

Guide to Replacement of Cardiac Implantable Pulse Generators

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ACKNOWLEDGMENTS

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INTRODUCTION

Purpose of this Guide

Pulse generator (PG) replacement procedures may be required for a variety of reasons and, in general, are considered to be fairly routine. However, the success of these procedures is largely dependent on the preoperative planning and technique of the physician.

The purpose of this guide is to communicate guidelines and suggestions to physicians performing cardiac implantable PG replacements. The guide includes information, warnings, and precautions on planning and performing replacement procedures as well as troubleshooting suggestions.

The information contained in this guide is not intended to supersede device-specific instructions for use, rather to serve as a supplemental resource for physicians caring for patients in the operating-room setting.¹

Note: *Boston Scientific does not endorse the use of any specific surgical technique. Proper surgical procedures and techniques are the responsibility of the medical professional. The procedures described herein are furnished for informational purposes only. Each physician must apply the information in these instructions according to professional medical training and experience.*

1. This guide applies to all products under either the Guidant or Boston Scientific brand.

General Precautions

The following are general precautions to be observed during any PG replacement procedure. This list is not meant to be comprehensive. Refer to later sections of the guide for specific warnings and precautions. Failure to observe these warnings and cautions about PG replacement procedures could result in damage to the leads and/or harm to the patient.

- Ensure that proper equipment such as heart monitoring, imaging, temporary pacing, and external defibrillation is functional and available to intervene in a cardiac emergency.
- For patients who require uninterrupted pacing, consider programming the PG to an asynchronous pacing mode as described in the PG's instructions for use.
- If applicable, turn defibrillation therapy off to prevent unwanted shocks and ensure that everyone participating in the replacement procedure is informed.
- Electrical signals introduced into the body by some hospital monitoring equipment² may result in accelerated pacing, possibly up to the maximum sensor-driven rate, when minute ventilation (MV) is programmed to On. Deactivate the MV sensor when interaction with this equipment is suspected. Additionally, consider turning all rate response features to Off, as XL rate response can also be activated by the PG manipulation required for removal from the pocket.
- Electrosurgical cautery on or in close proximity to the leads could induce ventricular arrhythmias and/or fibrillation. Additionally, electrocautery application on or in close proximity to the PG, may result in transient adverse device behavior including loss of output. If electrocautery cannot be avoided, observe the instructions provided in the appropriate device instructions for use.

2. Examples of this equipment include, but are not limited to, respiratory monitors, diagnostic echo imaging, surface ECG monitors, and hemodynamic monitors. Deactivate the MV sensor when interaction with this equipment is suspected.

Table 1. Identification of Implanted System Components^a

Method	Source/Attribute
Implant data	<ul style="list-style-type: none"> • ID card • Transtelephonic monitoring records • Manufacturer's implant records • Following physician's records
Electronic analysis	<ul style="list-style-type: none"> • Magnet response • Interrogation
X-ray or fluoroscopy	<ul style="list-style-type: none"> • Size, shape • Identifying markings • Connector block type • Active- or passive-fixation leads • Number of high-energy coils
Invasive	<ul style="list-style-type: none"> • Direct visual inspection • Manufacturer's code/serial number • Type of connector • Size of lead header

a. Based on Ellenbogen KA, Kay GN, Wilkoff BL. *Clinical Cardiac Pacing and Defibrillation*. 2nd ed, W.B. Saunders Company, 2000, pp. 645-68.

PLANNING REPLACEMENT PROCEDURES

PG replacement may be required for a variety of reasons but is most often performed when the device reaches its replacement indicator. The elective replacement indicator signifies that PG replacement must be scheduled.

In general, PG replacement procedures are fairly routine. However, the success of these procedures is largely dependent on the preoperative planning and technique of the physician. Proper preoperative planning for replacement procedures includes, but is not limited to, the following items:

- Verify the date of implant and identity of the system components currently in use (as well as those implanted but no longer in use) by the manufacturer and the model and serial numbers (Table 1).
- Consider a pre-procedure x-ray to determine the location of implanted system components as well as other out-of-service components (if any).
- When programming the new device, consider settings that have been programmed and diagnostic data that have been collected with the old device.
- Consider implanted lead polarity, whether unipolar by intent or by a lead safety switch.

Planning Replacement Procedures

- Consider the unique needs of each individual patient, including pacemaker dependency, before detaching the lead(s). For pacemaker-dependent patients, temporary pacing may be established to ensure the availability of continuous pacing during the procedure.
- Ensure that the selected replacement PG is compatible with the existing leads. If it is not, then a lead adaptor will be necessary or the leads will require revision. Contact Technical Services or your local sales representative to inquire about device and lead compatibility.
- If planning to reuse the existing leads, test the leads using the implanted device prior to surgery to achieve a baseline evaluation of their performance.
Note: *Battery depletion may preclude testing the leads using the device.*
- Ensure that sterile duplicates of all implantable items are available in case accidental damage or contamination occurs.
- Consider administering prophylactic antibiotics systemically before and/or after the replacement procedure and locally, in the pocket. If planning to reuse a pocket, be aware that scar tissue formation will inhibit systemic antibiotic access.

WARNING: Check for drug allergies or interactions before administering antibiotics.

EXPOSING THE EXISTING DEVICE

Determine the location of implanted system components as well as other out-of-service components (if any) by fluoroscopy.

WARNING: Verify lead position on x-ray. Extreme care should be taken not to puncture the lead insulation or otherwise compromise lead integrity during system dissection.

Once the pocket is opened, slide the PG out of the pocket, being careful not to stress the leads. Visually inspect the pocket for signs of infection and the leads for any breach in integrity.

WARNING: If a unipolar configuration is being used, pacing will no longer be delivered to the patient once the PG is removed from the pocket.

Attention has been drawn to pocket infections at the time of device replacement. Contemporary practice includes the use of pocket irrigation with antibiotic solution in an attempt to prophylaxe against pocket infection. Additionally, debridement of scar tissue lining the pocket may increase pocket vascularity and improve the ability of the immune system to detect the presence of infectious agents.

WARNING: Check for drug allergies or interactions before administering antibiotics.

CAUTION: Take care to avoid damage to the leads when removing scar tissue from the pocket.

DISCONNECTING THE LEADS

Removing Leads from the Header

WARNING: Leads are not designed to tolerate excessive flexing, bending, tension, or injection pressure. This could cause structural weakness, conductor discontinuity, and/or lead dislodgment.

Retract the setscrews using a Boston Scientific Model 6628 (or compatible) calibrated torque wrench. If applicable, remove and discard the tip protector before use. To loosen the setscrew, gently insert the wrench blade through the pre-slit center depression of the seal plug at a 45° angle. Give careful attention when using this torque wrench with PGs having clear seal plugs. The additional counterclockwise torque of this wrench may cause the setscrews in these pulse generators to become stuck if tightened against the stop. Similar consideration is required when using this torque wrench with lead adapters and lead extenders that have setscrews that tighten against a stop when fully retracted. Apply gentle downward pressure until the blade is fully engaged within the setscrew cavity. When the blade is fully engaged within the setscrew cavity, turn counterclockwise slowly until the lead connection is loose. If the wrench clicks during counterclockwise turning, stop. The screw has reached its maximum counterclockwise position. Do not turn the wrench further.

Once the setscrew is loosened, grasp the lead as close to the terminal pin as possible and apply gentle traction to free the lead. Repeat this procedure for all leads connected to the PG.

Disconnecting the Leads

During most PG replacement procedures, the lead(s) are removed from the device header with minimal resistance. On occasion, leads may become or feel frozen in the header of the device for various reasons including, but not limited to:

- Stuck setscrews
- Fluid in the header
- Residual medical adhesive in the lead barrel
- Silicone-to-silicone bonding of the lead to the header sealing rings
- Close tolerance of the header–lead interface

For suggestions on how to free frozen leads, see Appendix – Troubleshooting (Page 16). These techniques should be used as a final measure to prevent lead replacement.

Returning Explanted Devices

Defibrillation therapy should be programmed to Off to prevent unwanted shocks. Return all explanted devices. Examination of explanted PGs and leads can provide information for continued improvement in system reliability. Use a Returned Product Kit to properly package the device and/or lead and complete an Observation/Complication/Out-of-Service Report form. Send the form and kit to Boston Scientific at the address on the back cover of this manual.

VERIFYING LEAD INTEGRITY

Do not rely on chronically implanted leads without first verifying their compatibility with the selected replacement PG. Using incompatible leads can damage the connector or result in potential adverse consequences, such as undersensing of cardiac activity or failing to deliver necessary therapy. For confirmation of lead/PG compatibility, contact Technical Services or your local sales representative.

Each PG replacement requires integrity testing of the chronic lead(s) to ensure suitability for continued use. Follow normal lead-verification procedures to determine whether continued use of the lead is appropriate. Standard lead testing, including visual inspection and electrical performance, can be used to assess lead system integrity. If results indicate that a lead has been compromised, lead revision may be necessary.

Visual Inspection

Leads should be evaluated by x-ray or fluoroscopic imaging as well as visual inspection of exposed lead body insulation, terminal ring and pin, and sealing rings.

Electrical Performance

Verify electrical performance of the lead by using a pacing system analyzer or similar monitor after disconnecting the lead from the PG. Perform measurements for voltage threshold, intrinsic amplitude, and pacing impedance and ensure the absence of noise for each lead according to its original manual's specifications.

