General Instructions: Fill out all blanks and checkboxes as required.

Patient Name: Country:

Email: Complaint Date - Day: Month: Year:

Surgeon's Information

Surgeon's Name Country:

Email Address:

Product Information

Which device is related to your complaint?			
Motiva Breast Implant Matrix®		GlutealArmonic® SilkSurface®	
Anatomical TrueFixation®		Tissue Expander®	
Motiva Implants Ergonomix2®		Motiva Implants Ergonomix2 Diamond.	
Other			

Event Information

Day of the Initial Surgery:	Day:	Month:	Year:
Event's Date of Occurrence:	Day:	Month:	Year:
Reoperation:	Day:	Month:	Year:

Product - Right Side	**Product** - Left Side	**Indication**		
Serial Number:	Serial Number:	Augmentation □	Primary □	Secondary □
		Reconstruction □	Primary □	Secondary □

Reason for Complaint

Allergies		Gel Fractured		Rotation	
Seroma		Deformation		Rupture After Implantation	
Bottoming out-Ptosis		Hematoma			
Capsular Contracture Baker Grade III		Infection			
Capsular Contracture Baker Grade IV		Rupture During Implantation			

If Other, please specify:

Clinical Evidence required per event

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) • 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 or Ultrasound, or high-resolution ultrasound, or MRI scan (including the technical report confirming the diagnosis)	• Clinical history and operatory information • Photographs of the patient (frontal and lateral) showing the breast's appearance before and after the complication prior to the explant procedure. • Culture • Blood tests
Rupture	**Flipping (Rotation), bottoming out, rippling, allergies**
• Clinical History and operatory information • Imaging: CT Scan, Ultrasound, MRI (images and report) • If the unit is already explanted, please send the Explant (Device)	• Clinical history and operatory information Photographs of the patient (frontal and lateral) showing the breast's appearance before and after the complication prior to the explant procedure. • 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 • 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

The information incorporated into the questionnaire is real, and ESTA has your consent for reviewing and analyzing the information provided.

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: Patient´s signature	Date: