

-----Original Message-----

From: Allen, Samie Niver [mailto: SXN@CDRH.FDA.GOV]
Sent: Wednesday, December 22, 2004 5:35 AM
To: 'Free, Donna'
Subject: FW: P030053a5 - Attachments 8 and 17

-----Original Message-----

From: Free, Donna [mailto: DFree@mentorcorp.com]
Sent: Monday, October 11, 2004 1:46 PM
To: 'Allen, Samie Niver'
Cc: Michael, Maher
Subject: RE: P030053a5 - Attachments 8 and 17

Hi Samie,

Below, please find our responses to your questions pertaining to Attachments 8 and 17. I believe that this information will adequately address your concerns. Please let me know if you require any additional information.

Thanks

Donna

-----Original Message-----

From: Allen, Samie Niver [mailto: SXN@CDRH.FDA.GOV]
Sent: Friday, October 01, 2004 11:24 AM
To: 'Free, Donna'
Cc: Michael, Maher
Subject: P030053a5 - Attachments 8 and 17

Donna,

Please address the following issues. Thanks, Samie

1. With regards to the testing in Attachment 8:

a. On p.2780, you showed 7 product lines. However, Appendix A does not have a consistent list in terms of the smooth devices. It shows an "old low profile," not "low profile. Appendix A also shows a new high profile, but p.2780 does not. Please explain.

The Smooth Low Profile listed on p. 2780 is the same as the Smooth "Old LP" listed in Appendix A (Catalog#350-9XXXBC). It is also the same as the Smooth "Low Pro." listed in Appendix B (Catal----- 350-9XXXBC). We stopped selling that Low Profile model in -----; therefore, the referen----- "old." We should have included that -----product was last sold in ----- on p. 2780.

2005-410131-01-04_CREATE FOLD-EMAIL-MENTOR.

The listing of devices on p. 278-----dvertently left out the Smooth New High Profile device (first sold in -----).

b. The rate of 0% for the new HP, non-iatrogenic appears to be misleading because I did not find these data in Appendix A. Please clarify.

The data appear in Appendix B.1., at the very bottom of p. 2802. (Appendix A contains iatrogenic data only. Appendix B contains non-iatrogenic rupture data.)

c. For each of the devices applicable to this PMA (i.e., Siltex Moderate Profile, Siltex New High Profile, Smooth Low Profile, Smooth Moderate Profile, and Smooth New High Profile), please provide the number of rupture complaints excluded as per your criteria on p.2778. I'm trying to put your data into perspective.

(Please note that the Smooth Low Profile device is not a part of Mentor's Gel PMA submission.)

Product	# Complaints Excluded by Criteria		
	No Device Returned	In Class Action Settlement	Not Related to Rupture
Siltex Moderate Profile (354-XXX7)	-----	----	---
Siltex New High Profile (354-4XXX)	-	-	-
Smooth Moderate Profile (350-7XXXBC)	----	----	-
Smooth New High Profile (350-XXX4BC)	---	-	-

2. With regards to the testing in Attachment 17, FDA recognizes that this was preliminary data. However, please provide a magnified sketch or photograph of the test set-up. In addition, please provide a more complete description of how these devices are placed on the test fixture and loaded. Is the test performed in load or strain control?

