



ALLERGAN

301 W Howard Lane #100, Austin, TX 78753 - Phone: (800) 624-4261 Fax: (800) 972-2368

Re: Reference No:

Thank you for bringing to our attention a recent complaint involving our product. A detailed examination was performed on the returned product. Below are our findings regarding the complaint:

Patient:
Catalog Number:
Serial #:
Implant Date:
Explant Date:
Reported event(s):

LABORATORY ANALYSIS

The laboratory analysis is limited to what is observed at the time of analysis and is not intended to communicate causality.

The implant weighed 341.14 grams. Orange particles were observed on the outer surface of the implant. Orange and brown particles were observed in the gel. Creases were observed on the outer surface of the implant. A portion of the implant was missing. One striated opening, typically associated with the use of a surgical tool, was located approximately on the anterior portion of the implant.

Although the incidence of rupture is extremely low and may be attributable to various causes, we recommend that all patients be informed of the potential for rupture. With current silicone technology, it is expected that there will be occasional implant rupture, for various reasons including those of unknown etiology, as is noted in the DFU.

The manufacture of all products is strictly controlled via detailed procedures and quality control specifications. Each and every product is inspected at a variety of steps during the manufacturing process, including tests for product integrity. Allergan will not release any product that does not meet all manufacturing specifications and requirements.

Thank you again for your confidence in our products. Please be assured that we continue to be dedicated to ensuring the best possible experience when working with our products and our company. If I can be of further assistance, please do not hesitate to contact me at (800) 624-4261 or AUS-ProductSupport@Allergan.com.

Kind Regards,

Shari Jones
Product Surveillance Supervisor

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