CONNECTING THE REPLACEMENT PG

Follow the implantation instructions described in the instructions for use for the new device. The information in this section should be considered a general guide for implanting the replacement device.

Lead-to-PG Connection

1. Insert the torque wrench into the center, pre-slit depression of the seal plug located near the tip of the fully inserted lead connector pin.

Note: Setscrews require use of the bidirectional torque wrench included in the package.

CAUTION: Failure to properly insert the torque wrench into the pre-slit location of the seal plug could result in damage to the plug and its sealing properties. Failure to use the supplied torque wrench could result in damage to the setscrew or connector threads.

2. Insert the lead terminal into the connector.

CAUTIONS:

- Do not insert a lead into the PG header without first visually verifying that the setscrews are sufficiently retracted to allow insertion.
- Insert the lead connector straight into the lead port. Do not bend the lead near the lead-header interface. Improper insertion can cause insulation damage near the terminal ring that could result in lead damage.

Connecting the Replacement PG

Notes:

- If necessary, lubricate the lead terminal sealing rings sparingly with sterile water or sterile mineral oil to make insertion easier.
 - For proper connection of an IS-1 lead to the PG, be certain that the connector pin visibly extends through the connector block at least 1 mm.
 - For proper connection of a 3.2-mm (i.e., not an IS-1-style) lead to the PG, be certain that the lead connector pin is within 1 mm of the end of the device lead barrel.
3. Ensure the torque wrench is seated perpendicular (90°) to the connector block. While maintaining pressure on the lead, tighten the setscrew by **slowly** rotating the torque wrench clockwise until it ratchets 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 captive setscrew; additional force is unnecessary.
 4. Remove the torque wrench.
 5. Verify lead connection by applying gentle traction to each *individual lead terminal*. Do not pull on the yoke or 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, and repeat Steps 2-5.

PG Insertion

1. Place the device into the subcutaneous implant pocket.

The physician should keep the eventual replacement of the device in mind and take care to ensure its accessibility. See step 4 below for information regarding the placement of leads into the pocket.

If the device is coated, the uncoated window must face away from the muscle to reduce the possibility of muscle stimulation. Use caution to prevent damage to the silicone coating during the implant procedure.

CAUTION: If pacing is unipolar, be sure that electrical contact has been established and maintained between the PG can and subcutaneous tissue. Otherwise, therapy may not be delivered to the patient.

2. Verify device operation using an ECG.

Interrogate the PG with a programmer to verify telemetry before pocket closure.

If the patient's intrinsic rhythm is above the programmed rate, use a magnet to temporarily switch the pacemaker to an asynchronous magnet rate of 100 ppm. If proper pacing and/or sensing are not demonstrated, disconnect the lead from the pacemaker and visually inspect the connector and leads. If necessary, retest the lead and/or change programmers. Inadequate signals could indicate possible lead dislodgment, which would necessitate lead repositioning. This use of the magnet application is not appropriate for ICDs and CRT-D devices.

3. Suture the device in position.

Use the suture hole in the device top to secure the device in the subcutaneous pocket. This may facilitate MV sensing.

CAUTION: Implanting a replacement device in a subcutaneous pocket that previously housed a larger device may result in pocket-air entrapment, migration, erosion, or insufficient grounding between the device and tissue. Flooding the pocket with sterile saline solution decreases the possibility of pocket-air entrapment and insufficient grounding. Suturing the device in place reduces the possibility of migration and erosion.

4. Place any excess lead length into the pocket.

Giving consideration to patient anatomy and PG size and motion, gently coil any excess lead length and place adjacent to the pulse generator. It is important to place the lead into the pocket in a manner that minimizes lead tension, twisting, sharp angles, and/or pressure.

Note: Refer to lead-specific instructions for use for information on handling leads.

CAUTION: Before closing the subcutaneous pocket, ensure that the setscrews are properly tightened and that the device functions properly.

APPENDIX—TROUBLESHOOTING

During most PG-replacement procedures, the lead(s) are removed from the device header with minimal resistance. On occasion, leads may become or feel frozen in the header of the device for various reasons including, but not limited to:

- Stuck setscrews
- Fluid in the header
- Residual medical adhesive in the lead barrel
- Silicone-to-silicone bonding of the lead to the header sealing rings
- Close tolerance of the header-lead interface

It is important that the leads be rescued as a first priority. Boston Scientific has tested a variety of techniques for successfully freeing frozen leads that can be used as a final measure to prevent lead replacement. Some of these techniques have been developed by physicians for physicians in the operating-room setting. The following guidelines should be regarded as options you might consider if you encounter difficulty removing leads during a PG-replacement procedure.

- Loosening Stuck Setscrews (Page 17)
- Lubricating the Lead-PG interface (Page 22)
- Exposing Lead by Cutting Header (Page 25)

Note: Please report lead-removal difficulty or other adverse product performance observations to Technical Services or your local sales representative.

Lead damage is a possibility with any PG-replacement procedure. As with any procedure, standard medical practice should be followed to ensure continuous pacing for pacemaker-dependent patients throughout this or any other cardiac rhythm management system removal process. Lead integrity testing is also recommended to ensure that chronic leads remain suitable for continued use.

Loosening Stuck Setscrews

On occasion, setscrews may become stuck in the extended position causing the leads to become frozen in the header. The following procedure has been identified to realign the setscrew mechanism and loosen stuck setscrews using the Boston Scientific Model 6628 (or compatible) calibrated torque wrench.

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

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

CAUTION: When inserting the torque wrench into the setscrew hexagon-shaped slot, take care to avoid damaging the seal plug.

2. Determine whether the stuck setscrew is in the retracted or extended position (Table 2).

Table 2. Verification of Setscrew Location

If setscrews are stuck in the retracted position,	If setscrews are stuck in the extended position,
the wrench will ratchet immediately upon rotation in either direction.	the wrench will ratchet immediately upon rotation in either direction.
no downward movement of the setscrew will occur.	no upward movement of the setscrew will occur.
the setscrew will not be visible in the lead barrel.	the setscrew will be visible in the lead barrel and may prevent full insertion of a lead.
leads already in the lead barrel can easily be removed.	leads already in the lead barrel cannot be removed.

3. Realign the setscrew mechanism to loosen the stuck setscrew. From a perpendicular position, tilt the wrench to the side 20° to 30° from the vertical center axis of the screw (Figure 1). Tilting the hex wrench to this angle will result in a slight bend of the hex wrench blade. Testing has shown that a new wrench blade will not break when tilted to this slight angle.

Perform the appropriate rotational movement of the wrench to either retract or extend the screw (Figure 2 and Figure 3).



Figure 1. Tilt wrench 20° to 30° from its axis.

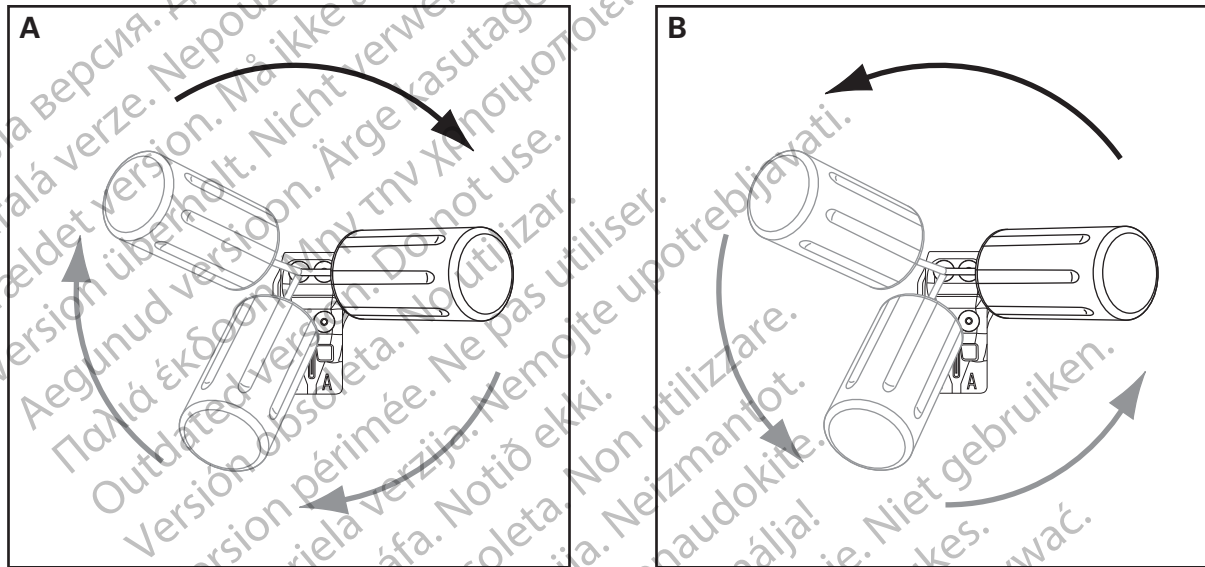


Figure 2. Top view of wrench rotation (A) in the clockwise direction to free setscrews stuck in the retracted position, and (B) in the counterclockwise direction to free setscrews stuck in the extended position.

