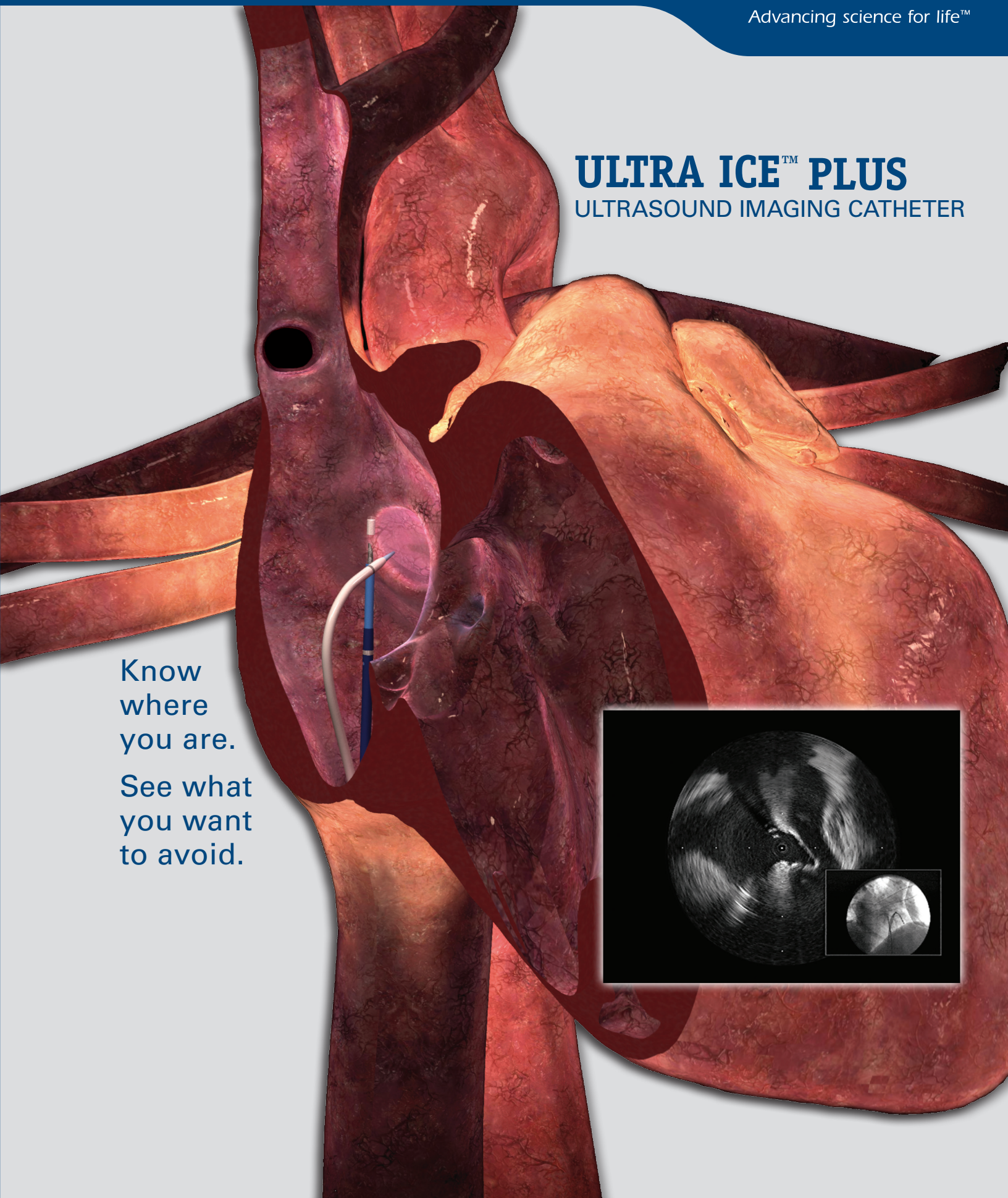
Boston Scientific

Advancing science for life™

ULTRA ICE™ PLUS

ULTRASOUND IMAGING CATHETER



Know where you are.

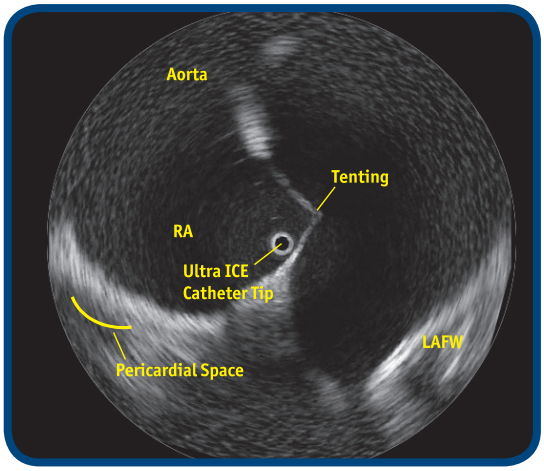
See what you want to avoid.

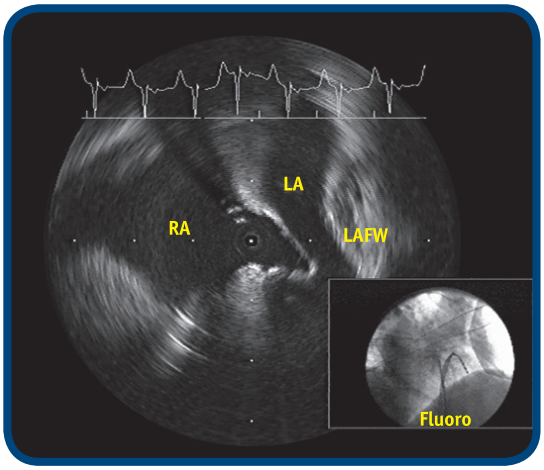
ULTRA ICE™ PLUS for Transseptal Puncture

Know where you are. See what you want to avoid.

