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1.0 PURPOSE

To evaluate explanted silicone Gel-Filled mammary prostheses from patients enrolled in the Core Gel IDE study in accordance with the Explanted Device Retrieval Protocol as well as document and catalogue various failure modes. This addendum includes information from an additional fifteen explanted devices that were tested after the completion of the previous core gel report (HS220.020819.02).

2.0 BACKGROUND

As part of the Core Gel IDE, Mentor Corporation in collaboration with the FDA developed a protocol to evaluate explanted silicone gel-filled mammary prostheses from patients enrolled in the Core Gel IDE study. This protocol is entitled "Mentor Silicone Gel-Filled Mammary Prosthesis Explanted Device Retrieval Protocol", HS220.030328.03.

The retrieval study involves two portions. The first portion of the study involves the collection of implant/surgery information and clinical data at the time of explantation pertaining to the (condition) of the device. The second portion of the retrieval study involves visual inspection and physical testing of the explanted devices.

The retrieval study outlined in this report is an extension of the existing complaint handling process. Mentor initially evaluates the returned devices in accordance with Complaint and MDR procedures (SOP-HS-112, Product Complaint Handling System and SOP-HS-113, Regulatory Agency Reporting). A description of the device failure is documented in writing, on a diagram, as well as photographed according to procedure (DOP-QA-4015, Product Evaluation Laboratory Procedure).

3.0 DEVICE RETRIEVAL

The explanted devices were returned to Mentor using the prescribed decontamination process outlined in the protocol and the Core Gel return kit. The product returned kit contains the Field Experience Report (FER) and other necessary documentation to capture all patient medical information and explanted device information including authorization for examination of the device and authorization for release of medical information.

4.0 DEVICES IMPLANTED

As of July 9, 2004 a total of ----- gel mammary devices were implanted in ----- patients. There were ----- smooth devices and ---- textured devices. The total units implanted include those implant devices used for secondary surgeries on patients enrolled in the study. The number of devices implanted will change as additional re-implantations are required.



5.0 RESULTS

An analysis was performed on the following categories to identify specific trends correlating to device failures: device type, size, clinical variables, visual observations, *in-vivo* time, surgical approach, device placement, incision size and pocket irrigation usage. Additionally, the devices underwent the following physical testing to assess the physical characteristics of the explanted devices: tension set, joint strength, ultimate elongation and gel cohesion.

5.1 Devices Explanted

A total of fifty-seven (57) devices were explanted and retrieved through July 9, 2004. Forty-two (42) devices were Smooth Moderate Profile (MP) gels and fifteen (15) were Textured Moderate Profile (MP) gels. Table 2 outlines the number of devices that were explanted by device name as well as the average *in-vivo* time for the explanted devices. The average *in-vivo* time for Smooth MP Gel returned devices was 422.0 days. The average *in-vivo* time for Textured MP Gel returned devices was 619.1 days. Table 3 delineates the size distribution of explanted devices.

Table 1 –Device Implant/Explant Summary

	# Devices Explanted	% of Total Devices Explanted	Total # Devices Implanted	% of Total Devices Implanted
Smooth Round MP Gel	42	74%	-----	-----
Textured Round MP Gel	15	26%	----	-----

Table 2 –Explanted Devices, Days *In-Vivo*

Device Name	Number of Explanted Devices	Days <i>In-Vivo</i> (Days)		
		Mean	Standard Deviation	Range
Smooth Round Moderate Profile Gel	42	422.0	345.9	0 to 1091
Textured Round Moderate Profile Gel	15	619.1	343.5	42 to 1213



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Table 3 – Explanted Device Sizes

Size (cc)	Smooth Round Moderate Profile Gel	Textured Round Moderate Profile Gel
125	0	0
150	0	0
175	2	0
225	1	0
250	1	0
275	2	1
300	2	1
325	4	3
350	9	1
375	4	1
400	1	1
450	3	3
500	8	2
550	4	2
600	1	0
700	0	0
800	0	0

5.2 Reasons for Explant/Visual Observations

Retrieved devices were handled and evaluated according to DOP-QA-4015. All devices were first visually evaluated with the naked eye. The as received condition of the device was recorded. This included the measurements and location of any tear, pinhole, or abnormality. All openings were visually examined with a microscope. Openings that showed signs of parallel striations were classified as damaged by sharp instrument. Parallel striations through the surface indicate that a sharp instrument very likely damaged the shell material. Thirty-three (33) explanted Smooth devices showed no abnormalities/failures upon visual examination. Seven (7) Smooth devices revealed parallel striations indicative of sharp instrument damage. None of the sharp instrument damage incidences were noted on the Field Experience Report (FER) by the investigators. One (1) smooth device rent that occurred intra-operatively revealed no indication as to its cause after examination. Thirteen (13) textured explanted devices showed no signs of abnormalities upon visual examination. Two (2) textured explanted devices contained rents of unknown cause. The most common reasons for explants were patient request/size change and capsular contracture. A summary of reasons for explant and visual observations is outlined in Table 4.



Table 4 Reasons for Explant/Visual Observations

		Smooth Round Moderate Profile Gel	Textured Round Moderate Profile Gel	Totals
Physician Reason for Explant	Asymmetry	1	1	2
	Capsular Contracture	6	0	6
	Extrusion	1	1	2
	Infection	1	2	3
	Patient Request/Size change	22	9	31
	Ptosis	1	0	1
	Rupture	1	2	3
	Placement or Intra-Operative Damage	4	0	4
	Loss of Projection	2	0	2
	Disliked Result	3	0	3
Laboratory Visual Observations	Unknown Cause of Rent	1*	2	3
	Crease Fold	1	0	1
	Sharp Instrument Damage	7**	0	7
	No Abnormality	33	13	46

* Physician reason for explant: placement or intra-operative damage

**Physician reason for explant: 3 placement or intra-operative damage, 2 capsular contracture, 2 patient request/size change

5.3 Implant/Surgery Data

Tables 5 through 9 describe the implant/surgery information of the patients whom had devices explanted. There were fourteen (14) Reconstruction, twenty-five (25) Augmentation and fourteen (14) Revision patients with explanted devices (See Table 5). The reason for surgery for four (4) explanted devices was unknown. The most common surgical approach for explanted Smooth and Textured Core Gel devices was infra-mammary. The infra-mammary surgical approach was used for thirty-one (31) out of fifty-seven (57) returned devices (See Table 6). The most common device placement for returned MP gel devices was sub-muscular. Thirty-five (35) out of fifty-seven (57) MP Gel devices were implanted sub-muscularly. (See Table 7). The most commonly used irrigants were saline and/or antibiotics. Some investigators used more than one irrigation solution, e.g., some pockets were irrigated with saline and antibiotics. (See Table 8). The most common incision size was distributed between 4 and 6 cm (See Table 9).



Table 5 - Indication for Surgery

Indication for Surgery	Smooth Round MP Gel	Textured Round MP Gel	Total
Augmentation	18	7	25
Reconstruction	9	5	14
Revision	11	3	14
Unknown	4	0	4

Table 6 - Surgical Approach

Surgical Approach	Smooth Round MP Gel	Textured Round MP Gel	Total
Inframammary	22	9	31
Mastectomy Scar	9	2	11
Transaxillary	4	0	4
Periareolar	3	4	7
Unknown	4	0	4

Table 7 - Device Placement

Device Placement	Smooth Round MP Gel	Textured Round MP Gel	Total
Submuscular	27	8	35
Subglandular	7	6	13
Subpectoral	4	0	4
Unknown	4	1	5

Table 8 - Pocket Irrigation

Pocket Irrigation	Smooth Round MP Gel	Textured Round MP Gel	Total
Saline	2	3	5
Betadine	2	0	2
Antibiotic	7	5	12
Saline and Betadine	5	1	6
Saline and Antibiotic	6	1	7
Anesthetic and Antibiotic	3	2	5
Saline, Antibiotic, and Anesthetic	1	0	1
None	2	0	2
Unknown	14	3	17



Table 9 - Incision Size

Incision Size	Smooth Round MP Gel	Textured Round MP Gel	Total
0-3 cm	8	5	13
4-6 cm	21	7	28
7-9 cm	7	3	10
Unknown	6	0	6

5.4 Observed Abnormalities

The location of all openings on smooth devices was documented on the lab evaluation diagram. The observed abnormality for five (5) of the ten (10) devices with openings was on the anterior aspect. The summary of the observed Abnormalities is outlined on Table 10.

Table 10 – Observed Abnormalities

Device Name/Size	Anterior	Posterior	Radius	Comment
Smooth Round MP Gel (375 cc)	1	N/A	N/A	Initial opening extended to both sides of the device
Smooth Round MP Gel (375 cc)	1	N/A	N/A	Initial opening extended to both sides of the device
Smooth Round MP Gel (350 cc)	1	N/A	N/A	N/A
Smooth Round MP Gel (500 cc)	N/A	1	N/A	N/A
Smooth Round MP Gel (250 cc)	N/A	1	N/A	Initial opening extended to both sides of the device
Smooth Round MP Gel (500 cc)	1	N/A	N/A	N/A
Smooth Round MP Gel (500 cc)	1	N/A	N/A	N/A
Siltex Round MP Gel (325 cc)	N/A	N/A	1	N/A
Siltex Round MP Gel (325 cc)	N/A	N/A	1	N/A
Smooth Round MP Gel (325 cc)	N/A	1	N/A	N/A
Total	5	3	2	



5.5 Physical and Mechanical Testing

5.5.1 Tension Set

Tension set testing of a rubber or thermoplastic elastomer evaluates the residual elongation of a test sample after being stretched and allowed to relax in a specified manner. This elongation consists of both permanent and recoverable components. Therefore, the time for stretching and recovery are both important factors. A high % Tension Set result means that a material is unable to return to its initial shape after stress. A low % Tension Set result means that a material is capable of returning to its initial shape after stress.

Tension Set specimens were prepared and tested per TM000406, "Determination of % Tension Set of Elastomeric Materials" which is based on the ASTM Test Method D 412, "Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers – Tension". One tension set specimen is cut from the anterior aspect of each device with an ASTM D412 Die C. Tension set specimens are marked with a calibrated benchmark prior to the tension set test. The initial distance between the marks on the specimens is measured and recorded. First, the test specimens are elongated to 300%. Then, the specimens are held at 300% elongation for three minutes. After three minutes of elongation, the specimens are allowed to relax for three minutes. After the three minute relaxation, a final distance between the marks on the specimens is measured and recorded.

The % Tension Set is derived from the following formula:

$$\% \text{ Tension Set} = \left[\frac{(L - L_o)}{L_o} \right] \times 100$$

L_o = Initial Distance

L = Final Distance

All of the tension set specimens extracted from returned devices exhibited %Tension Set results that were less than the maximum specification of 10% (Table 11).

Table 11 - Tension Set

Device Name	Tension Set (%)		
	Mean	Standard Deviation	Range
Smooth MP Round Gel	3.59	0.71	1.35 to 4.90
Textured MP Round Gel	3.39	0.75	1.35 to 4.86
Specification	< 10%		



5.5.2 Joint Strength

The Joint Strength test examines the ability of the shell/patch bond to withstand stress while the shell material adjacent to the bond is elongated to 200% and held for ten seconds. Joint Strength specimens were prepared and tested per TM000401, "Determination of Joint Bond Strength" which is based on the ASTM Test Method F 703, "Standard Specification for Implantable Breast Prostheses". One joint strength specimen is cut from the posterior aspect of each device with an ASTM D412 Die C. A mark is placed on the joint bond of each Joint Strength specimen. A mark is also placed five millimeters from the joint on the test region of the Joint Strength specimens. Next, the specimens are elongated until the marked area achieves 200% elongation. Then the specimens are held at 200% elongation for ten seconds. Finally, the specimens are elongated until failure. All of the Joint Strength specimens taken from returned devices passed the required specification of 200% elongation for 10 seconds (see Table 12).

Table 12 - Joint Strength (Pass/Fail)

Device Name	Joint Strength	
	Pass	Fail
Smooth MP Round Gel	42	0
Textured MP Round Gel	15	0
Specification	200% Elongation for 10 seconds	

5.5.3 Tensile/Elongation

The tensile test is the most widely used mechanical property test. The intent is to measure inherent material behavior. If both the elongation and the force are measured in the tensile test, then Young's modulus as well as yield stress and strain, and strength can be determined. Tensile specimens were prepared and tested per TM000019, "Determination of Tensile/Elongation Properties of Elastomeric Materials" which is based on the ASTM Test Method D 412, "Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers – Tension". One tensile/elongation specimen was cut from the anterior aspect of each device with an ASTM D412 Die C. All percent elongation results were greater than the minimum specification of 350% (see Table 13).

Table 13 - Tensile Elongation

Device Name	Percent Elongation (%)		
	Mean	Standard Deviation	Range
Smooth MP Round Gel	599.5	66.5	453.0 to 728.1
Textured MP Round Gel	479.8	64.5	369.7 to 574.8
Specification	> 350%		



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5.5.4 Gel Cohesion

The Gel Cohesion test examines the cohesiveness of the gel implant filler. A more cohesive gel is less likely to migrate away from the implant and into the body in the event of a rupture. Gel Cohesion samples were prepared and tested per TM000366, "Gel Cohesion Test Method" which is based on the ASTM Test Method F 703, "Standard Specification for Implantable Breast Prostheses". An incision is made on the posterior aspect of the devices to expose the gel. A designated amount of the gel (determined by weight) is allowed to fall from away from the shell and into a test fixture. The gel is allowed to settle for ten minutes inside the test fixture. Then, the gel is allowed to fall through the opening in the test fixture for thirty minutes. After thirty minutes, the length of any gel hanging below the bottom surface of the test fixture is measured.

