MENTOR

ENGINEERING STUDY REPORT FOR EVALUATION OF GEL BLEED FOR MENTOR GEL FILLED IMPLANTS

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1.0 PURPOSE

The following report documents the results of the ASTM F703 method to evaluate the diffusion of silicone gel through Mentor Silicone Gel Filled Mammary implants. This diffusion will be referred as "gel bleed" in this report.

2.0 DISCUSSION

This test was conducted in accordance to ASTM F703; Section X2 "FEASIBILITY PROTOCOL FOR GEL BLEED IN-VITRO TESTING BY MEANS OF A SILICONE DISK". Test samples from three (3) Mentor Smooth Round Moderate Gel Implants P/N 3507100BC/Lot #259334 were evaluated during this experiment.

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. The intent of this test method is for the comparison of smooth, non-textured implants only.

Per Section X2.6 through X2.8 of ASTM F703, the three (3) test samples were prepared and conditioned in an oven for 8 weeks at 110°F, a temperature exceeding an extremely high fever condition in humans. This serves to expose the implants to a worst case temperature condition that can occur after implantation. Test results however, are not intended to be indicative of the actual in vivo situation.

Three additional silicone disks (control samples) were used as environmental controls to measure unalterable factors which cause the silicone disks to gain or lose weight (for example, humidity).

At weekly intervals, the test and control samples were removed from the oven, allowed to equilibrate at room temperature, and weighed. The results are documented below in section 3.0.

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3.0 RESULTS

Per the ASTM F703 Specification, the following information is required for a gel bleed report: (See Also Table 1)

- Records of all measurements of silicone disk weight for each time interval
- Records of temperature and humidity of laboratory at each time period
- Calculated average amount of gel per surface area diffusing out of test specimens
- Calculated average rate of gel diffusing out of test specimen
- Lot number.
- Part number
- Volume(s) of devices
- Type of product
- Sterilization method
- Sterilization lot numbers

3.1 DATA ANALYSIS

The weekly data was compiled after the 8th week and formulated per ASTM F703 Section X2.10. The Average Weight Of Gel Diffusion Per Surface Area (W_g) and The Average Weight Of Gel Diffusion Per Surface Area Per Time Interval (R_g) were calculated as follows:

$W_g=[(T_t-T_i)-(C_t-C_i)]/A_s$
$R_g=W_g/t$

Where:

W_g=average weight of gel diffusion per surface area (g/cm2)
R_g=average weight of gel diffusion per surface area per time interval (g/cm2/t)

T_t=average weight of test discs at each time interval (g)
T_i=average weight of test discs at beginning of test (g)
C_t=average weight of environmental control discs at each time interval (g)
C_i=average weight of environmental control discs at beginning of test (g)
A_s=surface area of silicone disc (cm2)
T=cumulative time from beginning of test to each interval (weeks)

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Table 1
Gel Bleed Data

Gel Bleed Data Sheet
Type of Sterilization: Dry Heat
Humidity Control: 3 disc
Test Samples: 3

Oven Temperature: 110F (43.3C)(Oven Cure-10)
PN: 3507350BC
LN: 259334
Size: 350cc

Drop Gauge EQ# K0146
Scale EQ# B0151
SP# 5107

	Sample	Area		Thickness	Sample Weight (g)								
	No	(in^2)	(cm^2)	(in)									
Date					6/27/03 (T_i)	7/4/03	7/11/03	7/18/03	7/25/03	8/1/03	8/8/03	8/15/03	8/22/03
No of Days					0	7	14	21	28	35	42	49	56
Temp (C)					28.0	20.6	20.0	23.0	21.7	21.7	20.0	21.7	20.0
RH (%)					37.0	38.0	42.0	41.0	37.0	39.0	40.0	37.0	42.0
Control Sample	H1	7.7264	19.6250	0.12230	7.4616	7.4596	7.4616	7.4600	7.4602	7.4617	7.4620	7.4608	7.4614
Control Sample	H2	7.7264	19.6250	0.12240	7.4617	7.4595	7.4614	7.4592	7.4594	7.4612	7.4610	7.4595	7.4598
Control Sample	H3	7.7264	19.6250	0.12285	7.4967	7.4943	7.4963	7.4949	7.4948	7.4965	7.4965	7.4951	7.4959
Test sample	T1	7.7264	19.6250	0.12255	7.4691	7.5250	7.5708	7.5994	7.6249	7.6463	7.6604	7.6777	7.6967
Test sample	T2	7.7264	19.6250	0.12215	7.4500	7.5261	7.5676	7.5987	7.6206	7.6477	7.6674	7.6803	7.7000
Test sample	T3	7.7264	19.6250	0.12290	7.4861	7.5540	7.5898	7.6268	7.6522	7.6745	7.6924	7.7111	7.7279
T_t		7.5350	7.5761	7.6083	7.6326	7.6562	7.6734	7.6897	7.7082				
T_i	7.4684												
T_t-T_i		0.0666	0.1077	0.1399	0.1642	0.1878	0.2050	0.2213	0.2398				
C_t		7.4711	7.4731	7.4714	7.4715	7.4731	7.4732	7.4718	7.4724				
C_i	7.4733												
C_t-C_i		-0.0022	-0.0002	-0.0020	-0.0019	-0.0002	-0.0002	-0.0015	-0.0010				
W_g		0.00351	0.0055	0.00722887	0.00846	0.00958	0.01045	0.01135	0.01227				
R_g		0.00351	0.00275	0.00240962	0.00212	0.00192	0.00174	0.00162	0.00153				

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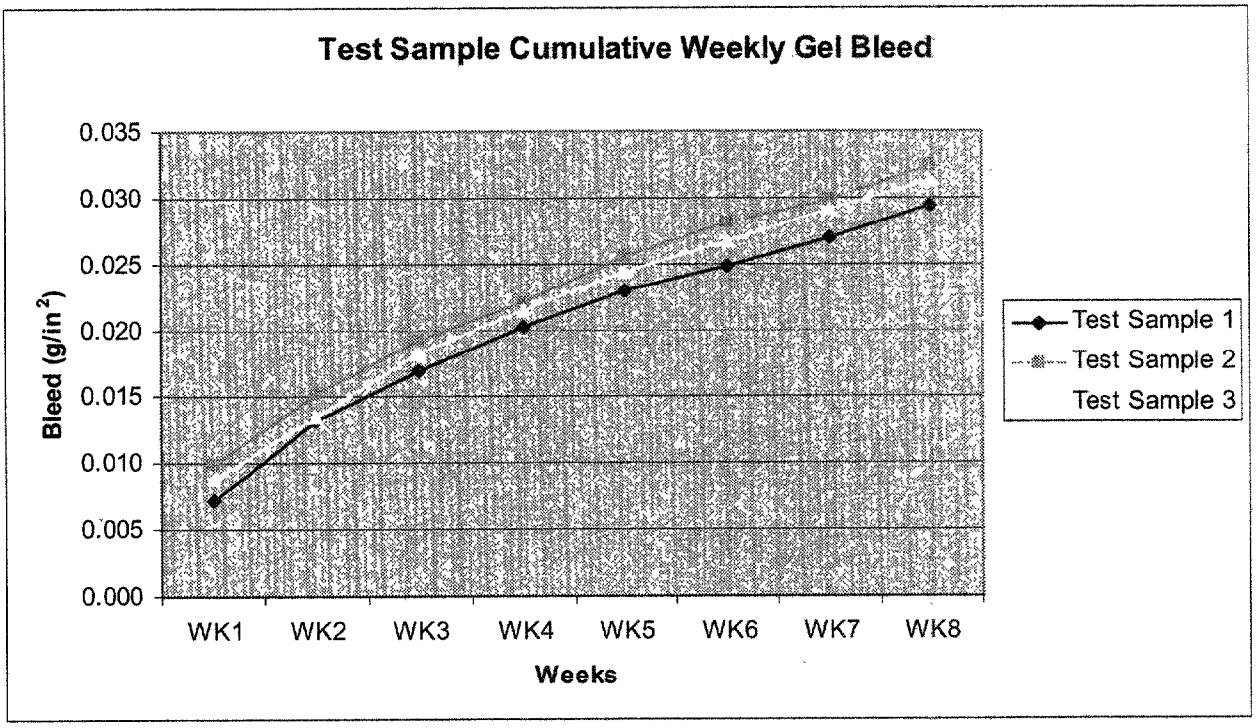
Additionally, the data was charted to show cumulative gel bleed per week over the conditioning period (See Figure 1).

Figure 1



This report has documented the raw data from the testing of Mentor Gel Filled Implant test samples. The report also documents the calculation of that data per the requirements for gel bleed testing listed in ASTM F703. No comparison to or development of specifications is required per ASTM F703 and will not be indicated in this report.

4.0 REFERENCES

4.1 GSL Special Project #5107
4.2 ASTM F703 "Standard Specification for Implantable Breast Prostheses"