Complaint Notification (Customer)

Establishment Labs

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

Distributor / Importer Name: Country:

Email: Complaint Date - Day: Month: Year:

Surgeon's Information

Surgeon's Name: Country: Phone Number:

Fax Number: Email Address: City:

Address:

Extended Warranty

Yes ○ No ○

1. Communication channel used to notify the complaint:

2. Product Information

Type	Mini	Demi	Full	Corsé
Round	○	○	○	○
Ergonomix®	○	○	○	○
Sizer	○	○	○	○
Antatomical TrueFixation™			○	○
GlutealArmonic™ SilkSurface®		○	○	
Ergonomix® Oval	○	○	○	○

If other, specify

3. Complaint Information

Day of the Surgery - Day: Month: Year:

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

Type of surgery:

Primary Augmentation ○ Secondary/Revision Augmentation ○ Primary Reconstruction ○ Revision Reconstruction ○

	○ Breast implants - Right Side			○ Breast implants - Left Side		
Implant Information	Catalogue Ref:	Number (LOT):	Serial Number:	Catalogue Ref:	Number (LOT):	Serial Number:
Contains Qid® (ESN):	Yes ○	No ○	ESN Number	Yes ○	No ○	ESN Number
Incision Site	Periareolar	Inframammary	Trans-Axillary	Periareolar	Inframammary	Trans-Axillary

If other, please specify

Implant Placement	Subglandular	Submuscular	Dual Plane	Subglandular	Submuscular	Dual Plane
If other, please specify						
Implant Information	○ Gluteal implant - Right Side			○ Gluteal implant - Left Side		
	Catalogue Ref:	Number (LOT):	Serial Number:	Catalogue Ref:	Number (LOT):	Serial Number:
Contains Qid® (ESN):	Yes ○	No ○	ESN Number	Yes ○	No ○	ESN Number
Incision Site	Bilateral Supragluteal	Infragluteal	Intergluteal crease	Bilateral Supragluteal	Infragluteal	Intergluteal crease
If other, please specify						
Implant Placement	Subcutaneous	Submuscular	Intramuscular	Subcutaneous	Submuscular	Intramuscular
If other, please specify						

3.1. Reason for Complaint

☐ Allergies	☐ Gel Fractured	☐ Rotation (Flipping)
☐ Bubbles	☐ Gel Fractured During Explantation	☐ Rupture After Implantation
☐ Bottoming out	☐ Hematoma	☐ Rupture During Explantation
☐ Cosmetic Defect	☐ Infection	☐ Rupture During Implantation
☐ Capsular Contracture Baker Grade III	☐ Labeling	☐ Seroma (Early)
☐ Capsular Contracture Baker Grade IV	☐ Packaging	☐ Seroma (Late)
☐ Device Deformation	☐ Rippling	☐ Sterile Barrier Compromised
☐ Gel fracture during implantation		

Particle or foreign material (indicate type and location):

Other, please specify:

Additional information to better describe as reported condition:

3.2. Clinical Evidence Attached:

Capsular contracture		Infection	
Clinical history and operatory information	☐	Clinical history and operatory information	☐
Photograhs	☐	Photograhs	☐
Ultrasound or MRI report and their corresponding images	☐	Hemogram of Culture	☐
Capsule biopsy (If the patient was already explanted)	☐	Laboratory test (mandatory)	☐

Rupture		Flipping (rotation), bottoming out, rippling, allergies	
MRI and report (In case of rupture after implantation)	☐	Clinical history and operatory information	☐
Explant (Device)	☐	Photographs (If the case is related to Anatomical TrueFixation®, the device is required)	☐

Seroma – Hematoma

Clinical history and operatory information	☐	Ultrasound or MRI report	☐
Photographs	☐		

4. Complaint Report

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.

☐ All submitted personal information have been collected with the appropriate patient consent.
Establishment Labs will treat the submitted information in strict compliance with the General Data Protection Regulation and only for post market surveillance purposes.

Form completed by: Date:

Surgeon's stamp or signature: