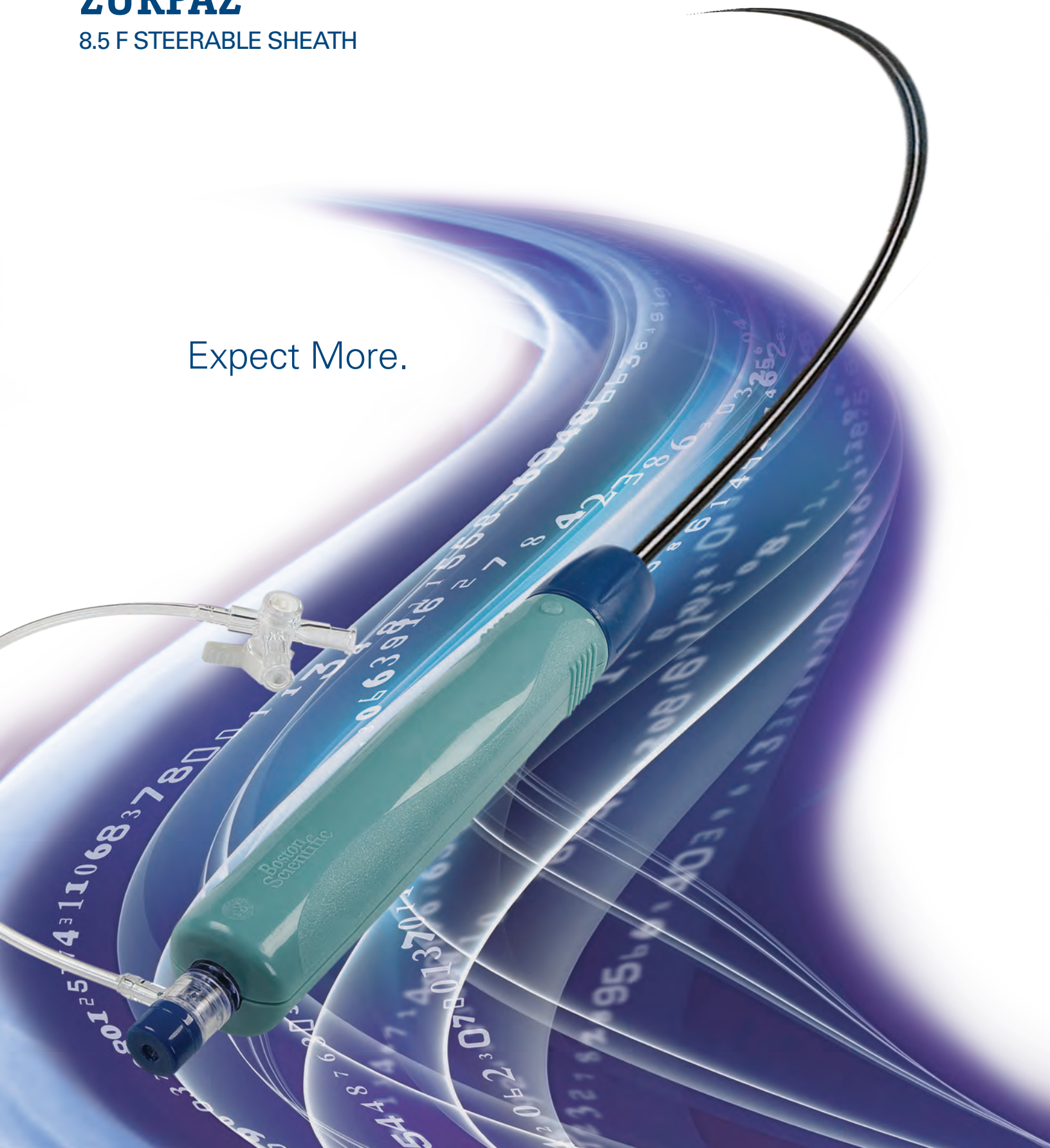
Boston Scientific
Advancing science for life™

