCRIPTION	PAGE	RESOLUTION	REF #
2 YEAR VISIT	Left Breast: Breast sensation changed from "Acceptable" at 1 year visit to "Unacceptably Low" at 2 year visit. But it's not listed as an AE. Please clarify. Additional Clarification:	75	<div style="border: 1px solid black; padding: 5px; min-height: 150px;"> <p style="font-family: cursive; font-size: 1.2em;">There is an adverse event report for this (see attached copy)</p> </div>	14722 A

* If a more detailed explanation is needed, please attach
 I have reviewed the above and supplied data as indicated. I have retained a copy for the patient's CRF file, and I authorize the CRF to be changed accordingly

INVESTIGATOR'S SIGNATURE : _____ DATE : _____

Above Data Clarification(s) obtained via telephone call to _____

CRA's SIGNATURE : _____ DATE : 10-31-03



MENTOR

**Core Gel Breast
IDE Clinical Trial**

ADVERSE EVENTS

02 YEAR VISIT

PATIENT STUDY ID:	TRIAL NO	COUNTRY NO	SITE NO	PATIENT NO	
	10-009	0 0 1	[] [] []	[] [] []	[REDACTED]

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)			OUTCOME 1 = Resolved 2 = Ongoing 3 = Death 4 = Unknown	RESOLUTION DATE		
				month	day	year		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)	4	5		3	Procedure Type Code†:	Procedure Date:
6	<input checked="" type="checkbox"/> 1 <input type="checkbox"/> 3 <input type="checkbox"/> 2 <input type="checkbox"/> 4	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2	<input checked="" type="checkbox"/> 0 <input type="checkbox"/> 3 <input type="checkbox"/> 1 <input type="checkbox"/> 2		02	24	03	<input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3	<input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 Procedure Type Code†: _____ Procedure Date: ____/____/____	<input type="checkbox"/> 4 ____ days, Date: ____/____/____ <input type="checkbox"/> 5 _____	<input type="checkbox"/> 1 <input type="checkbox"/> 4 <input checked="" 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 Procedure Type Code†: _____ Procedure Date: ____/____/____	<input type="checkbox"/> 4 ____ days, Date: ____/____/____ <input type="checkbox"/> 5 _____	<input type="checkbox"/> 1 <input type="checkbox"/> 4 <input type="checkbox"/> 2 <input type="checkbox"/> 3				

Investigator's Signature _____

11/01/09/2003
month day year

****Complete Secondary Procedures Report. If new study device is implanted, complete Re-Implantation Report.**

***ADVERSE EVENT 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 _____

†SECONDARY PROCEDURE TYPE CODES

- 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: _____

4844



Mentor

Core Gel Breast IDE Clinical Trial

ADVERSE EVENTS

02 YEAR VISIT

PATIENT STUDY ID:	TRIAL NO	COUNTRY NO	SITE NO.	PATIENT NO
	10-009	0 0 1	C	[REDACTED]

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)			OUTCOME 1 = Resolved 2 = Ongoing 3 = Death 4 = Unknown	RESOLUTION DATE		
				month	day	year		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)	4 ___ days, Date: ___/___/___	5 _____		3 Procedure Type Code†: _____ Procedure Date: ___/___/___	month	day
6	<input checked="" type="checkbox"/> 1 <input type="checkbox"/> 3 <input type="checkbox"/> 2 <input type="checkbox"/> 4	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2	<input checked="" type="checkbox"/> 0 <input type="checkbox"/> 3 <input type="checkbox"/> 1 <input type="checkbox"/> 2		02	24	03	<input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3	<input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 Procedure Type Code†: _____ Procedure Date: ___/___/___	<input type="checkbox"/> 4 ___ days, Date: ___/___/___ <input type="checkbox"/> 5 _____	<input type="checkbox"/> 1 <input type="checkbox"/> 4 <input checked="" 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"/> 2 <input type="checkbox"/> 3 Procedure Type Code†: _____ Procedure Date: ___/___/___	<input type="checkbox"/> 4 ___ days, Date: ___/___/___ <input type="checkbox"/> 5 _____	<input type="checkbox"/> 1 <input type="checkbox"/> 4 <input type="checkbox"/> 2 <input type="checkbox"/> 3			

Investigator's Signature _____
 month day year 11 01 19 21 11 13

****Complete Secondary Procedures Report. If new study device is implanted, complete Re-implantation Report.**

<p>*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>29 = Other, specify: _____ _____ 30 = Other, specify: _____ _____ 31 = Other, specify: _____ _____ 32 = Other, specify: _____ _____ 33 = Other, specify: _____ _____</p>	<p>†SECONDARY PROCEDURE TYPE CODES</p> <p>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>
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Core Gel 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

Transferred to Mirabite #409

Listing 1
Adverse Events

Center/ Patient	Outcome	AE Description	Breast	Onset Date	Resolution Date	Treatment Required #	Date
[]	Ongoing	Nipple - Unacceptably Low Sensitivity	Right	04/18/2001		None	
		Nipple - Unacceptably Low Sensitivity	Left	04/18/2001		None	
		Baker III Capsular Contracture	Left	01/17/2002		Medication: PAVOBID X 2 MONTHS / Other: CLOSED CAPSULOTOMY	
	Resolved	Hematoma	Left	04/24/2001	05/16/2001	Sec Proc: 91	

Program Name: Q:\MENTOR\COREGEL\ADHOC\AE.SAS

Creation Date, Time: 30JUN03 11:50

Unk indicates a field that was left blank



MENTOR

**Core Gel Breast
IDE Clinical Trial**

ADVERSE EVENTS

1 YEAR VISIT

PATIENT STUDY ID:	TRIAL NO.	COUNTRY NO.			SITE NO.	PATIENT NO.	<input type="checkbox"/> No Adverse Events
	10-009	0	0	1	[]	[]	

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		EVENT SIDE	ASSOCIATED BREAST PAIN	ONSET DATE	SEVERITY	TREATMENT REQUIRED (check all that apply)			OUTCOME	RESOLUTION DATE		
	1 = Procedure related 2 = Device related 3 = Unknown 4 = Other	1 = Right 2 = Left					0 = N/A 1 = Mild 2 = Moderate 3 = Severe	month	day		year	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)	4 ___ days, Date: ___/___/___
3	<input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2	01 17 2002	<input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	<input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 PAVOBIN X 2 months <input type="checkbox"/> 3 Procedure Type Code: _____ Procedure Date: ___/___/___	<input type="checkbox"/> 4 ___ days, Date: ___/___/___	<input checked="" type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3				
	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 3 <input type="checkbox"/> 4	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2	<input type="checkbox"/> 0 <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"/> 2 <input type="checkbox"/> 3 Procedure Type Code: _____ Procedure Date: ___/___/___	<input type="checkbox"/> 4 ___ days, Date: ___/___/___ <input type="checkbox"/> 5 _____	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3				

****Complete Secondary Procedures Report. If new study device is implanted, complete Re-Implantation Report.**

Investigator's Signature: []
 Date: 07 | 17 | 2002
 month day year

*ADVERSE EVENT CODES			†SECONDARY PROCEDURE TYPE CODES
1 = Asymmetry	15 = Lymphadenopathy	28 = Lactation Difficulties, specify _____	81 = Biopsy
2 = Baker II Capsular Contracture with Surgical Intervention	16 = Necrosis		82 = Capsulectomy
3 = Baker III Capsular Contracture	17 = New Diagnosis of Breast Cancer		83 = Explantation with Replacement**
4 = Baker IV Capsular Contracture	18 = New Diagnosis of Rheumatic Disease, specify: _____	29 = Other, specify: _____	84 = Explantation without Replacement
5 = Breast pain not associated with any other complication	19 = Nipple—Unacceptably Low Sensitivity		85 = Incision and Drainage
6 = Breast—Unacceptably Low Sensitivity	20 = Nipple—Unacceptably High Sensitivity	30 = Other, specify: _____	86 = Mastopexy
7 = Breast—Unacceptably High Sensitivity	21 = Position Change		87 = Open Capsulotomy
8 = Calcification	22 = Ptosis		88 = Position Change
9 = Delayed Wound Healing	23 = Rupture		89 = Scar Revision
10 = Extrusion	24 = Seroma		90 = Skin Adjustment
11 = Granuloma	25 = Size Change—Patient Request		91 = Other, specify: _____
12 = Hematoma	26 = Size Change—Physician Assessment only		
13 = Hypertrophic Scarring	27 = Wrinkling		92 = Other, specify: _____
14 = Infection			

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Core Gel 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

Listing 1

Adverse Events

Center/ Patient	Outcome	AE Description	Breast	Onset Date	Resolution Date	Treatment Required #	Date
[]	Ongoing	Nipple - Unacceptably Low Sensitivity	Right	04/18/2001		None	<i>ongoing 7/16/02</i>
		Nipple - Unacceptably Low Sensitivity	Left	04/18/2001		None	<i>ongoing 7/16/02</i>
	Resolved	Hematoma	Left	04/24/2001	05/16/2001	Sec Proc: 91	

Program Name: Q:\MENTOR\COREGEL\ADHOC\AE.SAS

Creation Date, Time: 04JUN02 10:03

Unk indicates a field that was left blank

MENTOR	Core Gel Breast IDE Clinical Trial		ADVERSE EVENTS				6 MONTH VISIT
	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO. [] [] []	PATIENT NO. [] [] [] [] [] []	FEB - <input checked="" 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			SEVERITY 1 = Mild 2 = Moderate 3 = Severe	TREATMENT REQUIRED (check all that apply)			OUTCOME 1 = Resolved 2 = Ongoing 3 = Death 4 = Unknown	RESOLUTION DATE			
				month	day	year		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)	4 ___ days, Date: ___/___/___	5 _____		Procedure Type Code†: _____	Procedure Date: ___/___/___	month	day
19 1/30/10	<input checked="" type="checkbox"/> 1 <input type="checkbox"/> 3	<input type="checkbox"/> 0	<input checked="" type="checkbox"/> 0 <input type="checkbox"/> 3			04	18	2001	<input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2	<input type="checkbox"/> 4 ___ days, Date: ___/___/___	<input type="checkbox"/> 5 _____	<input type="checkbox"/> 1 <input type="checkbox"/> 4			
19 1/30/10	<input checked="" type="checkbox"/> 1 <input type="checkbox"/> 3	<input type="checkbox"/> 0	<input checked="" type="checkbox"/> 0 <input type="checkbox"/> 3			04	18	2001	<input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2	<input type="checkbox"/> 4 ___ days, Date: ___/___/___	<input type="checkbox"/> 5 _____	<input type="checkbox"/> 1 <input type="checkbox"/> 4			

Investigator's Signature: _____
 month: 10 day: 15 year: 2001

****Complete Secondary Procedures Report. If new study device is implanted, complete Re-Implantation Report.**

***ADVERSE EVENT 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

†SECONDARY PROCEDURE TYPE CODES

- 28 = Lactation Difficulties, specify: _____
- 29 = Other, specify: _____
- 30 = 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: _____

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Core Gel 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

Listing 1
Adverse Events

Center/ Patient	Outcome	AE Description	Breast	Onset Date	Resolution Date	Treatment Required #	Date
[]	Resolved	Hematoma	Left	04/24/2001	05/16/2001	Sec Proc: 91	

5/16/01 evacuation of
hematoma (L) side



Core Gel Breast
IDE Clinical Trial

ADVERSE EVENTS

RECEIVED INTERIM VISIT

PATIENT STUDY ID:

TRIAL NO. 10-009 COUNTRY NO. 0 0 1 SITE NO. [] PATIENT NO. []

No Adverse Events

Enter one adverse event per line. If the event was experienced at more than one body site, enter each body site

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
12	<input type="checkbox"/> 1 <input type="checkbox"/> 3 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 4	<input type="checkbox"/> 0 <input type="checkbox"/> 1	<input type="checkbox"/> 0 <input type="checkbox"/> 3 <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2	04 24 2001	<input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 3 Procedure Type Code: 91 Procedure Date: 05/16/2001	<input checked="" type="checkbox"/> 1 <input type="checkbox"/> 4 <input type="checkbox"/> 2 <input type="checkbox"/> 3	05	16	2001
	<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"/> 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			

DID NOT RESULT IN ACTIVITY AS DESIRED

Investigator's Signature

06 14 2001
month day year

**Complete Secondary Procedures Report. If new study device is implanted, complete Re-implantation Report.

*ADVERSE EVENT 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: _____

†SECONDARY PROCEDURE TYPE CODES

- 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: Evacuation of Hematoma
- 92 = Other, specify: _____

Suspected Rupture Patient Summary

Study ID: [redacted]
Cohort: Reconstruction
DOS: 10/11/01
Implant Type: textured round gel filled breast implant
Placement: submuscular
MRI Substudy: Yes
MRI scan dates: 11/13/02, 8/29/03
Investigator: [redacted]

This patient was diagnosed with left breast cancer in 10/2000. She underwent a left mastectomy with tissue expander placement on 10/23/2000. On 10/11/2001 she was implanted with a Core Gel implant on the left side and entered in the Core Study.

This patient underwent her 1 Year MRI scan on 11/13/02. Both the Local Reader and the Central Reader reported no rupture or extracapsular silicone.

The patient underwent her 2 year MRI scan on 8/29/03. The Local Reader reported a hyperintense spot, possibly within in lymph node, which might possibly indicate extracapsular rupture on the left side. The Local Reader also noted artifact as the patient could not hold still. The Central Reader reviewer noted no evidence of rupture or extracapsular silicone. The Central Reader also notes no abnormal lymph nodes.

The results of this scan were discussed with Dr. [redacted]. He said the patient was too sick to undergo another MRI scan and he would discuss alternate imaging methods, such as ultrasound. Dr. [redacted] stated that did not agree that there was a rupture and given the fact that she was dying of breast cancer, he did not feel it was appropriate or important to prove or disapprove his impression.

The patient died of breast cancer in January 2004 before any other imaging studies could be performed.



MENTOR

MRI Silicone Breast Implant Evaluation Data Sheet

PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO. C 716	PATIENT NO. [REDACTED]	DATE OF EVALUATION [REDACTED]	PATIENT SOCIAL SECURITY NO. [REDACTED]
--------------------------	----------------------------	---------------------------------	--------------------------	----------------------------------	---	--

MRI EVALUATION

Patient's Date of Birth: [REDACTED]

MRI Reviewer: DEBRUHL

Date of MRI Evaluation: 08 / 29 / 2003
month day year

Scan Quality (check one):
 1 Good
 2 Adequate
 3 Inadequate

	RIGHT	LEFT
	<input checked="" 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: Check one Type: 1 <input type="checkbox"/> Intracapsular 2 <input type="checkbox"/> Extracapsular Check one Condition: 1 <input type="checkbox"/> Uncollapsed 2 <input type="checkbox"/> Partially Collapsed 3 <input type="checkbox"/> Fully Collapsed (linguini sign)	1 <input checked="" type="checkbox"/> No Evidence of Rupture 2 <input type="checkbox"/> Indeterminate Evidence of Rupture 3 <input type="checkbox"/> Rupture: Check one Type: 1 <input type="checkbox"/> Intracapsular 2 <input type="checkbox"/> Extracapsular Check one Condition: 1 <input type="checkbox"/> Uncollapsed 2 <input type="checkbox"/> Partially Collapsed 3 <input checked="" 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 checked="" type="checkbox"/> No Evidence of Extracapsular Silicone 2 <input type="checkbox"/> Indeterminate for Extracapsular Silicone 3 <input type="checkbox"/> Definite Extracapsular Silicone

Notes: 2 YEAR DATE OF BIRTH incorrect above
See correction

Please be advised: Report is inaccurate: DAP has only one implant on the left. Trace peri-implant fluid. No evidence of rupture. No abn lymph node.

Reviewer's Signature: [Signature] 10 / 02 / 2003
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.

PATIENT NAME: [REDACTED]
DATE OF BIRTH: [REDACTED]
IDENTIFICATION #: [REDACTED]
REFERRED BY: [REDACTED] ID
DATE OF EXAM: 08/29/2003

file pt.
purple chart

CORRECTED REPORT

MRI BILATERAL BREAST WITHOUT CONTRAST, MRI BREAST MENTOR CORE FILM CODE,

CLINICAL HISTORY: This is an asymptomatic patient with history of breast cancer, diagnosed in August 2000. She had a recurrence in March 2003. Patient has a left silicone implant with no implant on right. The breast MRI has been requested as part of a study to evaluate for silent implant rupture.

TECHNIQUE: Several imaging sequences have been obtained including T2 weighted turbo spin echo, STIR and STIR with water suppression sequences in the axial plane and STIR with water suppression sequences in the sagittal plane.

INTERPRETATION: No hypointense curved lines seen within the implants. However, there is one focus of hyperintense material outside of the implant, in the very posterolateral left breast. This has a reniform shape, consistent with a lymph node in the lower axilla. No other areas of hyperintense signal seen within the tissue surrounding the implants. Trace fluid is seen around the implant. This study is compared to an earlier one done on 11/13/02. This area of increased intensity was present on the prior study, but was very subtle at that time. It is definitely present on the current study.

CONCLUSION:

- 1) Hyperintense material seen within the posterolateral left breast, probably within a lymph node. This would indicate an extracapsular rupture. No other free silicone is evident, however.
- 2) It should be noted that there is a significant amount of artifact on this study. I spoke with the technologist who did the study, and she stated that the patient was unable to stay still for very long. She was trying to cooperate, but this was essentially as still as she could be.

[]
[]

[]
[]

BTJE



PATIENT NAME: [REDACTED]
DATE OF BIRTH: [REDACTED]
IDENTIFICATION #: [REDACTED]
REFERRED BY:
DATE OF EXAM: 08/29/2003

MRI BILATERAL BREAST WITHOUT CONTRAST, MRI BREAST MENTOR CORE FILM CODE,

CLINICAL HISTORY: This is an asymptomatic patient with history of breast cancer, diagnosed in August 2000. She had a recurrence in March 2003. Patient has bilateral silicone implants, and the breast MRI has been requested as part of a study to evaluate for silent implant rupture.

TECHNIQUE: Several imaging sequences have been obtained including T2 weighted turbo spin echo, STIR and STIR with water suppression sequences in the axial plane and STIR with water suppression sequences in the sagittal plane.

INTERPRETATION: No hypointense curved lines seen within the implants. However, there is one focus of hyperintense material outside of the implant, in the very posterolateral left breast. This has a uniform shape, consistent with a lymph node in the lower axilla. No other areas of hyperintense signal seen within the tissue surrounding the implants. Trace fluid is seen around the implant. This study is compared to an earlier one done on 11/13/02. This area of increased intensity was present on the prior study, but was very subtle at that time. It is definitely present on the current study.

CONCLUSION:

- 1) Hyperintense material seen within the posterolateral left breast, probably within a lymph node. This would indicate an extracapsular rupture. No other free silicone is evident, however.
- 2) It should be noted that there is a significant amount of artifact on this study. I spoke with the technologist who did the study, and she stated that the patient was unable to stay still for very long. She was trying to cooperate, but this was essentially as still as she could be.



BT:JE



MRI Silicone Breast Implant Evaluation Data Sheet

PATIENT STUDY ID:	TRIAL NO. 10-009	COUNTRY NO. 0 0 1	SITE NO. []	PATIENT NO. []	PATIENT INITIALS []	PATIENT SOCIAL SECURITY NO. [REDACTED]
--------------------------	---------------------	--------------------------	-----------------	--------------------	-------------------------	---

MRI EVALUATION

Patient's Date of Birth: [REDACTED]

MRI Reviewer: []

Date of MRI Evaluation: 1 | 1 | 13 | 20 | 02
month day year

Scan Quality (check one):
 1 Good
 2 Adequate
 3 Inadequate

	RIGHT	LEFT
	<input checked="" 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 checked="" 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 checked="" 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: Check one Type: 1 <input type="checkbox"/> Intracapsular 2 <input type="checkbox"/> Extracapsular Check one Condition: 1 <input type="checkbox"/> Uncollapsed 2 <input type="checkbox"/> Partially Collapsed 3 <input type="checkbox"/> Fully Collapsed (linguini sign)	1 <input checked="" type="checkbox"/> No Evidence of Rupture 2 <input type="checkbox"/> Indeterminate Evidence of Rupture 3 <input type="checkbox"/> Rupture: Check one Type: 1 <input type="checkbox"/> Intracapsular 2 <input type="checkbox"/> Extracapsular Check one Condition: 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 checked="" type="checkbox"/> No Evidence of Extracapsular Silicone 2 <input type="checkbox"/> Indeterminate for Extracapsular Silicone 3 <input type="checkbox"/> Definite Extracapsular Silicone

Notes: 7/28/23
Ex 1yr

Reviewer's Signature: []

Date: 06 | 30 | 20 | 23
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.

M
11/20/02

NAME: [REDACTED]
DOB: [REDACTED]
ID: 3 [REDACTED]
REFERRING MD: [REDACTED]
DATE OF EXAM: 11/13/02

BREAST MRI [REDACTED]

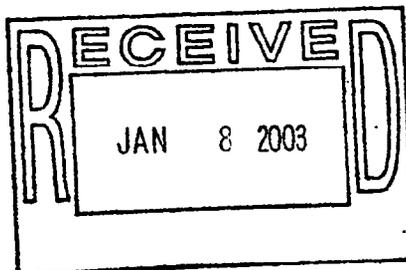
CLINICAL HISTORY: She has no breast symptoms at this time. This breast MRI has been requested as part of the study to evaluate for silent implant rupture.

TECHNIQUE: Several imaging sequences have been obtained including T2-weighted turbo spin echo, STIR and STIR with water suppression sequences in the axial plane and STIR with water suppression sequences in the sagittal plane.

FINDINGS: No hypointense curved lines are seen within the implant(s). No hyperintense material is seen in the tissue surrounding the implant(s). Trace fluid surrounds the implant(s).

CONCLUSION: No evidence of intracapsular rupture or extracapsular extravasation.

CC: MENTOR



[]

OPERATIVE REPORT

PATIENT: [REDACTED]
DOB: [REDACTED]
SURGEON: []

MEDICAL RECORD #: []
DATE OF PROCEDURE: 10/11/2001

PREOPERATIVE DIAGNOSIS:

- 1. Personal history of breast cancer.
- 2. Left mastectomy defect.
- 3. Right breast ptosis.

[]

POSTOPERATIVE DIAGNOSIS: Same.

OPERATIVE PROCEDURE:

- 1. Left second stage breast reconstruction with Mentor textured gel implant (275 cc).
- 2. Right mastopexy for symmetry.

HISTORY: This is a 33-year-old female who presents for second stage of her breast reconstruction. She previously had a left mastectomy with immediate first stage reconstruction using a latissimus flap and underlying tissue expander. She underwent adjunctive chemotherapy and radiation therapy. As a result she developed the expected the capsule around the tissue expander on the left side. She presents at this time for second stage reconstruction and has elected to proceed with silicone gel implant. She would like to participate in the core gel study and understands this is a 10-year follow up and understands the implications and issues involved with the study. She understands the implants are under investigation and carry risks and complications which include, but are not limited to, bleeding, infection, hematoma, seroma, implant rupture, implant exposure, capsular contracture, visible or palpable wrinkling, asymmetry and the need for revision surgery. She understands she may have an unacceptable result. To achieve symmetry the patient has elected to have a mastopexy on the contralateral breast. She understands this will leave significant scars, she understands that she may have numbness, loss of viability in the nipple-areolar complex, distortion and the need for revision surgery. She appears to understand and accept the risks

OPERATIVE PROCEDURE: The patient was seen in the preinduction room, placed in the upright position. The midline of the chest, the meridian of each breast and inframammary folds were drawn out. We designed the mastopexy so the nipple would end up at approximately 20.5 cm. This is at a spot that is similar to the skin paddle on the reconstructed breast and where in the future nipple reconstruction will reside. We used a periareolar inferior V-technique. It was apparent that on the reconstructed side we needed to lower the pole slightly and perform an extensive capsulotomy.

The patient was brought to the operating room where she was induced under general anesthesia. She was given preoperative antibiotics, and was prepped and draped in the usual sterile fashion in a beach chair position. We performed a mastopexy first by infiltrating 1% Lidocaine with epinephrine into the dermis of the skin to be resected, a 38 mm nipple ring was used to inscribe a circle around the nipple areolar complex of the right breast and the excess skin was de-epithelialized. We then created short skin flaps to allow upward mobility of the breast mound relative to the skin. The skin was then redraped around the nipple areolar complex using interrupted #3-0 and #4-0 Vicryl in the subcutaneous layer. The nipple was inset using #5-0 Vicryl cuticular suture. The vertical skin as

OPERATIVE REPORT

PATIENT:



MEDICAL RECORD #:

168116

DOB:

SURGEON:



DATE OF PROCEDURE:

10/11/2001

approximated and with the patient nearly upright we determined that a horizontal wedge was necessary to excise inferiorly, giving the areola the full distance of 5.5 cm. This wedge was excised and the horizontal limb was closed with interrupted #4-0 Vicryl in a subcutaneous layer and a running #4-0 Vicryl cuticular suture in the skin. This gave a satisfactory appearance to the breast. On the left side, a 6 cm incision was used around the skin paddle of the previous latissimus flap. The subcutaneous tissue was incised with electrocautery and underlying muscle was divided into the periprosthetic pocket. We removed the underlying Spectrum implant. We also created a counter incision over the remote port to deliver the port and remove it as well. We examined the pocket and there was no evidence of abnormality. We performed an extensive capsulotomy with electrocautery, circumferentially at the base of the capsule, but also with several radial scores and criss-cross pattern inferiorly to allow lower pole dilatation. We expanded the pocket laterally. We achieved hemostasis with electrocautery and irrigated with antibiotic saline. We chose sizing implants to determine the appropriate implant and elected to proceed with a Mentor textured gel implant with Catalog #354-2757G and Lot #221952. The implant was carefully inspected. There were no abnormalities noted. It was externally irrigated with antibiotic saline and was placed in the appropriate orientation in the breast pocket. It appeared that we had achieved satisfactory symmetry. We then instilled 20 cc of .125% Marcaine into the breast pocket and closed all incisions in layers with interrupted #4-0 Vicryl in the subcutaneous layer, and a running #4-0 Vicryl cuticular suture in the skin. Sterile dressings were applied including a lightly compressive dressing using Kerlix gauze and an Ace bandage. The patient tolerated the procedure well without apparent complication. Estimated blood loss was minimal. All sponge and needle counts were correct. The patient returned to the postanesthesia recovery room in stable condition.

/ck

D: 10/11/2001 - 903

T: 10/12/2001

cc: Referring Physician

Local Radiologist Assessment

MENTOR		MRI Silicone Breast Implant Evaluation Data Sheet				
PATIENT STUDY ID:	TRIAL NO: 10-009	COUNTRY NO. 0 0 1	SITE NO	PATIENT NO	PATIENT INITIALS	PATIENT SOCIAL SECURITY NO.
MRI EVALUATION						
Patient's Date of Birth: [REDACTED]						
Local MRI Reviewer: [REDACTED]				Scan Quality (check one):		
Date of MRI Evaluation: 11 13 2002				1 <input type="checkbox"/> Good <i>NA</i>		
				2 <input type="checkbox"/> Adequate		
				3 <input type="checkbox"/> Inadequate		
	RIGHT			LEFT		
	<input checked="" 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: Check one Type: 1 <input type="checkbox"/> Intracapsular 2 <input type="checkbox"/> Extracapsular Check one Condition: 1 <input type="checkbox"/> Uncollapsed <i>NA</i> 2 <input type="checkbox"/> Partially Collapsed 3 <input type="checkbox"/> Fully Collapsed (linguini sign)			1 <input checked="" type="checkbox"/> No Evidence of Rupture 2 <input type="checkbox"/> Indeterminate Evidence of Rupture 3 <input type="checkbox"/> Rupture: Check one Type: 1 <input type="checkbox"/> Intracapsular 2 <input type="checkbox"/> Extracapsular Check one Condition: <i>NA</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 checked="" type="checkbox"/> No Evidence of Extracapsular Silicone 2 <input type="checkbox"/> Indeterminate for Extracapsular Silicone 3 <input type="checkbox"/> Definite Extracapsular Silicone		
Notes: <i>This form was completed by Carolyn Offutt using information from Consulting radiologist, LTD radiology report 4/22/04</i>						
Reviewer's Signature: <i>N/A</i>				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.

Local Radiologist Assessment

 MENTOR		MRI Silicone Breast Implant Evaluation Data Sheet					
PATIENT STUDY ID:	TRIAL NO 10-009	COUNTRY NO 0 0 1	SITE NO.	PATIENT NO.	PATIENT INITIALS	PATIENT SOCIAL SECURITY NO.	

MRI EVALUATION

Patient's Date of Birth: [REDACTED]

Local MRI Reviewer: [Signature]

Date of MRI Evaluation: 08/29/2003
month day year

Scan Quality (check one):
 1 Good *NA*
 2 Adequate
 3 Inadequate

	RIGHT	LEFT
	<input checked="" 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. Check one Type: 1 <input type="checkbox"/> Intracapsular 2 <input type="checkbox"/> Extracapsular Check one Condition: 1 <input type="checkbox"/> Uncollapsed <i>NA</i> 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 checked="" type="checkbox"/> Rupture: Check one Type: 1 <input type="checkbox"/> Intracapsular 2 <input checked="" type="checkbox"/> Extracapsular Check one Condition: <i>NA</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 checked="" type="checkbox"/> No Evidence of Extracapsular Silicone 2 <input type="checkbox"/> Indeterminate for Extracapsular Silicone 3 <input type="checkbox"/> Definite Extracapsular Silicone

Notes: *this form was completed by Casslyn Offutt using information from Consulting Radiologists limited radiology report 4/22/04*

24r

NA

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.



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.



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.

Table with columns: AE CODE*, CAUSALITY, IMPLANT SIDE, ASSOCIATED BREAST PAIN, ONSET DATE, SEVERITY, TREATMENT REQUIRED, OUTCOME, RESOLUTION DATE. Includes handwritten entries for event 29.

Investigator's Signature: [Handwritten Signature]

Date: 01/22/2004

**Complete Secondary Procedures Report. If new study device is implanted, complete Re-implantation Report.

*ADVERSE EVENT 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

†SECONDARY PROCEDURE TYPE CODES

- 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:

Handwritten notes: DEATH FROM PROGRESSION OF DISEASE. 29 = Other, specify: DEATH. 30 = Other, specify: DEATH. 31 = Other, specify: MAR 3 2004. 32 = Other, specify: MAR 3 2004. 33 = Other, specify:

Suspected Rupture Patient Summary

Study ID: .

Cohort: Revision

DOS: 11/17/00

Implant Type: textured round gel filled breast implant

Placement: subglandular

MRI Substudy: YES

MRI scan dates: 2/27/03, 3/20/02, 12/17/03

Investigator []

This patient was originally implanted with gel implants from another manufacturer in 1984 for general breast enlargement.

She was enrolled in the Core Gel study 11/17/00 at which time these gel implants were replaced with Core Gel implants. She had capsular contracture and a probable rupture on the right side. This is documented by mammography on 10/16/00 and ultrasound on 11/2/00 prior to study entry.

This patient suffered an embolic stroke on 8/3/01 resulting in right hemiparesis and hemiplegia. She subsequently developed pain and discoloration in her left hand. She was started on coumadin, heparin and other anticoagulant therapy at that time. An unsuccessful attempt was made to remove the clots by thrombectomy on 10/1/01. Her left hand was amputated on 10/30/01. This patient also developed a perinephretic hematoma as a result of her anticoagulation therapy.

On 3/20/02 the patient had her Year 1 study MRI. Both the Local Reader and the Central Reader reported no rupture and no evidence of extracapsular silicone.

On 2/27/03 she had her Year 2 study MRI scan. The Local Reader reported findings suspicious for intracapsular rupture of both implants. The Central Reader reported indeterminate evidence of rupture bilaterally. It was suggested that the patient be rescanned. She was rescanned on 12/17/03 and both the Local Reader and the Central Reader reported bilateral intracapsular ruptures. After she had been taken off coumadin, these implants were removed and replaced on 3/30/04. Both implants were sent to Mentor Product Evaluation where tests confirmed bilateral ruptured implants. The Product Evaluation reference number is 200404-0199

This patient continues to be followed in the Mentor Core Gel Study by []
She will undergo her Year 4 MRI scan in 2005 in accordance with the MRI protocol.

Device A: Microscopic examination of the edges of the remaining shell material revealed no indication as to the cause of the separation.

Device B: Microscopic examination of the edges of the observed rent in the shell of the device revealed no indication as to its cause. PE inadvertently cut the shell of the device during the evaluation.

ADDITIONAL EXAMINATION

Device A: PE made a second attempt to find the area of missing material within the gel returned with this device. The material was not located.

CONCLUSION

Based on the information received, the patient experienced bilateral ruptures. Based on the results of the laboratory evaluation and testing, PE observed a large hole in the shell of the left device and a large rent in the shell of the right device. Microscopic examination of the edges of the hole and rent revealed no indication as to their cause. Rupture is a known complication associated with these devices and is referenced in our Product Insert Data Sheet; however, trends for Mentor devices will continue to be monitored by Quality Assurance.

After thorough examination of the patient's left device and its gel, PE was unable to locate the area of missing shell material. Therefore, no further conclusion as to the cause of the large hole in the shell of this device can be drawn.

Mentor performs 100% inspection and testing of all devices prior to release and maintains a comprehensive quality assurance (QA) system in compliance with the FDA's Good Manufacturing Practice (GMP) regulations. The system is designed to provide to our customers the maximum assurance of the high quality of our products.

If you have any further questions on this incident, please do not hesitate to call me. Thank you.

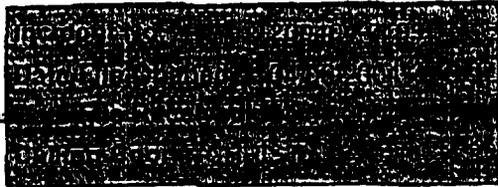
Sincerely,



Christy Babb

Product Evaluation Department

Incident Information



CLASSIFIED

Reporting Person

RN, STUDY COORDINATOR

Tel.

Contact:

T

OK 73116

Fax:

Sales Rep :

Reporter?

Facility Rep :

CLASSIFIED

A

B

Catalog No. : 354-3257G

354-3257G

Size : 325

325

Product : CLINICAL GEL SILTEX

CLINICAL GEL SILTEX

Family : GELS

GELS

Lot Prefix :

Lot No. : 217513

217513

Lot Suffix :

Serial No. :

Mfg Site : Texas

Texas

MDR :

Is Product Return Expected ? :

Yes No

Prod. Receipt Date :

RGA No. :

CLASSIFIED

Is this a Complaint? Yes No

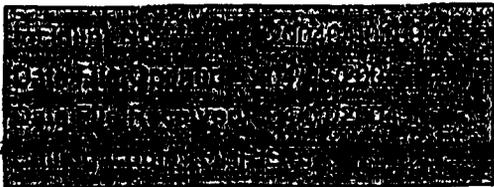
If no, explain :

<u>A or B</u>	<u>Code</u>	<u>Mode</u>	<u>Priority</u>
A	45	RUPTURE	
B	46	RUPTURE	

Incident Information

Patient Name : [REDACTED]	Patient SS# : [REDACTED]	<input type="radio"/> Yes <input checked="" type="radio"/> No
DOB : [REDACTED] Weight : 130	Patient Contact : <input checked="" type="radio"/> C <input type="radio"/> N	
	<u>A</u>	<u>B</u>
Date of Implant:	11/17/2000	11/17/2000
Date Prob. Observed:	12/17/2003	12/17/2003
When Did Prob. Occur:	After surgery	After surgery
Date of Explant:	03/30/2004	03/30/2004
Reason for Surgery:	A	A
Placement of Device:	SG	SG
Surgical Approach:	IMF	IMF
Final Fill Volume:		
Capsular Contracture:	<input type="radio"/> Yes <input checked="" type="radio"/> No <input type="radio"/> Unk	<input type="radio"/> Yes <input checked="" type="radio"/> No <input type="radio"/> Unk
Baker Grade:		
Infection Suspected:	<input type="radio"/> Yes <input checked="" type="radio"/> No	<input type="radio"/> Yes <input checked="" type="radio"/> No
Culture Results:		
Device Damaged:	N	N
Explain:		

Reporting Flag: FDA	
Is This a 5-day Reportable MDR ? : <input type="radio"/> Yes <input checked="" type="radio"/> No	Is This a 30-day Reportable MDR ? : <input type="radio"/> Yes <input checked="" type="radio"/> No
MDR 5-day Report Date :	MDR 30-day Report Date :
Is This a Summary Reportable MDR ? : <input checked="" type="radio"/> Yes <input type="radio"/> No	
MDR Reference No. :	
Is This a 10-day Reportable Incident : <input type="radio"/> Yes <input checked="" type="radio"/> No	Is This a 30-day Reportable Near Incident : <input type="radio"/> Yes <input checked="" type="radio"/> No
MDV 10-day Report Date :	MDV 30-day Report Date :
EVS Reference No. :	
Notified Body Country :	Incident Country :
MDR Description:	



Incident Information

Investigation

Is Investigation Required ? : Yes No Decision By :

If No Reason :

Evaluation

Lab Evaluation :

EXAMINATION PERFORMED

Gross Evaluation

Two Siltex Gel-Filled Mammary Prostheses were returned to Mentor for product evaluation. The devices were returned autoclaved. PE designated the left device, Device A and the right device, Device B.

Device A

As received, the device weighed 305.4 gm and contained clear gel. An area of shell material measuring approximately 7 cm x 6 cm was observed missing from the anterior aspect of the device extending to the posterior aspect. No other anomalies were observed.

Device B

As received, the device weighed 246.7 gm and contained clear gel. Foreign black and orange materials were on the shell surface and within the device. A rent measuring approximately 21 cm in length was located on the radius of the device. No other anomalies were observed.

TESTING PERFORMED

Device A: Because of the as received condition of the device, PE was unable to perform a leak test.

Device B: Because of the as received condition of the device, PE was unable to perform a leak test.

MICROSCOPIC EXAMINATION

Device A: Microscopic examination of the edges of the remaining shell material revealed no indication as to the cause of the separation.

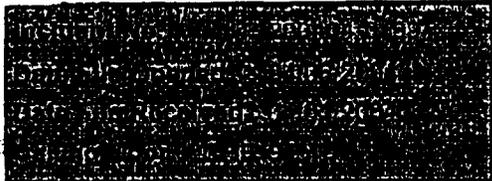
Device B: Microscopic examination of the edges of the observed rent in the shell of the device revealed no indication as to its cause. PE inadvertently cut the shell of the device during the evaluation.

A or B Investigators

A EGS

B EGS

Incident Information



	<u>A</u>	<u>B</u>
Product Receipt Date:	04/01/2004 41978	04/01/2004 41978
Lab Log Number:	04/01/2004	04/01/2004
Authorization for Return and Exam of Medical Device Receipt Date:	04/07/2004	04/07/2004
Evaluation Date:		
Decontamination Method:		

Return Kit

DHR Analyst : _____ Date : _____
DHR Search : _____
Authorization for Return and Examination of Medical Device
Initial Date : _____ Followup Date : _____
Additional Info Requested Date : _____
Return Kit: _____ Title _____
Date _____ Sent By _____

No Cost Replacement (NCR):

	<u>A</u>	<u>B</u>
NCR Catalog #:		
NCR Sales Order #:		
NCR Sent Date:		
NCR Quantity:		
Backup Sales Order #:		
Backup Order Quantity:		
Credit Memo #:		
Consignment Order #:	TX1374320	TX1374332
Device Replaced Cat. #:	354-3257	354-3257
Device Replaced Lot #:	251591	251591

Observation/Failure

<u>A or B</u>	<u>Code</u>	<u>Observation</u>	<u>Priority</u>
A	81	RENT - SHELL	
B	81	RENT - SHELL	

<u>A or B</u>	<u>Code</u>	<u>Failure</u>	<u>Priority</u>
A	143	RENT - UNKNOWN CAUSE	
B	143	RENT - UNKNOWN CAUSE	

	<u>A</u>	<u>B</u>
Aging Code:	H	H
Description:	1-5 years	1-5 years

Activities

<u>A or B</u>	<u>AI Type</u>	<u>AI Number</u>	<u>Open Date</u>
---------------	----------------	------------------	------------------

Letters

<u>Name</u>	<u>Title</u>	<u>Date</u>
Device Receipt Acknowledgement Letter :		
Authorization for Return and Examination of Medical Device :		
Quarterly Update Letter :		
Final Response Letter :		

Investigation/Action

Investigation Summary :
 Background: As indicated in the Product Insert Data Sheet (PIDS), rupture is a known complication associated with Mentor Mammary Prostheses. Mentor is aware that, over time, gel-filled implants

may rupture due to fluid leakage. Causes of rupture of gel-filled implants include, but are not limited to the following events:

- Damage from surgical instruments
- Intraoperative or postoperative trauma
- Excessive stresses or manipulations as may occur during daily routines such as vigorous exercise, athletics, routine manual massage and intimate physical contact,
- Mechanical damage prior to or during surgery
- Closed capsulotomy
- Capsular contracture
- Origins which are simply unknown.

Device Evaluation and Investigation Findings:

EXAMINATION PERFORMED

Gross Evaluation

Two Siltex Gel-Filled Mammary Prostheses were returned to Mentor for product evaluation. The devices were returned autoclaved. PE designated the left device, Device A and the right device, Device B.

Device A

As received, the device weighed 305.4 gm and contained clear gel. An area of shell material measuring approximately 7 cm x 6 cm was observed missing from the anterior aspect of the device extending to the posterior aspect. No other anomalies were observed.

Device B

As received, the device weighed 246.7 gm and contained clear gel. Foreign black and orange materials were on the shell surface and within the device. A rent measuring approximately 21 cm in length was located on the radius of the device. No other anomalies were observed.

TESTING PERFORMED

Device A: Because of the as received condition of the device, PE was unable to perform a leak test.

Device B: Because of the as received condition of the device, PE was unable to perform a leak test.

MICROSCOPIC EXAMINATION

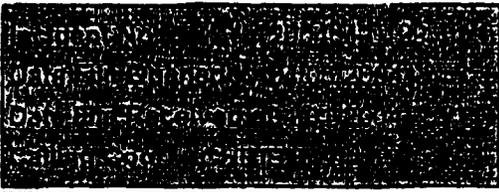
Device A: Microscopic examination of the edges of the remaining shell material revealed no indication as to the cause of the separation.

Device B: Microscopic examination of the edges of the observed rent in the shell of the device revealed no indication as to its cause. PE inadvertently cut the shell of the device during the evaluation.

Root Cause: A root cause of the failure could not be determined.

Corrective Action: Because PE was unable to confirm any unusual failure mode, no corrective action will be taken at this time.

Conclusion Statement: Based on the information received, the patient experienced bilateral ruptures. Based on the results of the laboratory evaluation and testing, PE observed a large hole in the shell of the left device and a large rent in the shell of the right device. Microscopic examination of the edges of the hole and rent revealed no indication as to their cause. Because Mentor performs 100% inspection and testing of all devices prior to release, PE concluded that the hole and rent occurred sometime subsequent to the removal of the devices from their protective packaging. Rupture is a



Incident Information

known complication associated with these devices and is referenced in our Product Insert Data Sheet; however, trends for Mentor devices will continue to be monitored by Quality Assurance.

Assessed By: Rabb

Date: 04/09/2004

Assessment Summary

Assessment Summary :

Based on the information received, the patient experienced bilateral ruptures. Based on the results of the laboratory evaluation and testing, PE observed a large hole in the shell of the left device and a large rent in the shell of the right device. Microscopic examination of the edges of the hole and rent revealed no indication as to their cause. Rupture is a known complication associated with these devices and is referenced in our Product Insert Data Sheet; however, trends for Mentor devices will continue to be monitored by Quality Assurance.

Closed By : CSB

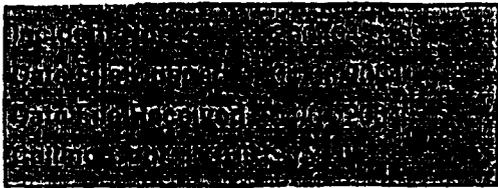
Date : 04/09/2004

Reopened By : CSB

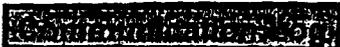
Date : 04/23/2004

Reclosed By : CSB

Date : 04/23/2004



Incident Information



4/6/04 CSB
REC'D DEVICES, P TO A, ROMI AND CUST FER. BILATERAL RUPTURE.
4/23/04 CSB
REC'D OP REPORTS, OP NOTES AND OTHER DOCUMENTATION FROM THE CLINICAL
PROGRAMS DEPT.

-015

MENTOR Customer Field Experience Report (FER)
Telephone # 1-800-258-3487 Fax # 972-659-6687

Demographic Information

Patient Name [Redacted] SS# [Redacted]
Date of Birth [Redacted] Weight 130
Physician's Name Paul S. [Redacted] MD Customer [Redacted]
Address [Redacted] 73116
Phone # [Redacted] Fax # [Redacted]

Complaint/Implant Description (if device is explanted complete Explant History below)

LEFT SIDE
Product (include size) Siltey gel 325cc
Catalog # 354 32575 Lot # 217513
Complaint Rupture
Date Problem Observed MRI 12/17/03
Caps. Contracture Yes No Unk Grade 1
Infection Yes No Unk
Culture Result _____

RIGHT SIDE
Product (include size) Siltey gel 325cc
Catalog # 354 32575 Lot # 217513
Complaint Rupture
Date Problem Observed MRI 12/17/03
Caps. Contracture Yes No Unk Grade 1
Infection Yes No Unk
Culture Result _____

Implant History

Date of Implant 11/17/00
Indication: 1*Augmentation 1*Reconstruction
Revision Reconstruction Revision Augmentation
Placement Submuscular Subglandular
Incision Site Inframammary
Incision Size 6 cm
Final Fill Volume N/A
Fill Schedule N/A
Betadine Usage Yes No Unk Conc. Skin prep
Soak Yes No Unk
Pocket irrigation Yes No Unk
Pocket rinsed Yes No Unk gentamycin solution
Intraluminal Use Yes No Unk
Did the device come into contact with the patient? Yes No
Is patient currently involved in any clinical studies? Yes No If yes, specify COLE Study

Date of Implant 11/17/00
Indication: 1*Augmentation 1*Reconstruction
Revision Reconstruction Revision Augmentation
Placement Submuscular Subglandular
Incision Site Inframammary
Incision Size 6 cm
Final Fill Volume N/A
Fill Schedule N/A
Betadine Usage Yes No Unk Conc. Skin prep
Soak Yes No Unk
Pocket irrigation Yes No Unk gentamycin solution
Pocket rinsed Yes No Unk
Intraluminal Use Yes No Unk
Did the device come into contact with the patient? Yes No
Is patient currently involved in any clinical studies? Yes No If yes, specify COLE Study

Explant History

Date of Explant 3/30/04
Capsul. Contracture Yes Grade 1 No Unk
Reason for Explant Rupture
Incision Site Inframammary
Incision Size 6 cm
Fill Volume N/A
Infection Yes No Unk
Culture Result _____
Description of explant:
(Continue description on page 2, if necessary)
Is saline clear/transparent in color? Yes No N/A
If no, describe N/A
Any apparent damage? Yes No
If yes, describe Rupture - tear
Any tissue ingrowth on valve? Yes No
If yes, describe _____
Any tissue adherence to shell? Yes No
If yes, describe _____

Date of Explant 3/30/04
Capsul. Contracture Yes Grade 1 No Unk
Reason for Explant Rupture
Incision Site Inframammary
Incision Size 6 cm
Fill Volume N/A
Infection Yes No Unk
Culture Result _____
Description of explant:
(Continue description on page 2, if necessary)
Is saline clear/transparent in color? Yes No N/A
If no, describe _____
Any apparent damage? Yes No
If yes, describe Rupture
Any tissue ingrowth on valve? Yes No
If yes, describe _____
Any tissue adherence to shell? Yes No
If yes, describe _____

REV. C

MENTOR Customer Field Experience Report (FER) continued

Any damage during explantation? Yes No
If yes, describe _____
Is there a probable cause of damage? Yes No
If yes, describe _____

Any damage during explanation? Yes No
If yes, describe _____
Is there a probable cause of damage? Yes No
If yes, describe _____

Additional description of saline:

Additional description of saline:

Additional description of explant:
Implant removed with
silicone observed in
capsule upon opening.
Noted in the capsule (was)
in the anterior aspect (superiorly)
of implant - Very large
TEAR.

Additional description of explant:
Complete separation of Rims
of the shell of implant
top to bottom - circumferentially

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 2
Replacement device: (L) Cat # 354 3257 Lot# 1374320
(R) Cat # 354 3257 Lot# 1374332
Explain _____

Method of Decontamination Autoclave Date 3/30/04
Comments _____

Provider of Information [_____] Title RN - Study coordinator

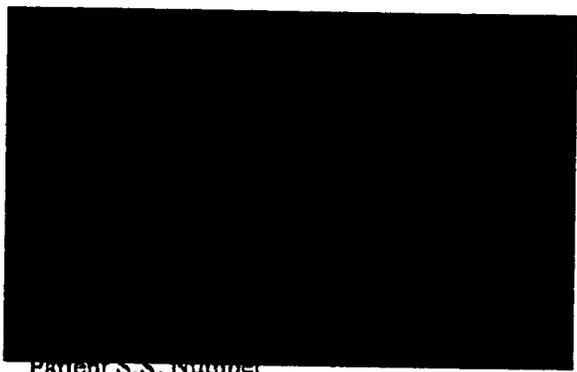
AUTHORIZATION FOR RELEASE OF MEDICAL INFORMATION

(ROMI)

Please release to Mentor, Product Evaluation Department, one complete copy of all medical records in your possession which relate to me, the undersigned, including but not limited to, all office notes, consultation records, correspondence, operative reports, laboratory results, prescription records, patient instruction forms and consent forms.

3/30/04
Date

C
Witness



Patient S.S. Number

**Mentor Product Evaluation Department
3025 Skyway Circle North
Irving, TX 75038**

FORM DOP-QA-4007C
REV. B

**DOMESTIC (U.S.) AUTHORIZATION FOR
RETURN AND EXAMINATION OF MEDICAL DEVICE(S)**

I agree to return the explanted device(s) to the Mentor Product Evaluation Department.

I authorize Mentor to examine, and if necessary, alter the condition of the device(s) as may be necessary for the purpose of safety and to facilitate the evaluation of the device(s).

Mentor may retain possession of the explanted device(s) and save and/or perform destructive testing to the device(s) as deemed appropriate by Mentor.

3/30/04
Date

Witness Signature



**Mentor Product Evaluation Department
3025 Skyway Circle North
Irving, TX 75038**

FORM DOP-QA-4007F
REV. B

OFFICE VISITS		CPT	FEE	
NEW PATIENT				
Limited/Problem Focused	99201			
Expanded Problem	99202			
Intermediate/Detailed	99203			
Comprehensive	99204			
Second Opinion Consultation	99273			
ESTABLISHED PATIENT				
Postoperative/Minimal	99211			
Limited/Problem Focused	99212			
Intermediate/Expanded	99213			
Detailed	99214			
Comprehensive/History & Physical	99215			
Post Op	99024	N/CHG		
OTHER				
No Show				
Cancellation				
Rescheduled				
Void				
Burn Debridement				
Ultrasound				
INJECTIONS				
Therapeutic	11900			
Keloid/Steroid	11900			
Tet Toxoid	90703			
SUPPLIES				
Surgical Appliance	99070			
Burn Dressings	99070			
Silicon Scar Sheet	99070			
MISCELLANEOUS				
Deposition Time	99075			
Medical Testimony Time	99075			
Medical Report	99080			
Worker's Comp Report	99080			
TESTS/LAB WORK				
EKG	Hgb	GLU	K+	CO ₂
MAMMO	Hct	BUN	Cl	Na+

Place: Major OR Minor OR Hospital

Time: 8:30 Date: 3-30-04

Anesthesia: Local General With

Anesthesia Fee \$ _____ Prepay \$ _____ Facility Fee Yes No

Surgeon Fee \$ _____ Prepay \$ _____ Bill Ins. \$ 5000

DIAGNOSIS:
V43.82, 996.54
SIP Bil. R+R, Poss. Bil. Ruptured Implants

PROCEDURE:
19371, 19371-50, 19340-51, 19340-52-57
Bil. R+R

SURGERY/EXAM:
Ruptured (L) Implant
(R)

INSTRUCTIONS:
JP down
Menton Siltey gel mod profile
(R) 325cc
(L) 325cc

DATE	TIME	PATIENT	REASON	PRIOR BALANCE	SURGEON'S FEE	ANESTHESIA'S FEE	SUPPLIES
					TOTAL \$ _____	TOTAL \$ _____	TOTAL \$ _____
					PREPAY \$ _____	PREPAY \$ _____	PREPAY \$ _____
					CHECK # _____	CHECK # _____	CHECK # _____
					CHECK \$ _____	CHECK \$ _____	CHECK \$ _____
					CASH \$ _____	CASH \$ _____	CASH \$ _____
					VISA/MC \$ _____	VISA/MC \$ _____	VISA/MC \$ _____
					AMEX \$ _____	AMEX \$ _____	AMEX \$ _____
					FIN \$ _____	FIN \$ _____	FIN \$ _____
					TOTAL PAID \$ _____		SIGNED _____
					NEXT APPOINTMENT: _____		
					Days _____	Weeks _____	Months _____
					Appt Time: _____		Arrival Time _____
					BALANCE DUE		



OPERATIVE REPORT

DATE: March 30, 2004

PATEINT NAME: [REDACTED]

SURGEON: [REDACTED]

ANESTHESIOLOGIST:

ANESTHESIA: General

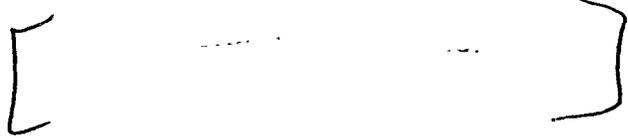
PRE-OP DIAGNOSIS: Status Post Bilateral Augmentation Mammoplasty, Bilateral R & R, Bilateral Ruptured Breast Implant Prosthesis Confirmed by MRI

POST-OP DIAGNOSIS: Status Post Bilateral Augmentation Mammoplasty, Bilateral R & R, Bilateral Ruptured Breast Implant Prosthesis Confirmed by MRI

PROCEDURE: Bilateral Open Capsulectomy with Removal and Replacement of Breast Implant Prosthesis

Procedure: Under satisfactory general anesthesia and after routine prep and drape with Betadine scrub and solution a 6 centimeter incision was made just above the inframammary crease of both breasts. Using a hot knife the incision was carried down through the subcutaneous tissue to the pectoralis major muscle layer. The scar capsule was identified, and then by sharp dissection it was totally excised from its adhesions to the breast glandular tissue superiorly and the pectoralis major fascia inferiorly. The margins of the pocket were expanded by sharp dissection and hemostasis achieved by electrocautery. After complete removal of the scar capsule hemostasis was again checked with electrocautery and the wound irrigated with Gentamycin irrigant solution. Both implants were noted to be ruptured. The right implant was replaced with a 325cc Mentor Moderate Profile Siltex Silicone Gel-Filled implant prosthesis, and the left implant was replaced with a 352cc Mentor Moderate Profile Gel-Filled implant prosthesis. The wounds were then closed with subcutaneous interrupted sutures of 3-0 Ethibond followed by intra-dermal sutures of 4-0 Maxon followed by cutaneous over-and-over sutures of 5-0 Prolene. Prior to closure, bilateral 10mm Jackson-Pratt drains were inserted through a separate stab wound in the lateral aspect of each breast. The patient tolerated the procedure well. A sterile dressing was applied, followed by a bulky dressing wrapped in an Ace bandage. The patient was awakened and returned to the recovery room in good condition.

[REDACTED] 
PS:hri



OPERATION Bilat Breast RSR DATE 3/30/24 PHYS STATUS 1 (2) 3 4 5 6 E
 PRE-MED Ø
 SURGEONS Silverstein
 ANESTHESIOLOGIST ALLERGIES NKOA

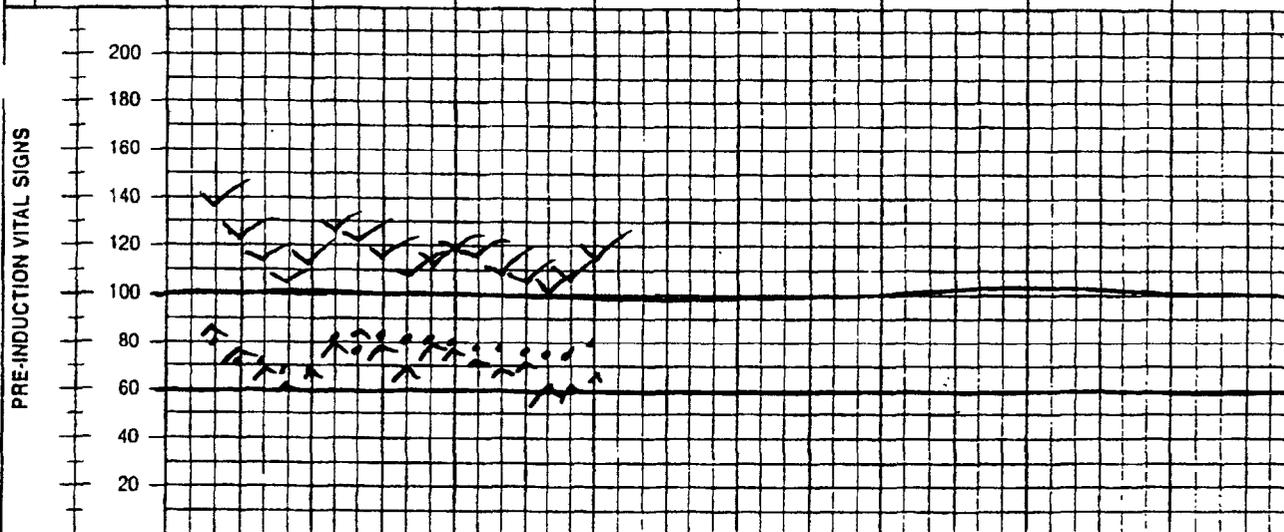
Start 0830
 Stop 1005
 Start 0922
 Stop 1001
 TOTALS

TIME 0830 1000 30 1100

Agents / Drugs	<u>2</u>	<u>5-2</u>	<u>1000</u>	<u>30</u>	<u>1100</u>
<u>Fentanyl</u>	<u>2.0</u>	<u>3.0</u>	<u>1.5</u>	<u>1.00</u>	
<u>Propofol</u>	<u>2</u>	<u>50</u>	<u>100</u>		
<u>MS</u>			<u>10</u>	<u>100</u>	
<u>Zotem</u>	<u>4</u>				

IV	<u>NS #1</u>				
MONITORS	<u>EtCO2</u>	<u>SR</u>	<u>SR</u>	<u>SR</u>	
	<u>SaO2</u>	<u>99</u>	<u>99</u>	<u>99</u>	
	<u>ETCO2</u>	<u>38</u>	<u>49</u>	<u>48</u>	

- GA
- MONITORS / EQ
- Patient ID
 - Machine Ck
 - EKG
 - SaO2
 - NIBP
 - Temp
 - Stethoscope P/E
 - Eye Care
 - O2 Analyz
 - Discon Alarm
 - Humidifier
 - Air Blanket
 - Fluid Warmer



- AIRWAY
- M LMA ET
 - Size 3
 - O N L/R
 - Grade
 - Easy / Difficult
 - O / N Cannula
- VENTILATION
- A C
 - BS L = R

Time Of Remarks
 Position

REMARKS
mgm / 200 - Mon placed - P 92
1000 - Induction smooth -
LMA #3 - exp line top tube
Arms pad + pad -

RECOVERY	BP	P	R	SaO2	CONTROLLED DRUGS	Drug / Amt	Given	Waste
	<u>99/94</u>	<u>102</u>	<u>16</u>	<u>100</u>		<u>Fentanyl</u>	<u>250</u>	<u>Ø</u>
					<u>MS</u>	<u>20</u>	<u>Ø</u>	
					<u>Propofol</u>	<u>2</u>	<u>Ø</u>	

PREOPERATIVE QUESTIONNAIRE

Have you had OR do you have

- High blood pressure Yes No
- Heart attack Yes No
- Chest pain (angina) Yes No
- Fast or skipped heart beats Yes No
- Fainting or blackout spells Yes No
- Asthma Yes No
- Emphysema, bronchitis Yes No
- Shortness of breath Yes No
- Seizures or stroke 2001 Yes No
- Paralysis or numbness Yes No
- Hepatitis or jaundice Yes No
- Kidney disease Yes No
- Heartburn or hiatal hernia (reflux) Yes No
- Back or neck injuries Yes No
- Glaucoma Yes No
- Diabetes Yes No
- Anemia or bleeding problems ASA #1 Yes No
- Muscle disease or weakness Yes No
- Thyroid disease Yes No
- Arthritis DANKLE Yes No
- Loose or cracked teeth Yes No
- Dentures or caps Yes No
- Lens implants or contact lenses Yes No
- A positive AIDS blood test Yes No
- Psychiatric or mental disorders Yes No
- Motion sickness Yes No
- Other _____

Do you

1. Smoke? (pkg/day _____) Yes No
2. Use alcoholic beverages? Yes No
3. Use drugs not prescribed by a doctor? Yes No
(cocaine, heroin, etc.)
4. Object to blood transfusion if needed to save your life? Yes No
5. Have any body piercings? EARS Yes No
(tongue, belly button, etc.)
6. Have any problems to discuss with the anesthesiologist? Yes No

Date of last chest x-ray 10-01
Date of last EKG 3-24-04

Previous anesthetic history
Date of last anesthetic or sedation 10-30-01
Any abnormal reactions? Yes No
Relative with abnormal reactions to anesthetics? Yes No
(i.e., high fever)

Comments _____

List previous surgeries

Type	Date
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

List medications you are presently taking
(prescription and over-the-counter medications or herbal preparations)

- LEVOLX 10.05 HYZAAR 100-25
- KOL 30 MG TRAZODINE 50 MG
- OPROL XL 50MG LYNELLE DASH OILING
- ASPIRIN 81MG PRAVACHOL 20MG 2x daily
- WARFARIN 7MG 2x DAY 6.5x DAY

List allergies (drug, sulfite sensitivity, other)
NKDA

Time of last food or drink _____
Age 50 Height 5'5 Weight 132

If female of child bearing age

1. Is there any possibility you could be pregnant? Yes No
2. Date of last menstrual cycle _____

10:45
Time

PREPARED BY NURSE

1. Have discussed risks and benefits of anesthesia/conscious sedation with patient. informed consent given. Yes No
2. Patient is an appropriate candidate for planned anesthesia/sedation Yes No
3. EXAM: Airway AOK
Heart M
Lungs C
4. PLAN: ASA status: 1 2 3 4 5 E
Anesthetic proposed: General Local standby
 Spinal Conscious sedation
 Regional

Anesthesia evaluation and notes
Dis 14332 GA
? 22-116
Pl - GA

Physician's signature

Date

[]

DATE 3/25/04
 AN [REDACTED] AGE: 50 OCCUPATION: Retired
 HEIGHT: 5'5" WEIGHT: 135 BRA SIZE: 36C AGES OF CHILDREN: 1

FAMILY HISTORY OF BREAST CANCER: _____
 DATE OF LAST MAMMOGRAM: 12/03 MRI LOCATION (MAMMOGRAPHY FACILITY) _____

BREAST FEEDING _____ LMP: 1980 U U U

MEDICINES: 500 sheet HORMONES: patch

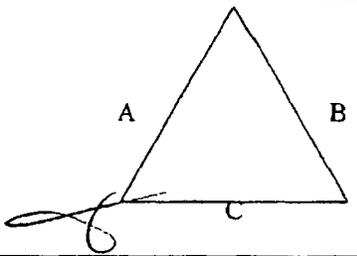
PREVIOUS BREAST SURGERY: 1984 - Aug R/R 2000

ALCOHOL: 8mg/day SMOKER: quit 9/03 ALLERGIES: NKA

DIET: H SYMMETRY: =

GLANDULAR CONSISTENCY: soft masses

NEOPIASIS AND AREOLAE: sensation present



INCISION: inframammary REDUCTION TECHNIQUE: 6

ANESTHESIA: general PROSTHESIS SIZE: 325

APPROXIMATE BRA SIZE DESIRED: 36C SURGICAL FEE: N/A

PROSTHESIS PLACEMENT: Submam

The results cannot be guaranteed. Differences in breast size and shape which might exist prior to surgery are to be expected after surgery. Marked differences will be pointed out and attempts may be made to minimize asymmetry if at all possible.

No surgical procedure can be expected to be pain free, and complications are possible. Infection, post-surgical bleeding and sensory deficits of the nipple (usually transient) are potential hazards of breast enlargement surgery. These hazards have been discussed. Development of fibrous capsules around the prostheses are normal in the healing process. On occasion, these fibrous capsules may cause firmness, and surgery, at additional cost, may be recommended in an attempt to soften the breasts. Scars are the natural result of all surgical procedures. The scars of reconstructive breast surgery, such as breast reduction, subcutaneous mastectomy and mammary suspension for ptosis, may be more extensive than the scars of cosmetic surgery. The location of the surgical scars has been discussed. In breast reduction and in subcutaneous mastectomies, nipple sensation may be markedly diminished.

The incisions, possible complications, and surgical fees have been discussed and are understood. Permission is granted to perform the surgery and to take the necessary pre and post operative photographs.

 (Patient) _____ (Surgeon) _____ M.D.

 (Witness) _____ (Date) 3/25/04

jm

OFFICE VISITS		CPT	FEE	SURGERY SCHEDULE		
NEW PATIENT				Place: Major OR	Minor OR	Hospital
Li. J/Problem Focused	99201			Time:	Date:	
Expanded Problem	99202			Anesthesia: Local	General	With
Intermediate/Detailed	99203			Anesthesia Fee \$	Prepay \$	Facility Fee. Yes No
Comprehensive	99204			Surgeon Fee \$	Prepay \$	Bill Ins. \$
Second Opinion Consultation	99273			DIAGNOSIS: <i>v67.0</i> <i>2yr post bil R/R</i> <i>upper tummy tuck</i> <i>1/2 lipos upper hips</i>		
ESTABLISHED PATIENT				PROCEDURE:		
Postoperative/Minimal	99211			SURGERY/EXAM: <i>Breasts - soft, supple!!</i> <i>NO supples. NO lumps, NO capsules</i> <i>MRT 12/01 m/f</i>		
Limited/Problem Focused	99212			INSTRUCTIONS: <i>Monitor sites 325cc gel</i> <i>Vitamin E 1000iu / day</i>		
Intermediate/Expanded	99213					
Detailed	99214					
Comprehensive/History & Physical	99215					
Post Op	99024	N/CHG				
OTHER						
No Show						
Cancellation						
Rescheduled						
Void						
Burn Debridement						
Ultrasound						
INJECTIONS						
Therapeutic	11900					
Keloid/Steroid	11900					
Tet Toxoid	90703					
SUPPLIES						
Surgical Appliance	99070					
Burn Dressings	99070					
Silicon Scar Sheet	99070					
MISCELLANEOUS						
Deposition Time	99075					
Medical Testimony Time	99075					
Medical Report	99080					
Worker's Comp Report	99080					
TESTS/LAB WORK						
EKG	Hgb	GLU	K+	CO ₂		
MAMMO	Hct	BUN	Cl	Na+		

FE	TIME	PATIENT	REASON	PCT	PRIOR BALANCE	SURGEON'S FEE	ANESTHESIA'S FEE	SUPPLIES
			F/U COPE	198	0.00	TOTAL \$	TOTAL \$	TOTAL \$
				198	0.00	PREPAY \$	PREPAY \$	PREPAY \$
CHECK NO.	DR #	DOCTOR	LOCATION	DOB	TODAY'S CHARGE	CHECK #	CHECK #	CHECK #
			OFFICE	10/27/83	<i>MC</i>	CHECK \$	CHECK \$	CHECK \$
PATIENT NO	RESPONSIBLE PARTY	PH #	REFERRING DR		ADJUSTMENTS	CASH \$	CASH \$	CASH \$
		72-4839				VISA/MC \$	VISA/MC \$	VISA/MC \$
M	F	ADDRESS	CITY/STATE	ZIP CODE		AMEX \$	AMEX \$	AMEX \$
			GA 30130			FIN \$	FIN \$	FIN \$
OVER 90	OVER 60	OVER 30	CURRENT	TOTAL DUE	PT	BC	CS	PAY CHOICE
COMPANY	BA	SCT	POLICY ID	RELATIONSHIP TO INSURED	TODAY'S PAYMENT	TOTAL PAID \$		
				SINGLE		SIGNED		
				SPOUSE	BALANCE DUE	NEXT APPOINTMENT: <i>1 yr</i>		
				CHILD		Days _____ Weeks _____ Months _____		
				OTHER		Appt Time _____ Arrival Time _____		

OFFICE VISITS		CPT	FEE
NEW PATIENT			
Limited/Problem Focused	99201		
Expanded Problem	99202		
Intermediate/Detailed	99203		
Comprehensive	99204		
Second Opinion Consultation	99273		
ESTABLISHED PATIENT			
Postoperative/Minimal	99211		
Limited/Problem Focused	99212		
Intermediate/Expanded	99213		
Detailed	99214		
Comprehensive/History & Physical	99215		
Post Op	99024	N/CHG	

OTHER:			
No Show			
Cancellation			
Rescheduled			
Void			
Burn Debridement			
Ultrasound			

INJECTIONS			
Therapeutic	11900		
Keloid/Steroid	11900		
Tet Toxoid	90703		

SUPPLIES			
Surgical Appliance	99070		
Burn Dressings	99070		
Silicon Scar Sheet	99070		

MISCELLANEOUS			
Deposition Time	99075		
Medical Testimony Time	99075		
Medical Report	99080		
Worker's Comp Report	99080		

TESTS/LAB WORK				
EKG	Hgb	GLU	K+	CO ₂
MAMMO	Hct	BUN	Cl	Na+

SURGERY SCHEDULE

Place: Major OR Minor OR Hospital

Time: 8:30 Date: 3-30-04

Anesthesia: Local General With

Anesthesia Fee \$ 6500 Prepay \$ 6500 Facility Fee Yes

Surgeon Fee \$ Prepay \$ Bill vs. \$

DIAGNOSIS:

Pre Op

PROCEDURE:

Bill PR

SURGERY/EXAM:

(needs photos)

Rx: Ceftin 250mg #12
Mepesone Hartsis #20
Darvocet 100 #20

INSTRUCTIONS:

Bill JP 10am

(?) 2 Brad

DATE	PATIENT NAME	REASON	PRIOR BALANCE	SURGEON'S FEE	ANESTHESIA'S FEE	SUPPLIES
				TOTAL \$	TOTAL \$ 6500	TOTAL \$ 2000
				PREPAY \$	PREPAY \$	PREPAY \$
TICKET NO.	DR #	DOCTOR	LOCATION	D.O.B.	TODAY'S CHARGE	
PATIENT NO.	RESPONSIBLE PARTY	PH #	REFERRING DR	ADJUSTMENTS	CHECK #	CHECK #
					CHECK \$	CHECK \$
					CASH \$	CASH \$
					VISA/MC \$	VISA/MC \$
					AMEX \$	AMEX \$
					FIN \$	FIN \$
					TOTAL PAID \$	SIGNED
					NEXT APPOINTMENT:	
					Days	Weeks
					Months	
					Appt. Time	Arrival Time

HISTORY AND PHYSICAL EXAMINATION

404-015

(PLEASE PRINT)

Date 3/25/04

Patient Name [redacted] Age 50 Date of Birth [redacted]

Occupation Retired Referred By Self

Present Problem (Reason for consultation with Dr. Silverstein) ? Ruptured implants

Date of Last Physical/Medical Examination 3/24/04 Physician

Date of Last Mammogram 12/10/03 Location (Mammography Facility)

Date of Last Electrocardiogram (EKG) 3/24/04 Date of Last Chest X-Ray

MR

MEDICAL/SURGICAL HISTORY

Procedure	Date	Surgeon
Hand amputation	10/30/01	Hickey
Bil R/R	11/16/00	Silver

Did you have any significant side effects or complications as a result of the surgical procedure listed above? Yes No

Please list all of your current medications: STASA/24, WAFARIN 7mg-6 1/2mg, Prava 20, Levokyl 0.05, Toprol XL 50mg, HYZAAR 100-25HS, Vivelle patch 0.1mg biweekly, KCL 20meq, Paxil 50mg, TRAZOPONE 50mg HS

Please list any KNOWN DRUG ALLERGIES: NKA

Please list any serious illness or health problems you have or have had in the past: hx stroke 2001

Please circle any illnesses you have or have had in the past of the following organ systems:

- Brain (including stroke or epilepsy)
- Lungs (including asthma)
- Endocrine or Diabetes
- Heart or Blood Vessels
- Eyes (including Glaucoma or dryness)
- Reproductive System
- Face (including paralysis)
- Nose, Sinus, Throat
- Arms or Legs
- Nervous System
- Breasts
- Urinary System
- Intestines
- Blood
- Ears
- Liver
- Stomach
- Bones or Joints

Please explain any problems you have or have had in the past with the conditions circled above: hx of stroke & subsequent (L) hand amputation 20 to cloggy vessels

FAMILY HISTORY

Has anyone in your immediate family had any of the following medical conditions? (Please circle)

- Cancer
- Heart Disease
- High Blood Pressure (Hypertension)
- Epilepsy
- Diabetes
- Tuberculosis (TB)
- Kidney Disease
- Blood or Bleeding Disorder
- Lung Disease

(Continued on back)

B+

PRE-OPERATIVE INFORMATION

Have you ever had a bad or adverse reaction to anesthesia?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	Are you allergic to adhesive tape?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Are you allergic to suture material?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	Do you bruise easily?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Do you have high blood pressure (hypertension)?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	Do you bleed unusually easily?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Have you ever had rheumatic fever?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	Are you a slow or poor healer?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Do you have frequent infections or "boils"?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	Do you form large scars or keloids?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Have you taken steroids (Cortisone) medications?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	Do you have any skin disease?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Do you have shortness of breath after walking?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	Have you ever had psychiatric care?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Does your religion prohibit blood transfusion?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	DO YOU SMOKE?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

Signature _____

Relationship to Patient _____

Date 3, 25, 04 11:00

PHYSICAL EXAMINATION (To be completed by Dr. Silverstein or nurse)

Pulse 72 Blood Pressure 140/90 Height 5'5" Weight 132 Temperatureafebrile

HEENT Pearl - WEARS Reading glasses

Oropharyngeal: clear - no breathing problems

NECK: Masses clear Trachea in line Thyroid w/ Prolonged Expiration clear

BREASTS: Soft 3 masses - MRI 12/03 Ruptured

HEART: Murmurs Thrills Rhythm P/R/R

ABDOMEN: Organomegaly Masses Tenderness none

SKIN: w/ 5 rashes or lesions

EXTREMITIES: @ hand amp

NEURO: intact

IMPRESSION: g/p r/r MRI reports but ruptured

Signature _____

at smoking .107

404-015

MICROFILM# 03230412145

PAGE 1	ACQUISITION NO. 4612992	ACCESSION NO. X0270926D	LAB REF. #	COLLECTION DATE & TIME 03232004 2:00 PM	LOG IN DATE 03232004	REPORT DATE 03242004	TIME 7:09AM
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REMARKS: Cardio CRP Pending

SSN: [REDACTED]

PATIENT ID: [REDACTED] ROOM NO. [REDACTED] AGE 50 SEX F PHYSICIAN SAADAH, HANNA A

CENTRIF TIME FASTING: Y

REPORT STATUS	TEST	RESULT		UNITS	REFERENCE RANGE	SITE CODE
		IN RANGE	OUT OF RANGE			
	Date of Birth: [REDACTED]					
	LIPID PANEL					
	TRIGLYCERIDES	84		MG/DL	<150	XC
	CHOLESTEROL, TOTAL	139		MG/DL	<200	XC
	HDL CHOLESTEROL	54		MG/DL	> OR = 40	XC
	LDL-CHOLESTEROL	68		MG/DL (CALC)	<130	XC
	CHOL/HDL RATIO	2.6		(CALC)	<4.4	XC
	COMPREHENSIVE METABOLIC PANEL					
	GLUCOSE					
		64 L		MG/DL	65-109	XC
	RED BLOOD CELLS WERE PRESENT IN THE SAMPLE UPON RECEIPT IN THE LABORATORY. THE TEST(S) ORDERED WERE PERFORMED. THE PRESENCE OF RED BLOOD CELLS HAS BEEN KNOWN TO AFFECT THE FOLLOWING ANALYTES: POTASSIUM, GLUCOSE, INORGANIC PHOSPHORUS, LACTATE DEHYDROGENASE AND IRON.					
	FASTING REFERENCE INTERVAL					
	UREA NITROGEN (BUN)	9		MG/DL	7-25	
	CREATININE	0.7		MG/DL	0.5-1.2	
	BUN/CREATININE RATIO	13		(CALC)	6-25	
	SODIUM		134 L	MMOL/L	135-146	
	POTASSIUM	3.8		MMOL/L	3.5-5.3	
	CHLORIDE		97 L	MMOL/L	98-110	
	CARBON DIOXIDE	21		MMOL/L	21-33	
	CALCIUM	9.6		MG/DL	8.5-10.4	
	PROTEIN, TOTAL	7.4		G/DL	6.0-8.3	
	ALBUMIN	4.6		G/DL	3.5-4.9	
	GLOBULIN	2.8		G/DL (CALC)	2.2-4.2	
	ALBUMIN/GLOBULIN RATIO	1.6		(CALC)	0.8-2.0	
	BILIRUBIN, TOTAL	0.3		MG/DL	0.2-1.3	
	ALKALINE PHOSPHATASE	67		U/L	20-125	
	AST	16		U/L	2-35	
	ALT	13		U/L	2-40	

SED RATE BY MODIFIED WESTERGEN 5 MM/HR (OR = 20) XC

>> REPORT CONTINUED ON NEXT PAGE - [REDACTED] X0270926D <<

MICROFILM# 0323041214

PAGE 2	REQUISITION NO. 461299E	ACCESSION NO. X0270926D	PATIENT ID	ROOM NO.	AGE 50	SEX F	PHYSICIAN
REMARKS			LAB REF #	COLLECTION DATE & TIME 03232004 2:00 PM	LOG IN DATE 03232004	REPORT DATE 03242004	& TIME 7:09AM

SS#: [REDACTED]

CENTRE TIME FASTING: Y

REPORT STATUS	FINAL	TEST	RESULT	UNITS	REFERENCE RANGE	SIDE CODE
			IN RANGE	OUT OF RANGE		

Date of Birth: [REDACTED]

ESR SPECIMENS ARE STABLE FOR 4-6 HOURS AT ROOM TEMPERATURE (12 HOURS IF REFRIGERATED). ESR RESULTS TREND LOWER WITH INCREASED SPECIMEN AGE. CONSIDER USE OF C-REACTIVE PROTEIN TO ASSESS ACUTE PHASE RESPONSES.

CBC (INCLUDES DIFF/PLT)	TEST	RESULT	UNITS	REFERENCE RANGE	SIDE CODE
WHITE BLOOD CELL COUNT		10.6	THOUS/MCL	3.8-10.8	X0
RED BLOOD CELL COUNT		4.63	MILL/MCL	3.80-5.10	
HEMOGLOBIN		14.0	G/DL	11.7-15.5	
EMATOCRIT		42.0	X	35.0-45.0	
MCV		90.7	FL	80.0-100.0	
MCH		30.2	PG	27.0-33.0	
MCHC		33.3	G/DL	32.0-36.0	
RDW		13.4	X	11.0-15.0	
PLATELET COUNT		344	THOUS/MCL	140-400	
ABSOLUTE NEUTROPHILS		6116	CELLS/MCL	1500-7800	
ABSOLUTE LYMPHOCYTES		3138	CELLS/MCL	850-3900	
ABSOLUTE MONOCYTES		954. H	CELLS/MCL	200-950	
ABSOLUTE EOSINOPHILS		329	CELLS/MCL	15-500	
ABSOLUTE BASOPHILS		64	CELLS/MCL	0-200	
NEUTROPHILS		57.7	X		
LYMPHOCYTES		29.6	X		
MONOCYTES		9.0	X		
EOSINOPHILS		3.1	X		
BASOPHILS		0.6	X		
TSH		3.68 ✓	MIU/L		X0

> 20 YEARS: 0.40-5.50

FOR PREGNANT PATIENTS:

FIRST TRIMESTER 0.30-4.50
 SECOND TRIMESTER 0.50-4.60
 THIRD TRIMESTER 0.80-5.20

>> REPORT CONTINUED ON NEXT PAGE - [REDACTED] X0270926D <<

MICROFILM 03230412149

PAGE 3	ACQUISITION NO 4612992	ACCESSION NO X0270926D	LAB REF. #	COLLECTION DATE & TIME 03232004 2:00 PM	LOG IN DATE 03232004	REPORT DATE 03232004	TIME 7:10AM
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REMARKS: SSN: [REDACTED] CENTRAL TIME FASTING: Y

REPORT STATUS	FINAL	TEST	RESULT	UNITS	REFERENCE RANGE	SITE CODE
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Date of Birth: [REDACTED] *CARDIO CRP 4.2 H MG/L XO

HIGH CARDIOVASCULAR RISK ACCORDING TO AHA/CDC GUIDELINES.

