

Technical Report on Gel Retrieval Program Styles 10, 20, 40, 45, 110, 120 and 153

Abstract

The Gel Retrieval Program is a study that has been performed to better understand possible modes of gel implant failures *in vivo*, which then could lead to improved designs or surgical techniques. The data evaluated in this study consists of physician and laboratory observations obtained from explanted gel-filled mammary devices received for Styles 10, 20, 40, 45, 110, 120 and 153. The focus of the study is on explanted gel-filled mammary devices that are associated with a complaint.

The retrieval study analyzes physician information and laboratory observations as follows:

- Physician observations are summarized into two categories: devices that are reported to be ruptured (completely or partially) *in vivo* and devices that are not reported as ruptured (i.e., they were removed for other reasons).
- Device characteristics as observed in the laboratory are divided into six categories: smooth-edge openings, sharp-edge openings, "broken device", device surface observations, gel-related observations and "functional" devices.

Data included in this report are representative of a small proportion of the total number of devices that have been implanted. Table 1 illustrates that the proportion of retrieved devices represented in this report are small in number as compared to the entire population of devices implanted.

Table 1: Total Number of Retrieved Devices

	Style 10	Style 20	Style 40	Style 45	Style 110	Style 120	Style 153	Total*
Total retrieved devices between 7/31/00 and 10/1/02	1	0	75	41	67	29	126	339

* Total for retrieved devices is comprised of devices reported as ruptured, non-ruptured, intra-operative or no information.

The low proportion of devices retrieved from the field is consistent with the rupture rates reported in the IDE Core Clinical Study and via Inamed's complaint system. Rupture rates for gel-filled devices are low, as illustrated in Table 2 (n represents the total number of patients enrolled in the study).

Table 2: Two-Year Implant Rupture Rates by Implant

Core Clinical Study Rupture Rates			Complaint Rupture Rate*
Augmentation	Reconstruction	Revision	
0.40% (n = 987)	3.3% (n = 361)	1.4% (n = 432)	0.17% to 0.91%**

*from prevalence rate calculations

**depending on style

The following are conclusions regarding the mode of failure for gel-filled devices:

- Smooth-edge openings are failure characteristics that are created by a fold-flaw.
- Sharp-edge openings are failure characteristics that can be created by a surgical instrument during surgery.
- "Broken device" is a failure characteristic that may be created due to propagation of a smooth-edge or sharp-edge opening.
- Device surface observations are characteristics that may be created due to a physician's implantation surgical technique.
- Gel-related observations are characteristic that may be created due to a physician's implantation surgical technique.
- "Functional" is a characteristic where no observed device failures, device surface observations or gel-related observations are confirmed by the laboratory.

The report concludes that some device failure characteristics, as observed in the laboratory, are truly representative of failure of the device while other characteristics are possibly artifacts. Mechanical testing of shell, patch and bladder of explanted devices has shown that there is no statistical difference in physical properties between devices reported as ruptured or non-ruptured.

The retrieval study results findings are inconclusive insofar as providing definitive data to be able to make a determination of any specific steps to be taken with regards to changes in device manufacturing, design, or labeling. Therefore, there have been no process, labeling or design changes initiated from these study findings. As part of this study, Style 153 was identified with a higher rate of sharp-edge openings at the posterior as compared to other styles. However, no statistical difference has been noted in mechanical properties of bladder joint between devices reported as ruptured or non-ruptured. The rate of the sharp-edge openings on Style 153 devices will continue to be monitored.