Establishment LABS

General Instructions: Fill out all blanks and check boxes as required.

Distributor / Importer Name: Country:

Email: Complaint Date - Day: Month: Year:

1. Surgeon's Information

Surgeon's Name: Country: Phone Number:

Fax Number: E-mail Address: City:

Address:

2. Patient's Information

Initials *(3 first letters of the name)*: ID Number:

Extended Warranty

Apply extended warranty? - Yes No

3. Product Information

Type	SilkSurface®	Mini	Demi	Full	Corsé
	VelvetSurface®	Mini	Demi	Full	Corsé
	Ergonomix® SilkSurface®	Mini	Demi	Full	Corsé
	Ergonomix® VelvetSurface®	Mini	Demi	Full	Corsé
	Sizer	Mini	Demi	Full	Corsé
	Anatomical TrueFixation™		Demi	Full	Corsé
	GlutealArmonic™ SilkSurface®		Demi	Full	
	Ergonomix® Oval		Demi	Full	

If other, specify:

Reference (REF): Lot Number (LOT): Base (BASE): Projection (PROJ):

Serial Number (SN): Volume (VOL): Contains Qid™ (ESN) - Yes No

ESN Number:

4. Information of Claim

Day of the Surgery - Day: Month: Year:

Check Side of Implantation - Left Side: Right Side:

Incision Site **(only applicable for breast implants)** - Periareolar Inframamary Trans-Axillary Other:

If other, specify:

Implant Placement **(only applicable for breast implants)** - Subglandular Submuscular Dual Plane

Other:

If other, specify:

Type of Surgery - Primary Augmentation Secondary Augmentation Reconstruction

4.1 Reason for Complaint

Sterile Barrier Compromised Packaging Labeling Cosmetic Defect Device Deformation Gel Fractured
Bubbles Gel Fractured During Implantation Rupture During Implantation Rupture After Implantation
Rupture During Explantantation Infection Seroma Late Seroma
Capsular Contracture - Baker Grade III Baker Grade IV
Particle or Foreign Material (Indicate type and location):
Other (specify):
Additional information to better describe as reported condition:

If the complaint is related to Capsular Contracture, complete the following clinical events:

4.2 Clinical Evidence Attached:

Pictures - Yes No
Clinical laboratory tests - Yes No Date - Day Month Year
US - Yes No Date - Day Month Year
MRI - Yes No Date - Day Month Year
Other (specify):

5. Complaint Report

Event's Date of Occurrence - Day: Month: Year:

Complaint Report - Please provide full details of the complaint in a readable format. Please provide a detailed description of the causes of this notification, feel free to attach a separate sheet if necessary.

Once completed, open a ticket in our website filling the requested information and attach this document.