FOR AGES > 17 YEARS:

CCRP MG/L	RISK ACCORDING TO AHA/CDC GUIDELINES
<1.0	LOW CARDIOVASCULAR RISK
1.0-3.0	AVERAGE CARDIOVASCULAR RISK
3.1-10.0	HIGH CARDIOVASCULAR RISK
>10.0	PERSISTENT ELEVATIONS MAY REPRESENT NON-CARDIOVASCULAR INFLAMMATION

TSH 3.68 MIU/L X

> 20 YEARS: 0.40-5.50

FOR PREGNANT PATIENTS:

FIRST TRIMESTER	0.30-4.50
SECOND TRIMESTER	0.50-4.60
THIRD TRIMESTER	0.80-5.20

Performing Site Code Key (continued from the back):

XO DIAGNOSTIC LABORATORY

>> REPORT CONTINUED ON NEXT PAGE

26D <<

Patient

HR: 67 BPM

Axis:

S RHYTHM

NORMAL ECG

Intervals:

P 49°

QRS 18°

T 23°

5.62

UNCONFIRMED REPORT

RR 893 ms

P 112 ms

PR 162 ms

QRS 88 ms

QT 412 ms

QTc 438 ms

P (II) 0.12 mV

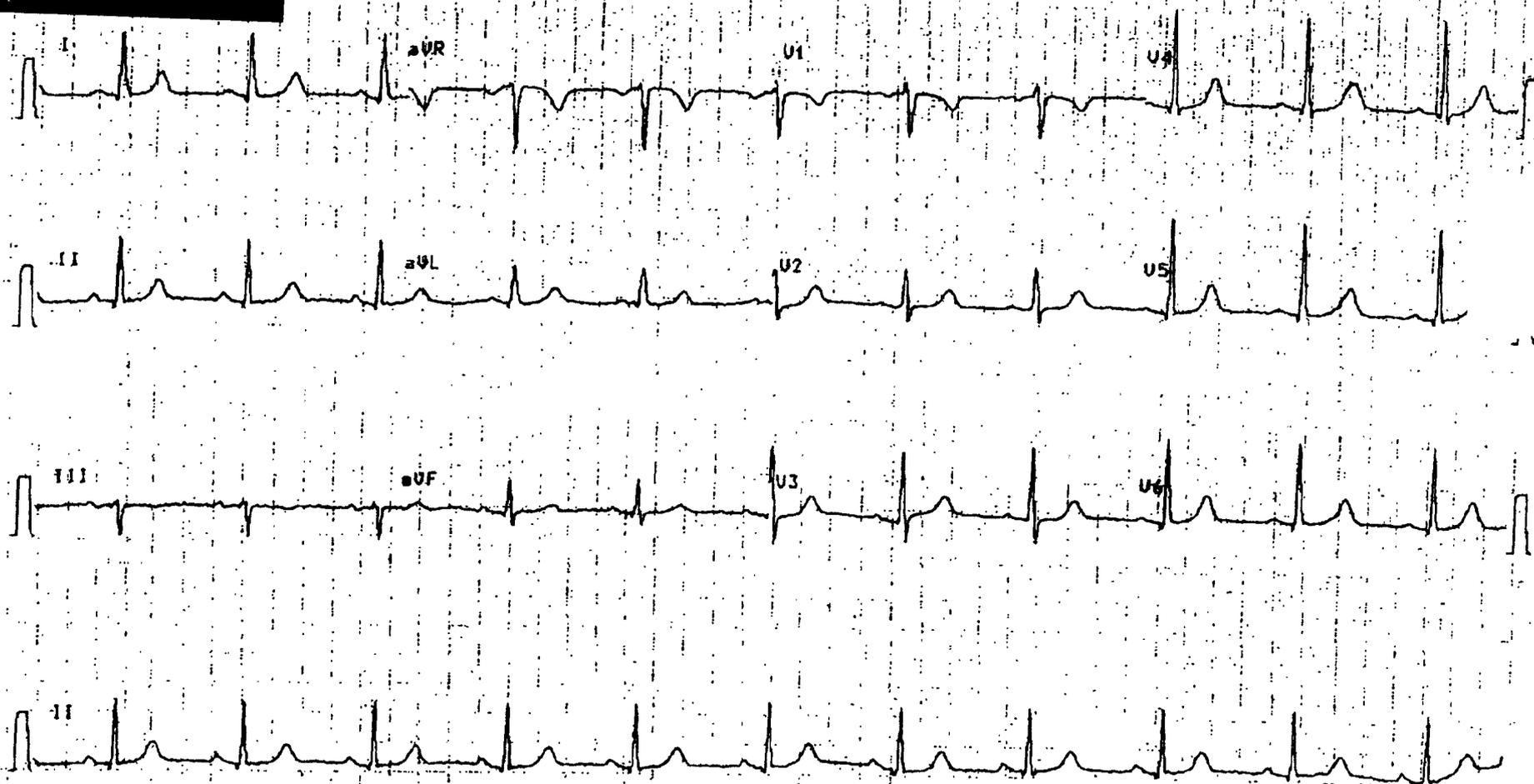
S (U1) 0.79 mV

R (US) 1.64 mV

Sokol 2.43 mV

10 mm/mV

10 mm/mV



25 /s

0.05-35Hz F60 55F 585 Tu 23-MAR-04 21:16:10

Widex

RT-2plus 12 C

4890

M. Patic



50 year / F
65 in. / 132 lb.
C

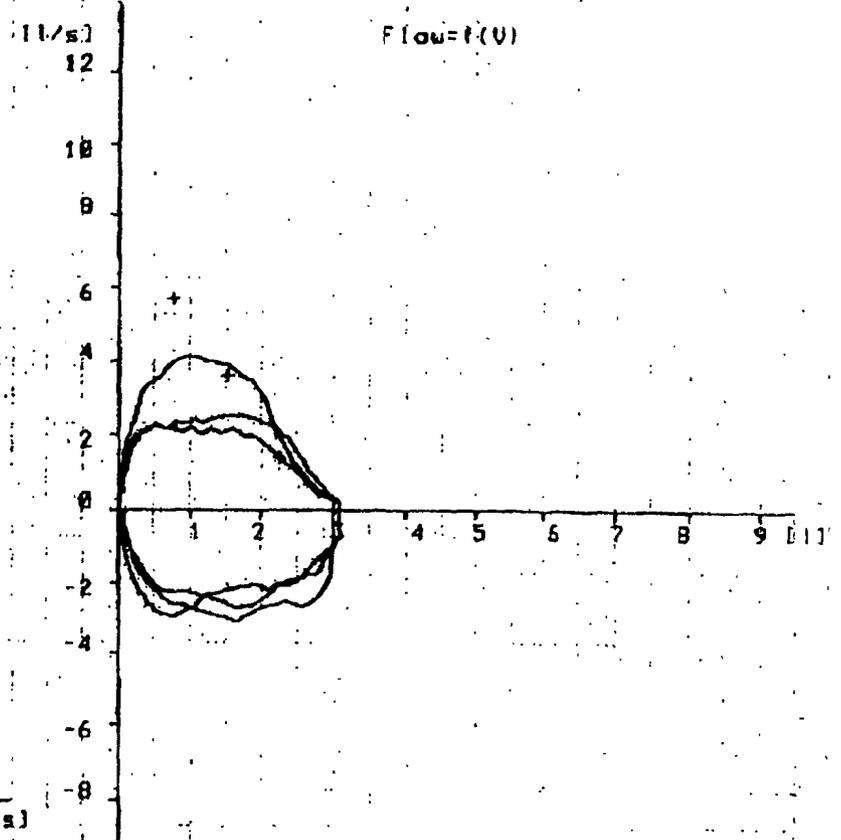
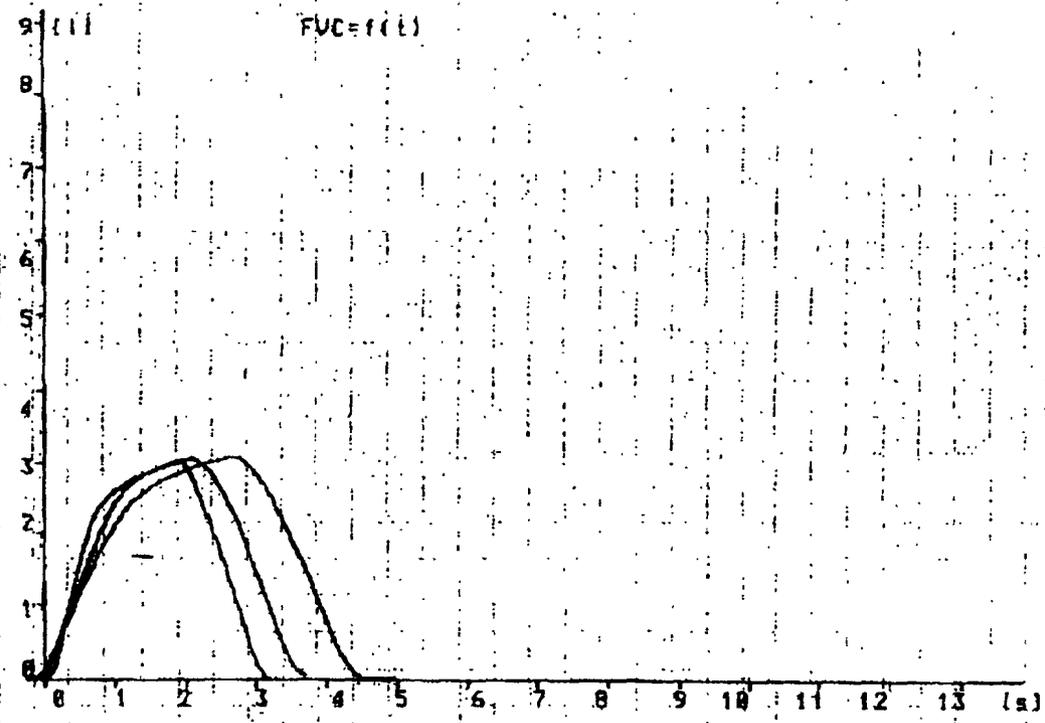
Normals : Composite

OBSTRUCTION SUGGESTED
OBSTRUCTION MAY BE UNDERESTIMATED
UPPER OBSTRUCTION SUGGESTED
POOR INITIAL EFFORT SUGGESTED
UNCONFIRMED REPORT

			PREU	APREU	
FVC	l	3.09	3.44	90	
FEV1	l	2.58	2.80	92	
FEV1/FVC	%	83.6	81.6	102	
PEF, 2-1.2	l/s	3.64	5.09	71	
FEF25-75x	l/s	3.45	2.86	121	
FEF75-85x	l/s	1.37	0.98	153	
PIF	l/s	4.12	5.97	68	
FEF25x	l/s	3.98	5.68	70	
FEF50x	l/s	3.98	5.59	109	
FEF75x	l/s	1.86	1.41	132	
FVC	l	3.07			
FEV1	l	2.78			
FEV1/FVC	%	90.6			
PIF	l/s	3.16			
PIF50x	l/s	3.05			

PREU	APREU	PREU	APREU
3.00	3.09	3.06	
2.58	2.89	2.42	
86.8	67.7	78.9	
3.64	2.12	2.28	
3.45	1.92	2.37	
1.37	1.82	1.62	
4.12	2.25	2.51	
3.98	2.17	2.32	
3.98	2.13	2.58	
1.86	1.38	1.95	
3.02	3.07	3.01	
2.78	1.89	2.13	
92.1	61.4	78.8	
3.16	2.48	2.77	
3.05	2.24	2.73	

all



Cal. : 03-22-04

TU 23-MAR-04 21:12:23

RT-2plus 4.12 C

ERROR: limitcheck
OFFENDING COMMAND:

%f1

' j% W }dl'uo \$ s1"z-E 0<{!j~ x`S'!' "

STACK:

```
/JBIG2Globals
-mark-
-filestream-
-filestream-
-mark-
/ Filters
[0.0 1.0 ]
/Decode
1
/BitsPerComponent
[2432.0 0.0 0.0 -3120.0 0.0 3120.0 ]
/ImageMatrix
3120
/Height
2432
/Width
1
/ImageType
-mark-
-savelevel-
```