



Boston Scientific

Xcela™ Power Injectable PICC

Directions for Use

4





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Xcela™

Power Injectable PICC

Rx ONLY

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

WARNING:

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.

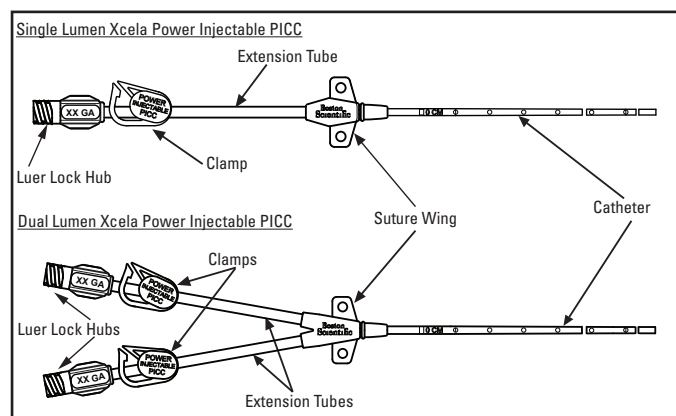
For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

DEVICE DESCRIPTION:

The Xcela Power Injectable Peripherally Inserted Central Catheter (PICC) is a radiopaque, polyurethane catheter with Luer lock hub(s), polyurethane extension tube(s) and suture wing. The catheter is available in single and dual lumen configurations. The lumens are differentiated by colored clamps and hubs that indicate lumen size. Maximum power injection flow rates are indicated on the clamp(s) (Figure 1 and Table 1).

Figure 1. Catheter Configurations



INTENDED USE/ INDICATIONS FOR USE:

The Xcela Power Injectable PICC is indicated for short or long-term peripheral access to the central venous system for intravenous therapy, including but not limited to, the administration of fluids, medications and nutrients; the sampling of blood; and for power injection of contrast media.

CONTRAINDICATIONS:

- Venous thrombosis in any portion of the vein to be catheterized
- Conditions that impede venous return from the extremity such as paralysis or lymphedema after mastectomy
- Orthopedic or neurological conditions affecting the extremity
- Anticipation or presence of dialysis grafts or other intraluminal devices
- Hypercoagulopathy unless considerations are made to place the patient on anticoagulation therapy
- Pre-existing skin surface or subsurface infection at or near the proposed catheter insertion site
- Anatomical distortion of the veins from surgery, injury or trauma
- Anatomical irregularities (structural or vascular) which may compromise catheter insertion or catheter care procedures

WARNINGS:

This Product Contains No Detectable Latex.

If using bacteriostatic saline, do not exceed 30 mL in a 24-hour period.

Do not fully insert catheter up to suture wing.

Do not use the catheter with chemicals that are incompatible with any of its accessories, as catheter damage may occur.

Do not place the catheter into the right atrium of the heart.

Failure to warm contrast media to body temperature prior to power injection may result in catheter failure.

Failure to ensure patency of the catheter prior to power injection studies may result in catheter failure.

Power injector's pressure limiting (safety cut-off) feature may not prevent over-pressurization of occluded catheter.

Exceeding the maximum allowable flow rate (Table 1) may result in catheter failure and/or catheter tip displacement.

Catheter indication for power injection of contrast media implies the catheter's ability to withstand this procedure, but does not imply appropriateness of this procedure for a particular patient. A trained clinician is responsible for evaluating the health status of a patient as it pertains to a power injection procedure.

The maximum pressure of power injectors used with the power injectable PICC must not exceed 300 psi.

PRECAUTIONS:

- If catheter and accessories show any sign of damage (crimped, crushed, cut, etc.), do not use.



- If using an introducer sheath other than the one provided (as in Modified Seldinger and IR kits), verify that the catheter fits easily through the sheath.
- Do not insert the blunt end of the guidewire into the vein.
- Exercise care when advancing the catheter or guidewire to avoid trauma to the vessel intima. Do not use clamps, ribbed forceps, or other instruments to advance or position catheter. Use non-serrated forceps only.
- Avoid sharp or acute angles during insertion which may compromise catheter functionality.
- Acetone and polyethylene glycol-containing ointments should not be used with polyurethane catheters, as these may cause failure of the device.
- Catheter replacement may be required if catheter is cut too short.
- Do not use sharp instruments near the extension tubes or catheter shaft.
- Do not suture through any part of the catheter. If using sutures to secure catheter, make sure they do not occlude, puncture, or cut the catheter.
- Following institutional policy, secure catheter externally to prevent catheter movement, migration, damage, kinking or occlusion.
- Ensure that gloves are free of residue.
- It is recommended that only Luer lock accessories be used with the Xcela™ Power Injectable PICC. Repeated over-tightening may reduce hub connector life. Do not use hemostats to secure Luer lock hub connections.
- If resistance is met while attempting to flush catheter, follow institutional protocol for occluded catheters.
- When discarding used accessories, follow institutional protocol.
- Incompatible drug delivery within the same lumen may cause precipitation. Flush catheter lumen following each infusion.
- It is recommended that institutional protocols be considered for all aspects of catheter use consistent with the instructions provided herein. Bench testing has demonstrated that the Xcela Power Injectable PICC is capable of withstanding five power injections, which could reasonably occur during a 90-day catheter indwelling period.
- Do not attempt to repair the catheter. If breaks or leaks are apparent in the catheter, remove the catheter immediately.
- Catheter removal is to be undertaken only by trained personnel.
- Use of force to remove the catheter may lead to catheter separation. Hold the catheter distal to the suture wing during removal.
- Patients must be educated regarding the care and maintenance of their PICC. The healthcare provider is responsible for this patient instruction.
- Avoid blood pressure measurement or the application of a tourniquet to an arm with an implanted device, since occlusion or other damage to the device may occur.
- Avoid pressure on the inner surface area or axilla of the cannulated arm while using crutches.

ADVERSE EVENTS:

- Air Embolism
- Bleeding
- Cardiac Arrhythmia
- Cardiac Puncture
- Cardiac Tamponade
- Catheter Dislodgement
- Catheter Embolism
- Catheter Erosion through Skin/Vessel
- Catheter Fragmentation
- Catheter Malfunction
- Catheter Malposition
- Catheter Migration
- Catheter Occlusion
- Catheter Retraction
- Catheter Rupture
- Death
- Drug or Contrast Medium Extravasation
- Drug or Contrast Medium Precipitate
- Embolism
- Endocarditis
- Exit Site Necrosis
- Fibrin Sheath Formation
- Foreign Body Rejection
- Hematoma
- Hemorrhage
- Hemothorax
- Infection
- Inflammation/Phlebitis
- Intolerance Reaction to Contrast Media
- Intolerance Reaction to Implanted Device
- Myocardial Erosion
- Nerve Damage
- Pain
- Pneumothorax
- Renal Compromise
- Sepsis
- Subintimal Venous or Myocardial Injection
- Thoracic Duct Injury
- Thrombophlebitis
- Vascular Thrombosis
- Vessel Damage

HOW SUPPLIED:

Contents supplied STERILE using an ethylene oxide (EO) process. Store in a cool, dry, dark place. Do not use if package is opened or damaged. Contents should be stored at 15 degrees – 30 degrees C (59-86 degrees F).

The Xcela Power Injectable PICC is provided in multiple packaging configurations, including:

- Catheter Kit
- Intermediate Peelable Safety Introducer Kit
- Safety Intermediate MST Kit with 45 cm Wire
- Safety MST Kit with 60 cm Wire
- Safety IR Kit with 145 cm Wire

Note: MST=Modified Seldinger Technique; IR= Interventional Radiology

OPERATIONAL INSTRUCTIONS:

The Xcela™ Power Injectable PICC is to be inserted, manipulated, and removed only by a qualified, licensed physician or other healthcare practitioner authorized by and under the direction of such physician. The techniques and procedures described in these instructions do not represent all medically acceptable protocols, nor are they intended as a substitute for a physician's experience and judgment in treating any specific patient. Please refer to the appropriate section based upon configuration selected.

Note: Strict aseptic technique must be used during insertion, maintenance and removal procedures.

Prior to use, carefully examine the product to verify that it has not expired and the sterile package has not been damaged in shipment.

Precaution: Do not use sharp objects to open package.

Table 1. Catheter Specifications

| French Size (Outer Diameter) | Lumens | Gauge Size (Inner Diameter)* | Catheter Length (cm) | Gravity Flow Rate (Water) | Maximum Flow Rate (with Warmed Contrast) | Priming Volume |
|------------------------------|--------|------------------------------|----------------------|---------------------------|--|----------------|
| 4F | 1 | 17.0 | 45 | 1076-1444 mL/hr | 4 mL/sec | < 0.9 mL |
| 4F | 1 | 17.0 | 55 | 890-1191 mL/hr | 3.5 mL/sec | < 1.0 mL |
| 5F | 1 | 15.5 | 55 | 2092-2428 mL/hr | 5 mL/sec | < 1.2 mL |
| 5F | 2 | 17.5** | 45 | 605-965 mL/hr | 5 mL/sec | < 0.9 mL |
| 5F | 2 | 17.5 ** | 55 | 494-776 mL/hr | 4 mL/sec | < 1.0 mL |
| 6F | 2 | 16.5** | 55 | 700-1148 mL/hr | 5 mL/sec | < 1.1 mL |

*Maximum guidewire compatibility is 0.018 in. (0.48 mm).

**Both lumens.

CATHETER INSERTION DIRECTIONS:

Patient Preparation

1. If placing catheter at patient bedside, apply tourniquet to upper arm. Select appropriate vein. Release tourniquet.
2. Prepare sterile field and supplies.
3. Prepare insertion site according to institutional protocol.
4. If placing catheter at patient bedside, apply sterile tourniquet.

Venous Access

5. Access vein using the appropriate method below.

Using guidewire

- a. Insert safety introducer needle, bevel up, into vein, and confirm vessel entry by aspirating blood. Cover hub of safety needle to prevent blood loss and/or air embolus.
- b. Release tourniquet, if one is used.
- c. Insert flexible end of guidewire through safety needle and into vein.

Note: If using 145 cm hydrophilic guidewire, flush packaging hoop with saline prior to removal.

- d. If IR-145 cm or MST-60 cm Kit is used, use fluoroscopic visualization to advance tip of guidewire to desired catheter termination location. Recommended tip location is at junction of superior vena cava and right atrium.

Precaution: If it is necessary to remove guidewire, remove needle beforehand.

- e. Gently withdraw safety needle from guidewire while holding guidewire in place.
- f. To activate safety mechanism, hold safety handle in one hand and rotate flashback chamber counter-clockwise.
- g. Pull back on flashback chamber until needle tip disappears into safety handle and locks securely into needle handle (indicated by audible click and feel).
- h. Verify needle tip is securely locked inside safety handle by pushing flashback chamber forward while holding safety handle. Repeat prior step, if necessary. Discard.

Without using guidewire

- a. Select peelable sheath safety introducer needle from tray. Remove paper safety tab and plastic needle protector.
- b. Insert peelable sheath safety introducer needle, bevel up, into vein. Confirm vessel entry by observing blood in flashback chamber.

Note: Ensure sheath lies within vessel.

- c. Release tourniquet.
- d. Retract needle half way out of peelable sheath, maintaining sheath position.
- e. Push locking mechanism on top of introducer needle hub forward, and depress button to retract needle.
- f. Hold peelable sheath in place, and remove safety needle by pulling back on flashback chamber. Discard.

Note: Do not reinsert introducer needle into peelable sheath, as this may cause damage to sheath.

- g. Apply light finger pressure externally on vein approximately 1.5 cm beyond tip of peelable sheath to reduce blood loss.



Catheter Preparation

Note: Catheter preparation may occur prior to venous access, if catheter is being placed at patient bedside.

- Determine catheter length.

Note: Recommended tip location is at junction of superior vena cava and right atrium.

- Bedside Placement:** Position patient with arm extended outward from body at a 90-degree angle, or as tolerated. Measure distance along vein track between selected insertion site and the desired catheter tip location.
 - Placement via Imaging:** Measure length of guidewire protruding from skin, or to 60 cm marking on guidewire (IR-145 cm Kit only). Use disposable tape measure to assess fractional lengths. Subtract measured length from 60 cm to determine cut length of catheter.
- Cut catheter to length, using previous measurements.

Note: Cut catheter tip square. Inspect cut surfaces to ensure there is no loose material or rough edges.

- Attach flush assembly to catheter hub. Ensure locking collar is in open position (Figure 2).

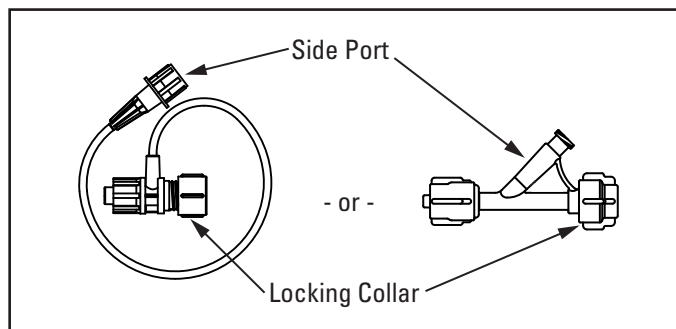


Figure 2. Flush Assemblies

Note: When inserting a dual lumen catheter either lumen may be used for stiffening wire placement.

- Draw 10 mL sterile normal saline into syringe, remove cap on side port of flush assembly, and attach syringe.
- While covering locking collar opening with finger to prevent fluid loss, prime flush assembly and catheter.

Note: For dual lumen catheters, be sure to prime each lumen prior to insertion, clamping unused lumen after it is primed.

- If stiffening wire is used (recommended for all techniques except for Seldinger technique), advance stiffening wire slowly through flush assembly locking collar into catheter until tip of stiffening wire extends beyond end of catheter. Continue to inject sterile normal saline, as needed, to assist in advancement.
- Retract stiffening wire until tip is well behind end of catheter (Figure 3).



Figure 3. Stiffening Wire Position within Catheter

Precaution: Failure to retract stiffening wire into catheter prior to catheter insertion may cause vessel damage during insertion procedure.

- Turn flush assembly locking collar clockwise to secure stiffening wire in place.

Note: Do not cut stiffening wire. Rough edges on stiffening wire may damage catheter. It is recommended that stiffening wire be inserted with flush assembly in place.

Note: Do not reinsert stiffening wire into catheter, as damage to catheter and vein may result.

Note: Be sure stiffening wire tip is straight before inserting into catheter.

Note: Do not apply any type of clamp on catheter or extension tube while stiffening wire is inside catheter. Stiffening wire may become kinked and damage catheter, resulting in leakage or fracture of catheter.

- Remove syringe from flush assembly and place cap on side port.

Catheter Placement:

Using guidewire

- Alongside guidewire, nick insertion site with safety scalpel. To use safety scalpel, depress top button on protective shield, and retract to rear locked position. Once nick is made, depress top button again and advance to forward locked position at lock indicator line.
- Advance peelable sheath/dilator assembly over guidewire. Using a slight twisting motion, advance assembly into the vein.
- Seldinger technique:** Withdraw the dilator, leaving the sheath and guidewire in place. **Modified Seldinger technique:** Withdraw dilator and guidewire, leaving peelable sheath in place. Cover opening to prevent blood loss and/or air embolism.

- Slowly and incrementally, insert catheter assembly through the peelable sheath 10-15 cm into the vein.

Note: If inserting dual lumen catheter, ensure that extension tube not being used is clamped.



Note: If practicing Seldinger technique, wet the exposed segment of the 145 cm guidewire with saline and thread catheter over guidewire first.

16. Holding catheter steady, slowly withdraw peelable sheath from insertion site.
17. Grasp wings of sheath firmly, and spread to separate sheath from catheter, removing it completely. Discard.
18. If placing catheter at patient bedside, turn patient's head toward insertion side with chin to shoulder.
19. Slowly advance remaining catheter into vein until "0" mark on catheter is at insertion site. Do not fully insert catheter to suture wing.
20. Once catheter is inserted, aspirate gently with syringe attached to flush assembly side port and observe for blood return.
21. Loosen flush assembly from catheter hub and withdraw, with stiffening wire or guidewire, while holding suture wing in place. Discard.

Note: Do not reinsert stiffening wire into catheter, as damage to catheter or vein may occur.

22. Close catheter clamp.
23. See **FLUSHING AND HEPARINIZATION** and **CATHETER SECUREMENT** sections for next steps.
24. Verify catheter tip location using radiographic visualization per institutional protocol.

Note: Patient movement may cause catheter tip displacement.

