MEDEC

EXPLANTED / CONTAMINATED MEDICAL DEVICE RETURN FORM

For use by healthcare facilities and other institutions when shipping explanted or otherwise contaminated medical devices to the manufacturer or distributor for inspection, analysis, investigation or disposal.

PROCEDURE FOR RETURNING EXPLANTED AND/OR CONTAMINATED MEDICAL DEVICE PRODUCTS

Do not autoclave the explanted device. Elevated temperatures may damage the device and inhibit device analysis.

1. Contact manufacturer/distributor for a return authorization code and return instructions
2. Clean the device of all biological material.
3. If a hazardous drug (such as Chemotherapy agents) has been accompanied with the device please affix a sticker marked “HAZARDOUS DRUGS ENCLOSED” to the outside of the mailing box.
4. Place and seal the device in a sealable biohazard bag.
5. If the device includes liquid or liquid contaminants, place sealed bag inside absorbent pouch and place inside a second biohazard bag or impermeable container. Alternatively, place absorbent material inside the external biohazard containment bag or container.
6. Place the sealed containers (with device) into a shipping container. Place completed form (this sheet) inside the shipping container – not within the sealable containment device (e.g. biohazard bag).
7. Seal the shipping box and ship to the address provided by the manufacturer/distributor.

REPORT DATE (dd-MMM-yyyy): ____________________

DEVICE RETURNING FACILITY INFORMATION:

Hospital/Facility Name:			
Address:			**Telephone #:**
City:	**Prov:**	**Postal Code:**	**Extension #:**
Physician Name:			**E-mail:**
Address (if different from Hospital)**:**			**Telephone #:**
City:	**Prov:**	**Postal Code:**	**Extension #:**
Reporter’s Name:			**E-mail:**
Address:			**Telephone #:**
City:	**Prov:**	**Postal Code:**	**Extension #:**

Device Name	Model #	Lot/Serial #	Implant Date or First Date of Use	Explant Date or Last Date of Use	Comments

EVENT INFORMATION:

Event date (dd-MMM-yyyy):	**Patient Initials or Case Identifier:**

Description of the event (Provide patient signs, symptoms, treatment, troubleshooting and patient history including pre-existing conditions.):

Was there patient death? ☐Yes ☐ No If yes, device related? ☐Yes ☐ No

Was there patient injury? ☐ Yes ☐ No

What was patient’s status after the device was removed? ☐ Recovered without sequela ☐ Recovered with sequela

Reason for removal or decommission of device: