



EXPLANTED IMPLANTS HANDLING PROTOCOL

1. GENERAL INFORMATION

This document describes the procedure for the decontamination and shipping of explanted Silicone Breast Implant(s) to be returned to Establishment Labs.

If the implant involved in the claim was explanted or came in contact with a patient's body fluids (blood, lymph, etc.), the medical center must decontaminate it per the procedure established by this protocol in order to avoid compromising Establishment Labs' environment or personnel. The explanted product must be considered biologically contaminated and must be subjected to strict rules and controls. The transportation of contaminated products is generally forbidden according to the European Community rules and most of the countries where Motiva Implants® are exported to. Therefore, it is mandatory to return the explanted prostheses only after they have been properly decontaminated.

2. SCOPE

This protocol applies to all explanted devices, devices that have been in contact with body fluids or devices that were removed from their sterile package during the surgical procedure, even though they were not implanted.

3. RESPONSIBILITY

It is the medical center's responsibility to make sure that all devices to be returned to Establishment Labs S.A. are subjected to the decontamination procedure explained below.

4. CLEANING PROCEDURE

4.1 Clean the implant with water to remove tissues, blood or body fluid. Ensure that all biological material has been removed from the device.

4.2 Completely immerse the explanted device in a solution of ethanol 70% v/v for 15 minutes.

4.3 After 15 minutes, dry the device with a lint-free cloth and make sure that all biological material has been removed and that the device is free of any lint/fiber material.

4.4 Proceed to wash the unit with chlorhexidine and once completed, let it dry on a sterile surface.



5. PACKAGING PROCEDURE

Establishment Labs will provide a "Return Kit" (refer to Attachment 1) for devices that need to be returned. The "Return Kit" consists of the following:

- Explanted Implants Handling Protocol: includes the "Explanted Implant Form"
- Return Kit Label: to identify the device.
- Biohazard Bag: to place the device.
- Packing Box: to ship the device.
- Hologram Sticker: to seal the packing box.

5.1 Place the decontaminated device in the self-sealing plastic bag (biohazard bag) provided in the "Return Kit" and seal the bag. Place this bag into the packing box provided in the "Return Kit".

5.2 Fill out the return kit label provided in the "Return Kit", peel, and stick on the outside of the box of the unit to be returned (refer to Attachment 1, Step 5).

5.3 Fill out the "Explanted Implant Form – Motiva Implants" (refer to page 3 of this document) and include it in the packing box along with the unit to be returned. There must be one form filled out for each device to be returned.

NOTE: If you do not have a "Return Kit" you can request one to your distributor or you can place the unit in a self-sealing plastic bag (i.e Ziplock) and place it in a carton box adequate to ship the unit. Please identify the unit appropriately.

5.4 Send the decontaminated explanted device to Establishment Labs' local representative or distributor who will check the package and ship it to the manufacturer. In case the explanted device is covered by Motiva Implant Matrix® Breast Implants Limited Warranty, it must be sent to Establishment Labs within 10 days of explantation along with the Report Form. In case direct shipment to manufacturer is required, ship to Establishment Labs S.A., Coyol Free Zone and Business Park, 0 Street, Building B-25, Alajuela, Costa Rica or you can send it to EDC Motiva BVBA BE0881512541 Nijverheidsstraat 96 Wommelgem 2160 BELGIUM.

5.5 In case that local legislation does not allow for the implant to be returned for sanitary reasons, Establishment Labs' local Representative will handle the device according to the manufacturer's directions.. If no local representative is available, please directly contact Establishment Labs S.A. Zona Franca Coyol, Distrito San José de Alajuela. Costa Rica; phone: +506 2434-2400; fax +506 2434-2450 or customerservice@establishmentlabs.com for instructions.



Attachment 1. Return Kit Diagram

