

Manual Product Complaint #: _____ Has complaint been submitted before? Yes No

Has complaint been reported to the Local Health Authority? Yes No

| | |
|------------------------|--|
| Product Tracking ID #: | |
|------------------------|--|

Demographics

Account/Facility Name: _____ Account #: _____
 Complaint Form Completed By: _____ Phone #: _____
 Event Country: _____
 Alert Date (Date Reported to J&J Employee): DD/MMM/YYYY (e.g. 01/JAN/2017) Date Form Completed: DD/MMM/YYYY (e.g. 2/JAN/2017)

| | Contact (1) | Contact (2) | Distributors Name |
|---------------------|--------------------------|--------------------------|--------------------------|
| Contact Name: | | | |
| Title: | | | |
| Contact Phone: | | | |
| Contact Address: | | | |
| Contact E-mail: | | | |
| Initial Reporter: | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Follow up Contact*: | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

***Follow Up Contact:** Individual identified on a product complaint who can be contacted to provide information on the event if follow-up is necessary.

Does the Customer require: _____ Send To (Use above table): _____
 Customer Concern Response (Letter detailing analysis findings) Y N Contact Contact 2 Other 3 _____

Patient Information

Sex: _____ Age: _____ Weight: _____ Height: _____ Pre-Existing Condition(s): _____
 DOB: (YYYY) _____ Patient Initials _____ Date of Death (if applicable) (DD/MMM/YYYY) _____

Event Information

Does the reported information reasonably suggest that one of the company's products or product instructions may have?

Caused or contributed to a death? Y N

Caused or contributed to a serious injury? Y N

Caused or contributed to the need for additional medical or surgical intervention? Y N

Malfunctioned? Y N

Note: If yes to any of the above please provide details in the event description.

Procedure Name? _____

| | | | |
|--------------------|---|--|---------------|
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|--------------------|---|--|---------------|

Procedure Date (DD/MMM/YYYY): _____

Event Date (DD/MMM/YYYY): _____
 (Date first observed - if different from Procedure date)

When did the event occur? N/A Pre-Op Intra-Op Post-Op Post Implant UNK

Event Description:

Product Location:

- Was the original intent of the procedure changed? Y N
- Was the sales representative present during the event? Y N
- Was the product used as indicated on label? Y N
- Was infection found? Y N
- Was there any surgery delay? Y N

If yes, How Long?

Were there any Patient Consequences? Y N If YES, please explain:

Note: If yes to any of the above please provide details in the event description.

| Product Name | Product Code # ³ | Lot # | Serial # | DOI ¹ (MM/DD/YY) | DOE ² (MM/DD/YY) | Qty. Involved | Available for Returned? Y/N | Qty to be returned | Reprocessed? Y/N | Reprocessor Name |
|--------------|-----------------------------|-------|----------|-----------------------------|-----------------------------|---------------|-----------------------------|--------------------|------------------|------------------|
| | | | | | | | | | | |
| | | | | | | | | | | |
| | | | | | | | | | | |

¹ Date of Implantation
² Date of Explanation
³ When product code is unknown above please describe product in the event description (i.e. Unknown Gel, Unknown Saline, Unknown Suture, etc.)

Implantable Device: Was device replaced during surgery Yes No

| Side | Product Name | Product Code # | Lot # | Serial # |
|-------|--------------------------------|----------------|-------|----------|
| Left | <input type="checkbox"/> _____ | | | |
| Right | <input type="checkbox"/> _____ | | | |

| | | | |
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|--------------------|--|--|---------------|

Product Location – Mentor

| Side | Placement (Sub. Muscular/Pectoral; Sub. Glandular; Sub. Facial; Subcutaneous) | Surgical Approach (Inframammary; Periareolar; Transaxillary) | Length of Incision (cm) | Final Fill Volume | Baker Grade (I, II, III, IV) |
|--------------------------------|--|--|--|--|--|
| Left (Device A if unknown) | <input type="checkbox"/> _____ <input type="checkbox"/> Unknown | <input type="checkbox"/> _____ <input type="checkbox"/> Unknown | <input type="checkbox"/> _____ <input type="checkbox"/> Unknown | <input type="checkbox"/> _____ <input type="checkbox"/> Unknown | <input type="checkbox"/> _____ <input type="checkbox"/> Unknown |
| Right (Device B if unknown) | <input type="checkbox"/> _____ <input type="checkbox"/> Unknown | <input type="checkbox"/> _____ <input type="checkbox"/> Unknown | <input type="checkbox"/> _____ <input type="checkbox"/> Unknown | <input type="checkbox"/> _____ <input type="checkbox"/> Unknown | <input type="checkbox"/> _____ <input type="checkbox"/> Unknown |

Additional Questions:

Did patient participate in a Post Approval Clinical Study? If yes, what study? _____ Patient Case Id# _____

How was this issue discovered or diagnosed? Imaging Patient symptoms During surgery After trauma Other:
Ultrasound MRI X-Ray CT Scan Visual Inspection

Procedure Name? N/A Augmentation (primary) Augmentation (revision) Reconstruction (primary) Reconstruction (Revision) Unknown

Outcome of the adverse event? N/A Fully recovered (no residual effects) Unchanged Worsened, please explain Death Unknown

Complaint Declaration

By checking this box, I certify that all information that are known/available has been disclosed. If any new information will be made available, the additional information will be submitted through CST or to designated CHU without further delay.

*****END OF DOCUMENT*****