MENTOR AND PEROUSE PLASTIE INTERNATIONAL
FIELD EXPERIENCE REPORT (FER) FORM

INSTRUCTIONS FOR COMPLETION

THIS FORM HAS TO BE FILLED OUT COMPLETELY AND MUST BE ENCLOSED WHEN THE PRODUCTS ARE RETURNED!

*If a section does not apply or if the requested information is not available, state: "**N/A**". Dates must be written as DD-MM-YYYY.*
The requested Complaint Code(s) can be found on the Complaint Code Form, which is also enclosed in the Product Return Kit.
*Print clearly and legibly in the **English** language. All attached and related documentation must be in the **English** language as well.*
*All returned products must be decontaminated and accompanied by a **signed** Authorization for Return and Examination / Decontamination form.*

General Information

Patient Initials:	Date of birth:
Name of Consulting Surgeon:	Country:
Name and Address of Hospital / Clinic:	
Distributor, Mentor Branch or J&J Affiliate:	Your REF#:
Was this event reported to the local Competent Authorities? ☐**Yes** ☐**No** *If Yes, please state the REF#:*	

Incident / Product Complaint Information

Type of Device: ❑ Mentor Gel ❑ Mentor Saline ❑ Mentor Becker ❑ Mentor Sizer ❑ Mentor Tissue Expander ❑ Mentor Spectra
❑ Perthese Gel ❑ Perthese Saline ❑ Perthese Sizer

Amount of sterilization cycles (only applicable for resterilizable Sizers):

Device A / Left		**Device B / Right**	
Complaint Code(s):		**Complaint Code(s):**	
Catalogue No:	**Lot No:**	**Catalogue No:**	**Lot No:**
Date of Implantation:		Date of Implantation:	
Date Problem Observed:		Date Problem Observed:	
Date of Explantation:		Date of Explantation:	
Saline Implants, Becker Implants, Adjustable Gel Implants and Expanders		*Saline Implants, Becker Implants, Adjustable Gel Implants and Expanders*	
Final saline volume:	*Fill Schedule, if applicable:*	*Final saline volume:*	*Fill Schedule, if applicable:*
Date fill tube removed:		*Date fill tube removed:*	
Capsular Contracture Baker Grade (if applicable):		Capsular Contracture Baker Grade (if applicable):	
Infection Found: ❑Yes ❑No *If Yes, Specify:*		Infection Found: ❑Yes ❑No *If Yes, Specify:*	
Was the implant replaced? ❑Yes ❑No	Catalogue No: Lot No:	Was the implant replaced? ❑Yes ❑No	Catalogue No: Lot No:

Reason for Surgery / Placement of Device(s) / Incision Site, Size of Incision Etc:

❑ Augmentation (primary) ❑ Augmentation (revision) ❑ Reconstruction (primary) ❑ Reconstruction (revision)	❑ Sub. Muscular ❑ Sub. Glandular ❑ Sub. Fascial ❑ Sub. Cutaneous	❑ Augmentation (primary) ❑ Augmentation (revision) ❑ Reconstruction (primary) ❑ Reconstruction (revision)	❑ Sub. Muscular ❑ Sub. Glandular ❑ Sub. Fascial ❑ Sub. Cutaneous
Surgical Approach:	Size of Incision (cm):	Surgical Approach:	Size of Incision (cm):

Description of Incident / Description of Patient's clinical condition:

Intervening Surgical Procedures? ❑Yes ❑No
If Yes, Specify:

Was Betadine (Povidone-Iodine) used intra-operatively? ❑Yes ❑No
If Yes, Specify:

Method of Decontamination *(Specify)*:	Device was damaged during Explantation or Decontamination: ❑Yes ❑No *If Yes, Specify:*
Date complaint received by Affiliate/Branch/Distributor	Date complaint forwarded to Mentor:
Name and Signature of Provider of Information:	Date:

INTERNATIONAL AUTHORIZATION FOR RETURN AND EXAMINATION OF MEDICAL DEVICE(S)

I am returning the explanted device(s) to the Mentor Product Evaluation Department. I authorize Mentor to examine, and if necessary, alter the condition of the device(s) as may be necessary for the purpose of safety and to facilitate the evaluation of the device(s). I have advised my patient, and my patient agrees, that I am returning the device(s) to Mentor for evaluation. Mentor may retain possession of the explanted device(s) and save and/or perform destructive testing to the device(s) as deemed appropriate by Mentor.

_____ _____

Patient Initials or Patient Identifier Physician's Name

_____

Physician's Signature

_____

Date

EXPLANT DECONTAMINATION INSTRUCTIONS

The following instructions are designed to achieve effective decontamination of devices being returned to Johnson & Johnson Medical.

I. Clean Device: Hand wash soiled device in a solution of mild surgical soap or a 1% anionic detergent. Remove any obvious blood, body fluid or tissue by gently swabbing with a cotton swab or soft disposable wipe. It is not necessary to remove intraluminal fluid (fill solution) from a device that is not leaking on gross examination. Rinse thoroughly with tap water and gently blot dry.

II. Device Decontamination: Mentor recommends high-level liquid disinfection for explant returns. Any liquid disinfection procedure specific to the policies of the explanting facility may be utilized. Devices should be soaked for a period of time sufficient to achieve *high level disinfection* according to product labeling and/or institutional policies.

III. Remove the device from solution, rinse thoroughly and gently blot dry.

IV. Place the decontaminated device into container supplied by Mentor.
If possible place Patient Identification label on outside of container.

V. Please identify the method of decontamination utilized, sign and date form.

Decontamination Method: _____

Signed: _____

Position_____

Date_____