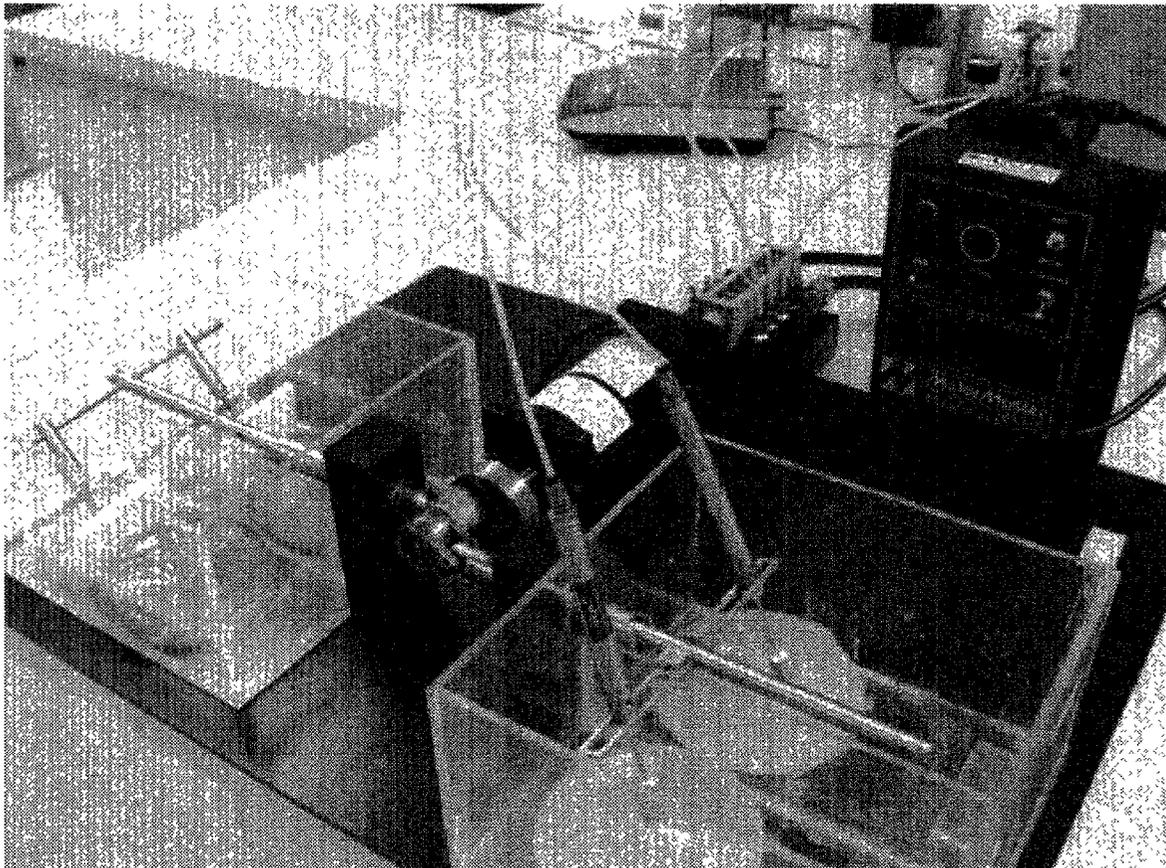
Cyclic Crease Fold Test

The cyclic crease fold test incorporates a bimodal stress event. A photograph of the instrument is shown in Figure 1 and is comprised of a crease fold fixture, in vitro test chamber and control apparatus. The fixture induces two modes of stress with independent control of each. One stress provides a constant static compression using a pneumatic piston and is load controlled. This mode

introduces a fold in the anterior region of the device that manifests as a crease in the radius region. The other stress provides cyclic transverse strain of the crease using a motor driven actuator. This mode is position controlled.

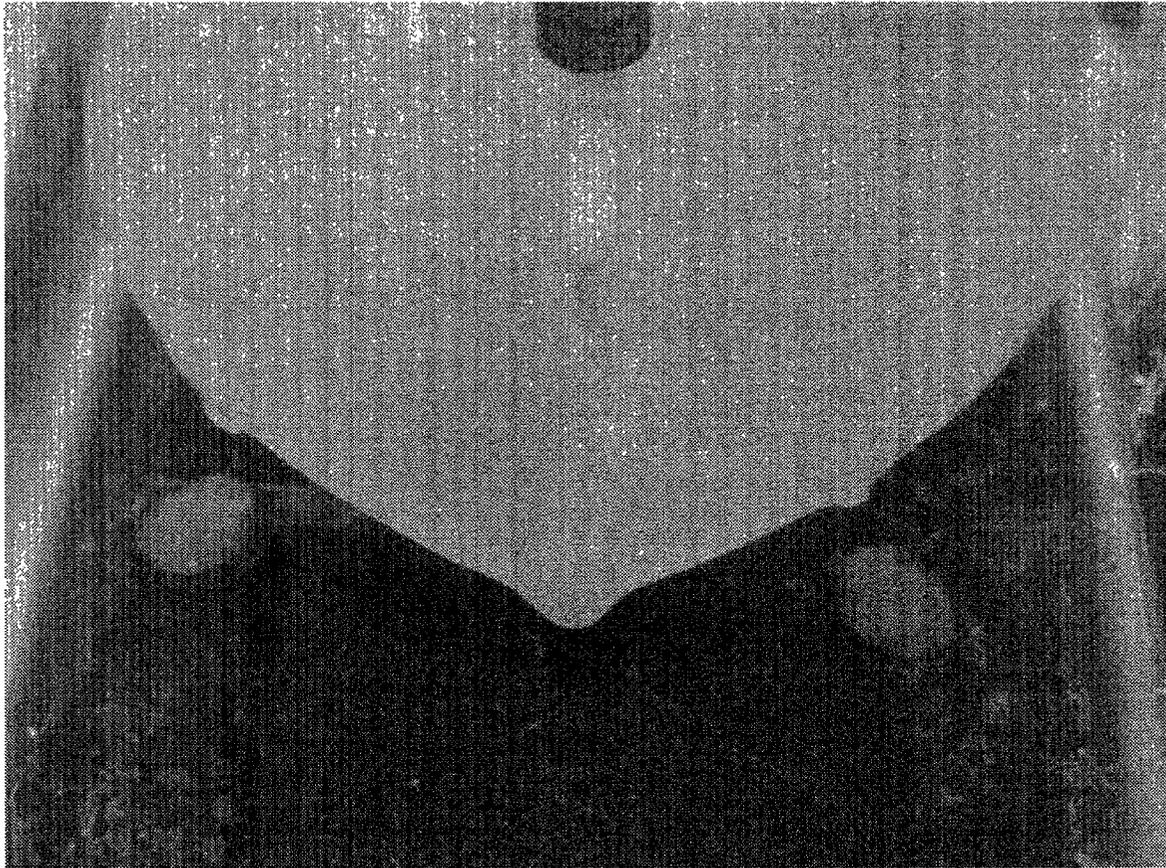
Figure 1 Cyclic Crease Fold Instrument

- Crease Fold Fixture and Test Chamber
- Pneumatic Piston Controller
- Mechanical Actuator Controller



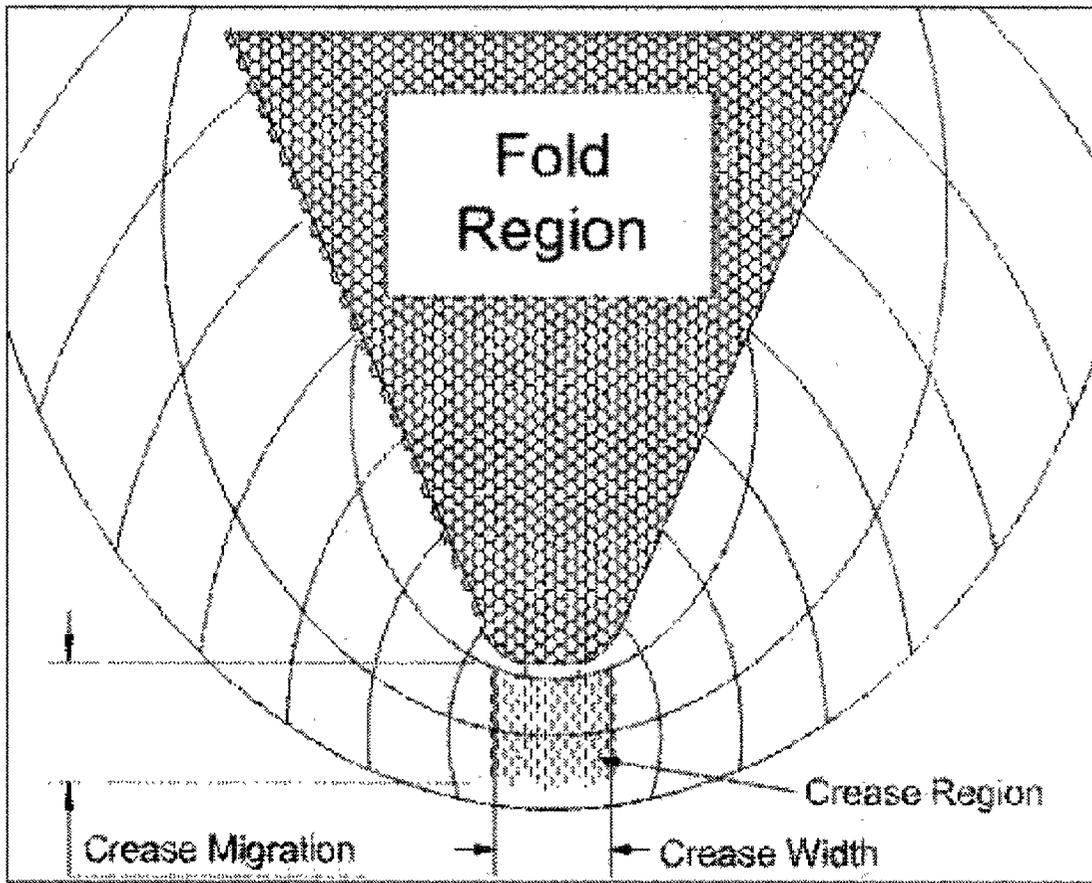
A device is placed in the test chamber and immersed in saline. The test fixture probe is positioned at the center of the device. Adjustment of the pneumatic piston pressure introduces a fold parallel to the diameter of the device. This results in a crease formation on the radius. A photograph of this configuration is shown in Figure 2. The mechanical actuator is activated to move the fixture probe transversely at frequency $f=1$ Hz with cyclic strain amplitude of $\gamma=1$ in.

Figure 2 Crease Fold Fixture and Mammary Implant



The crease formed on the device radius is represented by a small “pinch” or “wrinkle” of the shell with ~1-2 mm width. As the anterior region of the device travels transversely from the actuator cyclic travel the crease migrates back and forth along the device radius. The “rolling wrinkle” is associated with a cyclic tensile stress of the shell radius. A stress distribution model is illustrated in Figure 3 and is most dense in the vicinity of the crease. The effect of the crease migration results in cyclic fatigue of that region of the device. Accordingly the crease fold experiment is designed to induce failure at the site of the crease.

Figure 3 Stress Distribution of the Implant Crease Fold



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