The Gel Cohesion test can only be performed on intact devices. An intact device is defined as a device that is returned without openings, tears, or pinholes. The Gel Cohesion test was not performed on devices that were reported to have visual observations of sharp instrument damage or rents of unknown cause. All intact returned devices passed the required specification of a gel pendant less than 45 millimeters (Table 14).

Table 14 - Gel Cohesion

Device Name	Gel Cohesion		
	Pass	Fail	Not Tested (Device Not Intact)
Smooth MP Round Gel	34	0	8
Textured MP Round Gel	13	0	2
	Specification < 45 mm at 30 minutes		



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6.0 DISCUSSION

A total of fifty-seven (57) explanted devices have been tested since the beginning of the study through the database closure (September 2000 through July 9, 2004). Forty-two (42) of the explanted devices were Smooth Round Moderate Profile Gel devices and fifteen (15) were Textured Round Moderate Profile Gel devices. The average in-vivo duration for the smooth and textured explanted devices was 422.0 days and 619.1 days, respectively. Augmentation and revision were the predominant indications for surgery. The most common surgical approach was inframammary and submuscular was the most common surgical placement. The reported reasons for explant were predominantly patient request/size change and capsular contracture, followed by intra-operative damage, infection, and extrusion.

Visual observations for forty-six (46) of the fifty-seven (57) reported failures revealed no abnormalities. One (1) rent was caused by a crease fold. Seven (7) devices revealed edges with parallel striations that were deemed to be caused by sharp instruments. The cause of three (3) device rents was unknown. Further explanation of the rents of unknown cause can be found in Appendix C.

All tension set results were less than the maximum specification of 10%. All joint strength specimens passed the required specification of 200% elongation for 10 seconds. All tensile specimens elongated beyond the required specification of 350% elongations. All intact devices passed the gel cohesion specification of a gel pendant less than 45 millimeters.

7.0 CONCLUSION

As of July 9, 2004, fifty-seven (57) Core Gel devices have been explanted and returned for evaluation. It is difficult to perform meaningful analysis and trending based on this limited sample size. The reasons for explant were predominantly patient request/size change and capsular contracture. It should be noted that forty-six (46) of the fifty-seven (57) were returned intact and without abnormality (81% without abnormality). Seven (7) devices revealed edges with parallel striations that were deemed to be caused by sharp instruments. The cause of three (3) device rents was unknown (See Appendix C). One (1) device rent was caused by a crease fold.

Based on the aforementioned data, we are unable to draw conclusions or catalog the various failure modes regarding the explanted silicone Gel-Filled mammary prostheses from patients enrolled in the Core Gel IDE study at this time. However, we will continue to analyze explanted devices as they are returned to Mentor throughout the duration of the Core Gel IDE study. Additional failure mode evaluations are being conducted by Mentor to supplement the results of this core retrieval study. Please refer to the results in the supplemental reports for further characterization of failure modes.



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8.0 REFERENCES

- 8.1 Protocol HS220.030328.03, "Mentor Silicone Gel-Filled Mammary Prosthesis Explanted Device Retrieval Protocol"
- 8.2 SOP-HS-112, Product Complaint Handling System
- 8.3 SOP-HS-113, Regulatory Agency Reporting
- 8.4 DOP-QA-4015, Product Evaluation Laboratory Procedure
- 8.5 DOP-QA-7013, Excising Samples For Testing
- 8.6 DOP-QA-4004, Product Evaluation Coding System
- 8.7 TM000406, Determination of % Tension Set of Elastomeric Materials
- 8.8 TM000401, Determination of Joint Bond Strength
- 8.9 TM000019, Determination of Tensile/Elongation Properties of Elastomeric Materials
- 8.10 TM000366, Gel Cohesion Test Method
- 8.11 ASTM D 412, Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers – Tension
- 8.12 ASTM F 703, Standard Specification for Implantable Breast Prostheses

9.0 ATTACHMENTS

- 9.1 Appendix A: Field Experience Reports (FER)
- 9.2 Appendix B: Data Collection Sheets
- 9.3 Appendix C: Rent of Unknown Cause Memos