

SUMMARY

This article summarizes steps for a successful lead connection to Boston Scientific Pacemakers, Defibrillators, and S-ICDs referenced herein, including those with connections systems that meet DF-4 and IS-4 International Standards*. For complete lead connection instructions, reference the applicable product's Physician's Technical Manual.

*International standard ISO 27186:2010.

Products Referenced

All Boston Scientific Pacemakers, CRT-Ps, ICDs, CRT-Ds, S-ICDs, leads, and electrodes.

Products referenced are unregistered or registered trademarks of Boston Scientific Corporation or its affiliates. All other trademarks are the property of their respective owners.

For comprehensive information on device operation, reference the full instructions for use found at: www.bostonscientific-elabeling.com.

CAUTION: Law restricts this device to sale by or on the order of a physician. Indications, contraindications, precautions and warnings can be found with product labeling supplied with each device. Products referenced herein may not be approved in all geographies. Information is for the use in countries with applicable Health Authority product registrations.

All graphics produced by Boston Scientific Corporation, unless otherwise noted.

CRT-D: Cardiac Resynchronization Therapy Defibrillator
 CRT-P: Cardiac Resynchronization Therapy Pacemaker
 ICD: Implantable Cardioverter Defibrillator
 S-ICD: Subcutaneous Implantable Defibrillator

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Connecting Leads to Boston Scientific Pacemakers, Defibrillators, and S-ICDs

Boston Scientific lead/electrode terminals include an IS-1, IS-4, DF-4, or SQ-1 connector. During implant, follow instructions for use provided in the applicable manuals for devices and implant accessories. The steps summarized in this article may be helpful in achieving a successful connection with any of the connection types.

To connect the electrode or lead(s) to the implanted device, use only the tools provided in the sterile tray or accessory kit. Failure to use the supplied tools (connector tool and torque wrench) may result in damage to the setscrews, seal plugs, connector threads in the device header, or the terminal pin/electrode tip.

WARNING: For DF-4 and IS-4 leads, use caution handling the lead terminal when the EZ-4™ or ACUITY X4™ Connector Tool is not present on the lead. Do not directly contact the lead terminal rings with any surgical instruments or electrical connections such as PSA (alligator) clips, ECG connections, forceps, hemostats, and clamps. This could damage the lead terminal rings, possibly compromise the sealing integrity, and result in loss of therapy or inappropriate therapy.

Steps for Lead/Electrode Connection Success

STEP 1: Prior to insertion, look into lead ports to ensure that:

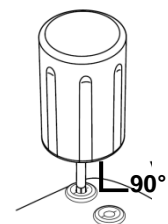
- the ports are clear
Check for the presence of blood or body fluids on the lead terminal/electrode tip and in header ports. Clean as necessary with sterile water.
- the setscrews are retracted sufficiently for insertion
Use the torque wrench to retract the setscrew if necessary. Verify that the stylet and any terminal pin accessories are removed prior to connecting the lead/electrode.



No setscrews or fluid visible in ports

STEP 2: Insert the torque wrench at a **90° angle** before inserting the lead/electrode.

- Gently insert the torque wrench at a 90° angle through the visible pre-slit center depression of the seal plug.
This provides a pathway to release air or fluid trapped in the port as the lead/electrode is inserted, mitigating potential pressure build-up in the lead barrel.



NOTE: Failure to properly insert the torque wrench in the pre-slit depression of the seal plug may result in damage to the plug and its sealing properties.

Do not implant the device if any seal plugs appear to be damaged.

STEP 3: Grip the lead/electrode near the proximal end of the terminal.	
<p>Once the torque wrench is in place, grip the terminal as close as possible to the proximal end of the terminal. DF-4 leads have a white terminal strain relief.</p> <p><i>Gripping the terminal as proximally as possible will reduce lead bending and increase force during insertion.</i></p>	

STEP 4: Fully insert the lead or electrode. Ensure that the terminal pin/electrode is clearly visible beyond the connector block.	
<p>With the torque wrench in place, fully insert the terminal into the lead/electrode port. If necessary, and as directed in product-specific labeling, lubricate connectors sparingly with sterile water or sterile mineral oil to make insertion easier.</p> <p>When fully inserted, the terminal pin will be clearly visible beyond the connector block when viewed through the header. If the inserted torque wrench prevents viewing of the terminal pin, flip the device to the opposite side to confirm the terminal pin extends beyond the setscrew block. It is not possible to over-insert a lead or electrode.</p> <p>PRECAUTION: Insert the lead/electrode terminal straight into the port. Do not bend the lead near the lead-header interface; do not fold the lead and then press against the fold. Improper insertion can cause insulation or conductor damage.</p>	<p>IS-1, IS-4, and DF-4 - Leads are clearly visible beyond the connector block</p>

STEP 4: Fully insert the lead or electrode. Ensure that the terminal pin/electrode is clearly visible beyond the connector block.	
	<p>SQ-1 - Electrode is clearly visible beyond the connector block</p>

STEP 5: Tighten the setscrew(s).	
<p>Ensure that the torque wrench is seated perpendicular (90°) to the connector block throughout this step.</p> <p>Apply gentle downward pressure on the torque wrench until the blade is fully engaged within the setscrew cavity.</p> <p>While maintaining pressure on the lead to ensure that it remains fully inserted, tighten the setscrew by slowly rotating the torque wrench clockwise until it ratchets (clicks) once. The torque wrench is preset to apply the proper amount of force to the setscrew; additional downward force and rotation are unnecessary.</p>	

STEP 6: Remove the wrench by pulling it straight out of the connector block, maintaining a 90° angle
Remove the wrench before applying gentle traction to each lead terminal (Step 7). In the event that the setscrew is accidentally loosened during wrench removal, this will help ensure that it will be detected by the terminal pull test.
STEP 7: Verify that the lead is secure.
After removing the torque wrench, verify lead connection integrity by applying gentle traction to <i>each lead terminal separately</i> . Do not pull on the yoke or on more than one lead terminal at a time. If a lead terminal is not secure, reinsert the torque wrench, loosen the setscrew by rotating the wrench counterclockwise until the lead is loose, and then repeat the steps above.
STEP 8: Ensure that <i>all</i> impedances (pacing/shocking) are stable and within recommended ranges.
Evaluate the electrical performance of each lead after connecting to the pulse generator to confirm proper connection. Verify that the baseline atrial and RV/LV channels are free of artifacts. An improper connection could result in loss of therapy or unneeded therapy. TIP: Evaluate each electrode of a rate sensing lead by programming and testing suitable pace/sense vectors from the Lead Settings Screen . If a high lead impedance measurement is observed for any one electrode , consider further investigation. If necessary, disconnect the lead and repeat the connection steps above. If reconnection does not eliminate the high impedance, contact Boston Scientific Technical Services for further assistance.