Loosening Stuck Setscrews

SUMMARY

The technique described in this article, and included within Boston Scientific's "Guide to Replacement of Cardiac Implantable Pulse Generators," may be used at implant or during pulse generator replacement to free Boston Scientific pulse generator setscrews that are stuck in either the retracted ("up") or extended ("down") position. This technique uses the standard Model 6628 (or compatible) Bi-Directional Torque Wrench.

Refer to product instructions for use, or the A Closer Look article *Bi-Directional Torque Wrenches and Setscrews,* to identify which Model wrench to use with a given family of pulse generators.

Products Referenced

All Boston Scientific Implantable Pulse Generators

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

Contact Information

United States
www.bostonscientific.com

Technical Services – U.S.
LATITUDE® Clinician Support – U.S.
1.800.CARDIAC (227.3422)
+1.651.582.4000
tech.services@bsci.com
latitude@bsci.com

Patient Services
1.866.484.3268

International
www.bostonscientific-international.com

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

International LATITUDE Customer Support
www.latitude.bostonscientific-international.com
latitude.international@bsci.com

On occasion, setscrews may become stuck in either the retracted ("up") or extended ("down") position. This article describes a technique to loosen stuck setscrews, utilizing the Boston Scientific Model 6628 (or compatible) Bi-Directional Torque Wrench.

NOTE: *New-generation Boston Scientific implantable pulse generators that include a "top hat" setscrew, are designed to reduce the incidence of setscrews stuck in a retracted position by eliminating the need for a setscrew retainer washer.*

Step 1. Insert Torque Wrench

Locate the pre-slit center depression in the seal plug and carefully insert the bidirectional torque wrench into the hexagon-shaped slot in the screw.

WARNING: *Use of a non-torquing wrench may result in rounding out of the hexagon-shaped slot.*

CAUTION: *When inserting the torque wrench, take care to avoid damaging the seal plug.*

Step 2. Verify Stuck Setscrew Position

Determine if the stuck setscrew is in the retracted or extended position, as described below:

Characteristics of setscrews that are stuck in the:	
retracted ("up") position	extended ("down") position
Wrench ratchets *immediately* upon rotation in either direction	Wrench ratchets *immediately* upon rotation in either direction
No downward movement of setscrew	No upward movement of setscrew
Screw not visible in lead barrel	Screw visible in lead barrel (may prevent full insertion of lead)
Leads already in lead barrel can be freely removed	Leads already in lead barrel cannot be removed

Step 3. Loosen stuck setscrew

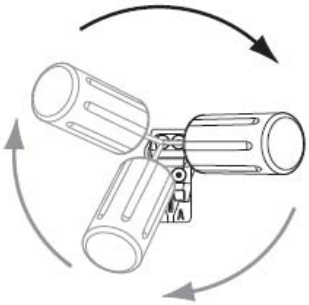
A. From a perpendicular position, tilt the wrench 20° - 30° from the vertical center axis of the screw (Figure 1).

Figure 1. Wrench tilted 20° to 30° from perpendicular position.

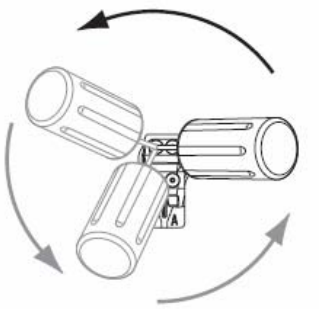
B. Perform rotational movement, as described below:

If the setscrew is retracted ("up"):	If the setscrew is extended ("down"):
• Rotate the wrench around the vertical axis three times in a clockwise circular pattern, such that the handle of the wrench orbits the centerline of the screw.	• Rotate the wrench around the vertical axis three times in a counterclockwise circular pattern, such that the handle of the wrench orbits the centerline of the screw.

The wrench handle should not twist or turn during this rotation.



Top view of clockwise wrench rotation.



Top view of counterclockwise wrench rotation.

- Do not turn or twist the hex wrench handle during this rotation.
- As needed, this process may be attempted up to four times with slightly more angle (not to exceed 30°) each time.

Side view of hex wrench during rotation.

Step 4. Once the setscrew has been freed, extend or retract the setscrew as appropriate.

This technique may be attempted up to four times (up to 12 rotational movements) with the same wrench. If the setscrew remains stuck after four attempts (12 rotations), no further attempts should be made.

NOTES:

- *Discard the torque wrench after each case in which this technique is used; Do not resterilize and re-use as calibration of the wrench cannot be ensured.*
- *Use of this technique applies to all Boston Scientific pulse generator header configurations.*
- *Tilting the hex wrench at a 20° to 30° angle will result in a slight bend of the hex wrench blade; this is expected.*
- *If the setscrew has not been loosened, use the #2 hex wrench from the Wrench Kit Model 6501.*