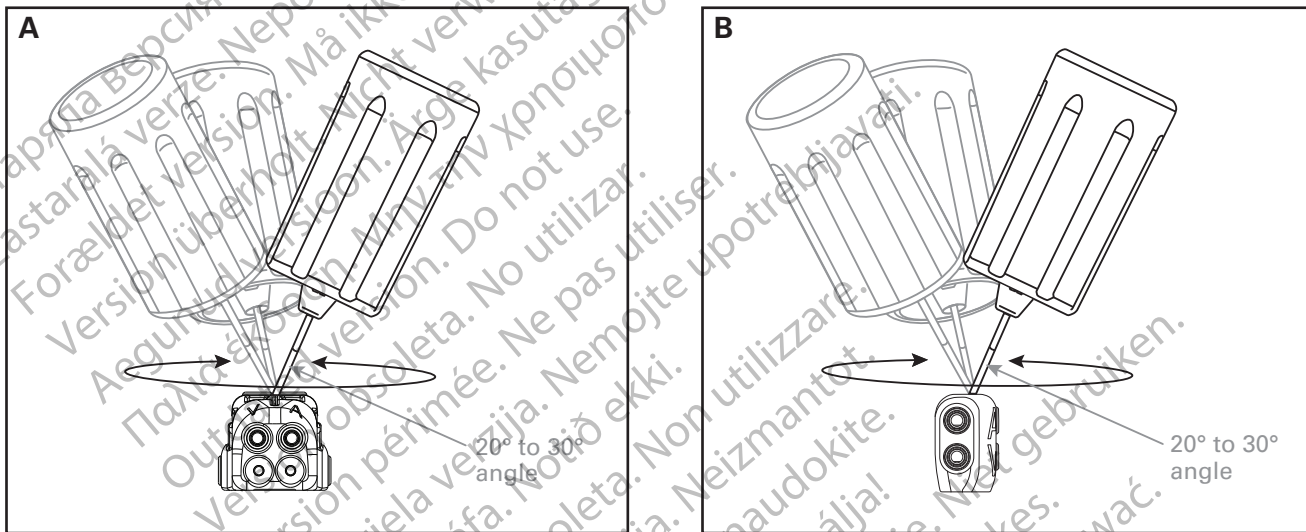


Figure 3. Side view of wrench rotation (A) for a Tachy device, and (B) for a Brady device.

4. Once the setscrew is free, proceed to extend or retract the setscrew as appropriate.

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.

Note: Discard the torque wrench after being used in this procedure. Do not resterilize and reuse as calibration cannot be ensured.

If the screw has not been fully loosened, use the #2 hex wrench from the Wrench Kit Model 6501.

Lubricating the Lead-PG Interface

If the setscrews are completely retracted and the lead is not easily removed, it may be frozen as a result of a seal formed by bodily fluids or silicone bonding. In this case, the leads may be freed by lubricating the lead-PG interface with sterile heparinized saline. If the lead is not removed from the header easily, stop, because excessive traction on the lead may result in lead damage, including lead/pin separation.

WARNING: This procedure is applicable to Brady devices and Brady ports in Tachy devices only. If attempting to lubricate the lead/PG interface of a Tachy device, it should always be programmed to Tachy Mode Off first.

WARNING: It is possible that this procedure may damage the lead seal, leading to immediate or gradual fluid infiltration. The absence or presence of visual damage is not a reliable indicator of functional damage to the lead. Therefore, in addition to visual inspection and rigorous electrical performance testing using the new PG, appropriate follow-up is recommended when using this technique.

1. Fill a 1-cc syringe with a 25-gauge needle with heparinized saline.
2. Carefully insert the needle into the lead barrel between the body of the frozen lead and the seals of the header up to the outermost connector block (Figure 4). The needle will be visible through the header material.

CAUTION: The needle should be inserted parallel to the lead. Do not insert the needle at an oblique angle because doing so may result in damage to the lead.

Notes:

- *Insertion may be easiest if approached from either the top or the bottom of the lead port.*
 - *The insertion path up to the outermost connector block may not be straight.*
3. Inject the heparinized saline into the lead barrel until the saline is visibly exiting the header via the setscrew seal plugs on the same side of the header.
 4. Grasp the lead as close to the terminal pin as possible and gently pull on the lead to remove it.

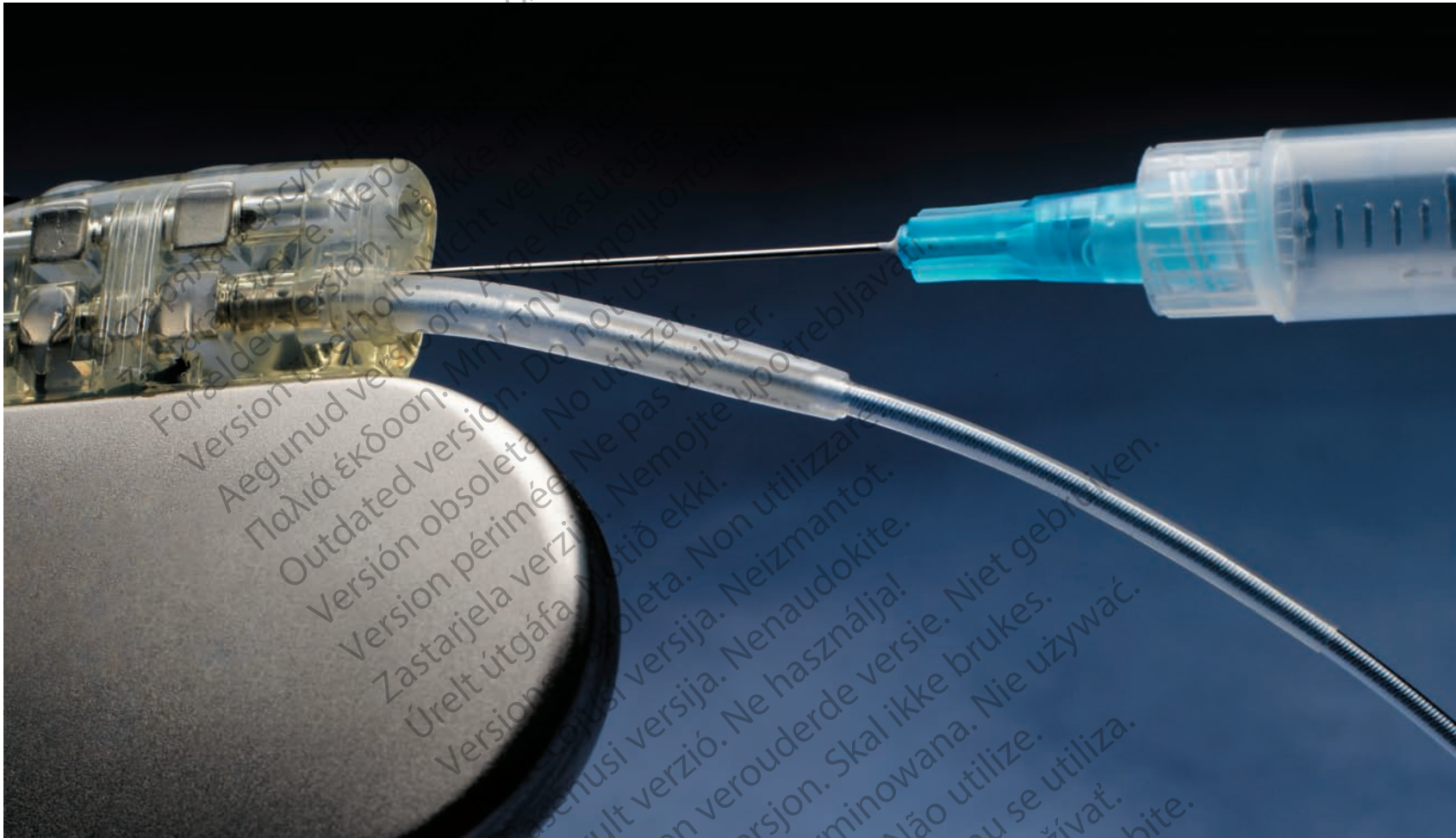


Figure 4. Insert the needle into the lead barrel parallel to the lead. Do not insert the needle at an oblique angle.

Exposing Lead by Cutting Header

In rare instances, the leads may not be safely removed from the connector block by loosening stuck setscrews and/or lubricating the lead-PG interface. If this is the case, then as a last resort, the leads may be rescued by sacrificing the PG. Fisher *et al.* have developed a method for cutting away the back of the PG header to retrieve frozen leads.³

WARNING: This procedure has been tested on Brady devices only. If attempting to cut through the header of a Tachy device, it should always be programmed to Tachy Mode Off first.

WARNING: Cutting the header will disrupt therapy delivery (i.e., no output with loss of pacing support to the patient) due to the location of circuitry wires within the cut area.

WARNING: If you have not previously used surgical cutting tools, practice is recommended as use of this type of tool could result in injury to the operator.

WARNING: The force required to cut the header may cause the cut piece to project away from the device. Eye protection is recommended to prevent injury to the operator.

3. Fisher, J.D. *et al.* (2004) Lead stuck (frozen) in header: salvage by bone cutter versus other techniques. PACE 27:1136.

The method developed by Fisher *et al.* is described below:

1. Hold the PG securely, ideally using Lorna non-perforating towel forceps. If this instrument is not available, any non-perforating forceps may be used.
2. Use large articulated cutting forceps (Figure 5). Position the cutting forceps on the back of the header at a safe distance from the end of the lead-tip terminal (Figure 6).

CAUTION: Position the cutting forceps beyond the lead tip (which may extend beyond the connector block) but within the lead barrel so as not to damage the lead terminal pins. The available cut area on the header is smaller in some models than others depending on the lead barrel length.



Figure 5. Example of articulated cutting forceps.

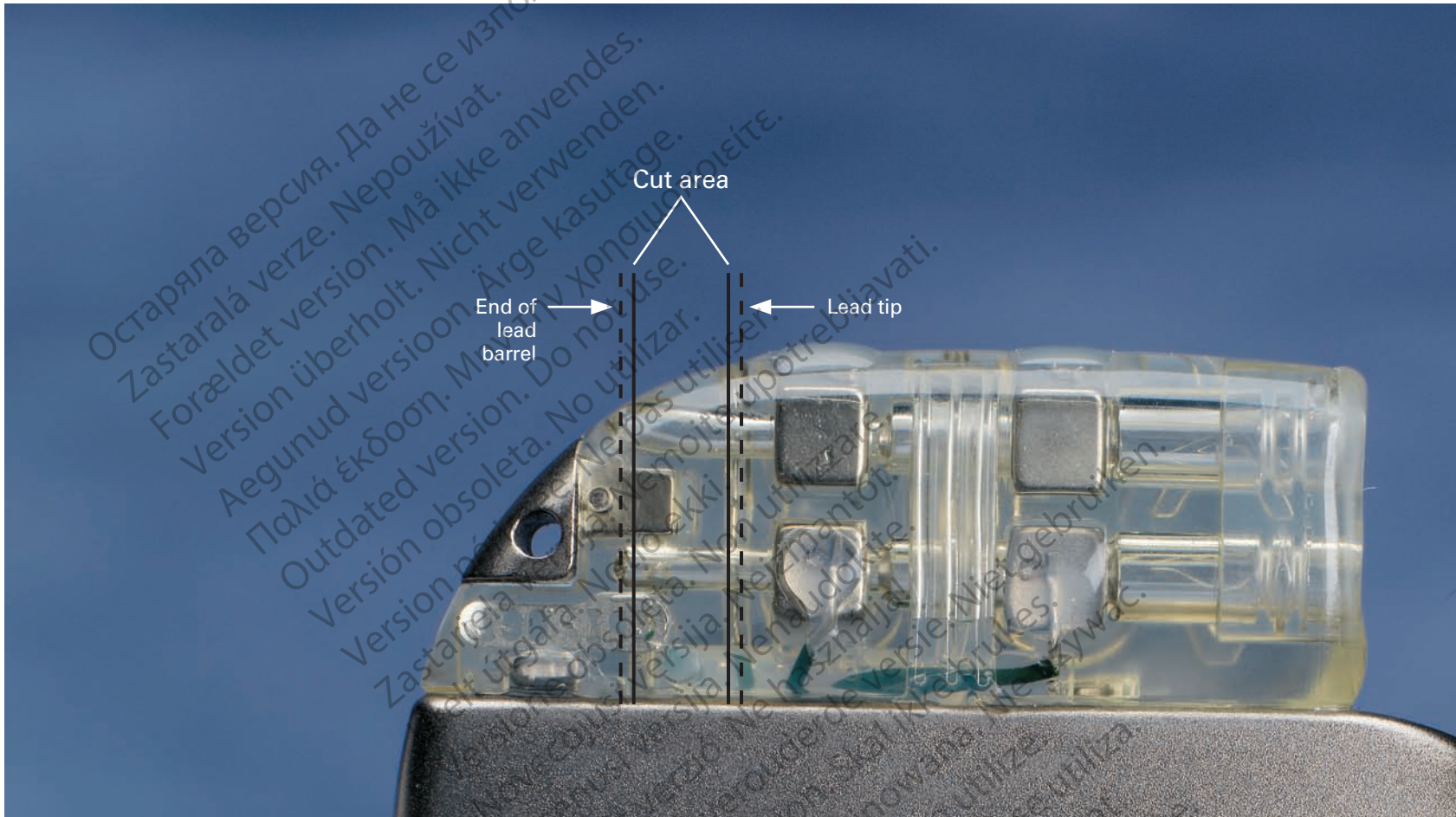


Figure 6. Safe cutting area in a typical PG.

3. Ensure that the surgical field is adequately covered to prevent debris from reaching the patient.
4. Compress the handles of the cutting forceps until they cut through the lead barrel(s) within the back of the header. This will expose the tips of the terminal pins (Figure 7). The degree of force required to cut through the header is dependent on the particular type of plastic used to make the header. In general, a low to moderate amount of force is needed for cutting Boston Scientific headers.

WARNING: Intermedics headers require significantly more strength to cut. In some test cases, the resulting force projected the cut piece away from the device. Placing your hand over the end of the header prior to cutting may help to contain the severed piece.



Figure 7. Cutting the header to expose the lead pins.

5. The cut portion of the header may completely detach or remain semiattached (Figure 8). The cut portion may be removed using either the cutting forceps or a large Kelly clamp.



Figure 8. With the header cut, the lead pins are exposed.

6. After gaining access to the lead barrel, use the torque wrench or a forceps to push the pin out of the header while simultaneously pulling gently on the lead terminal (Figure 9).

Note: If additional technical assistance is required, please contact Technical Services or your local sales representative.

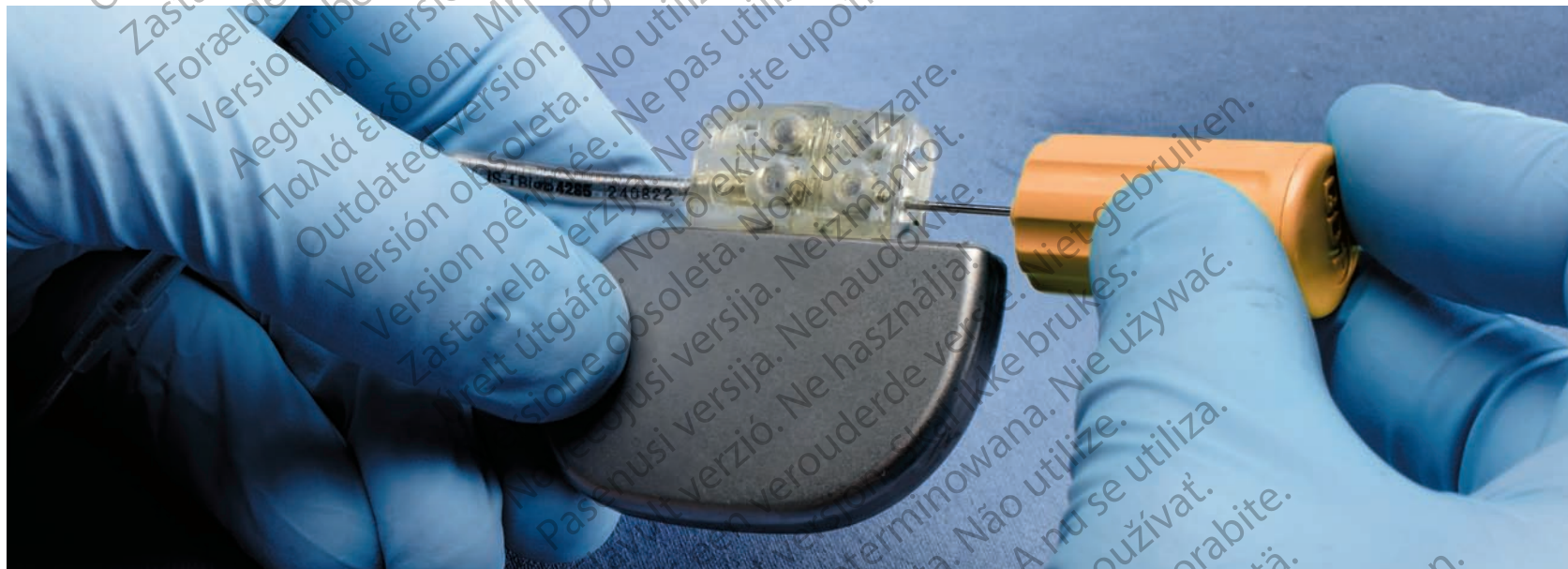


Figure 9. Push the lead pin out of the exposed lead barrel.

Остаряла версия. Да не се използва.
Zastaralá verze. Nepoužívat.
Forældet version. Må ikke anvendes.
Version überholt. Nicht kasutage.
Aegunud versioon. Ärge kasutage.
Παλιά έκδοση. Μην την χρησιμοποιείτε.
Outdated version. Do not use.
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Version périmée. Ne pas utiliser.
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Zastarjela verzija. Neizmantoť.
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Dit is een verouderde versie. Niet gebruiken.
Utdatert versjon. Skal ikke brukes.
Wersja przeterminowana. Nie używać.
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Versione expirată. A nu se utiliza.
Zastaralá verzia. Nepoužívať.
Zastarela različica. Ne uporabite.
Vanhentunut versio. Älä käytä.
Föråldrad version. Använd ej.
Ercel olmayan sürüm. Kullanmayın.

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Versione expirată. A nu se utiliza.
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