

## 1.0 EXECUTIVE SUMMARY

The results of Mentor's mechanical testing of its Gel-filled Mammary Prostheses are presented in this PMA (M020018/M2) module. The testing was conducted in accordance with the Food and Drug Administration's "Guidance for Saline, Silicone Gel, and Alternative Breast Implants; Guidance for Industry and FDA" (February 11, 2003) and ASTM F703-96 Standard Specification for Implantable Breast Prostheses. The testing performed included shell tensile testing (ultimate breaking force and elongation), shell tear resistance, patch-to-shell adhered joint testing, shell tension set; fatigue testing, gel cohesivity testing, and device bleed. Where appropriate, results are compared to ASTM F703-96 suggested requirements or Mentor's finished device specifications. In some areas testing beyond the requirements of the guidance document and the ASTM Standard was performed to provide additional information on the suitability of the devices for clinical usage.

Mentor manufactures low-bleed gel-filled mammary prostheses that consist of a silicone elastomer shell assembly filled with silicone gel. The devices are available in both smooth and textured (Siltex<sup>®</sup>) surfaces in a round design with three different profiles and varying sizes. Sterile devices or samples taken from sterile device components representative of devices made using current manufacturing processes, as described in the Manufacturing Module of this PMA, were used for the mechanical testing. In addition to the mechanical testing data on the current PMA product, this module also contains a comparison of physical properties of the current device to Mentor's previous gel-filled devices (made with prior vendor silicone materials).

The results of the mechanical testing of shells and shell assemblies demonstrate that Mentor's PMA Gel-filled Mammary Prostheses surpass all ASTM specifications. The ultimate elongation testing results exceed the ASTM F703-96 minimum requirement of 350% ultimate elongation (actual results greater than 500%). The breaking strength testing results demonstrate that Mentor's devices exceed the ASTM F703 minimum requirement of 2.5 pounds ultimate shell breaking strength (actual results greater than 5 pounds). While there are no minimum specifications for the shell tear resistance test, the PMA Gel-filled prostheses were shown to have 2.6–5.3 pounds of tear resistance. The joint strength data demonstrate that all samples passed the ASTM requirement of 200% elongation for 10 seconds, and all joints can withstand the shell breaking strength minimum requirement of 2.5 pounds. The tension set testing demonstrates that Mentor's prostheses have tension sets well below the ASTM F703-96 requirement of a maximum of 10% (actual results less than 4.2%).

The above results of mechanical testing of shells and shell assemblies indicate that Mentor's PMA Gel-filled Mammary Prostheses have high levels of elongation that will aid in withstanding the manipulation and stretching that occurs during surgical placement and *in vivo*. The results of these tests also provide evidence that the strength of both the shells and joints will resist failures due to stresses applied during insertion and *in vivo*, and indicate that the shells should resist the propagation of a tear that could result in extruded gel outside of the device shell. Moreover, Mentor's PMA Gel-filled Mammary Prostheses have the ability to recover from excessive stretching that could occur during placement or *in vivo*.

Cyclic fatigue testing and compression testing were performed on 100cc Smooth Round Moderate Profile, 100cc Siltex Round Moderate Profile, and 125cc Siltex Round High Profile Mammary Implants to represent all gel-filled device types and styles. Compression testing determined the maximum load applied as a single stroke that the device could withstand prior to rupture or failure. Cyclic fatigue testing determined the number of cycles for various load amplitudes at which devices fail or rupture. Applied force versus number of cycles to failure (AF/N) curves were then derived for each device style tested using maximum loads of 30–100 pounds. In addition, the endurance limit, or the load at which a device can endure ten million cycles without failure, was determined for these devices. Finally, the endurance limit was used to determine a safety factor ( $S_f$ ) by comparing this value to the calculated *in vivo* load experienced by a device during the common fatigue activity of walking.

Compression testing results for devices showed smooth device rupture at a mean of 380 pounds and textured device rupture at a mean of 452 pounds. The smooth and textured gel-filled device endurance limits were 20 and 30 pounds, respectively. Based upon the calculated *in vivo* load on the devices during walking, the implant safety factors for the devices tested were determined to be 5–8 for the largest sizes of the device types and 43–65 for the smallest sizes of the device types. Each of these safety factors exceeded the minimum allowable safety factor of two that was agreed to with FDA. These data suggest that the *in vitro* endurance limit of the devices is greater than the estimated *in vivo* load applied to a device during the common fatigue activity of walking.

Gel cohesion testing, penetrometer testing, and rheology testing were conducted to evaluate the cohesivity of the silicone gel used in Mentor's Gel-filled Mammary Prostheses. Specifications for gel cohesivity are set such that the gel mimics the aesthetics of breast tissue, while providing a resistance to flow in the event of a shell rupture. The results of the cohesion tests demonstrate that the gel used in Mentor's devices meet specifications and is cohesive.

Gel bleed testing of sterile Smooth Moderate Profile Gel-filled Mammary Prostheses was performed using the suggested bleed testing method in ASTM F703-96, Appendix X2. This method provides a worst case estimate of the amount of silicone gel diffusion through a shell. The results of such testing can be used for "comparison of gel bleed diffusion rates of various product configurations in a laboratory setting" (ASTM F703-96). ASTM standard clearly states, that "The results of this bleed test method can not be correlated with the actual physiological performance of an implant since the chemical gradient is not replicated." The data obtained in this test demonstrate a relatively low bleed rate (starting at 0.0035 g/cm<sup>2</sup>/week and decreasing to 0.0011 g/cm<sup>2</sup>/week at week 15) that became relatively constant after approximately five weeks.

In addition to the mechanical testing data on the PMA device described above, this module also contains a comparison of PMA device physical properties to Mentor's previous gel-filled devices made with prior vendor silicone components to provide supportive evidence that the long-term biological safety testing performed on prior versions of Mentor's gel-filled device shells directly apply to the current PMA devices. In combination with chemical extractables data and manufacturing process data (provided in previous PMA modules), this physical

testing data comparison demonstrated that current shells are physically not substantially different from the prior device shells used in the long-term biological testing.

Based on the data presented in this module, together with a history of safe and effective performance *in vivo*, it can be concluded Mentor's Gel-filled Mammary Prostheses that are the subject of this PMA are mechanically acceptable and safe for their intended use.

## 2.0 INTRODUCTION AND TESTING RATIONALE

Mentor's mechanical testing of Gel-filled Mammary Prostheses was conducted in accordance with the Food and Drug Administration's "Guidance for Saline, Silicone Gel, and Alternative Breast Implants; Guidance for Industry and FDA" (February 11, 2003) and ASTM F703-96 Standard Specification for Implantable Breast Prostheses. The testing performed included shell tensile testing (ultimate breaking force and elongation), shell tear resistance, patch-to-shell adhered joint testing, and shell tension set. Gel cohesion testing was performed, as well as device bleed and fatigue testing. Where appropriate, results are compared to ASTM F703-96 suggested requirements or Mentor's finished device specifications. In some areas testing beyond the requirements of the guidance document and the ASTM Standard was performed to provide additional information on the suitability of the devices for clinical usage.

The mechanical testing was performed on sterile devices or samples taken from sterile device components. The devices tested were representative of devices made with current manufacturing processes and materials as presented in the Manufacturing Module of this PMA (M020018/M2). Since Mentor makes three smooth and three textured gel-filled device configurations (see Section 3.0 Device Description and Raw Materials) that only differ in their height and projection dimensions, most data presented in this module are from one smooth (Round Moderate **Plus** Profile) and one textured (Round High Profile) device line. Those data are representative of the other two similar device lines (smooth or textured).

In addition to the mechanical testing data on the current PMA product (see Section 4.0), this testing section also contains a comparison of physical properties to Mentor's previous gel-filled devices (made with prior vendor silicone materials) in order to support Mentor's justification that the long term biological safety testing performed on older versions of Mentor's gel-filled device shells still directly apply to the current devices in this PMA (see Section 5.0). These mechanical testing data together with other data comparisons provided in the Chemical Module (M020018/M3) and Manufacturing Module (M020018/M2) of this PMA provide evidence that the previous devices and the current device are not substantially different, and thus the existing safety data also directly apply to the current PMA gel-filled devices.

### 3.0 DEVICE DESCRIPTION AND RAW MATERIALS

#### 3.1 Device Description

The Mentor low-bleed gel-filled mammary prostheses that are the subject of this PMA consist of a silicone elastomer shell assembly filled with silicone gel. They are available in smooth and textured surfaces in a round profile in varying sizes with three different profiles. The minimum shell thickness is 1.5 mm for the smooth implants and approximately 2.0 mm for the textured implants. The devices are single lumen devices and are summarized in the table below.

Catalog Number	Gel-filled Device Styles	Size Range
350-7XXXBC	Smooth Round Moderate Profile	100-800cc
354-XXX7	Siltex Round Moderate Profile	100-800cc
350-XXX1BC	Smooth Round Moderate <b>Plus</b> Profile	100-800cc
354-XXX1	Siltex Round Moderate <b>Plus</b> Profile	100-800cc
350-XXX4BC	Smooth Round High Profile	125-800cc
354-4XXX	Siltex Round High Profile	125-800cc

The three smooth gel-filled product lines utilize the same materials and processes for the shell, gel, patch, and other minor components. The three Siltex gel-filled product lines utilize the same materials and processes for the shell, textured surface, gel, patch, and other components.

During manufacture, the silicone gel is injected through the patch fill reinforcement of the shell assembly and the resulting fill hole is sealed using a small amount of the dispersion coating (dip coat seal). Graphical depictions of the Smooth and Siltex implants are provided in Figures 3-1 and 3-2.

All gel-filled mammary prostheses are sold packaged in double-sealed nested thermoforms, each with a Tyvek lid, and dry-heat sterilized. Devices are shipped to customers in individual boxes.

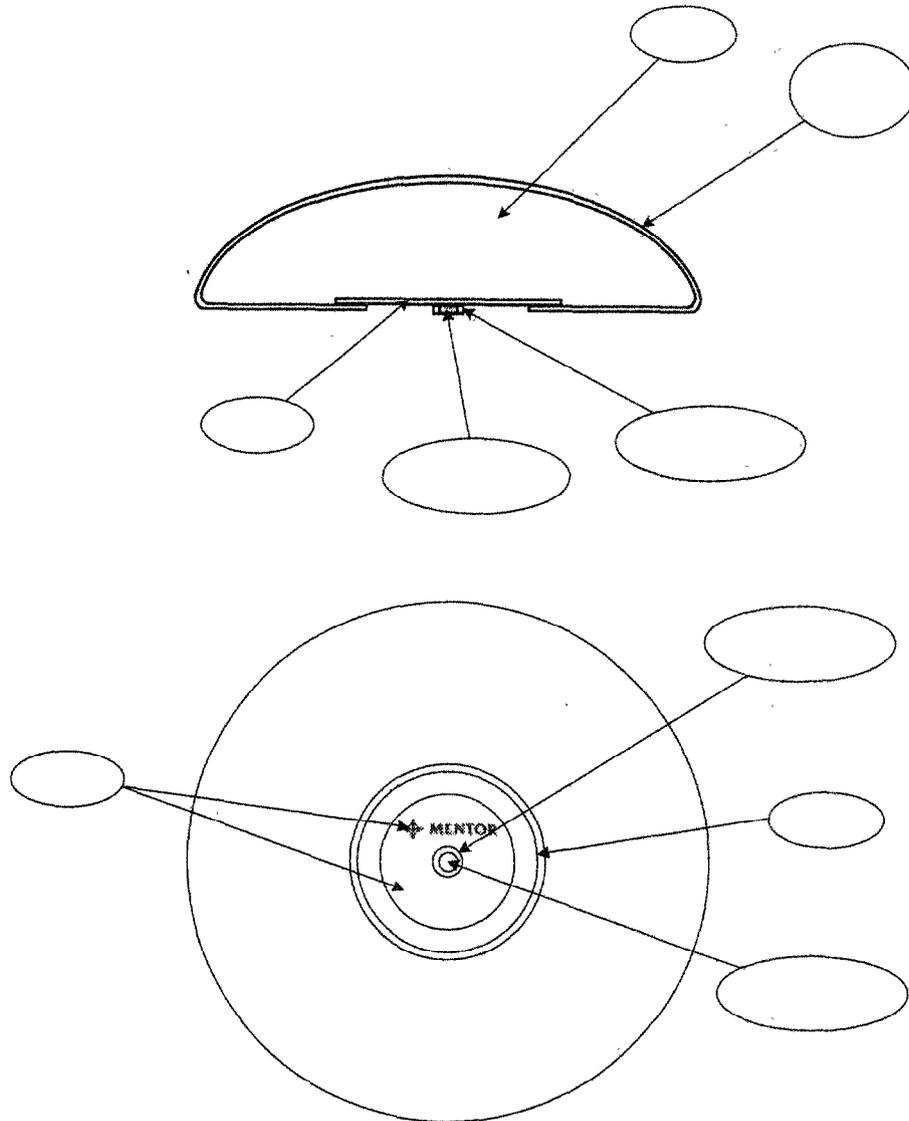
#### 3.2 Device Profiles

Mentor's silicone gel-filled mammary prostheses are manufactured in three different profiles to fit individual patient needs. The Moderate Profile Gel product line is available in both smooth and textured surfaces and offers a moderate amount of projection. This product works well for patients who have a wider chest wall and is a good choice for most body types. It is currently the most commonly used of these products.

The Moderate **Plus** Profile Gel (available in both smooth and textured surfaces) is intended for patients who require more projection and a slightly narrower base width. This product is an in-between choice if the Moderate Profile Gel is too wide for a given patient and the High Profile Gel is too narrow. The degree of projection also falls between the two other products.

