Complaint Notification (Custumer)

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	○	○	○	○
Anatomical 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:

Date of explantation - 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	UDI/DI	Yes ○ No ○	ESN Number	UDI/DI
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		UDI/DI	Yes ○ No ○ ESN Number		UDI/DI
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
Capsular Contracture Baker Grade III	Infection	Rupture During Implantation
Capsular Contracture Baker Grade IV	Labeling	Seroma (Early)
Device Deformation	Packaging	Seroma (Late)
Gel fracture during implantation	Rippling	Sterile Barrier Compromised
Tab Rupture	Please provide thread suture used:	

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 report from the surgeon indicating the evolution of the patient after the surgery and the evolution of the complication) ☐	Clinical history and operatory information ☐
Photographs of the patient (frontal and lateral), showing the appearance of the breast before and after the complication prior to the explant procedure ☐	Photographs of the patient (frontal and lateral), showing the appearance of the breast before and after the complication prior to the explant procedure ☐
Imaging: CT Scan, Ultrasound, or high-resolution ultrasound, or MRI scan (including the technical report confirming the diagnosis) ☐	Culture ☐
Capsule biopsy (If the patient was already explanted) ☐	Blood tests ☐

Rupture	Flipping (rotation), bottoming out, rippling, allergies
Clinical History and operatory information ☐	Clinical history and operatory information ☐
Imaging: CT Scan, Ultrasound, MRI (images and report) ☐	Photographs of the patient (frontal and lateral), showing the appearance of the breast before and after the complication prior to the explant procedure. ☐
Explant (Device) ☐	Imaging: CT Scan, Ultrasound, MRI (images and report) ☐
	If the case is related to Anatomical TrueFixation®, the device is required ☐

Seroma – Hematoma	
Clinical history and operatory information ☐	Photographs of the patient (frontal and lateral), showing the appearance of the breast before and after the complication prior to the explant procedure ☐
	Imaging: CT Scan, Ultrasound, MRI (images and report) ☐

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: