

Bi-directional Torque Wrenches and Setscrews

BACKGROUND INFORMATION

Implantable leads used with pacemaker and defibrillator systems are secured to the device header with setscrews utilizing a special **torque wrench**. This type of wrench limits the amount of force that can be applied to tighten or loosen an implantable device setscrew, thereby protecting the setscrew and lead from damage due to excessive force.

This article provides information on torque wrench operation and which wrenches to use with Boston Scientific implantable cardiac devices.

For information on how to use a torque wrench to loosen stuck setscrews, please refer to the **A Closer Look** article, *Loosening Stuck Setscrews* available on www.bostonscientific.com or through CRM Technical Services.

PDM: Pulsar®, Discovery®, Meridian®

PD II: Pulsar Max II, Discovery II

ICD: Implantable Cardioverter Defibrillator

CRT-D: Cardiac Resynchronization Therapy Defibrillator

CRT-P: Cardiac Resynchronization Therapy Pacemaker

CRM PRODUCTS REFERENCED*

All Boston Scientific pacemakers, ICDs, CRT-Ds, CRT-Ps, lead adapters, lead extenders, and Models 6628 and 6942 torque wrenches.

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

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Each bi-directional torque wrench (Table 1) is calibrated to apply a specific tightening force and a specific loosening force to correctly position an implantable device setscrew. When the setscrew is secure, a ratchet/clicking sound is heard from the torque wrench, even though the wrench handle will still rotate. Turning the wrench handle beyond one (1) ratchet/click is not necessary as additional ratcheting will not move the setscrew further. For optimal performance:

- **Use Boston Scientific torque wrenches with Boston Scientific devices only.** Using wrenches from other manufacturers with Boston Scientific devices may provide too much or too little torque such that the setscrew cannot be tightened/loosened appropriately, or the lead-to-device connection mechanism can become damaged.
- **Use a new torque wrench for each procedure.** Use of the same wrench for multiple implant procedures and after repeated re-sterilizations alters the amount of force delivered, and may contribute to damage or difficulty operating a setscrew. Boston Scientific pacemakers and defibrillators are supplied with a torque wrench calibrated to tighten/loosen setscrews for the device in which it is packaged. Torque wrenches are also packaged individually for device replacement and/or lead revision procedures.
- **Use the appropriate torque wrench: orange or green.** Boston Scientific currently manufactures two different torque wrenches, each preset to torque levels that match different device setscrew designs. Table 1 indicates which torque wrench (orange or green) should be used for optimal performance with different Boston Scientific implantable cardiac devices. Specifically:
 - An **orange** torque wrench should be used on setscrews covered with **WHITE** seal plugs.
 - A **green** torque wrench should be used on setscrews covered with **CLEAR** seal plugs.

NOTE: For replacement and lead repositioning procedures, the orange torque wrench may be used to loosen setscrews on devices with clear seal plugs. However, understand that when loosening setscrews, the orange wrench applies more force than the green wrench; this can potentially stick a retracted setscrew with a clear seal plug. Therefore, if using an orange wrench to loosen a setscrew covered with a clear seal plug, **stop** turning the wrench as soon as resistance is felt and prevent the wrench from ratcheting/clicking.

Table 1. Device Family with Associated Seal Plug Type and Wrench Color

Device Family	Seal Plug Type	Torque Wrench
<p><i>Pacemakers:</i> ALTRUA™ <i>ICDs:</i> CONFIENT™*, TELIGEN™ <i>CRT-Ds:</i> LIVIAN™*, COGNIS™ <i>Lead Adapters & Lead extenders:</i> with <i>white</i> seal plugs</p>	 White seal plugs	 Model 6628, orange wrench
<p><i>Pacemakers:</i> INSIGNIA®, PDM, PD II <i>ICDs:</i> CONFIENT*, VITALITY® / 2 / AVT, PRIZM® / 2 / AVT <i>CRT-D & CRT-Ps:</i> LIVIAN*, CONTAK RENEWAL 3 / 4 RF, CONTAK RENEWAL® / 2 / 3 / 4 / AVT, CONTAK RENEWAL TR® / TR 2 <i>Lead Adapters & Lead extenders:</i> with <i>clear</i> seal plugs</p>	 Clear seal plugs	 Model 6942, green wrench
<p>*All CONFIENT & LIVIAN devices distributed in international geographies have white seal plugs. In the U.S., some CONFIENT & LIVIAN devices have all white seal plugs and some devices have all clear seal plugs.</p>		