

## SUMMARY

Boston Scientific has introduced ICDs, CRT-Ds, and leads with connection systems that meet DF4 and IS4 International Standards\*. Only one setscrew is required to secure an electrical connection for four conductors per lead.

This article summarizes steps for a successful connection between Boston Scientific DF4 and IS4 leads and Boston Scientific ICDs and CRT-Ds.

For complete lead connection instructions, reference the applicable Physician's Technical Manual.

\*International standard ISO 27186:2010.

### Products Referenced

ENERGEN™, INCEPTA™, PUNCTUA™, AUTOGEN™, DYNAGEN™, INOGEN™, ORIGEN™ ICDs and CRT-Ds  
 RELIANCE™ 4-FRONT Leads with DF4-LLHH and DF4-LLHO connectors  
 ACUITY™ X4 Leads with IS4 four-pole connectors

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Products referenced herein may not be approved in all geographies. For comprehensive information on device operation, reference the full instructions for use found at: [www.bostonscientific.com/cardiac-rhythm-resources/international-manuals.html](http://www.bostonscientific.com/cardiac-rhythm-resources/international-manuals.html).

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.

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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 DF4 and IS4 Leads to DF4/IS4 Defibrillators

### Lead Connection Tips

- Ensure the port is clear and setscrew is retracted prior to lead insertion.
- Insert the torque wrench **before** the lead.
- Grip the lead close to the proximal end of the white terminal strain relief.
- Ensure the terminal pin is clearly visible beyond the connector block.
- Ensure that **all** pacing/shock impedances are within the recommended range.

### Steps for Lead Connection Success

**Verify ports are clear.** Check for the presence of any blood or other body fluids on the lead terminal and within pulse generator header ports. Clean as necessary with sterile water. Look down the lead ports to visually verify that the setscrew is sufficiently retracted to allow lead 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 to the pulse generator.

Verify that setscrews are not visible in lead ports.



To connect leads to the pulse generator, use only the tools provided in the pulse generator 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 lead terminal.

**WARNING:** For DF4 and IS4 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 compromising the sealing integrity and result in loss of therapy or inappropriate therapy, such as a high voltage short within the header.

**Insert torque wrench.** Gently insert the torque wrench blade into the setscrew by passing it through the preslit, center depression of the seal plug at a 90° angle. This will open up the seal plug, relieving any potential pressure build-up from the lead port by providing a pathway to release trapped fluid or air as the lead is inserted.

Inserting the torque wrench **before** the lead allows pressure to equalize



**NOTE:** Failure to properly insert the torque wrench in the preslit depression of the seal plug may result in damage to the plug and its sealing properties. Do not implant the pulse generator if the seal plugs appear to be damaged.

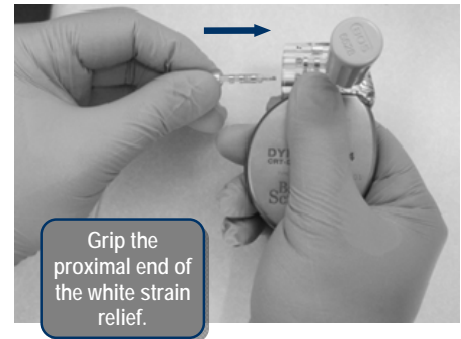
**Fully insert the lead.** With the torque wrench in place, fully insert the lead terminal into the lead port. To ease insertion, grip the terminal as close as possible to the proximal end of the white terminal strain relief. When fully inserted, the lead terminal pin will be clearly visible beyond the connector block when viewed through the pulse generator header, and for DF4/IS4 leads there will only be small gap between the proximal end of the white terminal strain relief and the colored header bore labels. It is not possible to over-insert a DF4 or IS4 lead. The lead is designed to hard stop in the header bore when fully inserted. 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.

**TIP:** Full lead insertion can be verified by observing the lead terminal pin as it passes beyond the connector block into the lead terminal pin cavity.

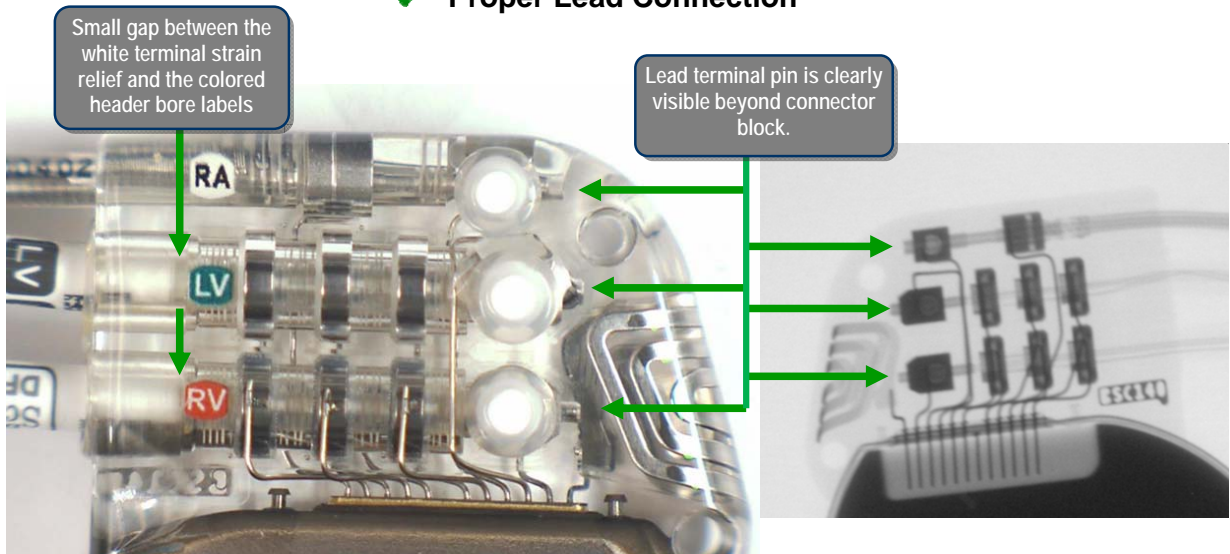
**NOTE:** If necessary, lubricate the lead connectors sparingly with sterile water to make lead insertion easier.

**CAUTION:** Insert the lead terminal straight into the lead port. Do not bend the lead near the lead-header interface. Improper insertion can cause insulation or connector damage

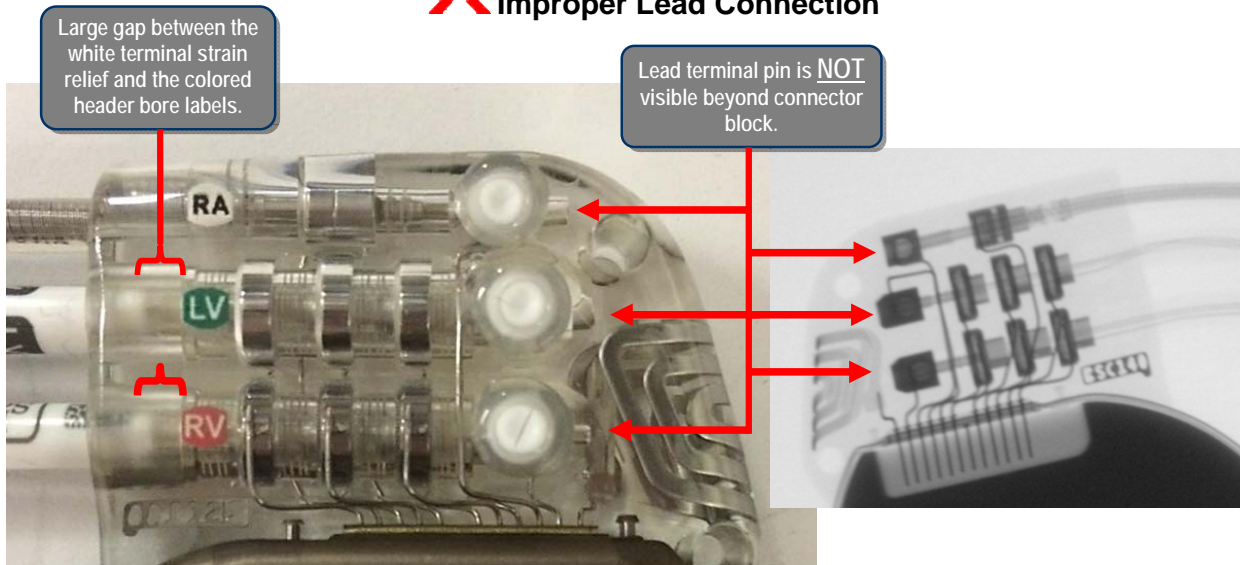
**NOTE:** Minor, inadvertent bending is acceptable during lead insertion, but do not fold lead and then press against the fold.



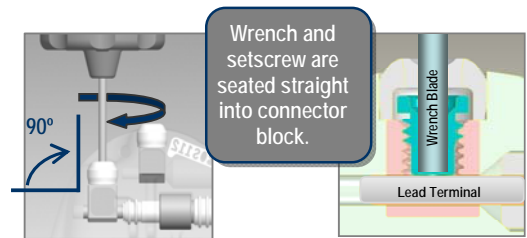
**✓ Proper Lead Connection**



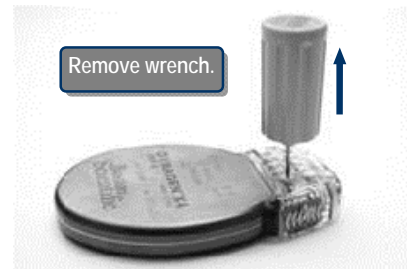
**✗ Improper Lead Connection**



**Tighten setscrew.** Apply gentle downward pressure on the torque wrench until the blade is fully engaged within the setscrew cavity, taking care to avoid damage to the seal plug. Ensure the torque wrench is seated perpendicular (90°) to the connector block. 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, keeping the torque wrench perpendicular to the connector block while tightening. The torque wrench is preset to apply the proper amount of force to the setscrew; additional rotation and downward force is unnecessary.



**Remove wrench.** Remove the torque wrench by pulling it straight out of the connector block.



**Verify lead is secure.** Apply gentle traction to the lead to ensure a secure connection. If the lead terminal is not secure, reinsert the torque wrench as described above, and loosen the setscrew by slowly turning the wrench counterclockwise, until the lead is loose. Then repeat the steps above.



**Evaluate Lead Signals.** Evaluate the electrical performance of each lead after connecting to the pulse generator to provide final confirmation of a proper connection. Ensure the baseline atrial and RV/LV channels are free of artifacts. An improper connection could result in loss of therapy or inappropriate therapy.

**TIP:** Evaluate each electrode of the IS4 lead by programming and testing suitable pace/sense vectors from the **Lead Settings Screen**. If a high (>2000 ohms) 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.

