Boston Scientific

PHYSICIAN'S LEAD MANUAL

FINELINE™ II STEROX EZ

Implantable Lead

REF 4469/4470/4471/4472/4473/4474

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DESCRIPTION

The FINELINE™ II Sterox EZ models 4469, 4470, 4471, 4472, 4473, and 4474 bipolar endocardial pacing leads are designed for atrial or ventricular use with implantable pulse generators for long-term cardiac pacing.

This literature is intended for use by professionals trained or experienced in device implant and/or follow-up procedures.

MR Conditional System Information

These leads can be used as part of the ImageReady™ MR Conditional Pacing System or the ImageReady MR Conditional Defibrillation System (hereafter each referred to as an MR Conditional System) when connected to Boston Scientific MR Conditional pulse generators. Patients with an MR Conditional System may be eligible to undergo MRI scans if performed when all Conditions of Use, as defined in the ImageReady MR Conditional Pacing System MRI Technical Guide or the ImageReady MR Conditional Defibrillation System MRI Technical Guide[1] (hereafter each referred to as the MRI Technical Guide), are met. Components required for MR Conditional status include specific models of Boston Scientific pulse generators, leads, and accessories; the Programmer/Recorder/Monitor (PRM); and PRM Software Application. For the model numbers of MR Conditional pulse generators and components, as well as a complete description of the ImageReady MR Conditional System, refer to the applicable MRI Technical Guide.

Implant-related MRI Conditions of Use

The following subset of the MRI Conditions of Use pertains to implantation, and is included as a guide to ensure implantation of a complete ImageReady MR Conditional System. For a full list of Conditions of Use, refer to the applicable MRI Technical Guide. All items on the full list of Conditions of Use must be met in order for an MRI scan to be considered MR Conditional.

- Patient is implanted with the ImageReady MR Conditional Pacing System[2] or the ImageReady MR Conditional Defibrillation System

1. Available at www.bostonscientific-elabeling.com.
2. Defined as a Boston Scientific MR Conditional pulse generator and lead(s), with all ports occupied by a lead or port plug.

- Bipolar pacing operation or pacing off with the ImageReady MR Conditional Pacing System
- Pulse generator implant location restricted to left or right pectoral region
- At least six (6) weeks have elapsed since implantation and/or any lead revision or surgical modification of the MR Conditional System
- No other active or abandoned implanted devices, components, or accessories present such as lead adaptors, extenders, leads, or pulse generators
- Pacing threshold ≤ 2.0 V in pace-dependent patients with the ImageReady MR Conditional Pacing System
- No evidence of a fractured lead or compromised pulse generator-lead system integrity

Lead Features

A silicone rubber collar at the distal tip contains 0.75 mg of dexamethasone acetate. Each lead is composed of two individually coated conductor wires coradially wound together to form a single conductor coil. The lead includes silicone rubber or polyurethane outer insulation, iridium oxide-coated (IROX™) titanium tip electrode and a platinum iridium anode. The cork-screw tip is coated with mannitol. The lead is compatible with pulse generators having IS-1[3] connectors.

Pacing and sensing impedance values, determined according to European Standard EN 45502-2-1:2003 (paragraphs 6.2.2 and 6.2.3), are within 780-1125 Ω and 595-790 Ω, respectively. Note that these values are derived from in vitro testing, and are not representative of clinically measured lead impedance.

This device is intended for single-use only.

INDICATIONS

The lead is intended for chronic pacing and sensing of the atrium or ventricle when used with a compatible pulse generator.

CONTRAINDICATIONS

Do not use this lead in patients with:

- mechanical tricuspid heart valves
- hypersensitivity to a nominal single dose of 0.75 mg dexamethasone acetate

3. IS-1 refers to the international standard ISO 5841-3:2013.

- an allergy to mannitol

WARNINGS

NOTE: MR Refer to the applicable MRI Technical Guide for a complete list of MRI-related Warnings and Precautions.

- MR Unless all of the MRI Conditions of Use (as described in the MRI Technical Guide) are met, MRI scanning of the patient does not meet MR Conditional requirements for the implanted system, and significant harm to or death of the patient and/or damage to the implanted system may result.
  Refer to the MRI Technical Guide for potential adverse events applicable when Conditions of Use are met or not met, as well as for a complete list of MRI-related Warnings and Precautions.
- MR Implant of the system cannot be performed in an MRI site Zone III (and higher) as defined by the American College of Radiology Guidance Document for Safe MR Practices[4]. Some of the accessories packaged with pulse generators and leads, including the torque wrench and stylet wires, are not MR Conditional and should not be brought into the MRI scanner room, the control room, or the MRI site Zone III or IV areas.
- The use of battery-powered equipment is recommended during lead implantation and testing to protect against fibrillation that may be caused by alternating currents.
- Line-powered equipment used in the vicinity of the patient must be properly grounded.
- Lead connector pins must be insulated from any leakage currents that may arise from line-powered equipment.
- Diathermy exposure. Do not subject a patient with an implanted pulse generator and/or lead to diathermy since diathermy may cause fibrillation, burning of the myocardium, and irreversible damage to the pulse generator because of induced currents.
- 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

4. Kanal E, et al., *American Journal of Roentgenology* 188:1447-74, 2007.

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.

PRECAUTIONS

General

- Inspect sterile packaging prior to opening. Do not use if damaged. (See “Sterilization” on page 7.)
- Prior to the implantation of this lead, confirm lead/pulse generator compatibility by contacting Boston Scientific using the information on the back cover.

NOTE: MR Use of Boston Scientific MR Conditional pulse generators and leads is required for an implanted system to be considered MR Conditional. Refer to the appropriate ImageReady MR Conditional Pacing System or Defibrillation System MRI Technical Guide for model numbers of pulse generators, leads, accessories, and other system components needed to satisfy the Conditions of Use for MR Conditional scanning.

NOTE: MR Other implanted devices or patient conditions may cause a patient to be ineligible for an MRI scan, independent of the status of the patient’s ImageReady MR Conditional System.

- Defibrillating equipment should be kept nearby for immediate use during the implantation procedure.
- It has not been determined whether the warnings, precautions, or complications usually associated with injectable dexamethasone acetate apply to the use of this lead. Refer to the current *Physicians’ Desk Reference*™ [5] for potential adverse effects.

Handling

- Avoid the use of excessive force or surgical instruments, as damage to the insulation could cause leakage and/or prevent proper lead function.
- Do not wipe or immerse the electrode in fluid.
- Use the suture sleeve when securing the lead to avoid placing the lead under extreme tension.

5. *Physicians’ Desk Reference* is a trademark of Thomson Healthcare Inc.

- Avoid bending the conductor coil, since attempts to restore the original shape may weaken the structure.

Implanting

- The subclavian venipuncture technique for lead introduction may be associated with an increased risk of conductor failure due to compressive forces generated in the medial angle between the clavicle and the first rib; thus, an extremely medial introduction site should be avoided.
- Remove the stylet and funnel/cap before connecting the lead to the pulse generator. Leaving the stylet in the lead could cause coil fracture and/or heart perforation.
- Do not suture directly to the insulation. Always use the suture sleeve to anchor the lead.

POTENTIAL ADVERSE EVENTS

Based on the literature and on pulse generator and/or lead implant experience, the following list includes the possible adverse events associated with implantation of products described in this literature:

- Air embolism
- Allergic reaction
- Arterial damage with subsequent stenosis
- Bleeding
- Bradycardia
- Breakage/failure of the implant instruments
- Cardiac perforation
- Cardiac tamponade
- Chronic nerve damage
- Component failure
- Conductor coil fracture
- Death
- Electrolyte imbalance/dehydration
- Elevated thresholds
- Erosion
- Excessive fibrotic tissue growth
- Extracardiac stimulation (muscle/nerve stimulation)
- Fluid accumulation
- Foreign body rejection phenomena
- Formation of hematomas or seromas
- Heart block
- Hemorrhage

- Hemothorax
- Inability to pace
- Inappropriate therapy (e.g., shocks and antitachycardia [ATP] where applicable, pacing)
- Incisional pain
- Incomplete lead connection with pulse generator
- Infection including endocarditis
- Lead dislodgment
- Lead fracture
- Lead insulation breakage or abrasion
- Malignancy or skin burn due to fluoroscopic radiation
- Myocardial trauma (e.g., tissue damage, valve damage)
- Myopotential sensing
- Oversensing/undersensing
- Pericardial rub, effusion
- Pneumothorax
- Pulse generator and/or lead migration
- Syncope
- Tachyarrhythmias, which include acceleration of arrhythmias and early, recurrent atrial fibrillation)
- Thrombosis/thromboemboli
- Valve damage
- Vasovagal response
- Venous occlusion
- Venous trauma (e.g., perforation, dissection, erosion)

MR For a list of Potential Adverse Events associated with MRI scanning, refer to the appropriate ImageReady MR Conditional Pacing System or Defibrillation System MRI Technical Guide.

WARRANTY

A limited warranty certificate for the lead is available. For a copy, contact Boston Scientific using the information on the back cover.

IMPLANT INFORMATION

NOTE: MR Refer to the appropriate ImageReady MR Conditional Pacing System or Defibrillation System MRI Technical Guide for considerations affecting choice and implant of leads for use as part of an MR Conditional system.

Proper surgical procedures and techniques are the responsibility of the medical professional. The described implant procedures are furnished for informational purposes only. Each physician must apply the information in these instructions according to professional medical training and experience.

Precautions

- Remove the stylet and funnel/cap before connecting the lead to the pulse generator. Leaving the stylet in the lead could cause coil fracture and/or heart perforation.
- Do not suture directly to the insulation. Always use the suture sleeve to anchor the lead.

Sterilization

This product is supplied in a sterile package for direct introduction into the operating field. The package and its contents have been exposed to ethylene oxide gas, and sterility is verified on each lot. Before the package is opened, it should be examined carefully for damage that may have compromised sterility. (For instructions on opening the sterile package, see Figure 1 and 2.) If such damage is detected, the entire contents should be returned to Boston Scientific.

Storage

Store at 25°C (77°F). Excursions permitted between 15°C to 30°C (59°F to 86°F). Transportation spikes permitted up to 50°C (122°F).

Handling

The conductor or its insulating material may be damaged if stretched, crimped, or crushed. Avoid subjecting the lead to these or other unusual stresses.

The lead's insulating material has an electrostatic affinity for particulate matter and thus should not be exposed to lint, dust, or other similar contaminants.

Precautions

- Avoid the use of excessive force or surgical instruments, as damage to the insulation could cause leakage and/or prevent proper lead function.
- Do not wipe or immerse the electrode in fluid.
- Use the suture sleeve when securing the lead to avoid placing the lead under extreme tension.
- Avoid bending the conductor coil, since attempts to restore the original shape may weaken the structure.

General Information

It is important to position the lead so as to minimize mechanical stresses and maximize electrical contact with the cardiac wall. Implantation should, therefore, be performed in a facility permitting fluoroscopic verification of satisfactory lead tip placement.

Available transvenous implantation routes include the cephalic, subclavian and external or internal jugular veins. Venous access can be gained by employing either the venipuncture (suitable for the subclavian or internal jugular routes) or cutdown (suitable for the cephalic or external jugular routes) techniques.

If the subclavian route is selected and access by venipuncture is preferred, a percutaneous lead introducer (7 French or larger) should be used, and its application should be guided by the following considerations:

Precautions

- The subclavian venipuncture technique for lead introduction may be associated with an increased risk of conductor failure due to compressive forces generated in the medial angle between the clavicle and the first rib; thus, an extremely medial introduction site should be avoided.

Insertion Procedures

The dissolvable mannitol capsule surrounding the fixation helix is designed to facilitate passage through the blood vessels and into the heart and to protect the helix from damage. As soon as the capsule is inserted into the vein, the capsule begins to dissolve. The fixation helix remains encapsulated for approximately five minutes.

NOTE: The mannitol capsule has varying dissolution rates based on the patient's cardiac anatomy, lead placement, and various implant conditions.

CAUTION: Approximately five minutes after introduction of the lead, the fixation helix will be exposed. If resistance is encountered and the dissolution time has expired, the lead should be rotated **counterclockwise** during advancement.

To employ the cutdown technique, expose and incise the desired vein. For the venipuncture technique, insert a lead-introducer sheath into the desired vein (see instruction sheet packaged with introducer). Under fluoroscopic observation and with a straight stylet fully inserted into the lead, either introduce the lead into the incised vein (for cutdown), or advance the lead through the lead-introducer sheath and into the desired vein (for venipuncture see Figure 5). If desired, the vein lifter included in the sterile package may be used to facilitate lead introduction (see Figure 6) when employing the cutdown technique.

Cautiously advance the lead. If resistance is encountered, simultaneously rotate the lead counterclockwise several turns while **gently** retracting it a short distance.[6] Then continue advancing the lead, maintaining the **counterclockwise** rotation, until it enters the right atrium. The lead tip can be advanced into the desired stimulation site by following one of the following two procedures:

Atrial Placement

1. After advancing the lead tip into the right atrium, withdraw the straight stylet and replace it with a J-shaped or curved stylet, fully inserted. (The straight stylets included in the sterile package may be shaped to the desired curve, as shown in Figure 7.)
2. Under fluoroscopic observation, rotate the stylet to direct the J curve anteriorly and toward the midline of the body.

NOTE: Generally, the atrial appendage is the preferred site, and it is recommended that the lateral wall of the atrium be avoided to minimize the possibility of phrenic nerve stimulation. Use care to avoid perforating the atrial wall.

3. When the lead tip is in the desired position, and at a 90-degree angle to the atrial wall, secure the tip in the endocardium using the following procedure: rotate the lead **clockwise** at the lead

6. If resistance persists, withdraw the stylet 2 or 3 cm to render the lead tip flexible, and carefully maneuver it around the obstruction.

introduction site (the stylet should remain stationary), allowing the entire lead body to rotate - approximately 4 turns for the polyurethane model 4469/4470/4471 or 6 turns for the silicone model 4472/4473/4474.

4. Verify fixation by releasing the excess torque in the lead body. If the tip is securely fixed, the lead body will unwind slightly (counterclockwise) when released. Enough slack should be left in the lead for the lead body to retain a loose J curve and for the lead tip to form a 90-degree angle with the atrial wall.

Ventricular Placement

1. After advancing the lead tip into the right atrium, withdraw the straight stylet 10 to 12 cm and continue advancing the lead.
2. When the tip contacts the atrial wall or some other atrial structure, a curve or loop will form in the lead body. Direct this loop into the tricuspid valve.
3. Gently advance the stylet back into the lead, taking care not to damage the conductor or its insulation, while guiding the loop through the tricuspid valve. Make sure to guide the lead through the tricuspid valve, rather than into the inferior vena cava. As the loop in the lead body is advanced into the right ventricle, the lead tip will be drawn backward through the tricuspid valve.[7]
4. When the lead enters the ventricle, fully reinsert the straight stylet and continue advancing the lead until the tip is situated at or near the apex. Exercise care to avoid perforating the ventricular wall.
5. Verify with lateral fluoroscopy that the lead is not in a posterior position, which would probably indicate that the lead has entered the coronary sinus and should be repositioned.
6. When the lead tip is in the desired position and at a 90-degree angle to the ventricular wall, secure the tip in the endocardium using the following procedure: rotate the lead **clockwise** at the introduction site (the stylet should remain stationary), allowing the entire lead body to rotate - approximately 4 turns for the polyurethane model 4469/4470/4471 or 6 turns for the silicone model 4472/4473/4474.

7. This maneuver is important for fixed-screw leads, as it prevents the tip from catching as it passes the valve.

7. Verify fixation by releasing the excess torque in the lead body. If the tip is securely fixed, the lead body will unwind slightly (counterclockwise) when released. When **gentle** traction is applied to the lead, resistance should be felt.

Repositioning or Removing

To reposition or remove a lead, fully insert the appropriate stylet in the lead (a J-shaped or curved stylet for a lead placed in the atrium, a straight stylet for a lead placed in the ventricle), and rotate the lead **counterclockwise** until the tip is freed from the endocardium. Once the lead tip is freed, whether the lead is to be repositioned or removed, continue rotating it **counterclockwise** while retracting it.

CAUTION: Once the mannitol capsule has dissolved, exposing the fixation screw, the lead must be rotated counterclockwise during any stage of withdrawal.

If the lead is to be repositioned, free the lead tip from the endocardium, and repeat the appropriate procedure for attaching the lead tip (see “Insertion Procedures” on page 8).

CAUTION: When removing a lead from the patient, it is best not to cut off the proximal end. If the proximal end is removed, however, firmly grasp both conductor coil and outer tubing before applying tension to the lead.

Threshold Measurements

A pacemaker system analyzer is recommended for measuring the stimulation threshold and the appropriate sensing signal amplitude. During this procedure, the stylet should be withdrawn.

The lowest possible pacing threshold should be sought to assure optimal long term pacemaker operation. Usually, using a 500 Ω load, an acute ventricular stimulation threshold can be obtained below 0.6 V or 1.2 mA; however, maintaining the same resistance, it should not exceed 1.0 V or 2.0 mA.

Acute stimulation thresholds in the right atrial appendage are generally higher than those obtained in the right ventricle with a stimulating electrode of similar surface area. Acute atrial stimulation thresholds below 1.0 V or 2.0 mA with a 500 Ω load are common. But any acute atrial threshold substantially higher than 1.5 V or 3.0 mA (using a 500 Ω load) indicates a need to reposition the lead.

For satisfactory sensing, the ventricular sensing signal amplitude should be at least 5.0 mV. The atrial sensing signal will typically

range from 0.5 to 4.0 mV, but a value of 1.5 mV or above is preferable.

The recommended ventricular or atrial impedance range is 200-2000 Ω.

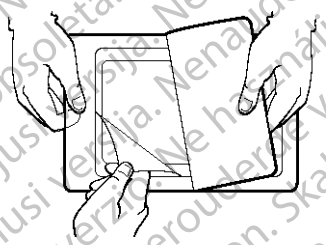
CAUTION: Be sure that the stylet has been removed before connecting the lead to the implanted pulse generator. Leaving the stylet in the lead could cause coil fracture and/or heart perforation. Also be sure that any funnel/cap installed over the lead connector(s) (as a guide for the stylet and to maintain lubrication of the connector) has been removed.

Securing the Lead

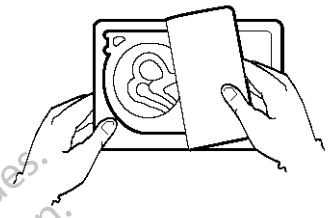
Once electrode stability and a satisfactory stimulation threshold have been attained, slide the pre-installed suture sleeve into position at the desired anchor point. Secure the sleeve to the lead by tying a non-absorbable suture around the sleeve near its middle (see Figure 8). Pass an end of the same suture through subcutaneous tissue and, once again, tie it around the sleeve.

Notes:

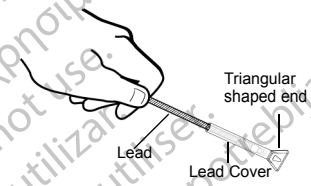
- The suture should be tied tight enough to prevent the lead from moving within the sleeve, but not so tight that it might deform the lead's conductor coil.
- Do not tie the suture directly to the lead body.



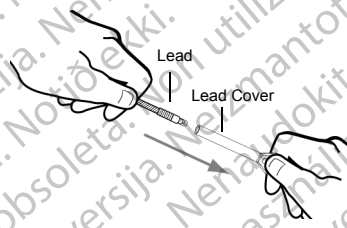
1. Peel back the cover from the outer tray. Using the folded corner flap, remove the sterile inner tray (Figure 1).



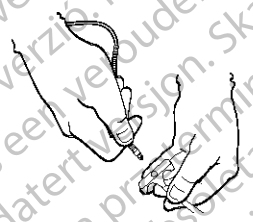
2. Peel the lid from the inner tray to present the lead and accessories (Figure 2).



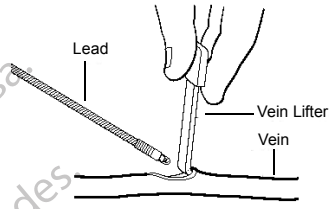
3. Remove the lead from the tray and note the protective cover on the distal end of the lead. The cover must be removed prior to insertion (Figure 3).



4. To remove the cover, grasp the triangular shape at the end of the cover and pull gently (Figure 4).

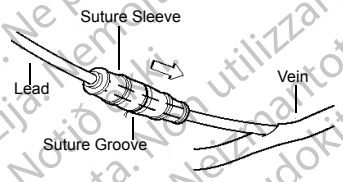


5. Advance the lead through the sheath of a percutaneous introducer and into the vein (Figure 5).



6. The vein lifter may be used to lift and dilate the incised vein for introducing the lead (Figure 6).

7. Impart a gentle curve to the stylet by drawing it through a gloved hand or across a smooth, sterile instrument (Figure 7).



8. Slide the integral suture sleeve into the desired anchor position, and secure with a nonabsorbable suture (Figure 8).

POSTIMPLANT

Perform follow-up evaluation as recommended in the applicable pulse generator physician's manual.

RETURNING EXPLANTED PRODUCTS

NOTE: Return all explanted pulse generators and leads to Boston Scientific. Examination of explanted leads can provide information for continued improvement in system reliability and warranty considerations.

NOTE: Disposal of explanted pulse generators and/or leads is subject to applicable laws and regulations. For a Returned Product Kit, contact Boston Scientific using the information on the back cover.

SYMBOLS ON PACKAGING

Symbol	Definition
	Opening instructions
	Do not reuse
	Consult instructions for use
	Do not resterilize
STERILE EO	Sterilized using ethylene oxide
REF	Reference number
	Use by
	Date of manufacture
LOT	Lot number
SN	Serial number
CE 2797	CE mark of conformity with the identification of the notified body authorizing use of the mark
	Do not use if package is damaged
EC REP	Authorized Representative in the European Community
	Manufacturer
AUS	Australian Sponsor Address
MR	MR Conditional

SPECIFICATIONS

	4469/4470/4471 (Atrial/Ventricular)	4472/4473/4474 (Atrial/Ventricular)
Polarity	Bipolar	Bipolar
Distal Assembly		
Introducer size/insertion diameter (minimum)	7 Fr/2.3 mm (1 lead) 10Fr/3.3 mm (2 leads)	7 Fr/2.3 mm (1 lead) 10Fr/3.3 mm (2 leads)
Eluting Collar	Silicone rubber	Silicone rubber
Steroid	Dexamethasone acetate (0.75 mg)	Dexamethasone acetate (0.75 mg)
Electrode		
Tip (cathode)		
Shape	Ring	Ring
Diameter	1.9 mm (5.7 French)	1.9 mm (5.7 French)
Surface area	5 mm^2	5 mm^2
Materials	IROX (Iridium oxide coated titanium)	IROX (Iridium oxide coated titanium)
Sleeve (anode)		
Surface area	31 mm^2	33 mm^2
Materials	Platinum iridium	Platinum iridium
Separation between electrodes	16 mm	16 mm
Corkscrewtip(electrically isolated)		
Length	1.6 mm	1.6 mm
Number of turns in helix	1.5	1.5
Material	Nickel-cobalt alloy	Nickel-cobalt alloy
Insulating material	Conformal polymer	Conformal polymer
Coating (soluble)[a]	Mannitol	Mannitol
Lead Body		
Conductor construction	Parallel-wound bifilar coil	Parallel-wound bifilar coil
Conductor material	Nickel-cobalt alloy with silver core	Nickel-cobalt alloy with silver core
Conductor wire insulation	Polymer material	Polymer material
Insulation	55D polyurethane	80A Silicone rubber
Length	4469: 45 cm 4470: 52 cm 4471: 58 cm	4472: 45 cm 4473: 52 cm 4474: 58 cm
Diameter	1.7 mm (5 Fr)	2 mm (6 Fr)
Resistance		
To tip	40 Ω maximum	40 Ω maximum
To sleeve	40 Ω maximum	40 Ω maximum

	4469/4470/4471 (Atrial/Ventricular)	4472/4473/4474 (Atrial/Ventricular)
Connector Assembly		
Diameter	3.2 mm (IS-1[b])	3.2 mm (IS-1[b])
Materials	Silicone rubber, 316L stainless steel	Silicone rubber, 316L stainless steel
Retention Strength[c]	10 N	10 N
Connector pin diameters		
Cathode	1.6 mm	1.6 mm
Anode	2.7 mm	2.7 mm
Connector pin length	5 mm	5 mm
Accessories included	Stylets Funnel Vein lifter	Stylets Funnel Vein lifter

a. The mannitol dissolves in approximately 5 minutes, exposing the corkscrew for easy fixation in either the atrium or the ventricle.

b. IS-1 refers to the international standard ISO 5841-3:2013.

c. Maximum proven connector retention strength in Intermedics' Side-Lock connector. Tested according to prEN45502-2, September 16, 1996.

Boston Scientific

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