ZURPAZ™

8.5 F STEERABLE SHEATH

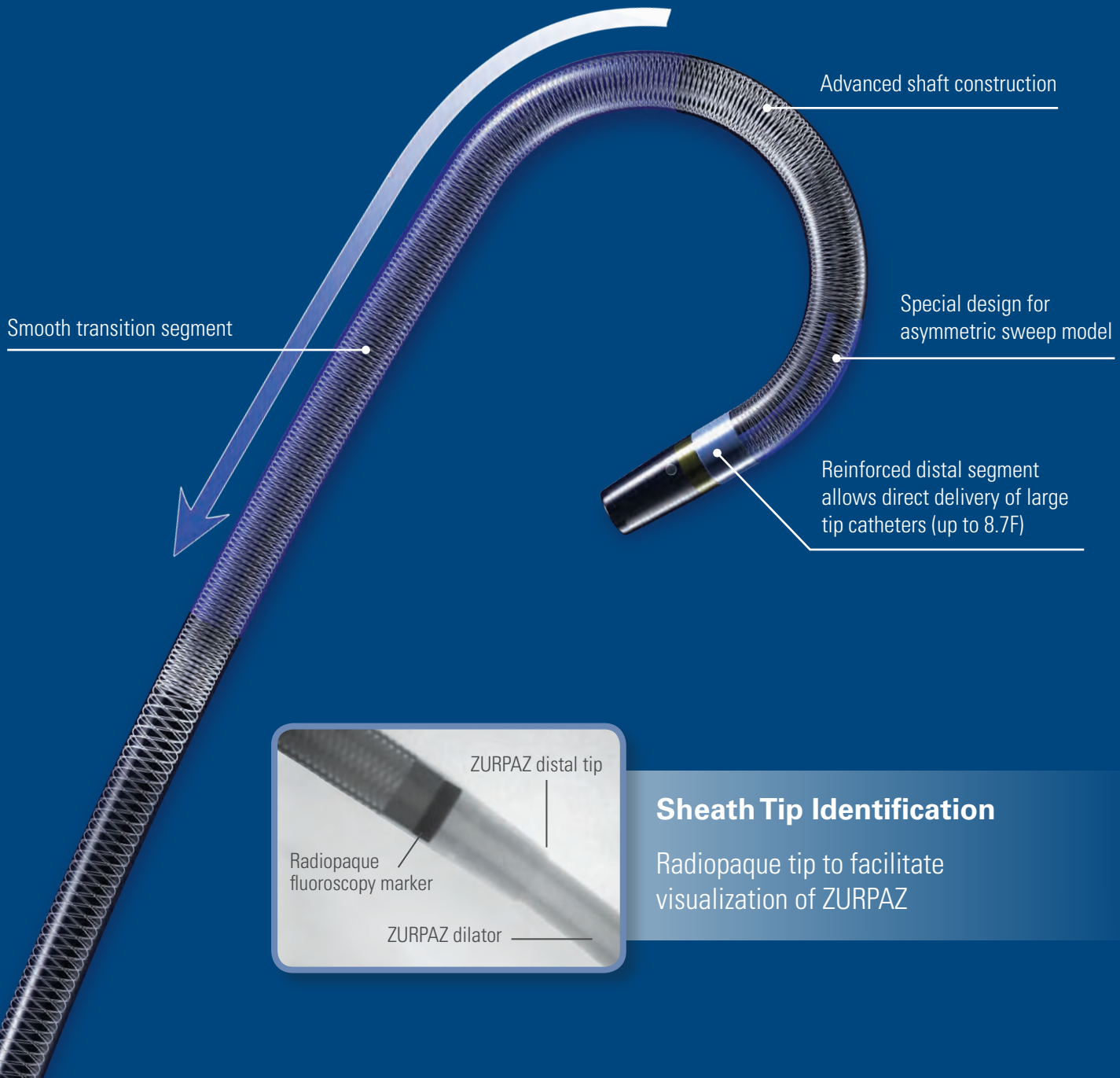
Expect More.



Expect More

The ZURPAZ™ 8.5F Steerable Sheath is designed to offer exceptional control, delivery, and performance during electrophysiology procedures.

Control. Delivery. Performance.



Sheath Tip Identification

Radiopaque tip to facilitate visualization of ZURPAZ

Expect More **Control**

Unique design of the ZURPAZ™ handle facilitates intuitive steering and hassle-free control.

360° Rotating Side Port

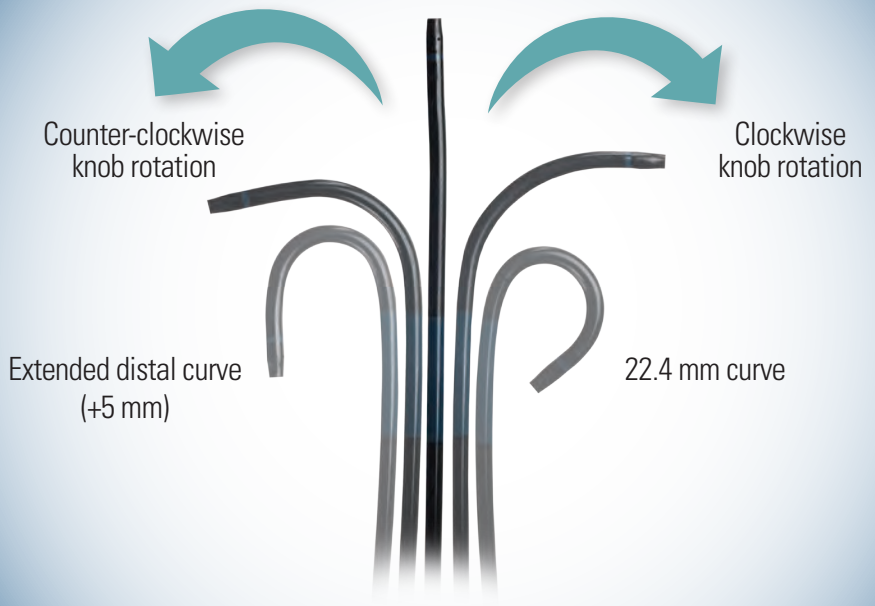
- Engineered to reduce potential tangling with catheters and lab equipment

Expect More **Delivery**

Enhanced shaft is engineered to enable accurate and efficient catheter delivery throughout the most difficult cases.

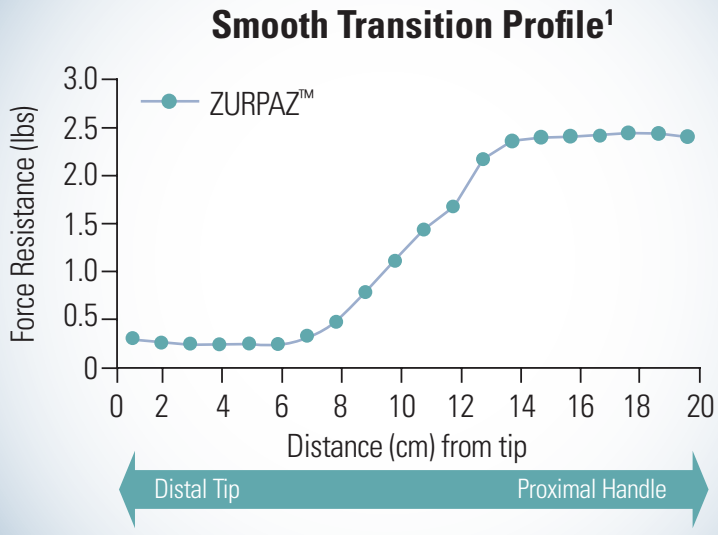
True Asymmetric Curve

- Allows multiple reach and delivery options on one sheath for increased maneuverability



Advanced Shaft Construction

- Smooth transition profile provides improved kink resistance, sheath durability, and curve durability
- Advanced shaft profile with quick response steering delivers a 1:1 torque ratio



1. Bench testing performed by Boston Scientific. Zurpaz N=15, Data on file. Bench test results may not necessarily be indicative of clinical performance.

Expect More **Performance**

Advanced tip construction promotes consistent performance that allows you to approach transseptal procedures with more confidence.

Smooth Tip-to-Dilator Transition

- Engineered to deliver a consistent crossing profile across anatomical structures

Soft Distal Tip

- Multiple and smaller distal tip side holes designed to reduce guidewire exit

Redefining Ablation Technology

At Boston Scientific, we are committed to introducing new technologies that are built upon a foundation of technical innovation and clinical success.

The introduction of the ZURPAZ™ 8.5F Steerable Sheath marks an additional milestone along Boston Scientific's journey to redefine ablation therapy.

To learn more about Boston Scientific's breakthrough cardiac rhythm technologies visit:
http://www.bostonscientific.com/en-US/medical-specialties/electrophysiology.html.

ZURPAZ™ 8.5F Steerable Sheath

Specification	ZURPAZ Symmetric	ZURPAZ Asymmetric
UPN	M004 **USMC8510** 0	M004 **USMCA8520** 0
Outer Diameter Compatibility	12F	
Inner Diameter Compatibility	8.7F	
Inner Diameter	9.0F	
Overall Length	92 cm	
Working Length	72 cm	
Tip Curve Dimension	22.4 mm @ 200°	
Fluoro Marker Distal Distance	7.0 mm	
Dilator Tip I.D.	0.041 in	
Guidewire Compatibility	0.032 in	
Guidewire Length	180 cm	
Kit Components	Steerable Sheath, Dilator, 0.032" Wire, Guidewire Introducer	
Curve Dimensions	Bidirectional Medium Curve (22.4 mm)	Medium Curve (22.4 mm) & Extended Curve

ZURPAZ™ Steerable Sheath Set

INTENDED USE/INDICATIONS FOR USE The Zurpaz™ Steerable Sheath is indicated for use when introducing various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum.

CONTRAINDICATIONS Patients who do not tolerate anticoagulation therapy, known or suspected atrial myxoma, recent cerebral vascular accident (CVA), myocardial infarctions within the last two weeks, patients with an active infection, unstable angina, presence of atrial thrombus, previous intra-atrial septal patch.

WARNINGS Do not alter this device in any way. Only those physicians who are trained in transseptal procedures and catheter delivery systems should use this device. Do not reuse this device. Thorough cleaning of biological and foreign material is not possible. Adverse patient reactions may result from reuse of this device. After use, dispose of product and packaging in accordance with hospital administrative and/or local government policy. Maintain continuous hemodynamic monitoring throughout the procedure. Always observe acceptable hemodynamics prior to advancing the dilator or any other component. Always withdraw components/aspirate slowly to minimize the vacuum created during withdrawal. From the sideport only - aspirate all air prior to fluid infusion. During radiofrequency (RF) ablation, position the ablation catheter so that the ablating tip and at least one ring electrode are exposed beyond the distal tip of the sheath to reduce the incidence of thermal deformation of the soft tip. Thermal deformation of the sheath tip may result in patient injury and/or damage to the sheath or to the other devices used concurrently. Provide continuous heparinized saline infusion while the sheath remains in the vasculature. Fibrin may accumulate in or on the sheath tip during the procedure. To prevent dislodgement of potential thrombus, aspirate when removing dilator or catheter. Prior to removing the steerable sheath, reinsert the guidewire through the sheath, reintroduce the dilator over the guidewire, straighten the sheath, then remove the dilator, guidewire, and sheath as a unit. Maximum in-vivo time: 7 hours.

PRECAUTIONS Carefully reading the Instructions before use of this device will help to reduce the potential risks and complications associated with the transseptal technique such as air emboli and/or perforation of the aorta and left atrium. Inspect all components before use. Do not use if the sterile package or items in the sheath set appear to be damaged or defective. The recommended diameter of any catheter inserted into the sheath is 8.7F (2.81mm). The sheath inner diameter is 9F (3mm). Do not attempt to insert a catheter having a distal tip or body size larger than the sheath size indicated. The steerable sheath is designed to interlock only with the Zurpaz™ sheath dilator. Misuse may result in serious complications. Do not attempt to use a guidewire larger than the maximum diameter specified on the package label. Prior to inserting the device into the patient, pre-assemble the steerable sheath and dilator. During insertion, use caution not to create excessive bends in this device. Frequently aspirate and saline flush the sheath to minimize the potential for thrombus formation. Do not remove dilator or catheter rapidly. Damage to the hemostasis valve may occur. Do not deflect the device beyond 180° prior to insertion of a catheter. If resistance is met when advancing or withdrawing guidewire or sheath, determine cause and correct before continuing with this procedure. Indwelling percutaneous introducer sheaths should always be supported with a catheter. Aspirate slowly, only from the sideport. Inject or saline flush only from the sideport. Certain conditions may require special consideration when using this product. These may be, but are not limited to Enlarged Aortic Root, Small Left Atrium, Marked Right Atrial Enlargement, Marked Distortion of the Thorax Configuration (i.e. Kyphosis or Scoliosis). STORE IN A COOL, DARK, DRY PLACE.

POTENTIAL ADVERSE EVENTS Adverse events may vary in severity and may require medical or surgical intervention. These potential adverse events may include, but are not limited to: Arrhythmias, Cardiac Tamponade, Effusion (Pericardial), Embolism, Hematoma, Hemorrhage, Infection (local/systemic), Intimal tear, Myocardial Infarction, Lead Displacement, Patent Foramen Ovale (PFO), Perforation, Thrombus formation, Valvular Damage, Please consult the respective manufacturer's labeling for adverse events associated with the use of either cardiovascular catheters and/or endomyocardial biopsy devices.
(Rev B)

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

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