

Loosening Stuck Setscrews

BACKGROUND INFORMATION

The technique described in this article, and contained within approved labeling/instructions for use, may be used to free setscrews in Boston Scientific pulse generators that are stuck in either the retracted (“up”) or extended (“down”) position, either at implant or during pulse generator replacement. The procedure uses the standard Model 6942 Bi-Directional Torque Wrench. This article was first published as a *Product Update* on November 1, 2005.

On occasion, setscrews may become stuck in either the retracted (“up”) or extended (“down”) position. A procedure utilizing the Model 6942 Bi-Directional Torque Wrench to realign the setscrew mechanism and loosen stuck setscrews is described below.

NOTE: Prior to wrench insertion, users should locate the preslit center depression in the seal plug within the device header; the wrench should be carefully and fully inserted into the setscrew hex slot, taking care to avoid damaging the seal plug.

Step 1. Verify Stuck Setscrew Location

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

Retracted (“Up”)	Extended (“Down”)
<ul style="list-style-type: none"> Wrench ratchets <i>immediately</i> upon <u>clockwise</u> rotation 	<ul style="list-style-type: none"> Wrench ratchets <i>immediately</i> upon <u>counterclockwise</u> rotation
<ul style="list-style-type: none"> No downward movement of setscrew 	<ul style="list-style-type: none"> No upward movement of setscrew
<ul style="list-style-type: none"> Screw not visible in lead barrel 	<ul style="list-style-type: none"> Screw visible in lead barrel (may prevent full insertion of lead)
<ul style="list-style-type: none"> Leads already in lead barrel can be freely removed 	<ul style="list-style-type: none"> Leads already in lead barrel cannot be removed

Step 2. Realign setscrew mechanism to loosen stuck setscrew

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



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

CRM PRODUCTS REFERENCED

All pulse generator headers.

CRM CONTACT INFORMATION

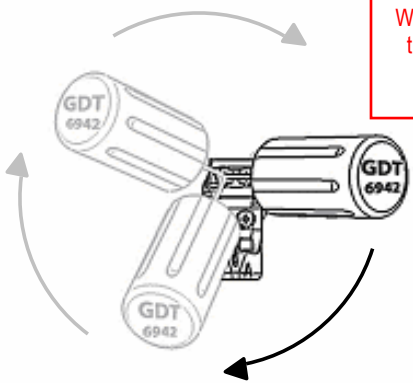
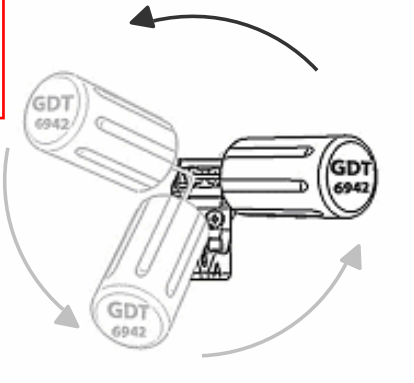
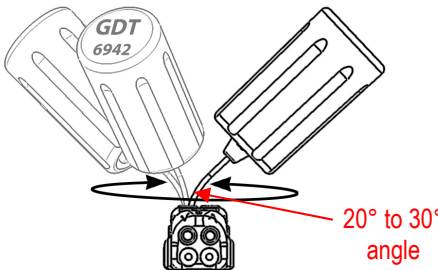
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B. Perform rotational movement, as described below:

Retracted (“Up”)	Extended (“Down”)
<ul style="list-style-type: none"> Rotate the wrench around the vertical axis three times in a <u>clockwise</u> circular pattern, such that the handle of the wrench orbits the centerline of the screw (Figure 2A).  <p data-bbox="726 398 1053 521" style="border: 1px solid red; color: red; padding: 2px;">Wrench handle does not twist or turn (“GDT 6942” namestamp remains in fixed orientation)</p> <p data-bbox="284 788 813 817">Figure 2A. Top view of clockwise wrench rotation.</p>	<ul style="list-style-type: none"> Rotate the wrench around the vertical axis three times in a <u>counterclockwise</u> circular pattern, such that the handle of the wrench orbits the centerline of the screw (Figure 2B).  <p data-bbox="885 788 1500 817">Figure 2B. Top view of counterclockwise wrench rotation.</p>
<ul style="list-style-type: none"> Do not turn or twist the hex wrench handle during this rotation. Note that the namestamp (“GDT”) on the top of the hex wrench remains in a fixed orientation during the rotation process (as depicted in Figure 2). As needed, this process may be attempted up to four times with slightly more angle (up to 30°) each time (Figure 3).  <p data-bbox="542 1294 1069 1323">Figure 3. Side view of hex wrench during rotation.</p>	

Step 3. Once the setscrew has been freed, proceed to extend or retract the setscrew as appropriate.

Notes

- **Discard the hex wrench after each case in which this procedure is used;** do not re-sterilize and re-use. (Bending the hex wrench blade weakens the blade such that it becomes susceptible to breaking after repeated use.)
- Use of this procedure has been thoroughly tested and has proven equally effective on all Boston Scientific pulse generator header configurations, with success typically achieved after only one attempt.
- Tilting the hex wrench at a 20° to 30° angle will result in a slight bend of the hex wrench blade; this is expected. Testing has shown that a new wrench blade will not break when tilted to this slight angle.
- This procedure 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.
- This technique is part of Boston Scientific’s approved labeling/instructions for use of the Model 6942 Bi-Directional Torque Wrench.