

Pacemaker, Defibrillator, and Lead Explant and Return Guidelines

SUMMARY

Boston Scientific CRM encourages returning all explanted devices and associated lead systems to the manufacturer.

Consider the following for explant and return of product:

- Collect information stored in the device
- Deactivate the device
- Return the product(s) to Boston Scientific following explant in a Returned Products Kit (Model 6499)

ICD: Implantable Cardioverter Defibrillator

CRT-D: Cardiac Resynchronization Therapy Defibrillator

CRT-P: Cardiac Resynchronization Therapy Pacemaker

CRM PRODUCTS REFERENCED*

All Boston Scientific ICDs, CRT-Ds, CRT-Ps and Pacing Systems

*Products referenced herein may not be approved in all geographies. For comprehensive information on device operation, reference the appropriate product labeling.

CRM CONTACT INFORMATION

Technical Services – U.S.
1.800.CARDIAC (227.3422)
Tech.Services@bsci.com

Technical Services – Europe
+32 2 416 7222
eurtechservice@bsci.com

LATITUDE Clinician Support
1.800.CARDIAC (227.3422)
latitude@bsci.com

Patient Services
1.866.484.3268 – U.S. and Canada
001.651.582.4000 – International

Returning explanted product allows Boston Scientific to analyze the product and provides information for continued improvement in device quality and reliability. Returning product also allows the company to process any applicable warranty, maintain accurate patient/device tracking records, and properly store or dispose of the device with minimal environmental impact. Consider the following for explant and return of product to Boston Scientific:

- 1. Collect information stored in the device.** Interrogate the device, print appropriate reports, print ECG strips, and save patient data to disk.
- 2. Deactivate the device.** The following programming actions prevent audible tones, unwanted shocks, and overwriting of stored therapy history.

Defibrillators	Pacemakers
Program the following features to Off: <ul style="list-style-type: none"> • Brady and Tachy modes • Magnet Response • Beep When Explant is Indicated (or Beep When ERI is Reached) <p><i>NOTE: An ICD or CRT-D may deliver an unwanted shock during or after explant if it has not been deactivated prior to explant.</i></p>	Program the pacing mode to VOO

- 3. Explant the device and leads.** Use standard surgical techniques to explant the device and lead system (if appropriate). Take care to remove the leads intact and avoid damage to the lead body.

NOTE: If the leads cannot be removed from the header of the device during a procedure such as a postmortem explant, the leads may be cut.

CAUTION: Explant the device before cremation. Cremation and incineration temperatures might cause the device to explode.

- 4. Return the explanted product to Boston Scientific using the Returned Products Kit.¹**
 - Place the explanted product in the sterile Specimen Transport Bag.
 - Complete an Observation/Complication/Out-of-Service report form.
 - In the event of patient death (regardless of cause), also include a copy of the autopsy report, if performed and permitted by patient privacy laws.
 - Place all paperwork in the enclosed envelope and place envelope and all other items into the return kit.
 - Close the kit, ensure that the locking tab is inserted securely, and return the kit to Boston Scientific.

¹The Returned Products Kit (Model 6499) complies with regulations associated with shipment of biologically hazardous materials and ensures that the product is physically protected during shipment. The kit can be ordered at no charge online at <http://www.bostonscientific.com/pr> (select the link Returning Products).