25. Upon confirmation, catheter is ready for use.

FLUSHING AND HEPARINIZATION:

1. Attach syringe to hub, open clamp, and aspirate blood.
2. Close clamp, detach syringe and discard.
3. Attach syringe filled with 10 mL sterile normal saline, open clamp, and flush lumen, using a "pulse" or "stop/start" technique.

Note: If flushing after a power injection, use 20 mL sterile normal saline.

4. Close clamp, detach syringe and discard.
5. Draw heparinized saline into syringe, and attach to hub.
6. Open clamp, and inject amount equal to or greater than priming volume into lumen (see Table 1).
7. Maintaining positive pressure on syringe, close clamp, detach syringe and discard.
8. Repeat for second lumen, if necessary.

Note: Never leave catheter uncapped.

Note: Flush catheter after every use. When not in use, flush at least every

12 hours, or according to institutional protocol to maintain patency.

CATHETER SECUREMENT:

1. Prepare securement site with alcohol and remove betadine, if present.
2. Apply skin prep solution for enhanced adherence and skin protection. Allow skin prep solution to completely dry (10-15 seconds).
3. Slide device under suture wing. Slide one suture hole over a post, then slide that post and suture wing toward opposite side until second suture hole easily fits over second post.
4. Close lids over posts to secure catheter.
5. Peel away paper backing and place on skin.
6. Apply adhesive strip at or near insertion site.

Contraindication: Patients with known tape or adhesive allergies.

Precaution: Do not use where loss of adherence could occur, such as with a confused patient, unattended access device, diaphoretic or non-adherent skin.

Precaution: Minimize catheter manipulation during application and removal.

Note: Monitor device daily. Replace at least every seven days.

POWER INJECTION:

Table 2. Power Injection Specifications

| French Size (Outer Diameter) | Lumens | Catheter Length (cm) | Maximum Flow Rate (mL/sec) ¹ | Maximum Catheter Pressure at Maximum Flow Rate (psi) ^{1,2} | Maximum Static Burst Pressure Post Injection (psi) ³ |
|------------------------------|--------|----------------------|---|---|---|
| 4F | 1 | 45 | 4 | 272 | 178 |
| 4F | 1 | 55 | 3.5 | 278 | 205 |
| 5F | 1 | 55 | 5 | 236 | 247 |
| 5F | 2 | 45 | 5 | 254 | 177 |
| 5F | 2 | 55 | 4 | 233 | 181 |
| 6F | 2 | 55 | 5 | 271 | 229 |

¹ Testing was conducted using contrast with viscosity of 11.8 centipoise (cP), measured at body temperature (37°C) with injector set at 300 psi. Data represent approximate flow capabilities of power injection of contrast media.

² Internal catheter pressure data point observed during power injection testing.

³ Burst pressure is the static burst pressure failure point of the catheter after completion of power injection testing.

Warning: During power injection testing catheter pressures did not exceed those outlined in Table 2.

Warning: During static burst pressure testing, catheter failure was





recorded as detailed in Table 2.

Warning: Exceeding maximum allowable flow rate (Table 2) may result in catheter failure and /or catheter tip displacement.

1. Verify power injector is appropriately programmed and does not exceed catheter flow rate limit (see Table 2).
2. Warm contrast to body temperature (37°C).

Warning: Failure to warm contrast media to body temperature prior to power injection study may result in catheter failure.

3. Inspect catheter for damage.
4. Attach syringe, open clamp, and aspirate amount greater than priming volume of catheter, or until blood return (Table 1). Close clamp, and remove and discard used syringe.
5. Attach syringe filled with 10 mL sterile normal saline, open clamp, and vigorously flush lumen.
6. Close clamp, and detach syringe and discard.

Warning: Failure to ensure catheter patency prior to power injection studies may result in catheter failure.

Precaution: If a needleless connector is attached to catheter hub, first ensure that it will sustain power injection.

7. Attach power injector to selected lumen hub per manufacturer's recommendations, and open clamp.
8. Complete power injection study taking care not to exceed maximum flow rate limit (Table 2), and close clamp.

Precaution: It is recommended that institutional protocols be considered for all aspects of catheter use consistent with the instructions provided herein. Bench testing has demonstrated that the Xcela™ Power Injectable PICC is capable of withstanding five power injections, which could reasonably occur during a 90-day catheter indwelling period.

9. Disconnect the power injector.
10. Refer to FLUSHING AND HEPARINIZATION section.

CATHETER MAINTENANCE:

It is recommended that institutional protocols be followed for all aspects of catheter care, use and maintenance. The following care, use and maintenance information is not intended as a substitute for institutional protocol, but rather, to describe guidelines and recommendations that can be used successfully with the Xcela Power Injectable PICC.

GENERAL CATHETER CARE AND USE:

- Use aseptic technique during catheter care and use.
- Use Standard and Universal Precautions during catheter care

procedures.

- Never leave catheter uncapped.
- Do not use clamps, or instruments with teeth or sharp edges on the catheter, as catheter damage may occur.

CARE OF INSERTION SITE AND DRESSING:

- Examine insertion site, including catheter securement device, routinely and with each dressing change, for complications.
- Follow institutional protocol for dressing change. It is recommended that dressings be changed weekly and as necessary.
- To maintain unobstructed flow, make sure there are no kinks in catheter or IV tubing.

Warning: Prior to dressing catheter and access site, inspect both to assure they are completely dry of isopropyl alcohol-based cleansing agents.

- A sterile, occlusive dressing covering the entire insertion site, suture wing and at least 2.5 cm of the extension tube is recommended.
- All efforts are to be made to keep insertion site and dressing clean, dry and intact.

DRESSING REMOVAL:

- Stabilize catheter and Luer lock hub during dressing removal to prevent accidental dislodgment.
- Separate dressing away from Luer lock hub and toward insertion site. As you separate, keep any tape and dressing close to patient's arm to avoid dislodging catheter or sutures.

ASSESSING CATHETER INTEGRITY:

Assess catheter integrity before any injection/infusion by completing the following steps:

- Examine and palpate catheter tract and insertion site for complications.
- Using syringe, aspirate slowly for blood return. Difficulty in withdrawing blood may indicate catheter compression, malposition, and/or obstruction. Discard syringe.
- Using second syringe, flush catheter with 10 mL of sterile normal saline to clear catheter.

Note: If catheter integrity is questioned as a result of any of the above steps, do not use catheter without further inquiry and resolution of the problem.

BLOOD SAMPLING:

1. Using aseptic technique, swab catheter hub and allow to air dry.
2. Use syringe to aspirate small amount of blood and fluid (3-5 mL minimum) to verify patency. Discard syringe.
3. Using second syringe, slowly withdraw specimen, and close clamp.



4. Refer to FLUSHING AND HEPARINIZATION section.
5. Transfer specimens as per institutional protocol.

CATHETER REMOVAL:

Catheter removal is per the discretion of the physician in regards to the patient's therapy regimen.

1. Position patient upright with arm at 45-degree angle outward from body. Maintain insertion site below level of heart.
2. See **DRESSING REMOVAL** section.
3. Open catheter securement device retainer lids and remove catheter from retainer.

Note: It is preferred to use aseptic technique for the following steps.

4. To remove catheter, grasp catheter between suture wing and insertion site and remove slowly, in small increments, keeping catheter parallel to skin surface. Do not grasp Luer lock hub to remove catheter, as catheter damage may occur.
5. If resistance is still met, follow institutional protocol for the management of difficult-to-remove catheters.
6. To verify that entire catheter has been removed, measure and compare catheter length with initial length recorded at time of insertion.
7. Apply generous amount of alcohol to loosen edges of catheter securement device. While lifting adhesive pad, gently stroke undersurface of pad with alcohol to dissolve adhesive.
8. Following removal of catheter, cover insertion site with occlusive dressing for at least 24 hours.

WARRANTY:

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose.** Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC's control directly affect the instrument and the results obtained from its use. BSC's obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **BSC assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.**

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Consult instructions for use.
Consulte las instrucciones de uso.
Consulter le mode d'emploi.
Gebrauchsanweisung beachten.
Consultare le istruzioni per l'uso.
Gebruiksaanwijzing raadplegen vóór gebruik.
使用方法を参照のこと。



Contents
Contenido
Contenu
Inhalt
Contenuto
Inhoud
内容物

EC REP

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Représentant agréé UE
Autorisierter Vertreter in der EU
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Fabricant légal
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Este producto no contiene látex detectable.

Ce produit ne contient pas de latex détectable.

Dieses Produkt enthält keinen nachweisbaren Latex.

Questo prodotto non contiene lattice rilevabile.

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