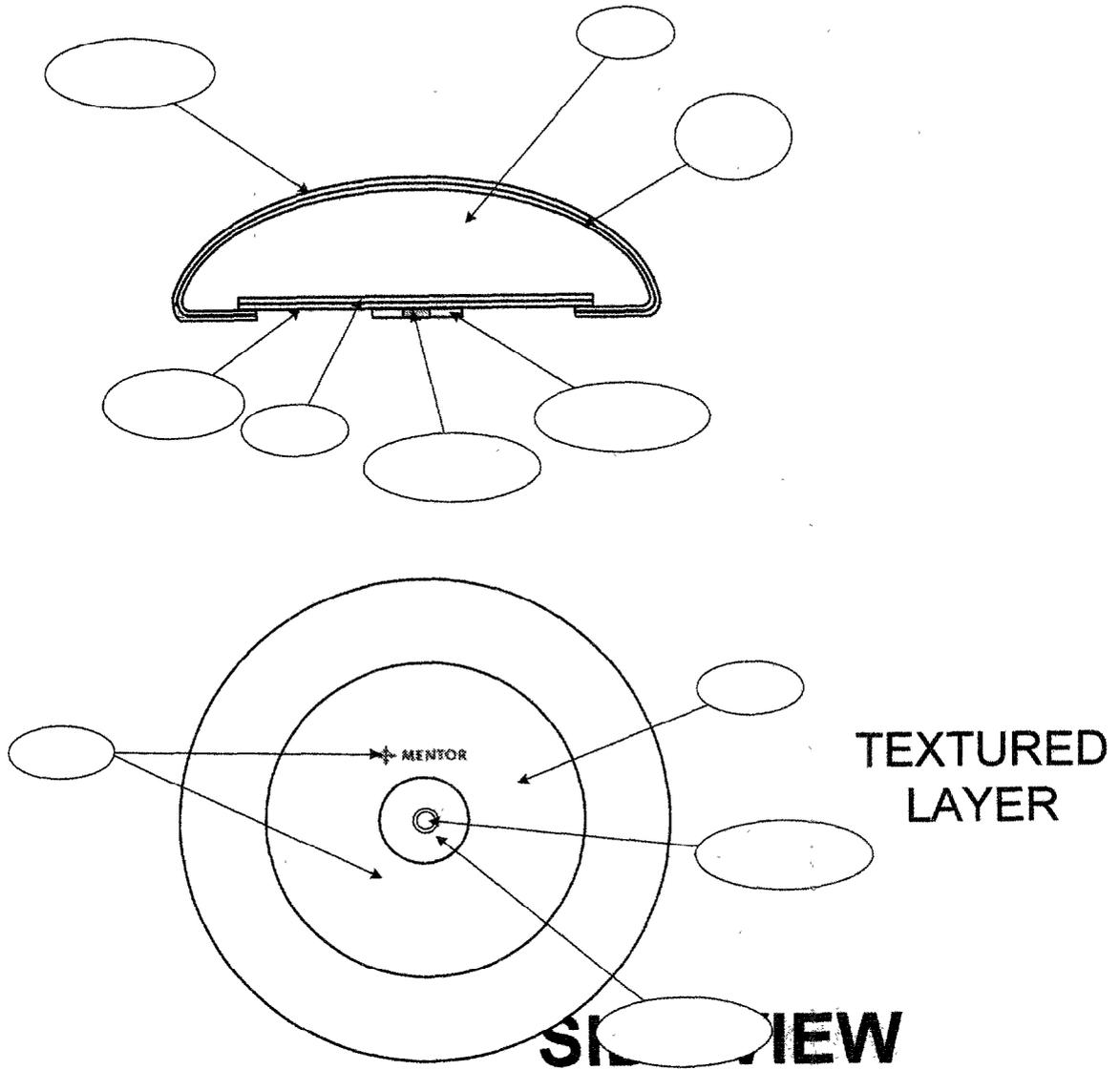
The High Profile Gel (available in both smooth and textured surfaces) is intended for patients with a narrow chest wall who are seeking more projection. This feature is especially relevant in the reconstruction procedures when the doctor is trying to match the opposite (non-reconstructed breast) and needs a high profile implant to achieve symmetry.

Figure 3-1. Smooth Round Gel-Filled Mammary Implant



**SIDE VIEW**

Figure 3-2. Siltex<sup>®</sup> Round Gel-Filled Mammary Implant



### 3.3 Raw Materials

A listing of raw materials used in the manufacture of Mentor's silicone gel-filled mammary prostheses is provided in Table 3-1.

**Table 3-1: GEL-FILLED MAMMARY PROSTHESIS RAW MATERIALS**

Component	Material Name(s)	Part Number(s)	Manufacturer/Supplier	Master Access File
-----	----- (Dimethylbenzene, CAS #106-42-3) Dimethyl Silicone Elastomer Dispersion ----- ----- ----- -----	----- ----- ----- -----	----- ----- ----- -----	-----  MAF #1040   MAF #1041  -----
Shell Texturing Dispersion Layer*, Patch, -----	----- ----- ----- (OR ALTERNATIVELY) ----- ----- -----	----- ----- ----- -----	----- ----- ----- -----	----- ----- ----- -----
Gel	Silicone Gel: ----- -----	----- -----	----- -----	MAF #1039
Dispersion Coating Seal (Dip Coat Seal)	----- (Silicone)	-----	-----	N/A

\* - Component only present on Siltex Gel-filled Mammary Prostheses

Table 3-1 (cont.): GEL-FILLED MAMMARY PROSTHESIS RAW MATERIALS

Component	Material Name(s)	Part Number(s)	Manufacturer/ Supplier	Master Access File	
Packaging	-----	-----	-----	----	
	-----	-----	-----		
	-----	112-8905)	104288-001	-----	
	-----	-----	-----	-----	----
	-----	-----	-----	-----	
	-----	112-8905)		-----	
	-----	-----	-----	-----	-----
	-----	Coating)	-----	-----	
	-----	1073B, Tolas TPT0282Z adhesive	-----	-----	-----
	-----	Coating)	-----	-----	
-----	-----	-----	-----	-----	
-----	Coating)	-----	-----		
-----	1073B, Tolas TPT0282Z adhesive	-----	-----	-----	
-----	Coating)	-----	-----		
-----	-----	-----	-----	-----	
-----	-----	-----	-----	-----	
-----	-----	102587-001	-----		
-----	-----	102587-002	-----		

Table 3-1 (cont.): GEL-FILLED MAMMARY PROSTHESIS RAW MATERIALS

Component	Material Name(s)	Part Number(s)	Manufacturer/ Supplier	Master Access File
Indirect Manufacturing Materials**	Polyet----- 100% virgin polye--- Federal Regulation 21CFR177.152)	-----	-----	---
	(CAS #7727-37-9)	-----	-----	---
		-----	-----	N/A
	Shell Dipping Mandrels:	-----	-----	---
	(OR ALTERNATIVELY) - 16 GA. 304 stainless stee-	103066-001 Through 103066-020	-----	---
	Polyethylene Bags	313982-020  213029-008	-----	N/A

\*\* - not present in the finished device, contacts components during manufacturing only

**4.0 FINISHED PRODUCT PHYSICAL TESTING**

Mentor's PMA gel-filled mammary prostheses are manufactured with two surfaces: smooth and textured (Siltex). Sterile finished devices were fabricated as part of Product Performance Qualifications (PPQs), the final step in validating the product and process for manufacturing, and also for additional physical property tests, as summarized in the table below.

<b>Device Configuration</b>	<b>Test Report<sup>1</sup></b>	<b>Parameters Tested</b>
450cc Siltex Round High Profile Devices <sup>2</sup>  Made with SiTech shell dispersio----- gel, and ----- sheeting	HS350.021202.03 Cumulative Product Performance Qualification (PPQ) for Gel Products Using Teflon Coated Stainless Steel ----- lender, ----- Laser ----- Reduced Dry Heat Sterilization Cycle – Summary Report	Physical properties of devices using a new sheeting calender, laser marked patches (for identification purposes), Teflon-coated stainless steel mandrels for shell dipping, and two dry heat sterilization cycles of 53 hours each
450cc Siltex Round High Profile Devices  Made with - ----- shell dispersio----- gel, and ----- sheeting	HS350.021202.03 AdC (Addendum C to above report)	Shell breaking strength data
100cc Smooth and 100cc and 800cc Siltex Round Moderate Profile devices  Made with - ----- shell dispersio----- e gel, and ----- (alternat-----	HS33.980925.03A – Product Performance Requalification Summary Report for Gel-filled Implants Using SiTech HTV Dispersions and Gel: Vendor Qualification	Physical property testing using standard mandrels for shell dipping, original calendar, and dry heat sterilized for 53 hours
100cc, 250cc, and 800cc Smooth Round Moderate <b>Plus</b> Profile devices <sup>3</sup>  Made with - ----- shell dispersio----- e gel, and ----- (alternat-----	Report HS72.030718.02 Product Performance Qualification Summary Report for the Smooth Moderate <b>Plus</b> Profile Gel Mammary Prosthesis	Physical property data on laser-marked devices, dipped using Teflon-coated stainless steel mandrels, and sterilized using a 35-hour dry-heat cycle.

<sup>1</sup>Test reports are provided in Appendix 1 of this PMA module.

<sup>2</sup> This device configuration and the Siltex Round Moderate Profile and Round Moderate **Plus** Profile Gel-filled Mammary Prostheses are made from the same materials using the same processes. The only difference between the three configurations is that a slightly different shaped mandrel is used to dip the device shells. As a result of the similarities in the three device lines, the physical testing data for the High Profile device is representative of the physical properties of all Siltex gel-filled mammary prostheses in this PMA.

<sup>3</sup>This device, the Smooth Round Moderate Profile, and the Smooth Round High Profile Gel-filled Mammary Prosthesis are made from the same materials using the same processes. The only difference between them is that a slightly different shaped mandrel is used to dip the device shells. As a result of the similarities in the three device lines, the physical testing data for the Smooth Moderate **Plus** Profile device is representative of the physical properties of all of the smooth gel-filled mammary prostheses in this PMA.

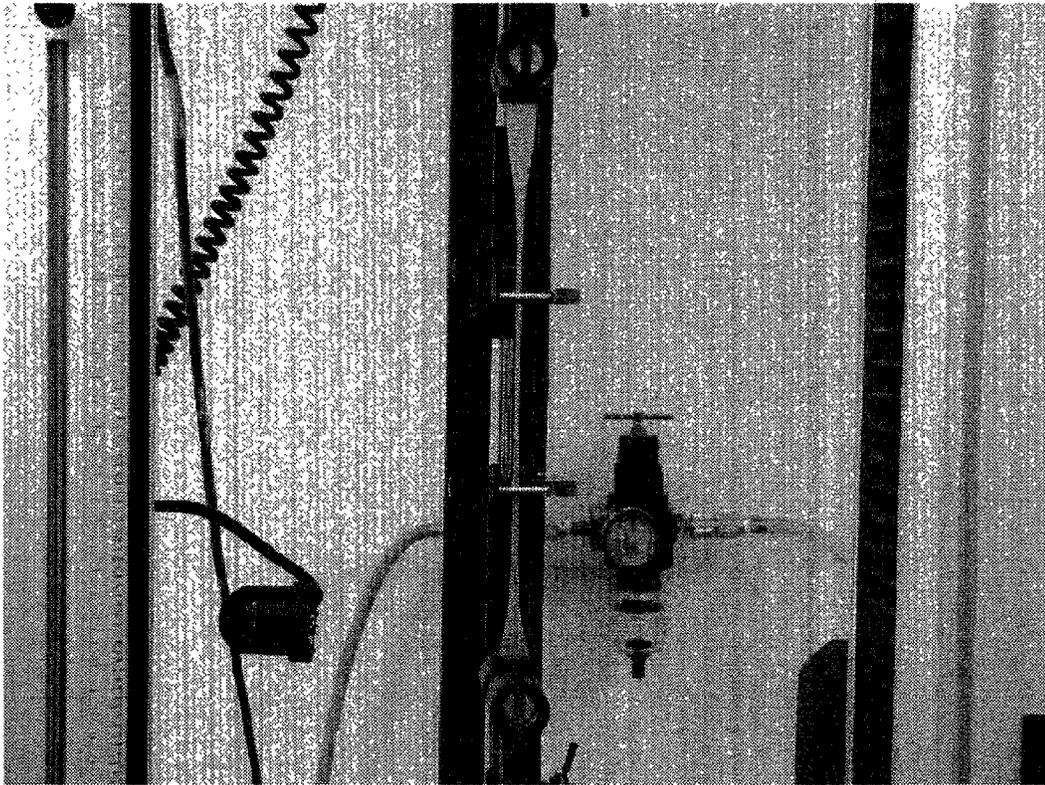
Testing samples were cut from sterile finished devices as specified in Spec. Drawing 800020 Dry Heat Sterilized Smooth Gel-Filled Mammary Performance Specifications or Spec. Drawing 800008 Dry Heat Sterilized Siltex Gel Filled Mammary Performance Specifications (see Appendix 2 of this PMA module for drawings).

The results of the physical testing conducted are provided in the sections below.

#### 4.1 Shell Ultimate Elongation Testing

Mentor tests gel-filled mammary prosthesis shells for ultimate elongation in conformance to ASTM F703-96 Standard Specification for Implantable Breast Prostheses and Mentor's TM 000019 (see Appendix 3 in this PMA module). Shell Ultimate Elongation is a basic material physical property and required by ASTM F703-96. Shell Ultimate Elongation is a measure of how much a sample is stretched when it breaks, which provides an indication of the device's ability to withstand stretching during implantation and *in vivo*.

