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.

<table>
<thead>
<tr>
<th>Defibrillators</th>
<th>Pacemakers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Program the following features to Off:</td>
<td></td>
</tr>
<tr>
<td>• Brady and Tachy modes</td>
<td></td>
</tr>
<tr>
<td>• Magnet Response</td>
<td></td>
</tr>
<tr>
<td>• Beep When Explant is Indicated (or Beep When ERI is Reached)</td>
<td></td>
</tr>
<tr>
<td><strong>NOTE</strong>: An ICD or CRT-D may deliver an unwanted shock during or after explant if it has not been deactivated prior to explant.</td>
<td></td>
</tr>
<tr>
<td>Program the pacing mode to VOO</td>
<td></td>
</tr>
</tbody>
</table>

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.

- 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.

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**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 explorant
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

**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

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1 The 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/ppr](http://www.bostonscientific.com/ppr) (select the link Returning Products).