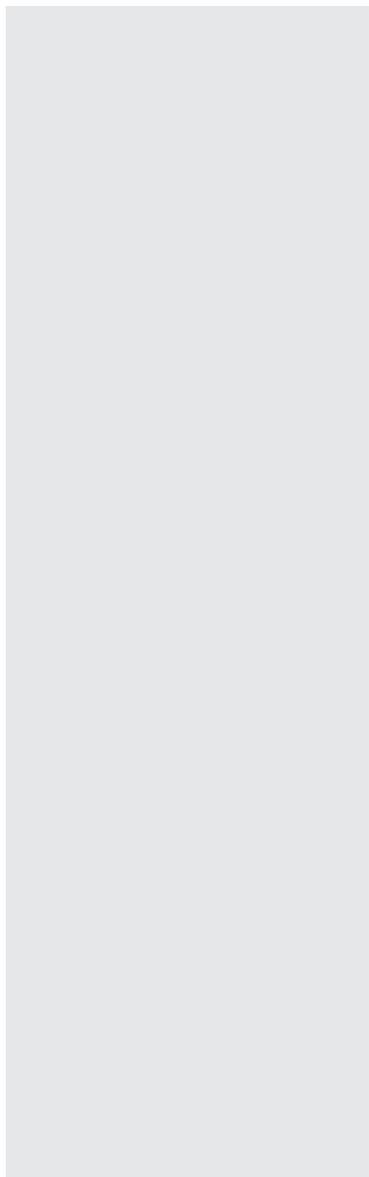


Avista™ MRI xx cm  
8 Contact Lead Kit  
Directions for Use



**Rx ONLY**

CAUTION: Federal law restricts this device to sale, distribution and use by or on the order of a physician.

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## Trademarks

All trademarks are the property of their respective holders.

## Guarantees

Boston Scientific Corporation reserves the right to modify, without prior notice, information relating to its products in order to improve their reliability or operating capacity.

Drawings are for illustration purposes only.

## Additional Information

For Indications and related information, see the *Indications DFU*. For contraindications, warnings, precautions, adverse events summary, physician instructions, sterilization, component disposal, and contact information for Boston Scientific, refer to the *Information for Prescribers DFU* for your spinal cord stimulator system. For other device-specific information not included in this manual, labeling symbols, and warranty, refer to the appropriate DFU as listed on your *Reference Guide*. For SCS implant conditions for MRI eligibility, refer to the appropriate MRI guidelines manual for your SCS system as listed on your *Reference Guide*.

## Product Model Numbers

Model Number	Description
SC-2408-xx	Avista™ MRI xx cm 8 Contact Lead
xx = Length in cm	

## Registration Information

### Registering the Avista™ MRI Lead

In accordance with international practice and regulatory legislation in some countries, a registration form is packed with each Boston Scientific lead/lead extension/splitter. The purpose of this form is to maintain traceability of all products and to secure warranty rights. It also allows the institution involved in the evaluation or replacement of a specific implanted lead, accessory or device to gain quick access to pertinent data from the manufacturer. Fill out the registration form included in the package contents. Return one copy to Boston Scientific, keep one copy for patient records, provide one copy to the patient, and one copy to the physician.

Boston Scientific Neuromodulation  
25155 Rye Canyon Loop  
Valencia, California 91355, USA  
Attention: Customer Service Department

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## Description

Leads function as a component of Spinal Cord Stimulator (SCS) systems by delivering electrical stimulation to the nerve structures in the dorsal aspect of the spinal cord, resulting in an inhibition of pain sensation. The eight-contact Avista™ MRI percutaneous lead is available in lengths of 56 cm and 74 cm. Each lead has eight electrode contacts located near the distal end. Each contact is 3 mm in length and is spaced 1 mm from the adjacent contact.

The Avista™ MRI Lead is designed using Boston Scientific's Heat-Canceling Technology: The triple layers of the lead are engineered to work together to minimize the RF energy that causes heat under the labeled MRI conditions for use.

## SCS Systems with ImageReady™ MRI Technology

When an appropriate Boston Scientific SCS System with ImageReady MRI Technology is implanted as directed (see “SCS *Implant Conditions For Full-body MRI Eligibility*” in this manual), a patient's full body may be eligible for MRI scans under specific conditions.

For detailed information about eligibility and conditions for MRI scanning, refer to the *ImageReady MRI Full Body Guidelines* for your SCS System.

## Package Contents

- (1) Percutaneous Lead with pre-loaded Curved Stylet
- (1) Stylet Ring with a Straight Stylet
- (2) Suture Sleeves
- (1) Insertion Needle with Stylet
- (1) Steering Cap
- (1) Lead Position Labels—left and right (non-sterile)
- (1) Device Registration Form/Temporary Patient Identification Card
- (1) Product Literature

## Lead Storage

Store components between 0 °C and 45 °C (32 °F and 113 °F) in an area where they are not exposed to liquids or excessive moisture. Temperatures outside of the stated range can cause damage.

## Instructions for Use

### SCS Implant Conditions for Full Body MRI Eligibility

**CAUTION:** To allow a patient full-body MRI scan eligibility under specific conditions, implant a Boston Scientific SCS System with ImageReady MRI Technology as described below. If the implant criteria are not met, the patient will not have an SCS system with full-body MRI scan eligibility. MRI scans performed under different conditions can result in patient injury or damage to the implantable device.:

- Use only ImageReady MRI SCS system components (e.g., leads and IPGs) as specified in the *ImageReady MRI Full Body Guidelines* for your SCS System.

**Note:** Lead extensions, adapters, and splitters are not full-body MRI scan eligible.

- Implant the IPG in the upper buttocks or lower flank.
- Implant the lead in the epidural space.

**Note:** Retrograde lead placements have not been evaluated for MRI.

- Use only the suture sleeves provided with the MRI lead kit or the Klik™ X MRI anchor to secure the leads.
- Explant any previously abandoned leads, extensions, splitters or adapters that may be in the patient (i.e. leads, extensions, splitters, or adapters, or portions of, that are not connected directly to an IPG).

**Note:** Other implanted medical devices may limit or restrict MRI scans.

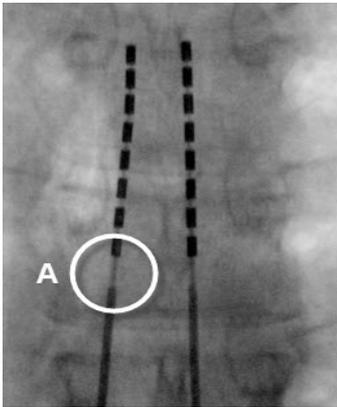
- It is recommended that you enter all component model number and implant location information using the *ImageReady MRI Full Body Patient Eligibility Checklist* and maintain it in the patient's medical records. When adding, changing, or removing IPGs, leads or accessories, it is recommended that you complete a new *ImageReady MRI Full Body Patient Eligibility Checklist* and maintain it in the patient medical record.
- For the full body MRI conditions and MRI-specific warnings and precautions for conducting an MRI scan, refer to the *ImageReady MRI Full Body Guidelines* for your SCS System.

### Use of X-ray Imaging to Identify an Implanted Avista MRI Lead

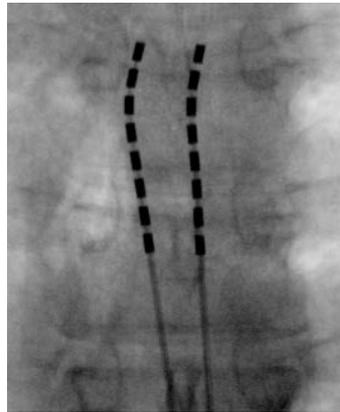
On the x-ray image, look for the radio-opaque suture sleeves as an identifier, and/or a radiolucency proximal to contact 8 (most caudad contact). See Figures 1-3.

**Note:** Do not use x-ray identification to conclude that the entire SCS system is full body MRI Scan eligible.

#### Figure 1: Avista MRI Lead with radiolucency proximal to contact 8 vs. Non MRI Leads

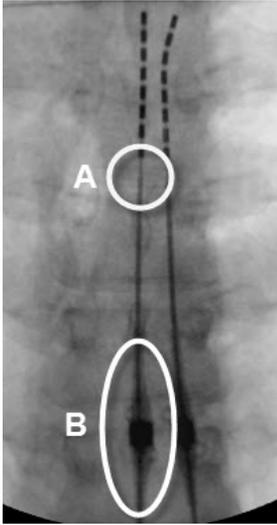


**Figure 1a:** Avista MRI Lead. Circle A shows region of radiolucency proximal to contact 8 (most caudad contact).

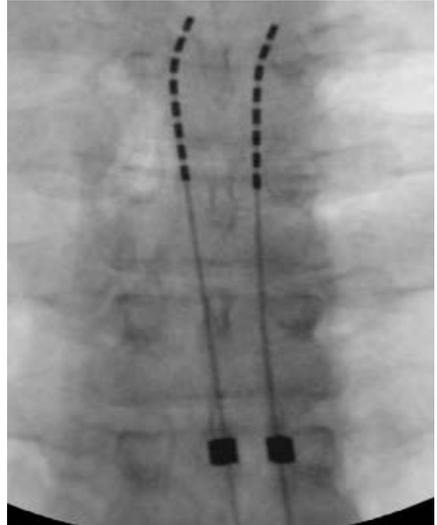


**Figure 1b:** Non-MRI Lead. Provided for reference.

**Figure 2: Avista MRI Lead with Klik X MRI Anchor vs. Non MRI Leads with Klik or Klik X Anchor**

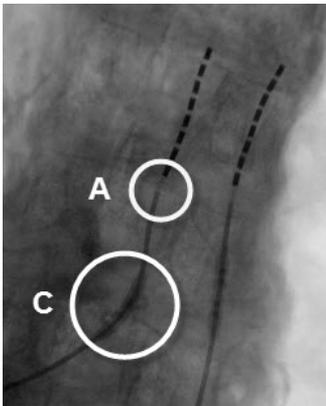


**Figure 2a:** Avista MRI Lead with Klik X MRI Anchor. Circle A shows region of radiolucency proximal to contact 8 (most caudad contact). Circle B shows the radio opaque Klik X MRI Anchor.

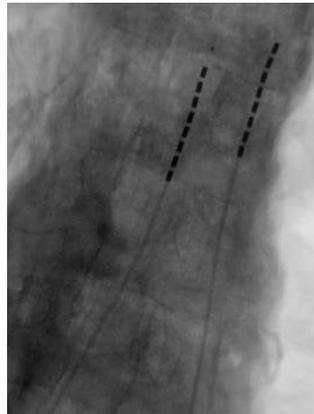


**Figure 2b:** Non-MRI Lead with Klik or Klik X Anchor. Provided for reference.

**Figure 3: Avista MRI Lead with radio opaque suture sleeve vs. Non MRI Leads**



**Figure 3a:** Avista MRI Lead with radio opaque suture sleeve. Circle A shows region of radiolucency proximal to contact 8 (most caudad contact). Circle C shows the radio opaque suture sleeve.



**Figure 3b:** Non-MRI Lead with suture sleeve (non radio opaque)

## Lead Handling

Physician training is required. Boston Scientific also recommends that implanting physicians read all product labeling prior to using our devices.

- Avoid damaging the lead with sharp instruments or excessive force during surgery.
- Do not sharply bend or kink the lead.

**WARNING:** If the patient receives an MRI scan, broken conductor wires and damage to the lead body could increase the risk of tissue heating, which could cause tissue damage or serious patient injury.

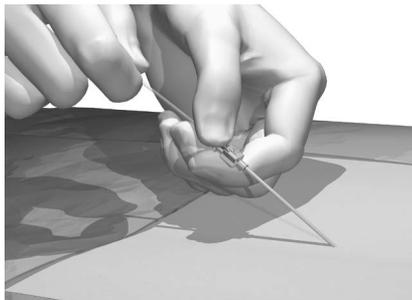
- Do not tie suture(s) directly to the lead; use the provided suture sleeves.
- For the Percutaneous Leads avoid forcing the lead into the epidural space by carefully clearing a path using the lead blank.
- Avoid pulling an implanted lead taut; provide a stress relief loop at the insertion site to minimize tension on the lead.
- Avoid handling the lead with sharp instruments; use only rubber-tipped forceps.
- Take care when using sharp instruments such as hemostats or scalpels to prevent damaging the lead.
- Wipe off any body fluids from the lead connector end before connecting it to any other component. Fluid contamination of these connections could compromise the integrity of the stimulation circuit.
- Wipe off any body fluids from the lead stylet before inserting or reinserting it into the lead.

## Percutaneous Lead Placement in the Epidural Space

1. Position, prep and drape the patient in the usual accepted manner. Inject a local anesthetic at the needle insertion site.
2. Under fluoroscopic guidance, place the insertion needle into the epidural space with the bevel facing up using an angle of 45° or less (Figure 4).

**CAUTION:** Use only an insertion needle provided by Boston Scientific. Other needles may damage the lead. The stamped number "14" on the needle hub (or the triangle on the hub of the curved Epimed needle, sold separately) corresponds to the orientation of the bevel, which must face up. Turning the bevel ventral (down) may result in lead damage. An angle of more than 45° increases the risk of lead damage.

**WARNING:** The angle of the insertion needle should be 45° or less (Figure 4). Steep angles increase the insertion force of the stylet and also present more of an opportunity for the stylet to pierce the lead and cause tissue damage.



**Figure 4:** Angle of Incision Needle

**WARNING:** Do not abandon leads or any portion of leads or extensions in the patient when changing components or permanently explanting the IPG. Abandoned components may prevent the patient from being allowed MRI scans in the future due to concerns of lead electrode heating that can result in tissue damage.

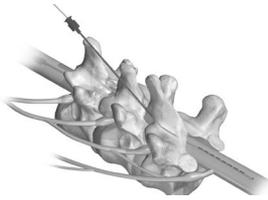
3. Remove the needle stylet from the insertion needle and verify entry into the epidural space using the standard technique.
4. OPTIONAL: Under fluoroscopic guidance, insert the lead blank through the insertion needle and into the epidural space. Advance the lead blank to verify entry into the epidural space, then withdraw the blank.
5. While holding the lead stylet handle, place the steering cap over the proximal end of the stylet handle with moderate force until it is held in place. Then slowly insert the lead, with stylet, through the insertion needle. The lead stylet should extend to the tip of the lead.
6. OPTIONAL: If exchange of the lead stylet is desired, carefully pull out the existing stylet and insert the preferred stylet. While inserting the stylet into the lead, if resistance is encountered, withdraw the stylet approximately 3 cm, rotate the lead and/or stylet, and gently advance the stylet. If resistance is still encountered, repeat the above procedure until the stylet can be fully inserted.

**WARNING:** Do not exchange the lead stylet while the electrode array of the lead is in the bevel of the insertion needle. If the electrode array is in the bevel area, remove the lead from the insertion needle before exchanging the stylet. Inserting the lead stylet in the lead while the electrode array is in the bevel of the insertion needle increases the risk of lead and tissue damage.

**WARNING:** If the lead stylet is removed and reinserted, do not use excessive force when inserting the stylet into the lead. The use of instruments, such as forceps, to grasp the stylet during insertion is not recommended as this could result in applying excessive force and could increase the risk of lead and tissue damage.

7. Advance the lead to the appropriate vertebral level under fluoroscopic guidance. A sufficient length of lead (for example, at least 10 cm, or approximately three vertebrae) should reside in the epidural space to aid in lead stabilization.

**CAUTION:** If other lead electrode locations are used (e.g. retrograde, head, or peripheral), MRI scan eligibility will be restricted. The patient will not be full-body eligible for MRI scans.



**Figure 5:** Lead placement in the Epidural Space

8. Proceed to the instructions for connecting to the OR Cable assembly and ETS in the Clinician Trial Manual for your SCS System. The appropriate *Clinician Trial Manual* for your SCS system is listed in the *Reference Guide*.

## Intraoperative Testing

The following steps are for procedural reference only. For detailed stimulation testing procedures and guidelines refer to the appropriate programming manual for your SCS system as listed in the *Reference Guide*.

1. After linking the Clinician Programmer to the Trial Stimulator, check impedances to verify that components are properly connected. Lead impedance is measured and displayed for each of the IPG's contacts.

Impedances, indicated by an orange circle on the Programmer software, are considered to be resultant from open or unconnected wires.

2. Using test stimulation, enlist patient feedback to verify lead placement and pain coverage.

**Note:** If lead repositioning is necessary, turn stimulation off before proceeding.

3. Reposition leads as necessary.

**CAUTION:** Do not force the stylet into the lead.

4. Steer lead to new position.
5. Remove stylet, wipe proximal ends of leads.
6. Check impedances.
7. Repeat steps 1-3 if the lead has been repositioned.
8. When the desired lead placement is achieved:

- a. Turn the Trial Stimulator off.
- b. Unlock each OR cable connector and disconnect from the lead(s).
- c. For percutaneous lead (s) - Slowly withdraw the stylet (s).

9. Record the lead position by capturing a fluoroscopic image to be sure the leads have not moved. Retest if necessary.

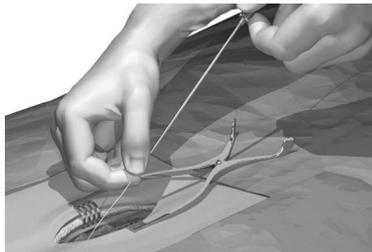
10. For a Permanent Trial or permanent IPG Implantation using percutaneous MRI leads, proceed to "Permanent Lead Anchoring and Tunneling".

Before receiving a permanent SCS system, it is recommended that patients undergo a trial procedure so that they can experience stimulation to evaluate if SCS is effective at treating their chronic pain.

## Permanent Lead Anchoring and Tunneling

### Removing the Insertion Needle

1. Cut down around the insertion needle to provide access for anchoring the lead.
2. Carefully withdraw the insertion needle from the epidural space by slowly pulling the needle up towards the proximal end of the lead while holding the lead in place (Figure 6).



**Figure 6:** Removal of the Insertion Needle

3. Once the insertion needle tip is exposed, hold the lead as close to the exit site as possible, then carefully pull the needle completely from the lead.
4. Remove the stylet.

## Anchoring the Lead

Leads can be permanently anchored with an included suture sleeve or with a Clik X MRI Anchor. Refer to the *Clik X MRI Anchor Directions for Use*, or continue with the following steps to anchor using a suture sleeve.

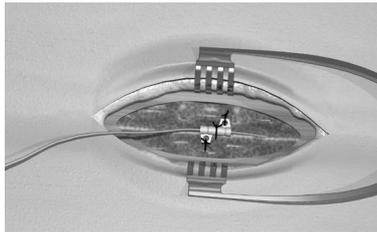
5. For percutaneous leads, carefully remove the lead stylet using fluoroscopy to ensure the lead position does not change.
6. Place a suture sleeve over the lead and down to the supraspinous ligament or deep fascial tissue.
7. Ligate the suture sleeve onto the lead by tying a 2-0 silk or other nonabsorbable suture around the center groove of the sleeve to prevent sliding. Circumferential stitches may be tied at the compression slots.

**CAUTION:** Do not use polypropylene sutures as they may damage the suture sleeve. Do not suture directly onto the lead, or use a hemostat on the lead body. This may damage the lead insulation. In addition, during an MRI scan, the patient could be at risk of tissue heating, resulting in tissue damage or serious patient injury.

**Note:** The 2.3 cm Suture Sleeves each have three (3) compression slots, which are designed to reduce slippage.

8. Suture the sleeve to the supraspinous ligament or deep fascia through the suture sleeve holes.
9. Tie multiple sutures as tightly as possible around the suture sleeve to secure it to the lead.

**CAUTION:** Tightening sutures directly on the lead can damage the lead. In addition, during an MRI scan, the patient could be at risk of tissue heating, resulting in tissue damage or serious patient injury.

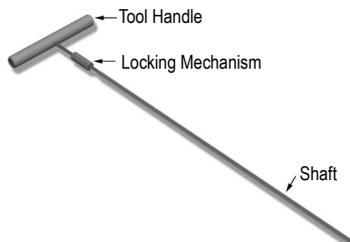


**Figure 7:** Securing the Suture Sleeve

10. For Permanent Trials, proceed to “Tunneling the Lead or Lead Extension”.
11. For permanent IPG implantation, refer to instructions for “IPG Implantation” in the IPG Directions For Use for your SCS system.

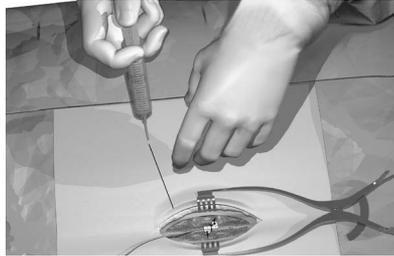
## Tunneling the Lead or Lead Extension

12. Attach the tunneling tool handle to the shaft by turning the locking mechanism clockwise.



**Figure 8:** Assembled Tunneling Tool

13. Mark the desired route of the tunnel.
14. Administer the appropriate local anesthetic along the tunneling path (Figure 9).



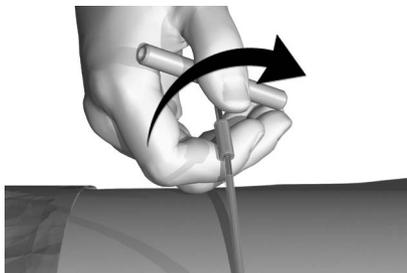
**Figure 9:** Administration of Anesthetic along the Tunneling Path

15. OPTIONAL: If necessary, bend the tool shaft to conform to the patient's body.
16. Make a small incision at the desired exit site.
17. Create a subcutaneous tunnel between the midline incision and the exit site until the straw is visible and accessible at the exit point (Figure 10).



**Figure 10:** Subcutaneous Tunnel

18. Unscrew and remove the tunneling tool handle (Figure 11).



**Figure 11:** Removing the Handle of the Tunneling Tool

19. Grasp the tip of the tool with one hand while holding the straw in place with the other hand. Pull the tunneling tool shaft out through the straw.
20. Push the lead or extension proximal ends through the straw, then withdraw the straw (Figure 12).



**Figure 12:** *Withdrawal of the Tunneling Straw*

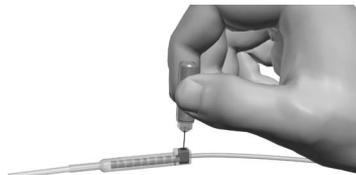
21. For Permanent Trials: proceed to “Connecting the Lead Extension”.
22. For Permanent IPG Implantation, refer to instructions for “Connecting the lead to the IPG” in the IPG Directions for Use for your SCS System.

**Note:** The following Codman Disposable Catheter Passers may be used in place of the Boston Scientific tunneling tool: REF 82-1515 (36 cm); REF 82-1516 (55 cm); and REF 82-1517 (65 cm). When using a Codman Disposable Catheter Passer, tunnel from the IPG pocket to the midline incision using the standard technique.

### Connecting the Lead Extension for Permanent Trials

**WARNING:** Physicians should not prescribe MRI for patients undergoing trial stimulation or who have any SCS system components that are not fully implanted. Explant all trial stimulation components if an MRI scan is required. MRI has not been tested on trial stimulation components and may cause heating of the lead electrodes, resulting in tissue damage or serious patient injury.

23. Wipe clean the proximal end of the lead, then insert the proximal end into the lead extension connector until it stops and the retention ring (long ring) is under the setscrew.
- Note:** If there appears to be an obstruction when inserting the lead into the lead extension connector, use the hex wrench to loosen (counterclockwise) the setscrew and/or gently rotate the lead to help advance the proximal end.
24. Ensure that the lead is fully inserted before tightening the set screw to prevent lead damage.
25. Using the hex wrench supplied, turn the extension connector setscrew clockwise until it clicks, indicating lock (Figure 13).



**Figure 13:** *Tightening of the setscrew in the Extension Connector*

**Note:** Ensure that the hex wrench is fully seated in the setscrew before tightening. The hex wrench is torque-limited and cannot be overtightened.

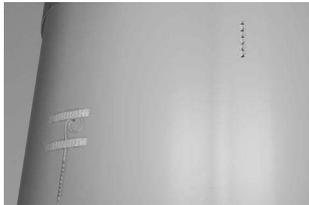
26. Form an appropriately-sized pocket using blunt dissection on either side of midline for coiled excess lead and extension connectors.

27. Place a small loop at the lead for slack. If necessary, loosely tie a suture around the lead-loop, but do not tighten onto the lead.

**CAUTION:** Tightening sutures directly on the lead can damage the lead. In addition, during an MRI scan, the patient could be at risk of tissue heating, resulting in tissue damage or serious patient injury.

28. Carefully remove excess slack by gently pulling the extensions from the exit wound.

29. For Permanent Trials, if desired, a small suture may be used to close the exit wound of the extension. Place and tape a stress relief loop and dress the wound. Proceed to the instructions to “Insert the Leads into the OR Cable Connector” in the appropriate Clinician Trial Manual.



**Figure 14:** Closed Exit Wound

30. For Permanent Implant, close the midline incision, and refer to instructions for “Connecting the Lead to the IPG” in the IPG Directions For Use for your SCS System.

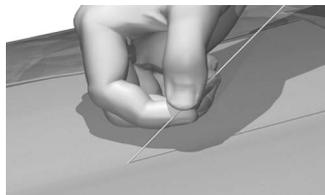
### Removal of Lead or Extension

Remove bandages and properly cleanse the exit site. The method of removal depends upon whether a temporary trial or permanent trial was performed.

#### Option A: Percutaneous Lead Removal After Temporary Trial

31. Clip sutures if used to secure the trial lead(s) in place.

32. Remove the lead(s) and discard.



**Figure 15:** Removal of the Trial Leads

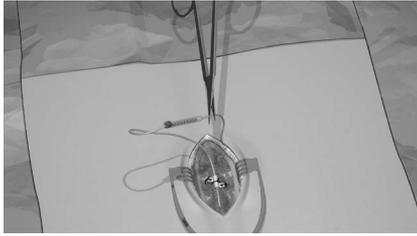
33. To replace the trial lead(s) with permanent Avista MRI percutaneous lead(s), proceed to the instructions for “Percutaneous Lead Placement in the Epidural Space” in this manual.

#### Option B: Removal of Lead Extension after Permanent Trial

34. Open the midline incision to expose the lead extension and connector.

35. Cut the lead extension at the connector. Do not cut the implanted lead.

36. Remove the extension, being careful not to contact non-sterile portions to the patient's body.



**Figure 16:** *Removal of Lead Extensions*

37. Loosen the extension connector setscrew using the hex wrench. Disconnect and remove the connector without moving the implanted lead.

**Note:** Lead extensions, adapters, and splitters are not full-body MRI scan eligible.

38. Proceed to the IPG Implantation instructions in the IPG Directions For Use for SCS System.

## Specifications and Technical Data

### Avista MRI Percutaneous Lead

Part	Specifications
Lead Lengths	56, 74 cm
Lead Shape	In-line
Lead Diameter	1.6 mm
Number of Electrode Contacts	8
Electrode Length	3 mm
Electrode Spacing	1 mm
Contact Material	Platinum/Iridium
Insulation Material	Polyurethane
Conductor Material	MP35N-DFT-28% Ag

**Contacting Boston Scientific**

**Argentina**

T: +5411 4896 8556 F: +5411 4896 8550

**Australia / New Zealand**

T: 1800 676 133 F: 1800 836 666

**Austria**

T: +43 1 60 810 F: +43 1 60 810 60

**Balkans**

T: 0030 210 95 37 890 F: 0030 210 95 79 836

**Belgium**

T: 080094 494 F: 080093 343

**Brazil**

T: +55 11 5853 2244 F: +55 11 5853 2663

**Bulgaria**

T: +359 2 986 50 48 F: +359 2 986 57 09

**Canada**

T: +1 888 359 9691 F: +1 888 575 7396

**Chile**

T: +562 445 4904 F: +562 445 4915

**China – Beijing**

T: +86 10 8525 1588 F: +86 10 8525 1566

**China – Guangzhou**

T: +86 20 8767 9791 F: +86 20 8767 9789

**China – Shanghai**

T: +86 21 6391 5600 F: +86 21 6391 5100

**Colombia**

T: +57 1 629 5045 F: +57 1 629 5082

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T: +420 2 3536 2911 F: +420 2 3536 4334

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**Finland**

T: 020 762 88 82 F: 020 762 88 83

**France**

T: +33 (0)1 39 30 97 00 F: +33 (0)1 39 30 97 99

**Germany**

T: 0800 072 3301 F: 0800 072 3319

**Greece**

T: +30 210 95 42401 F: +30 210 95 42420

**Hong Kong**

T: +852 2960 7100 F: +852 2563 5276

**Hungary**

T: +36 1 456 30 40 F: +36 1 456 30 41

**India – Bangalore**

T: +91 80 5112 1104/5 F: +91 80 5112 1106

**India – Chennai**

T: +91 44 2648 0318 F: +91 44 2641 4695

**India – Delhi**

T: +91 11 2618 0445/6 F: +91 11 2618 1024

**India – Mumbai**

T: +91 22 5677 8844 F: +91 22 2617 2783

**Italy**

T: +39 010 60 60 1 F: +39 010 60 60 200

**Korea**

T: +82 2 3476 2121 F: +82 2 3476 1776

**Malaysia**

T: +60 3 7957 4266 F: +60 3 7957 4866

**Mexico**

T: +52 55 5687 63 90 F: +52 55 5687 62 28

**Middle East / Gulf / North Africa**

T: +961 1 805 282 F: +961 1 805 445

**The Netherlands**

T: +31 30 602 5555 F: +31 30 602 5560

**Norway**

T: 800 104 04 F: 800 101 90

**Philippines**

T: +63 2 687 3239 F: +63 2 687 3047

**Poland**

T: +48 22 435 1414 F: +48 22 435 1410

**Portugal**

T: +351 21 3801243 F: +351 21 3801240

**Singapore**

T: +65 6418 8888 F: +65 6418 8899

**South Africa**

T: +27 11 840 8600 F: +27 11 463 6077

**Spain**

T: +34 901 11 12 15 F: +34 902 26 78 66

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T: 020 65 25 30 F: 020 55 25 35

**Switzerland**

T: 0800 826 786 F: 0800 826 787

**Taiwan**

T: +886 2 2747 7278 F: +886 2 2747 7270

**Thailand**

T: +66 2 2654 3810 F: +66 2 2654 3818

**Turkey – Istanbul**

T: +90 216 464 3666 F: +90 216 464 3677

**Uruguay**

T: +59 82 900 6212 F: +59 82 900 6212

**UK & Eire**

T: +44 844 800 4512 F: +44 844 800 4513

**Venezuela**

T: +58 212 959 8106 F: +58 212 959 5328

**NOTE:** Phone numbers and fax numbers may change.

For the most current contact information, please refer to our website at <http://www.bostonscientific-international.com/> or write to the following address:

**Boston Scientific Neuromodulation**

25155 Rye Canyon Loop  
Valencia, CA 91355 USA

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Boston Scientific Neuromodulation  
25155 Rye Canyon Loop  
Valencia, CA 91355 USA  
(866) 789-5899 in US and Canada  
(661) 949-4000, (661) 949-4022 Fax  
(866) 789-6364 TTY  
[www.bostonscientific.com](http://www.bostonscientific.com)  
Email: [neuro.info@bsci.com](mailto:neuro.info@bsci.com)



## Australian Sponsor Address

Boston Scientific (Australia) Pty Ltd  
PO Box 332  
BOTANY  
NSW 1455  
Australia  
Free Phone 1800 676 133  
Free Fax 1800 836 666



## EU Authorised Representative

Boston Scientific Limited  
Ballybrit Business Park  
Galway, Ireland  
T: + 33 (0) 1 39 30 97 00  
F: + 33 (0) 1 39 30 97 99

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