

MENTOR COMPLAINT SLIP INFORMATION

If any requested data is unavailable, please write “unknown” on the appropriate line.

PC COMPLAINT NUMBER: _____

PATIENT INITIALS (First and Last): _____

Ensure compliance to Local Data Privacy Regulations prior to adding any patient details.

PHYSICIAN NAME (First and Last): _____

DATE OF EXPLANT (DD/MON/YYYY): _____

Was the device damaged during explantation? YES NO

EXPLANT DECONTAMINATION INFORMATION

Decontaminated By:

Name

DATE (DD/MON/YYYY): _____

Method Used: _____

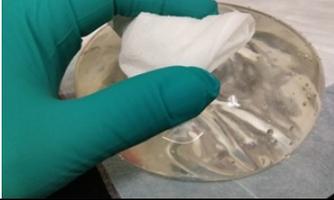
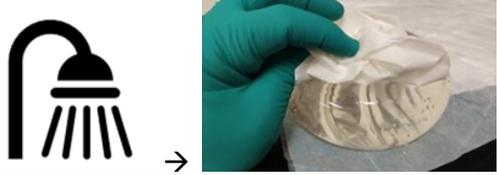
Refer to 173.199 Category B infectious substances.

Documents to return

This signed form with the return device(s)

The AUTHORIZATION FOR RETURN AND EXAMINATION OF MEDICAL DEVICE(S) (if has not been sent electronically)

EXPLANT DECONTAMINATION INSTRUCTIONS

<p><input type="checkbox"/>1. Hand wash soiled device in a solution of mild surgical soap or a 1% anionic detergent.</p>	
<p><input type="checkbox"/>2. 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.</p>	
<p><input type="checkbox"/>3. Rinse thoroughly with tap water and gently blot dry.</p>	
<p><input type="checkbox"/>4. Mentor recommends high-level liquid disinfection for explant returns. This may be accomplished by immersing the device in a 2% glutaraldehyde solution per manufacturer’s instructions. Other liquid disinfection procedures specific to the policies of the explanting facility may be utilized.</p> <p><input type="checkbox"/>5. Devices should be soaked for a period sufficient to achieve high level disinfection according to product labeling and/or institutional policies.</p>	 <p style="text-align: center; border: 1px solid black; padding: 5px;">2% glutaraldehyde solution</p>
<p><input type="checkbox"/>6. Remove the device from solution; rinse thoroughly and gently blot dry.</p>	
<p>Proceed to Steps 7-8 for <u>Ruptured Gel Devices Only</u></p>	
<p><input type="checkbox"/>7. Wrap the gel-prosthesis in a suitable wrapping material intended for autoclave use. Place the unit in a clean, open autoclaving tray.</p>	

8. Autoclave by one of the following Gravity Displacement Decontamination methods:
-Standard Cycle: 30 minutes at 250°F (121° C) and 15 psi
-Optional Cycle: 15 minutes at 270°F (132° C) and 30 psi
Caution: Do not use a pre-vacuum high temperature autoclave cycle or an ethylene oxide sterilization cycle. Do not dry the implant using a vacuum cycle.



Gravity Displacement Decontamination