Ultimate elongation testing was performed on Instron tensile testing equipment according to ASTM D412, Standard Test Methods for Rubber Properties in Tension at room temperature. A dumbbell shaped elastomer sample (whose dimensions are specified in ASTM D412) was cut from a shell using a cutting die. A drop gauge was used to measure the thickness of the sample in the narrowed mid-section of the sample. The sample was inserted into the pneumatic clamps of the Instron and two extensometer clips were attached one inch apart (called the gauge length) to the narrowed mid-section of the sample in order to measure the gauge length at ultimate failure. The pneumatic clamps were then pulled apart at a rate of 20 inches per minute until the sample failed (i.e., snapped apart). The computer provided the calculation for the percent elongation at ultimate failure of the sample (extensometer distance at failure compared to the initial gauge length).



The following elongation data (from Smooth Round Moderate **Plus** Profile devices) represent smooth PMA devices with all process and materials changes as listed in the table in Section 4.0:

Table 4-1: Elongation Testing of Smooth Round Moderate **Plus** Gel-filled Prostheses

Device	Lot Number	Specification (%)	Mean Ultimate Elongation (%) (SD*)	n =
100cc	264885	350 min.	614 (21)	20
250cc	264919	350 min.	654 (27)	20
800cc	264920	350 min.	689 (20)	20

\*Standard deviation

The following elongation data (from Siltex Round High Profile devices) represent smooth PMA devices with all process and materials changes (including) as listed in the table in Section 4.0:

Table 4-2: ----- Round High Profile Gel-filled Prostheses with  
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Device	Lot Number	Specification (%)	Mean Ultimate Elongation (%) (SD*)	n =
450cc	253537	350	601 (41)	20
450cc	253538	350	617 (35)	20
450cc	253539	350	600 (37)	20

\*Standard deviation

The following elongation-----represent texture-----h-----dispersion materials for the shell, ----- gel, as well as ----- materials (see report HS33.980925----- n Appendix 1 of -----):

Table 4-3: ----- x Round Moderate Profile Gel-filled Devices with  
-----

Device	Lot Number	Specification (%)	Mean Ultimate Elongation (%) (SD*)	n =
100cc	188747	350	514 (50)	30
800cc	188748	350	497 (38)	30

\*Standard deviation

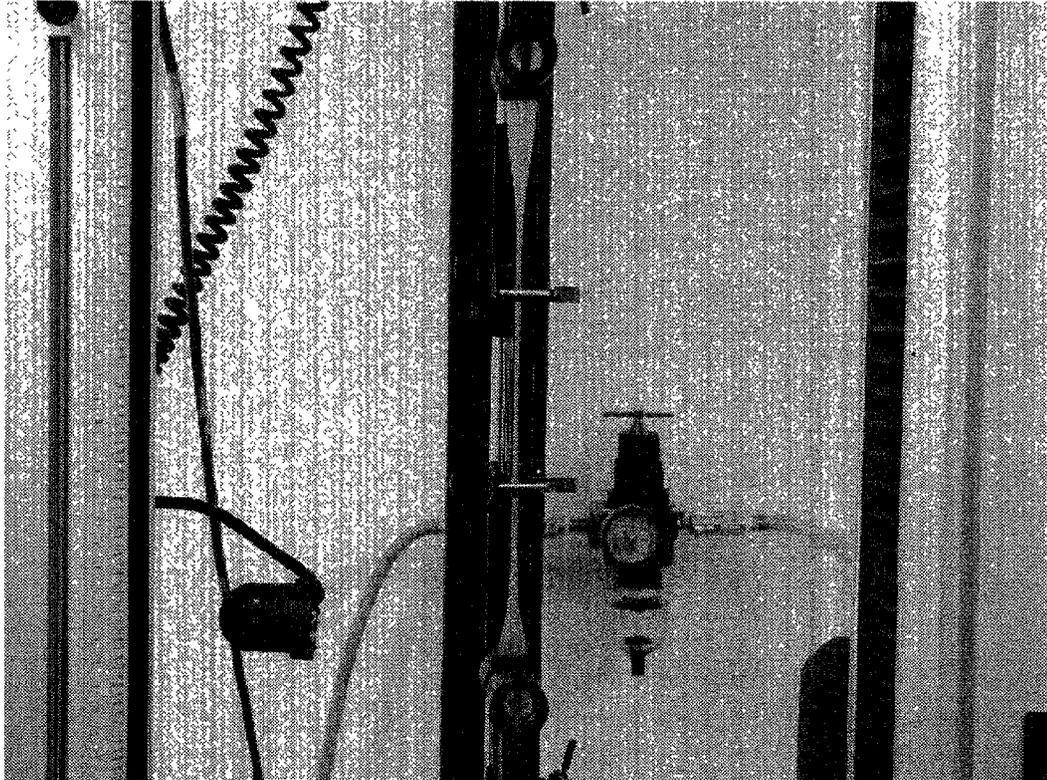
The dat----- r'----- Gel-filled Mammary Prostheses (made with either ----- exceed the ASTM F703-96 minimum require----- el----- Based on these data, it can be concluded that Mentor's devices have high levels of elongation that will aid in withstanding the manipulation and stretching that occurs during surgical placement and *in vivo*.

#### 4.2 Shell Breaking Strength Testing

Mentor tests Gel-filled Mammary Prostheses shells for breaking strength in conformance to ASTM F703-96 and Mentor TM 000019 (see Appendix 3 in this PMA module). Shell breaking strength is a measure of the maximum force applied to a sample before it breaks, and provides an indication of the device's ability to withstand forces during implantation and *in vivo*.

Breaking strength testing was performed on Instron tensile testing equipment according to ASTM D412, Standard Test Methods for Rubber Properties in Tension at room temperature. A dumbbell shaped elastomer sample (whose dimensions are specified in ASTM D412) was cut from a shell using a cutting die. A drop gauge was used to measure the thickness of the sample in the narrowed mid-section of the sample. The sample was inserted into the pneumatic clamps of the Instron and two extensometer clips were attached one inch apart (in order to measure the gauge length at ultimate failure for elongation testing). The pneumatic clamps were then pulled apart at a rate of 20 inches per minute until the sample fails (i.e., snaps apart). A load

cell measures the force necessary to cause the sample to fail in tension. The computer then recorded the force at ultimate failure of the sample.



The following shell breaking strength data (from Smooth Moderate **Plus** Profile devices) represent smooth PMA devices with all process and materials changes as listed in the table in Section 4.0:

Table 4-4: Breaking Strength Testing of Smooth Round Moderate **Plus** Gel-filled Devices

Device	Lot Number	Specification (lbs.)	Mean Breaking Strength (lbs.) (SD*)	n =
100cc	264885	2.5 min.	5.5 (0.3)	20
250cc	264919	2.5 min.	6.0 (0.5)	20
800cc	264920	2.5 min.	7.1 (0.4)	20

\*Standard deviation

The following shell breaking strength data (from Siltex Round High Profile devices) ----- es with all process and materials changes (including ----- - as listed in the table in Section 4.0:

Table 4-5: Break Strength Data for Round High Profile Gel-filled Devices  
with Siltex textured dispersion materials for the shell, as well as other materials (see report HS33.980925)

Device	Lot Number	Specification (lbs.)	Mean Breaking Strength (lbs.) (SD*)	n =
450cc	253537	2.5 min.	7.2 (0.7)	20
450cc	253538	2.5 min.	6.8 (0.6)	20
450cc	253539	2.5 min.	6.6 (0.9)	20

\*Standard deviation

allowing breaking strength data represent Siltex textured dispersion materials for the shell, as well as other materials (see report HS33.980925)

Table 4-6: Break Strength Data for Moderate Profile Gel-filled Devices  
with Siltex textured dispersion materials for the shell, as well as other materials (see report HS33.980925)

Device	Lot Number	Specification (lbs.)	Mean Breaking Strength (lbs.) (SD*)	n =
100cc	188747	2.5 min.	5.7 (0.6)	30
800cc	188748	2.5 min.	6.0 (0.6)	30

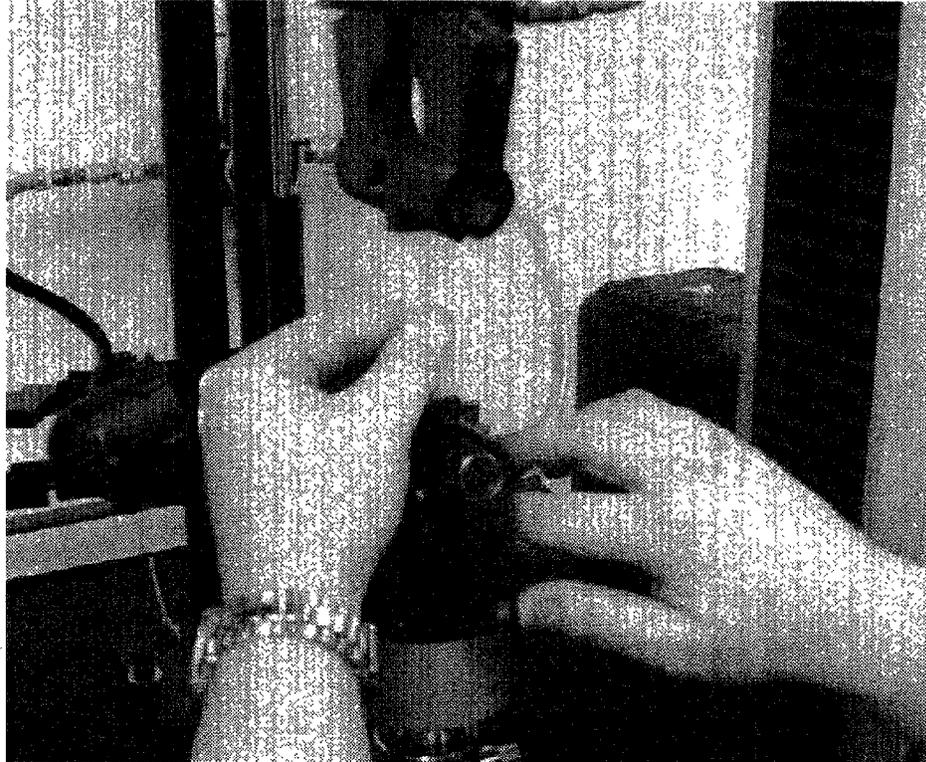
\*Standard deviation

All data show that Mentor's PMA Gel-filled Mammary Prostheses exceed the ASTM F703-96 minimum requirement of 2.5 pounds ultimate shell breaking strength, indicating that the shells will resist the forces applied during insertion and *in vivo*.

### 4.3. Shell Tear Resistance Testing

Mentor tests Gel-filled Mammary Prostheses shells for tear strength in conformance to ASTM D624-00 Standard Test Methods for Tear Strength of Conventional Vulcanized Rubber and Thermoplastic Elastomers and Mentor TM 000109 (see Appendix 3 in this PMA module). Tear resistance testing measures the force required to propagate or continue a tear in a shell once an opening has been made through the shell. This property is most relevant to exposing gel to the surrounding tissues after a shell is punctured. The more resistant a shell is to tearing, the less likely gel will be found outside the device shell.

Shell tear testing was performed on Instron tensile testing equipment according to ASTM D624, at room temperature. A tear testing coupon sample (whose dimensions are specified in ASTM D624) is cut from a shell using a cutting die. A drop gauge was used to measure the thickness of the sample in the center region of the sample where the tear was located. Each end of the sample was inserted into the pneumatic clamps of the Instron. The pneumatic clamps were then pulled apart at a rate of 20 inches per minute until the sample fails (i.e., tears apart). A load cell measured the force necessary to cause the sample to tear in tension. The computer then recorded the force at failure of the sample.



The following shell tear resistance data represent smooth and Siltex PMA devices with all process and materials changes as listed in the table in Section 4.0 (see HS350.021202.03AdD Cumulative Product Performance Qualification (PPQ) for Gel Products Using Teflon Coated Stainless Steel Mandrels, New Calender, SiTech HCE-4750, Laser Engraving and the Reduced Dry Heat Sterilization Cycle – Summary Report – Addendum D in Appendix 1 of this PMA module for the report):

Table 4-7: ----- sistance Testing of Gel-filled Devices with -----  
-----

Device	Lot Number	Specification	Mean Tear Resistance (lbs.) (SD*)	n =
100cc Siltex High Profile	264660	Information Only	4.2 (0.3)	30
100cc Smooth High Profile	264545	Information Only	2.6 (0.2)	30
800cc Siltex High Profile	264546	Information Only	5.3 (0.4)	30

\*Standard deviation

The following tear resistance data ----- nt Siltex texture----- -----  
dispersion materials for the shell, ----- gel, as well as -----  
materials (----- 0302.05 – -----nd Tensile Res-----  
Made with ----- Dispersions and Gel: Vendor Qualification in Appendix 1 of  
this PMA m-----

Table 4-8: Shell Tear Re----- -----Moderate Profile Gel-filled  
Devices with -----

Device	Lot Number	Specification	Mean Tear Resistance (lbs.) (SD*)	n =
100cc	188747	Information Only	3.5 (0.3)	30
800cc	188748	Information Only	4.1 (0.5)	30

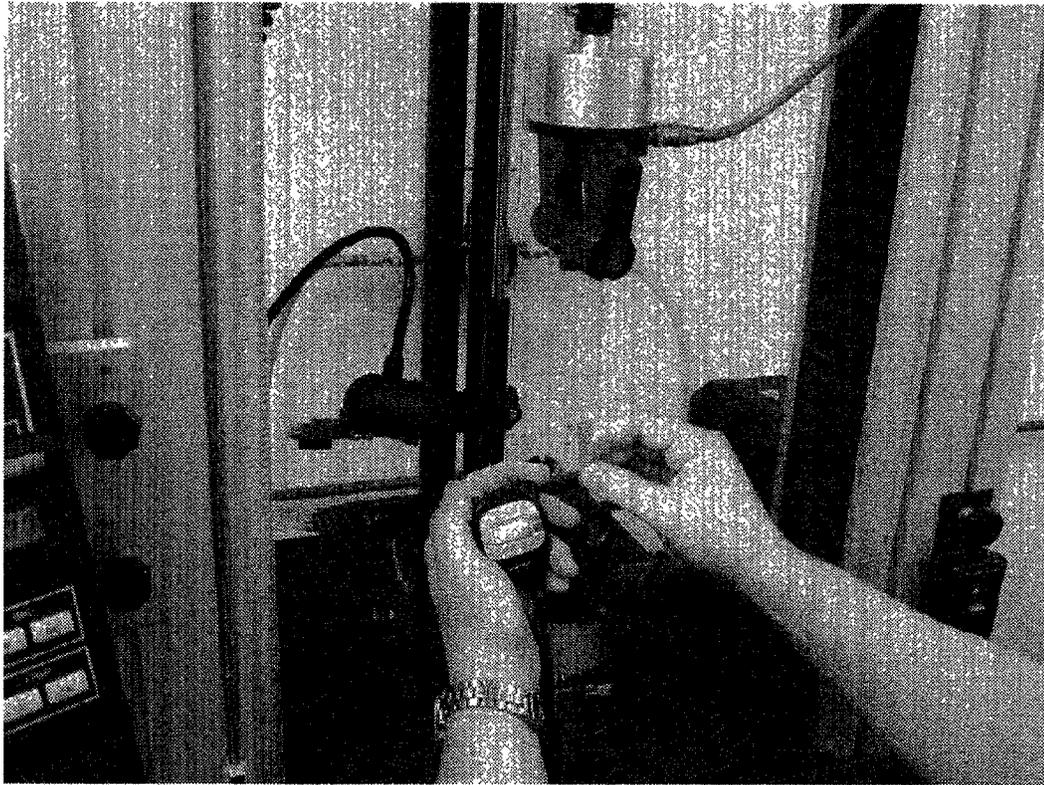
\*Standard deviation

There is no standard minimum specification for shell tear resistance results. The data are provided for informational purposes only and to enable comparison of breast implant shell tear resistance properties when warranted. Even though there are no minimum specifications for this test, it can be concluded that the tear resistances obtained with the shells (2.6–5.3 pounds) will assist in resisting tear propagation.

#### 4.4 Patch-to-Shell Adhered Joint Strength Testing

Patch to Shell Adhered Joint Strength testing consists of testing the ability of the joint to withstand 200% elongation for 10 seconds and subsequently measuring the ultimate joint strength. This testing is performed according to ASTM F703-96 and Mentor TM 000109. Patch-to-Shell Adhered Joint Strength testing is relevant to the devices ability to resist failure of the joint during insertion and in vivo.

Joint testing was performed on Instron tensile testing equipment according to ASTM F703-96, Standard Specification for Implantable Breast Prostheses at room temperature. A dumbbell shaped elastomer sample (whose dimensions are specified in ASTM D412) was cut using a cutting die in such a way as to position the vulcanized joint with some of the attached shell in approximately the center of the test specimen. A 5mm gauge length was then marked from the edge of the patch-to-shell joint to a point on the shell using a pen. The sample was then inserted into the pneumatic clamps of the Instron. The pneumatic clamps are then pulled apart at a rate of 10 inches per minute until the pen marks reach 1.5 cm in distance apart (200% elongation). The sample was then held at that elongation for 10 seconds to determine whether the sample breaks. If the sample does not break (and therefore passes this test), it was then immediately subjected to a continuation of the elongation until the sample broke. A load cell measured the force necessary to cause the sample to fail in tension. The computer then recorded the force at ultimate failure of the sample. The technician also records the location of the failure, i.e. patch, shell, joint.



Twenty devices from each of three lots were tested for their ability to withstand 200% elongation for ten (10) seconds without breaking—all samples passed the adhered joint testing requirement. In addition, once the ten-second period was completed, elongation of each sample was continued until failure and its ultimate joint strength was recorded.

The following patch-to-shell ultimate joint strength data (from Smooth Round Moderate Plus Profile devices----- ices with all process and materials changes (including ----- - as listed in the table in Section 4.0:

Table 4-9: Patch-to-Shell Adhered Joint Strength Testing of Smooth Round Moderate Plus Gel-filled Devices

Device	Lot Number	Specification: Must Withstand 200% Elongation for 10 sec.	Mean Ultimate Joint Strength (lbs.) (SD*)	n =
100cc	264885	Pass	4.5 (0.5)	20
250cc	264919	Pass	4.8 (0.4)	20
800cc	264920	Pass	6.2 (0.5)	20

\*Standard deviation

The following patch-to-shell joint strength data (from Siltex Round High Profile Devices) represent----- ces with all process and materials changes (including ----- as listed in the table in Section 4.0:

Table 4-10: Patch-to-Shell Adhered -----ltex Round High Profile  
Gel-filled Devices with -----

Device	Lot Number	Specification: Must Withstand 200% Elongation for 10 sec.	Mean Ultimate Joint Strength (lbs.) (SD*)	n =
450cc	253537	Pass	6.5 (0.8)	20
450cc	253538	Pass	6.9 (0.6)	20
450cc	253539	Pass	6.1 (0.6)	20

\*Standard deviation

----- o-shell joint strength testing from b----- tured and-----  
----- dispersion materials for the shell, - ----- gel, and -----  
----- ls (see report HS33.980925.03A) h----- performe-----

Table 4-11: Patch-to-Shell Adhered Joint Str----- odate  
Profile Gel-filled Devices with -----

Devices	Lot Number	Specification: Must Withstand 200% Elongation for 10 sec.	Mean Ultimate Joint Strength (lbs.) (SD*)	n =
100cc Siltex	188747	Pass	4.9 (0.8)	30
800cc Siltex	188748	Pass	5.8 (0.8)	29
100cc Smooth	188759	Pass	4.2 (0.4)	30

\*Standard deviation

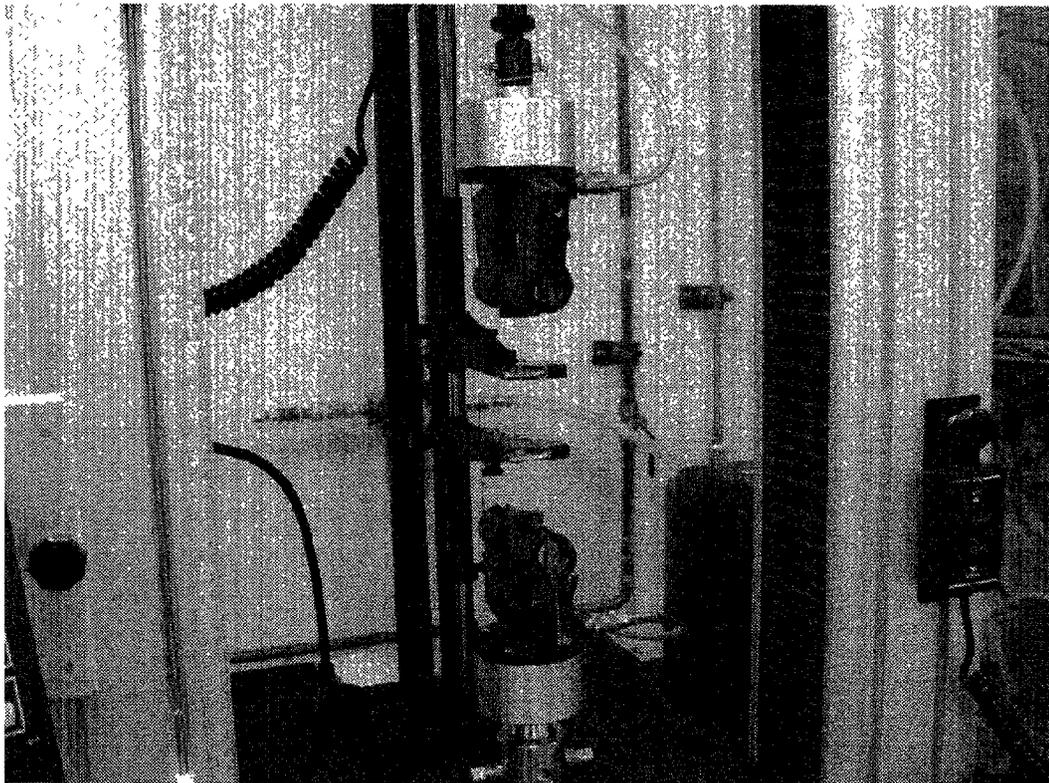
All of the joint strength data show that all samples passed the 200% elongation for 10 seconds ASTM requirement. ASTM does not suggest a minimum ultimate joint strength; howeve-----  
----- length data suggest that the device joint of  
smooth and both ----- devices are stronger than the shell breaking  
strength minimum----- aid in resisting failure due to stresses applied  
during insertion and *in vivo*.

#### 4.5. Shell Tension Set

Mentor tests Gel-filled Mammary Prostheses shells for tension set in conformance to ASTM F703-96 and Mentor TM 000406 (see Appendix 3 in this PMA module). Shell Tension Set is a measure of the shell's ability to recover from a 300% elongation held for three minutes and to return to its original shape after stretching (i.e., resist permanent deformation). The more able the device is to return to its original shape, the less likely the device will produce or show wrinkles or appear to be misshapen *in vivo* after significant elongation.

Tension set testing was performed on Instron tensile testing equipment according to ASTM F703-96, Standard Specification for Implantable Breast Prostheses at room temperature. A dumbbell shaped elastomer sample (whose dimensions are specified in ASTM D412) was cut from a shell using a cutting die. A one inch gauge length (or

benchmark) was marked on the narrowed mid-section of the sample. The ends of the sample were inserted into the pneumatic clamps of the Instron and two extensometer clips were attached at the gauge marks (in order to measure the gauge length while the sample was being elongated). The Instron pneumatic clamps were then pulled apart at a rate of 20 inches per minute until the sample reached 300% elongation. At that point the stretching was stopped and the sample held in that elongated position for three minutes. After that time, the Instron pneumatic clamps were brought back to their original starting position and the sample unloaded from the machine and placed on a flat surface. After a three minute rest period, the length of the original one inch gauge length was re-measured. The tension set was calculated as any increased gauge length divided by the original one inch length.



The following shell tension set data (from Smooth Round Moderate **Plus** devices) represent smooth PMA devices with all process and material changes as listed in the table in Section 4.0:

Table 4-12: Tension Set Testing of Smooth Round Moderate Plus Gel-filled Devices

Device	Lot Number	Specification (%)	Mean Tension Set (%) (SD*)	n =
100cc	264885	< 10	2.9 (0.2)	20
250cc	264919	< 10	3.0 (0.2)	20
800cc	264920	< 10	2.1 (0.2)	20

\*Standard deviation

The following shell tension set data (from Siltex Round High Profile d----- devices with all process and material changes (including ----- as listed in the table in Section 4:

Table 4-13: ----- x Round High Profile Gel-filled Devices with -----

Device	Lot Number	Specification (%)	Mean Tension Set (%) (SD*)	n =
450cc	253537	< 10	4.0 (0.6)	20
450cc	253538	< 10	4.2 (0.6)	20
450cc	253539	< 10	3.7 (0.2)	20

\*Standard deviation

The following tension ----- are ----- th ----- dispersion materials for the shell, ----- gel ----- m----- (see report HS33.980925.03A):

Table 4-14: Tensi----- Round Moderate Profile Gel-filled Devices with -----

Device	Lot Number	Specification (%)	Mean Tension Set (%) (SD*)	n =
100cc	188747	< 10	3.3 (0.1)	30
800cc	188748	< 10	3.3 (0.1)	30

\*Standard deviation

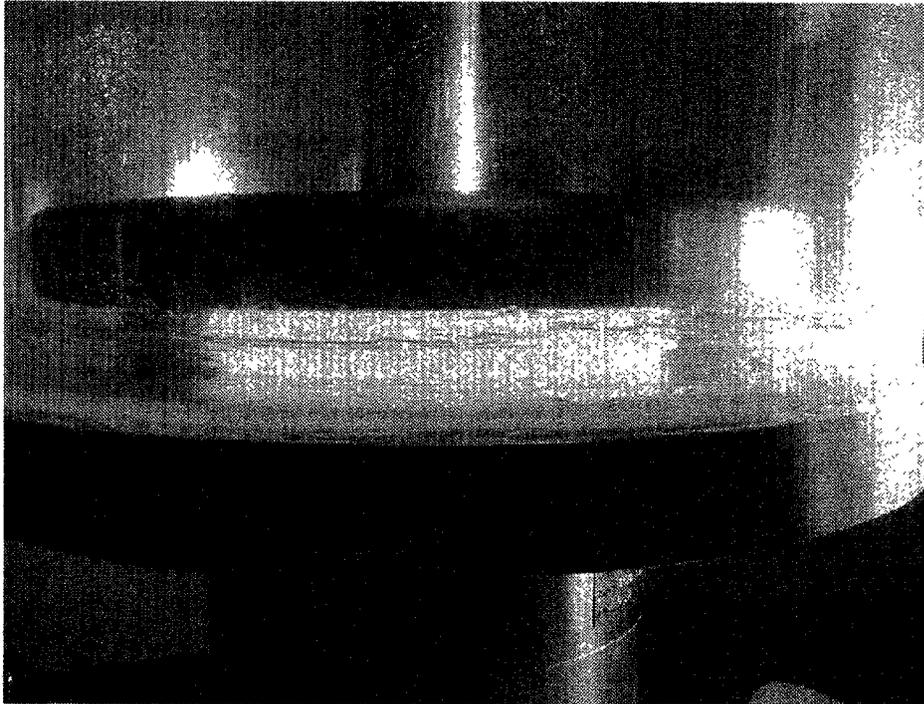
All data show that Mentor's ----- stheses shells both smooth and those made with either ----- have tension sets that fall well below the ASTM F703 ----- 0%, indicating their ability to recover from significant stretching.

#### 4.6 Fatigue Rupture

Breast implants experience various kinds of mechanical loading *in vivo*. The stresses caused by normal everyday activities such as walking or breathing are the most common and occur in a repetitive fashion for extended periods of time during the useful life of the implant. These stresses are best modeled as fatigue stresses in fatigue testing experiments.

Cyclic fatigue testing of gel mammary implants has been completed to fulfill the requirements of FDA's Guidance for Saline, Silicone Gel, and Alternative Breast Implants; Guidance for Industry and FDA for Premarket Approval application (see report M 028 Cyclic Fatigue Analysis of Silicone Gel-filled Mammary Implants in Appendix 1 of this PMA module). Experiments were performed to determine the number of cycles for various loads at which devices fail or rupture and the endurance load at which devices do not fail (the latter also called the endurance limit). Mentor defines the endurance limit as the highest maximum measured load at which a device can endure ten million fatigue cycles without rupture. Using the fatigue endurance limit, a safety factor was calculated by comparing the experimentally determined fatigue endurance limit to an estimated typical *in vivo* load.

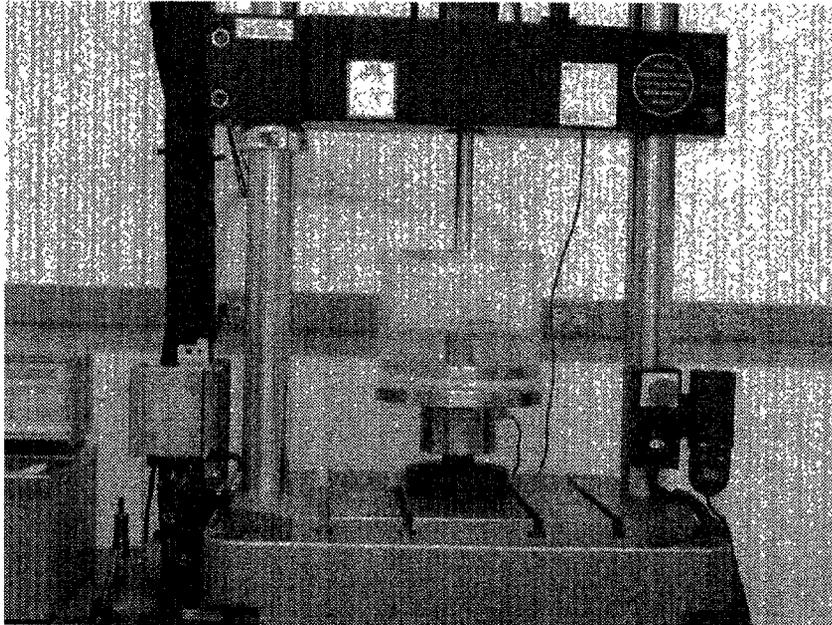
Cyclic fatigue testing is conducted utilizing Instron servohydraulic testing equipment configured with a parallel plate fixture enclosed in a testing chamber containing saline at 37° C. For a fatigue test, the top plate moved up and down in order to apply a cyclical load to the device which was located between the plates. The bottom plate was attached to a compression load cell in order to measure the load applied to the device. Foam sheeting was placed between the device and each plate to prevent abrasion of the shell surface by the metal plates.



For cyclic fatigue testing the servohydraulic tester was operated in load control (20–100-pound maximum load including a 10 pound holding load). Devices tested were Smooth Round Moderate Profile Gel-Filled Mammary Implants (100 cc), Siltex Round Moderate Profile Gel-Filled Mammary Implants (100 cc) and Siltex Round High Profile Gel-Filled Mammary Implants (125 cc). Devices tested were dry heat

sterilized finished product. These samples were assembled representing minimum thickness and minimum textured Load and red for each test.

Applied force versus number of cycles to failure (AF/N) curves were constructed for device styles by varying the load amplitude during cyclic fatigue testing and determining the number of cycles at failure for the different loads. The endurance limit load was experimentally derived by determining the maximum load at which a device could endure ten million fatigue cycles without failure. All endurance limit testing was performed at a speed of five cycles per second (5 Hz) and most AF/N curve testing was performed at a speed of 1 Hz.



Devices exhibited fatigue failure for a load range of 30–100 pounds with corresponding cycles-to-failure of  $N \sim 10^4$ – $10^6$  (see Figures 4-1 to 4-3). Typically, a minimum of three load amplitude level tests resulting in failure was conducted for each device. The endurance limit tests that did not result in failure at run out ( $10^7$  cycles) exhibited maximum loads of 20 and 30 pounds for smooth and textured devices respectively. Failure modes were usually characterized by a small tear located in the radial region of the device.

Safety factors were calculated by dividing a device's maximum endurance limit load by its calculated maximum *in vivo* load during walking for the smallest and largest smooth and textured devices. The endurance limit loads for the largest devices were assumed to be the same as that found for the small devices tested. Testing the smallest device was deemed the worst case as they are subjected to a higher stress *in vivo* than the largest devices for a given load because larger devices tend to have thicker shells.

(Stress equals the load on the shell divided by the cross sectional area of the shell.) Based upon the above information, the safety factor ( $S_f$ ) was determined to be  $S_f \sim 5-8$  for the largest volume devices and  $S_f \sim 43-65$  for the smallest volume devices (see Table 4-15).

The large difference in safety factor for small versus large devices is not unexpected since the safety factor is dependent on the calculation of the endurance limit (assumed to be the same for a large device and a small device) divided by the calculated *in vivo* load on the device.

$$\text{Safety Factor}(S_f) = \frac{\text{Endurance Load}}{\text{In Vivo Load}}$$

The calculated load *in vivo* on a large device is larger than a small device; therefore, the safety factor for a large device will be much smaller than for a small device.

All of these safety factors exceed the minimum safety factor of two as agreed upon between Mentor and FDA in the testing protocol. The data suggest that the *in vitro* endurance limit of the devices is greater than the estimated *in vivo* load applied to a device during the common fatigue activity of walking.

Table 4-15: Device Safety Factors

Device	Size (cc)	Safety Factor Specification	Endurance Limit Load (lbs.)	<i>In Vivo</i> Load (lbs.)	Safety Factor*
Smooth Rnd. Moderate Profile	100	2 min.	20	0.46	43.5
	800	2 min.	20	3.67	5.4
Siltex Rnd. Moderate Profile	100	2 min.	30	0.46	65.2
	800	2 min.	30	3.67	8.2
Siltex Rnd. High Profile	125	2 min.	30	0.57	52.6
	800	2 min.	30	3.67	8.2

\* Safety Factor = Endurance Limit Load/*In Vivo* Load

In addition to cyclic fatigue, single stroke compression tests were also performed. Single stroke compression testing applied a single compressive stroke to a device located between the parallel plates of the servohydraulic tester in order to determine the maximum load necessary to rupture the device (i.e., monotonic rupture). This testing was performed at 23° C.

Monotonic compression results indicate that Smooth and Siltex Round Moderate Profile and Siltex High Profile Gel-Filled Mammary Implants exhibited rupture at a mean of 380 and 452 pounds, respectively (see Table 4-16). As a worst case comparison, for a woman weighing 300 pounds approximately 75 pounds of force would be compressing the device if she was lying on her chest (i.e., one-quarter of the body weight). Since the device static rupture exceeds 75 pounds, the device will be able to withstand the worst everyday compressive forces expected to occur *in vivo*.

Table 4-16: Monotonic Rupture Testing

<b>Device</b>	<b>Size (cc)</b>	<b>Specification (lbs.)</b>	<b>Load at Rupture (lbs.) (SD*)</b>
Smooth Rnd. Moderate Profile	100	Information Only	380 (30)
Siltex Rnd. Moderate	100	Information Only	452 (31)

\*Standard deviation

Figure 4-1 Cyclic Fatigue Testing of Smooth Round Moderate Profile Gel-Filled Mammary Implants

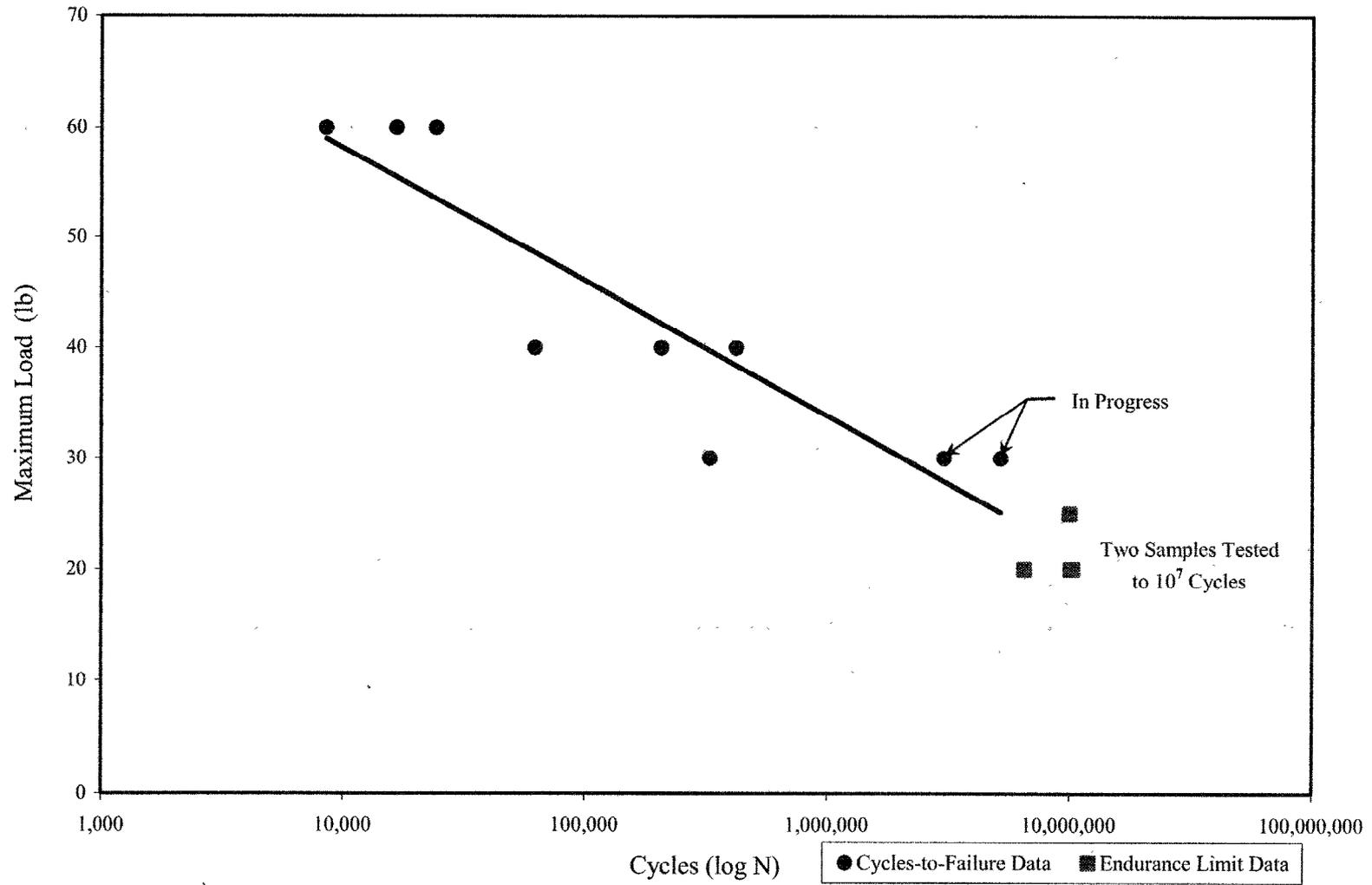


Figure 4-2 Cyclic Fatigue Testing of Siltex Round Moderate Profile Gel-Filled Mammary Implants

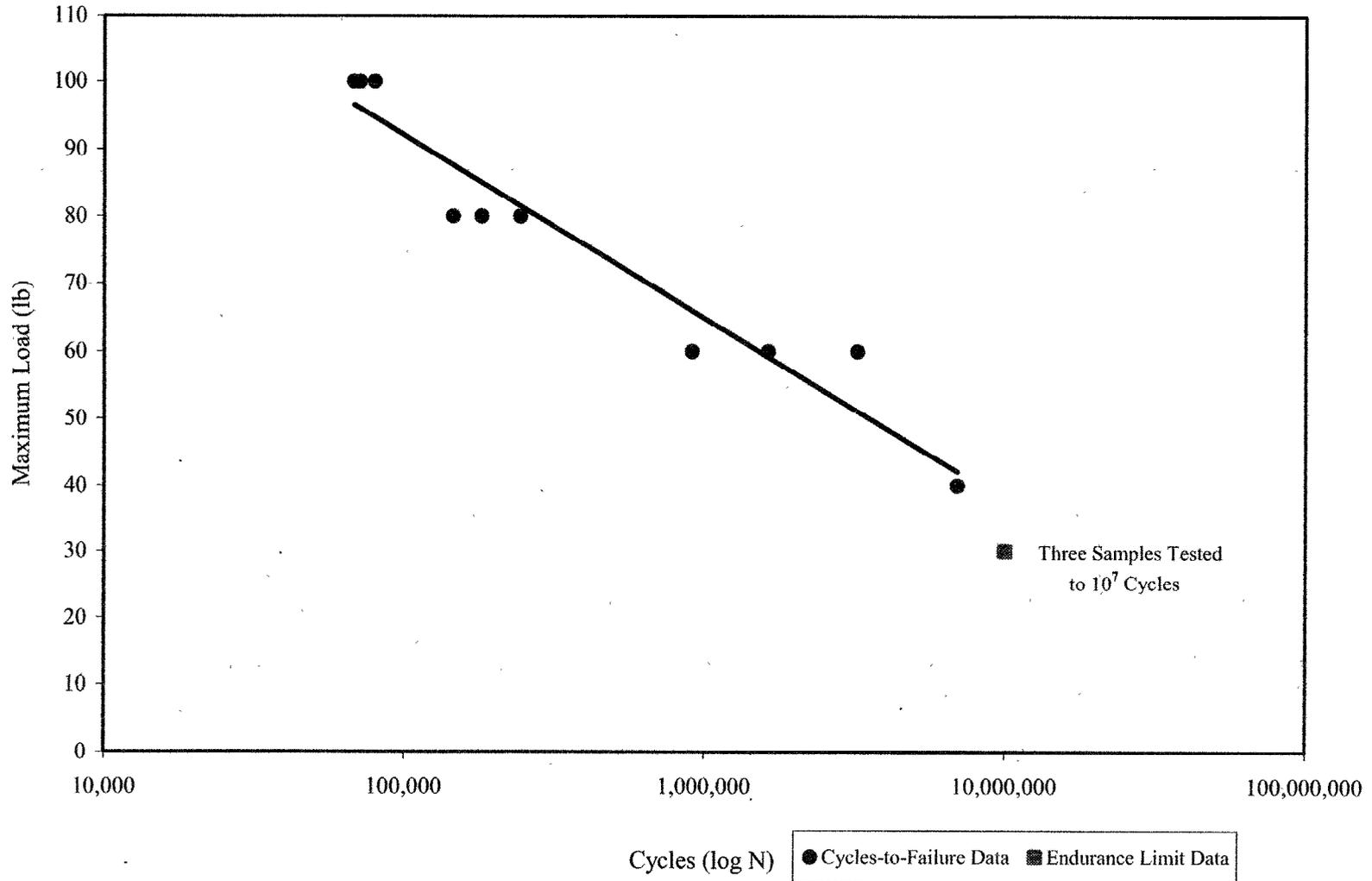
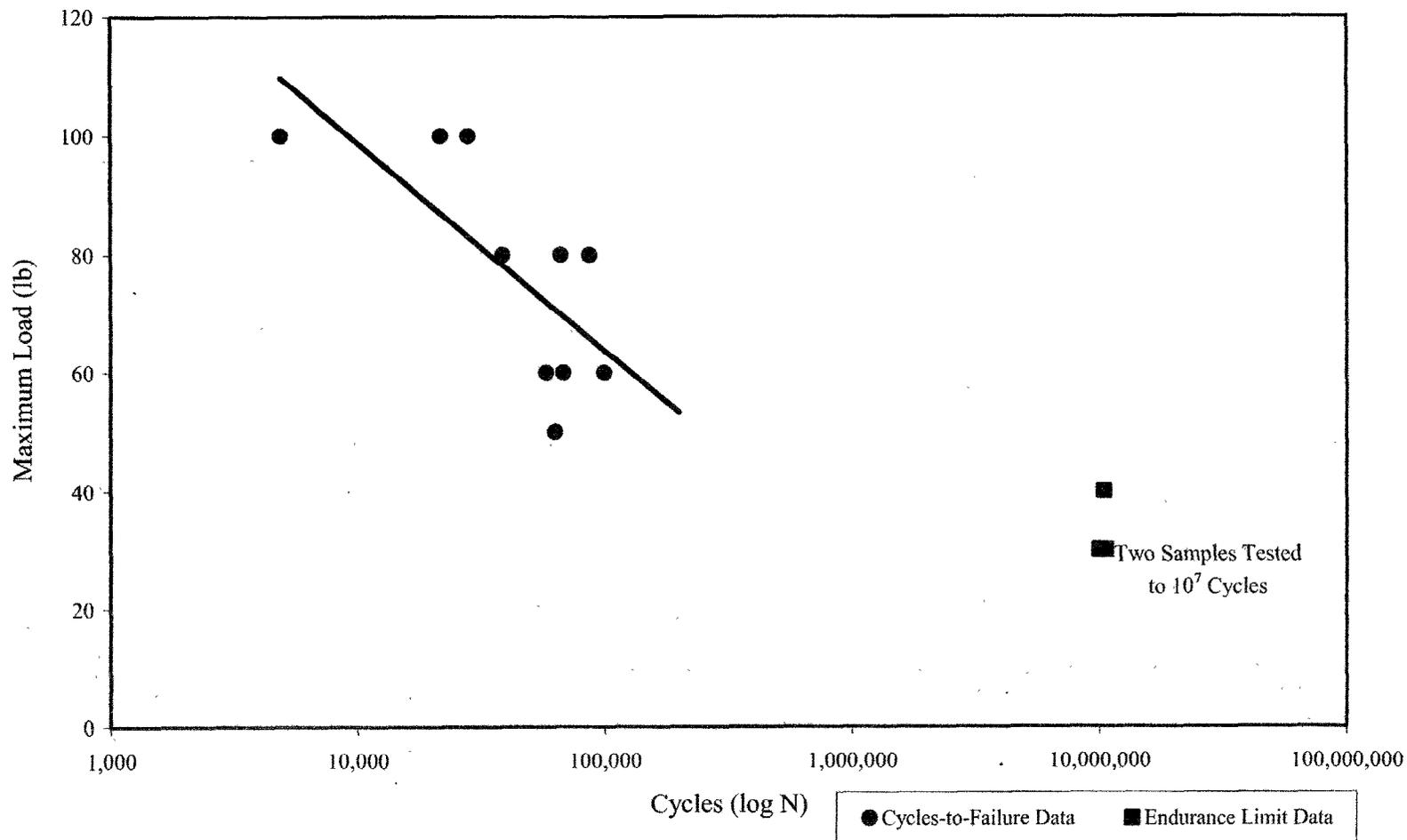


Figure 4-3 Cyclic Fatigue Testing of Siltex High Profile Gel-Filled Mammary Implants



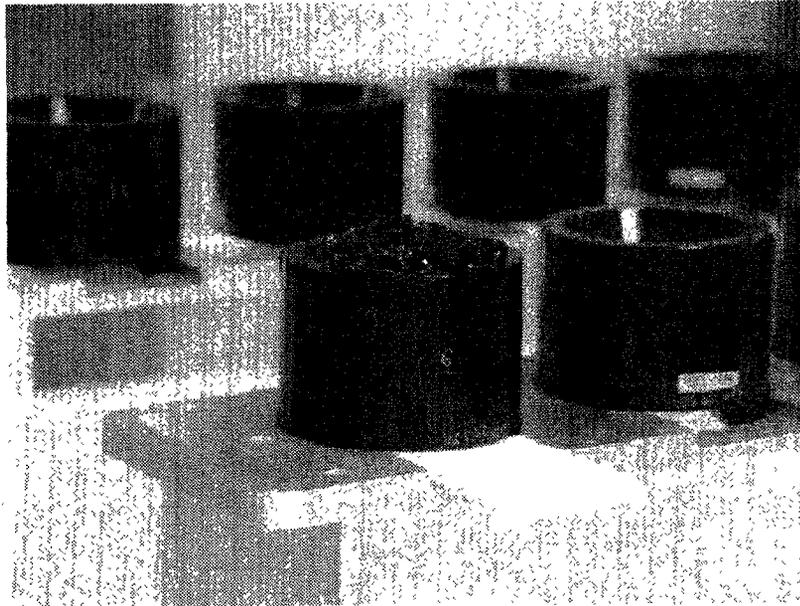
## 4.7 Cohesivity of Silicone Gel

Cohesivity of silicone gel is evaluated through three different tests: Gel Cohesion, Penetrometer, and Gel Rheology testing. Gel cohesion is a measure of the tendency of a gel to resist flow. Penetrometer test data provide an assessment of the stiffness of a gel and an indication of the cross link density of the gel. Gel Rheology testing also provides measures of gel cohesion and extent of cross linking. Additional testing beyond that required by ASTM was performed through gel rheology.

### 4.7.1 Gel Cohesion Testing

Mentor performs sterile finished device gel cohesion testing using the ASTM F703-96 Cone/Pendant Gel Test Method and Mentor TM 000366 (see Appendix 3 in this PMA module). Gel cohesion is a measure of the tendency of a gel to resist flow. Cohesiveness is related to viscosity, or thickness of the gel. Gel cohesion is an important property for a material used in breast implants because cohesion can be varied to help mimic the feel of natural breast tissue. Additionally, gel cohesion limits to some extent the tendency for the gel to flow in the event of shell rupture.

A single intact mass of gel weighing between 98 and 105 gms taken from a sterilized finished device was placed into a conically shaped test fixture with dimensions as specified in the ASTM document. The gel in the test fixture was left undisturbed for ten minutes with the bottom of the conically shaped test fixture sealed. After that time period, the bottom of the fixture is opened to allow the gel to flow and hang down through the opening. Movement through the hole resulting in a length of gel to hang below the test fixture is dependent on the cohesivity of the gel. After a thirty minute period in the open position, the length of gel hanging from the bottom of the testing apparatus was measured. If the pendant length of gel is less than 4.5 cm, the gel passed the cohesion test.



**Gel Cohesion Test**

Gel testing was performed on sterile Smooth Moderate **Plus** Profile finished devices produced as part of report HS72.030718.02 (see Appendix 1 of this PMA module).

Table 4-17: Gel Cohesion Testing of Smooth Moderate **Plus** Profile Gel-filled Devices

Device	Lot Number	Specification (cm)	Mean Gel Cohesion (cm) (SD <sup>1</sup> )	n =
100cc	264885	<4.5	---- <sup>2</sup>	----
250cc	264919	<4.5	0 (0)	20
800cc	264920	<4.5	0 (0)	20

<sup>1</sup>Standard deviation

<sup>2</sup>Gel cohesion testing cannot be performed on 100cc devices due to a lack of gel volume in the device

The gel testing was performed on sterile Siltex Round High Profile devices produced as part of report HS350.021202.03 (see Appendix 1 of this PMA module).

Table 4-18: Gel Cohesion Testing of Siltex Round High Profile Gel-filled Devices

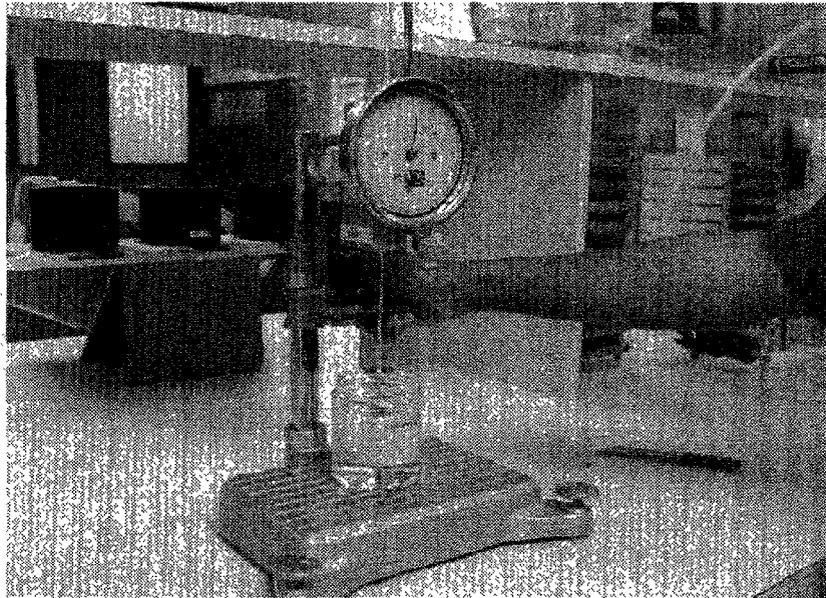
Device	Lot Number	Specification (cm)	Mean Gel Cohesion (cm) (SD*)	n =
450cc	253537	<4.5	0.1 (0.3)	20
450cc	253538	<4.5	0 (0)	20
450cc	253539	<4.5	0 (0)	20

\*Standard deviation

The data show that cured gel from Mentor's smooth and textured gel-filled mammary implants exhibits adequate cohesion and meets the ASTM F703-96 requirement of less than 4.5 cm of pendant gel. The more cohesive the gel within the device, the less propensity for it to flow through a hole in the shell. In-process and finished goods quality assurance testing ensures that each lot meets specifications for silicone gel cohesion.

#### 4.7.2 In-process Penetrometer (or Texture Analyzer) Testing

Penetrometer testing measures the ability of a given weight of given diameter to penetrate into a jar of gel in a given time. Penetrometer data provide an indirect assessment of the cross link density of the gel by measuring gel stiffness. Less cross linking than desired could result in a more easily flowing gel. This is particularly relevant if the gel escapes the shell through a rupture. If the penetrometer reading and cross link density are higher than desired, the gel could be too hard or stiff than is cosmetically acceptable.

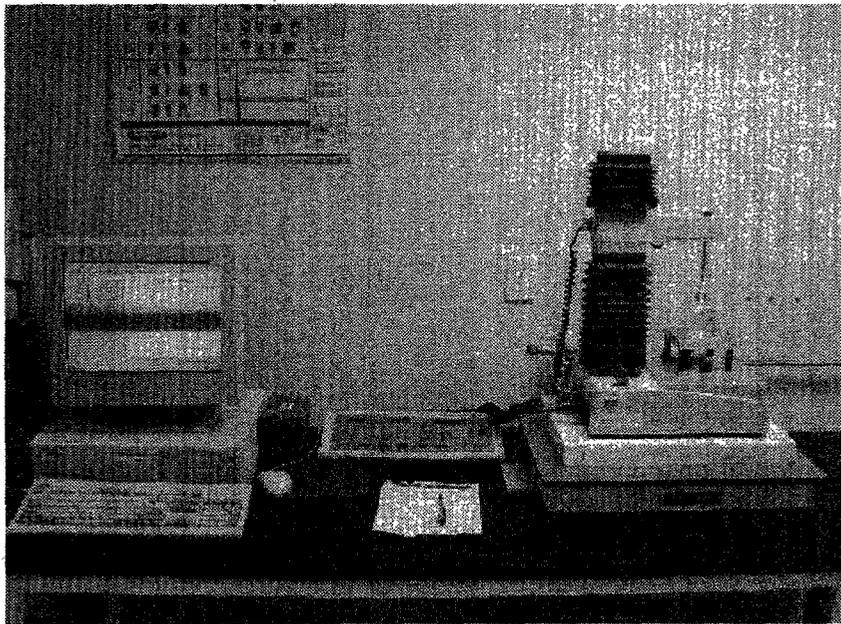


#### Penetrometer Test

Mentor's penetrometer testing utilized a modified American Society for Testing and Materials (ASTM) Cone Penetrometer. The device placed a weighted plunger/head onto the surface of a gel and recorded how far into the gel the plunger/head penetrated after a given amount of time. The equipment used for Mentor's testing was operated identically to the ASTM version, and used a flat head plunger assembly, that was 14.5 grams in weight and 1 inch in diameter, to measure the gel penetrometer. This plunger/head configuration was developed and used by Dow Corning to determine the stiffness of their gel materials.

In order to produce consistent results, the gel was cured in a standardized glass jar to produce a smooth flat gel surface. The penetrometer head assembly was gently placed on the surface of the gel and then the measuring head released by the operator and allowed to penetrate for five seconds. The penetrometer records the head's penetration into the gel in tenths of a millimeter.

Mentor has also validated the use of a Texture Analyzer (Stable Micro Systems, Ltd.) to measure the stiffness of silicone gels during the manufacturing process. The Texture Analyzer uses the same general principles to measure a gel's stiffness as the penetrometer, but is more automated thus limiting chances for operator error. The device utilizes a load cell mounted on a crosshead assembly and a one inch diameter cylinder probe to measure the penetration properties of the gel. The Texture Analyzer delivers a pre-programmed amount of force for a pre-determined amount of time to perform the gel penetration test. The gel material for testing is cured in a standardized glass jar to ensure a smooth flat gel surface. The results are computer generated and expressed as tenths of a millimeter penetration. As part of the Texture Analyzer validation, it was determined that both this method and the penetrometer method produced equivalent results when testing the same gel lot.



Texture Analyzer

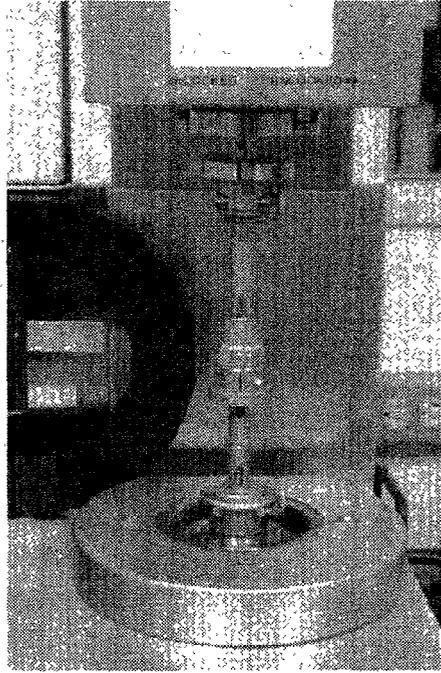
In-process penetrometer testing, TM000385, (or alternatively texture analyzer testing, TM000410) is performed as part of the routine manufacturing process to ensure that every device gel lot has been cured to specification. During the device manufacturing process, after devices have been filled with uncured gel, a standard container is also filled with an amount of uncured gel and placed into the curing

ovens along with the lot of devices. That container is used for penetrometer (or texture analyzer) testing as the means to determine that the gel in the device lot has been properly cured to the required specification. The cured gel acceptance specification of ----- for the penetrometer or texture analyzer can be found in Drawing 40059----- Appendix 2 of this PMA module). In-process quality assurance testing ensures that samples meet the acceptance criteria on each lot.

#### 4.7.3 Gel Rheology Testing

Rheological characterization has been performed on mammary implant finished product gel filler for characterization of extent of crosslinking and cohesion (see Report M 033 Extent of Crosslinking of Gel Mammary Implant Filler). The extent of gel crosslinking is related to manufacturing process control and reproducibility. Cohesion is related to the degree to which gel matrix constituents stick together tightly.

The rheometer twists the sample and measures the resultant load or torque. Gel filler was obtained directly from a finished product device and approximately 1 g was loaded between parallel plates of the fixture. The experiment was performed controlling the frequency of twisting, a parameter directly related to shear rate or tearing of the gel. Several experimental parameters were measured: complex modulus ( $G^*$ ), storage modulus ( $G'$ ), elastic modulus ( $G''$ ) and complex viscosity ( $\eta^*$ ). The magnitude of a calculated value called the crossover modulus (or  $G'/G''$ ) which is derived from two of the measured moduli was directly proportional to the extent of crosslinking. The magnitude of the complex modulus and complex viscosity were directly proportional to gel cohesiveness.



Several device gel fillers were chosen for rheological characterization. Devices included Siltex Round Moderate Profile Gel Mammary Implants (size 100 cc, 300 cc and 325 cc). Each size represented a separate manufacturing lot. Accordingly, lot-to-lot variance was also evaluated from test results. Three devices were selected from each lot, and three replicate determinations were performed for each device. Since gel filler is processed identically for Smooth and Siltex Moderate Plus and High Profile Gel Mammary Implants, the above devices were considered representative of all Mentor Gel-Filled Mammary Implants.

Results are summarized in Table 4-19. The crossover modulus exhibited a value of  $G'/G'' \sim 1425 \text{ dyn/cm}^2$ . Statistical comparison (F and t-Test) of all three lots indicated the same sample population demonstrating reproducibility of manufacturing process control. In addition a complex modulus of  $G^* \sim 5125 \text{ dyn/cm}^2$  and corresponding complex viscosity of  $\eta^* \sim 51 \text{ P}$ , both measured at frequency  $f = 100 \text{ rad/s}$ , are representative of the gel filler cohesiveness.

Table 4-19 Summary of Rheology Results: Lot-to-Lot Variance

Description	Crossover Modulus	Mean X	Standard Deviation s
	G'/G" (dyn/cm <sup>2</sup> )		
Siltex Round Moderate Profile Gel Mammary Implant 100 cc (L/N 251121)	1416	1396	67
	1451		
	1321		
Siltex Round Moderate Profile Gel Mammary Implant 300 cc (L/N 257949)	1617	1473	153
	1490		
	1312		
Siltex Round Moderate Profile Gel Mammary Implant 325 cc (L/N 257950)	1386	1401	46
	1364		
	1452		

In conclusion, gel cohesivity as determined by gel cohesion testing and penetrometer testing show that the gel meets the appropriate specifications and will help the device mimic actual breast tissue and resist movement of the gel in the event of shell rupture.

#### 4.8 Bleed Rate of Silicone Gel

Gel bleed testing of sterile Smooth Moderate Profile Gel-filled Mammary Prostheses has been performed using the bleed testing method specified in ASTM F703-96, Appendix X2. Measuring the gel bleed through a shell is requested in Section 6.5 of FDA's Guidance for Saline, Silicone Gel, and Alternative Breast Implants; Guidance for Industry and FDA (February 11, 2003), which mentions the ASTM F703 method.

Gel bleed testing is performed *in vitro*. As noted in ASTM F703-96, the "test protocol details a method to evaluate the diffusion of silicone gel through the silicone elastomeric membrane or shell of silicone gel-filled mammary implants. This diffusion is commonly referred to as 'gel-bleed'."

The results of such testing can be used for "comparison of gel bleed diffusion rates of various product configuration in a laboratory setting" (ASTM F703-96). It is critically important to note, however, as the ASTM standard clearly states, that "The results of this bleed test method can not be correlated with the actual physiological performance of an implant since the chemical gradient is not replicated." This point is reiterated in the test method summary which states that "test results, however, are not intended to be indicative of the actual *in vivo* situation." In explaining this further, ASTM notes that "since the silicone disk, implant shell and implant gel are similar in chemical composition and structure (primarily polydimethylsiloxane), the diffusion of gel bleed through the implant shell into the silicone disk is accelerated in comparison to other collection media due to the lower surface transport gradient." This exaggeration of gel bleed over what would be encountered *in vivo* (further enhanced by the elevated temperature of 110° F employed) is well known among researchers in the field.

The actual *in vivo* environment surrounding the mammary implant includes both extracellular fluid and a fibrous capsule. It is well recognized that the components of silicone bleed, including low molecular weight silicone extractables, are not appreciably soluble in water (most are in fact virtually insoluble in water). Therefore, "silicone bleed" would tend to accumulate on the surface of the device and eventually slow or stop the silicone bleed process due to the lack of a diffusion gradient, since diffusion is driven by a concentration gradient or difference through the shell. (In the gel bleed test, in contrast, silicone filler diffuses continuously from the high concentration area inside the shell to the lower concentration region of the silicone elastomer pad.)

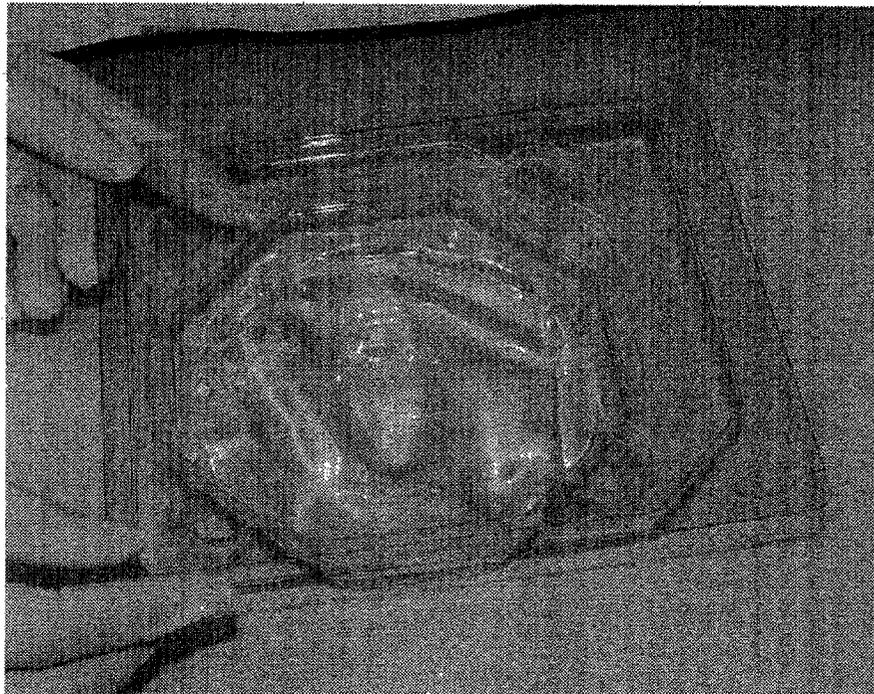
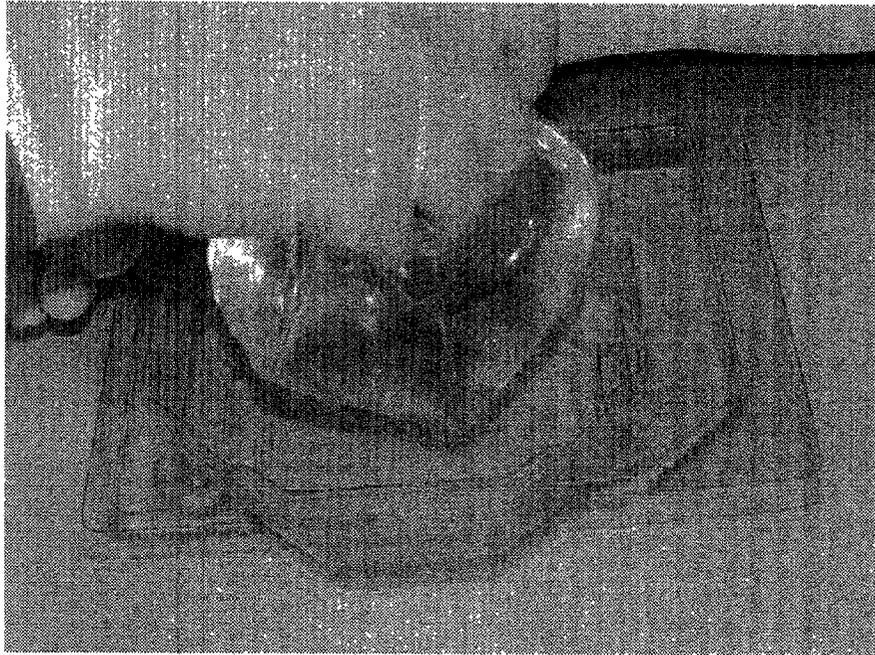
The ASTM F703-96 testing standard, reapproved in 2002, represents what is considered by biomaterials scientists to be the best available method to date. Nevertheless, ASTM notes in the testing standard that "Attempts to devise a test method representative of the aqueous *in vivo* environment by ASTM to date, have been unsuccessful." Indeed, attempts to develop a truly representative method for quantifying bleed rates have been ongoing since the early 1970s.

The utility of the ASTM 703-96 gel bleed test method, however, rests in its ability to generate measurable quantities of diffusion over relatively short periods of time and provide reproducible comparative results to elastomer shells that have been in clinical use for many years. The specifics of the method are detailed below.

An intact device shell surface was wiped clean using isopropyl alcohol. Silicone discs (50 mm diameter made from 70 durometer platinum cured silicone sheeting, 0.125 inches thick) were immersed in isopropyl alcohol and scrubbed to remove all possible foreign surface material. The cleaned discs were then equilibrated at 110<sup>0</sup>F for a minimum of 12 hours. To begin a test, a disk was removed from the incubator and allowed to equilibrate at room temperature for an hour prior to being weighed (to ± 0.0001 g). The disk was then placed on a flat surface in a test container, and the cleaned device placed patch side up on the silicone disk. A good contact between the disk and the device was ensured with no shell folding or wrinkling. The container with device was placed into the 110<sup>0</sup>F incubator along with an equal number of environmental control disks in containers. At weekly intervals, the containers were removed from the incubator. The device was removed from the container and the disc allowed to equilibrate for one hour at room temperature and humidity. The disc was weighed and then returned to the container (with the same disc side facing up). The device was replaced onto the disc, patch side up. The environmental control samples were also weighed each week using the same procedures followed for the device bleed discs. Bleed and bleed rate were calculated according to the ASTM specified method which uses the control discs to adjust for absorption of humidity into the silicone bleed test disc. The test was performed for a total of eight weeks as specified by the ASTM procedure and then continued out to 15 weeks.

This PMA covers several models -----  
-----  
-----

----- the silicone bleed rate of the other smooth device styles as well. Per ASTM F703-96 X2.1.5, that bleed testing method is not applicable to textured surface devices; therefore, textured surface device bleed testing was not performed. Textured devices are not tested because the textured surface is non uniform, and therefore it is not possible to calculate the surface area of a textured device. The total surface area of the textured surface cannot be made to contact the pad used to absorb the gel bleed, and therefore the rate of gel bleed would be dependent only on the surface area touching the pad.



Bleed testing per ASTM F703-96 is reported in report HS72.030826.01(Revision AdB) Engineering Study Report for Evaluation of Gel Bleed for Mentor Gel Filled Implants (see Appendix 1 of this PMA module). Smooth Round Moderate Profile Gel-filled Implants (350cc), catalog #350-7350BC, from finished goods inventory were tested. Table 4-20 shows the gel bleed data expressed as cumulative average weight of gel diffusion per surface area ( $W_g$ ) and average weight of gel diffusion per surface area per week ( $R_g$ ). The testing is reported through eight weeks per ASTM F703-96 and an additional seven weeks for additional information. Figure 4-4 shows a graphical representation of  $R_g$ , silicone bleed rate per week over the 15 week test period. The average shell thickness was ----- inches.

Table 4-20 Average Weight of Gel Diffusion Per Week

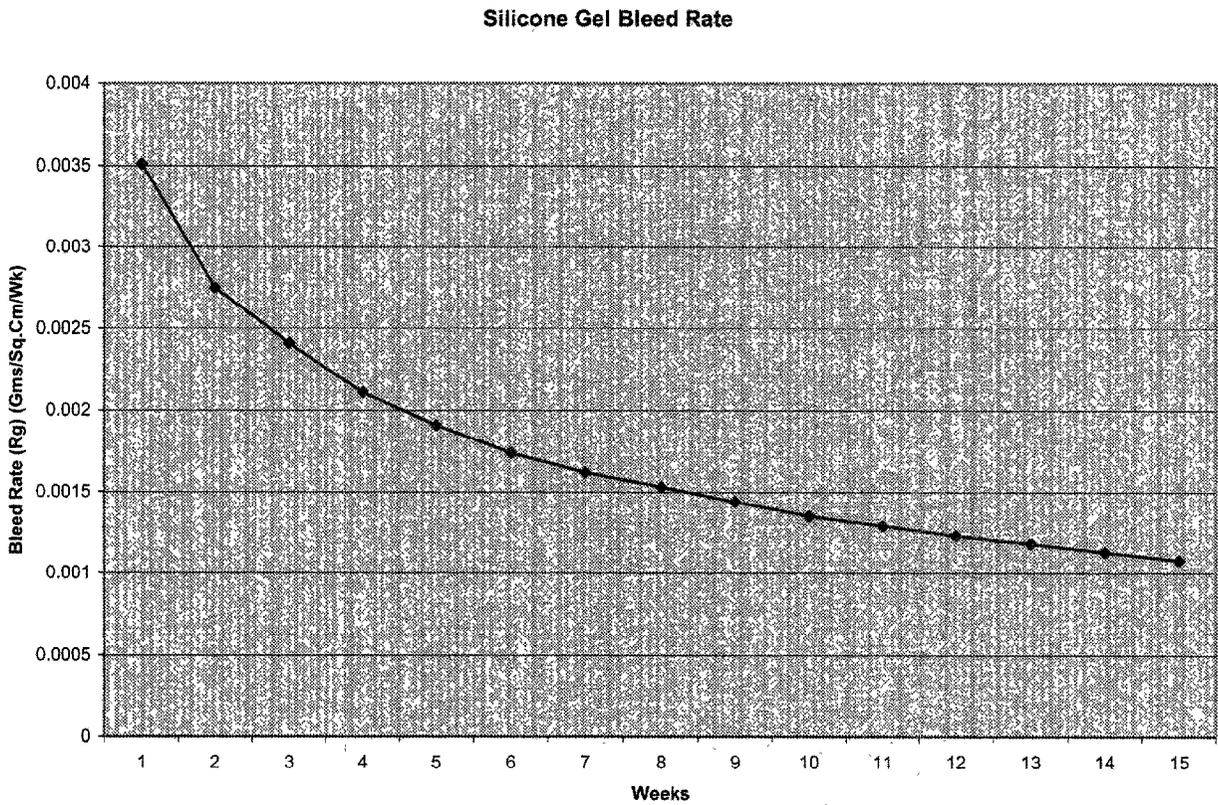
	TESTING INTERVAL								
	Wk 0	Wk 1	Wk 2	Wk 3	Wk 4	Wk 5	Wk 6	Wk 7	Wk 8
$W_g^*$ (g/cm <sup>2</sup> )	0	0.0035	0.0055	0.0072	0.0085	0.0096	0.0105	0.0114	0.0123
$R_g^{**}$ (g/cm <sup>2</sup> /wk)	0	0.0035	0.0028	0.0024	0.0021	0.0019	0.0017	0.0016	0.0015

	TESTING INTERVAL						
	Wk 9	Wk 10	Wk 11	Wk 12	Wk 13	Wk 14	Wk 15
$W_g^*$ (g/cm <sup>2</sup> )	0.013	0.0136	0.0142	0.0147	0.0153	0.0158	0.0162
$R_g^{**}$ (g/cm <sup>2</sup> /wk)	0.0014	0.0014	0.0013	0.0012	0.0012	0.0011	0.0011

\* $W_g$  = cumulative average weight of gel diffusion per surface area

\*\* $R_g$  = average weight of gel diffusion per surface area per week ( $R_g = W_g / \text{Time in weeks}$ )

Figure 4-4 Silicone Gel Bleed Rate Through 15 Weeks



The gel bleed data show a relatively low bleed rate with the rate slowing after about five weeks and decreasing through 15 weeks. As noted above, even this relatively low rate significantly exaggerates the gel bleed that might be encountered during actual clinical usage of devices. Intact, explanted devices that have been in vivo for many years do not exhibit evidence of substantial gel bleed; i.e., the devices do not show any significant loss of gel and are similar in appearance to new devices. Additional information will be included in the Clinical Module, Retrieval section.

**5.0 PHYSICAL PROPERTY COMPARISON OF PMA DEVICES WITH PREVIOUS VENDOR GEL-FILLED MAMMARY PROSTHESIS**

Mentor has performed long-term biological safety testing on \_\_\_\_\_ ary Prosthesis \_\_\_\_\_ in a prior vendor's [\_\_\_\_\_ dimethyl and \_\_\_\_\_ siloxane dispersions \_\_\_\_\_ re not substant\_\_\_\_\_ Mentor's current Gel-filled Mammary PMA Prosthesis shells based upon equivalence of the raw materials themselves (as shown in Master Access File side-by-side testing results), similarity of Mentor's device processing using either the current or former raw materials, finished device chemical extractables testing results, and finished device physical testing results. The evidence supporting the similarity in the raw materials and Mentor's device processing using either raw material was presented in the Manufacturing Module of this PMA (M020018/M2). Evidence of the similarity in the device extractables irrespective of whether the current or prior vendor raw materials were used was provided in the Chemical Testing Module (M020018/M3). This section of the PMA Mechanical Module will describe the similarity in the finished device physical properties when either current or prior vendor raw materials were used in the manufacturing process.

Prior long term biological\_\_\_\_\_r gel-filled mammary devices\_\_\_\_\_ e and \_\_\_\_\_ silo\_\_\_\_\_ and \_\_\_\_\_ om \_\_\_\_\_ with \_\_\_\_\_ shells can be \_\_\_\_\_ 1 Summary of PMA Finished Device Testin\_\_\_\_\_ 1991 (see Appendix 1 of this PMA module). Those results have been compared to the current PMA device PPQ testing results in Tables 5-2 and 5-3 below to show that the shells are physically not substantially different from those shells used in the long-term biological safety testing.

Table 5-1 Mentor Gel-Filled Mammary PMA Current Device Versus Prior Device Raw Material

Device Component	Current PMA Device	Prior Device
Shell	Dimethyl- _____ dispersion _____	Dimethylsiloxane dispersion _____
Silicone Gel	_____	_____
Textured Surface, Washers, Patches	_____	_____
Dispersion Coating (Dip Coat Fill)	_____	_____

Table 5-2: Shell Physical Property Comparison of Smooth Round Gel-filled Devices (PMA versus Previous Vendor Devices)

Physical Property	PMA Devices (size <sup>1</sup> )	Previous Vendor Devices (size)
Materials	----- ----- -----	----- ----- -----
Mean Breaking Strength (lbs.)	5.5 (100cc) 6.0 (250cc) 7.1 (800cc)	3.9 (275cc) <sup>1</sup> 3.7 (325cc) <sup>2</sup>
Mean Ultimate Elongation (%)	614 (100cc) 654 (250cc) 689 (800cc)	545 (275cc) <sup>1</sup> 518 (325cc) <sup>2</sup>
Mean Tension Set (%)	2.9 (100cc) 3.0 (250cc) 2.1 (800cc)	2.0 (275cc) <sup>1</sup> 2.6 (325cc) <sup>2</sup>
Mean Joint Strength (lbs.)	4.5 (100cc) 4.8 (250cc) 6.2 (800cc)	3.0 (275cc) <sup>1</sup> 2.7 (325cc) <sup>2</sup>

<sup>1</sup>One lot per size

<sup>2</sup>Two lots per size

Table 5-3: Shell Physical Property Comparison of Siltex Round Moderate Profile Gel-filled Devices (PMA versus Previous Vendor Devices)

Physical Property	PMA Devices	Previous Vendor D-----es (size)
Materials	----- ----- -----	----- Shell ----- -----
Mean Breaking Strength (lbs.)	6.9 <sup>4</sup> (450cc) <sup>1</sup>	4.4 (325cc) <sup>3</sup>
Mean Ultimate Elongation (%)	606 <sup>4</sup> (450cc) <sup>1</sup>	412 (275cc) <sup>2</sup> 436 (325cc) <sup>3</sup>
Mean Tension Set (%)	4.0 <sup>4</sup> (450cc) <sup>1</sup>	2.3 (275cc) <sup>2</sup> 2.2 (325cc) <sup>3</sup>
Mean Joint Strength (lbs.)	6.5 <sup>4</sup> (450cc) <sup>1</sup>	4.3 (275cc) <sup>2</sup> 4.9 (325cc) <sup>3</sup>

<sup>1</sup>Three lots per device size

<sup>2</sup>One lot per device size.

<sup>3</sup>Two lots per device size

<sup>4</sup>Mean of lots from Siltex PMA device data tables in this module

The above data show that finished device shells m--- from current ----- silico-----  
----- vious finished device shells made with ----- silicone disp--- --- and -----  
----- that were used in long-term biological s----- testing have similar physi-----

Prior PMA modules provide data demonstrating that the manufacturing processes and chemical extractables profile and extractables quantities of the shells were not substantially different. Based upon each of these data sets, Mentor believes that the long-term biological safety testing on earlier Low Bleed Gel-filled Mammary Prostheses is directly applicable to the current PMA devices.

## 6.0 MECHANICAL TESTING CONCLUSIONS

This PMA module presents data from mechanical tests that were conducted in accordance with FDA's "Guidance for Saline, Silicone Gel, and Alternative Breast Implants; Guidance for Industry and FDA" (February 11, 2003) and ASTM F703-96. Other tests not included in the previous standards were also performed. The testing performed included shell tensile (ultimate breaking force and elongation), shell tear resistance, patch-to-shell adhered joint testing, shell tension set, static and cyclic fatigue testing, gel cohesivity testing, and finished device gel bleed rate. The results demonstrate that Mentor's Gel-filled Mammary Prostheses surpass standard specification requirements as well as Mentor's own finished product specifications.

Mammary prosthesis performance specifications are set to ensure that the device will withstand the stresses typically encountered during surgical placement and *in vivo*, and have evolved over the years. Mentor's mammary prostheses have been manufactured according to these performance specifications for many years, and have demonstrated acceptable and reliable performance *in vivo*. Based on the data presented in this module, together with a history of safe and effective performance *in vivo*, it can be concluded Mentor's Gel-filled Mammary Prostheses that are the subject of this PMA are mechanically acceptable and safe for their intended use.