Fluoroscopy alone provides limited visualization of Intracardiac anatomy. Puncture of the aorta and left atrial free wall (LAFW) are serious complications that may occur more frequently in procedures guided by fluoro alone.

Transseptal Puncture





Know where you are.

The Boston Scientific ULTRA ICE PLUS Catheter is designed to provide the visualization of both:

- Intracardiac anatomy
- Devices positioned within the heart with precise details in real time.

Not only does it help you in identifying anatomical structures, it also helps you in visualizing where your devices are relative to those structures.

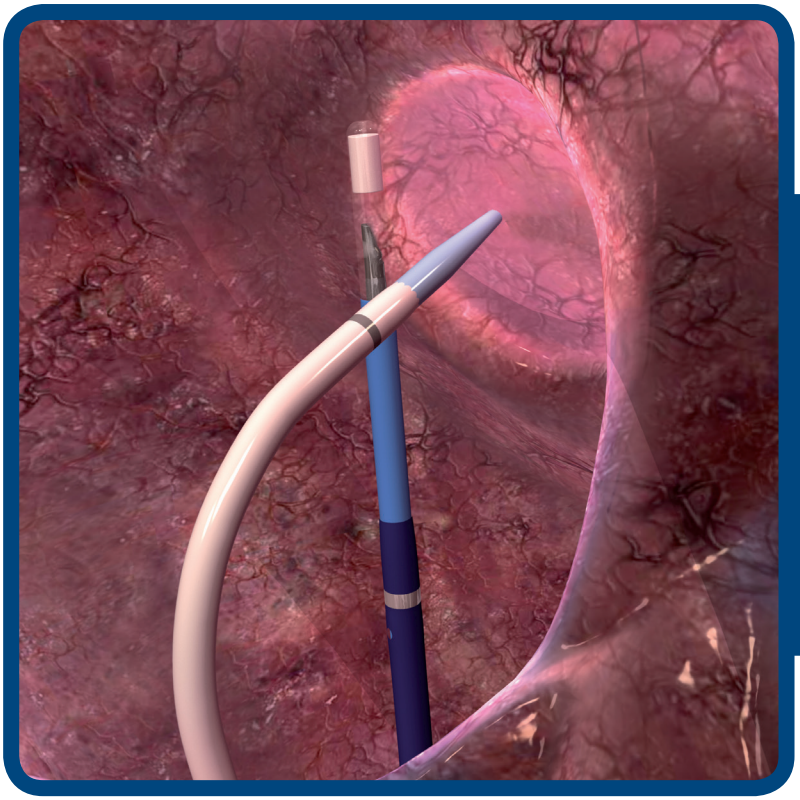
The images above show an ULTRA ICE PLUS Catheter positioned in the right atrium, adjacent to the fossa ovalis, visualizing the structures critical to successful transseptal puncture: the septum, aorta, needle position, tenting, and the LAFW.*

See what you want to avoid.

Performing a successful transseptal puncture involves not only making sure the needle passes through the fossa, but also assuring the needle AVOIDS structures such as the aorta and the left atrial free wall. Being able to visualize those structures can provide an added measure of confidence.

In the image to the right, notice the patient's reduced Left Atrium, the tenting of the septum and its relationship to the LAFW. The corresponding fluoroscopic image may suggest that puncture has already occurred. However, the ULTRA ICE PLUS image shows that this is not the case and guides the physician to redirect the needle in a puncture angle away from the LAFW.

* Results of one case study are not predictive of results in other cases. Results in other cases may vary.



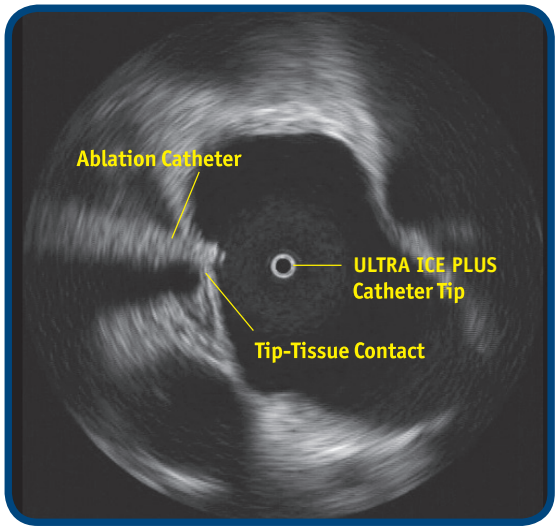
By using ULTRA ICE™ PLUS to visualize soft tissue in real-time, the user can observe catheter movement, monitor the interactions between devices and the tissue (e.g., tenting and puncture of the fossa ovalis), and guide devices into position relative to the anatomy.

Advanced Applications: *Crossing to the left side*

ULTRA ICE PLUS provides the combination of real-time imaging and soft tissue visualization that cannot be duplicated by fluoroscopy, pre-operative imaging (CT or MR) or electroanatomic mapping. Thus, ULTRA ICE PLUS can bring valuable clinical information, either when used by itself or in conjunction with these other imaging modalities.

A key application for the ULTRA ICE PLUS Catheter involves crossing the septum and then monitoring and helping to guide left-sided procedures. In this setting, ULTRA ICE PLUS Catheter is designed to allow the user to:

- Visualize left atrial anatomy
- Confirm catheter location relative to the anatomy
- Verify tip-to-tissue contact
- Identify location of the esophagus relative to the ablation catheter
- Characterize acute lesion morphology: swelling, dimpling, and crater formation
- Monitor for any early signs of thrombus formation, stenosis, or pericardial effusion

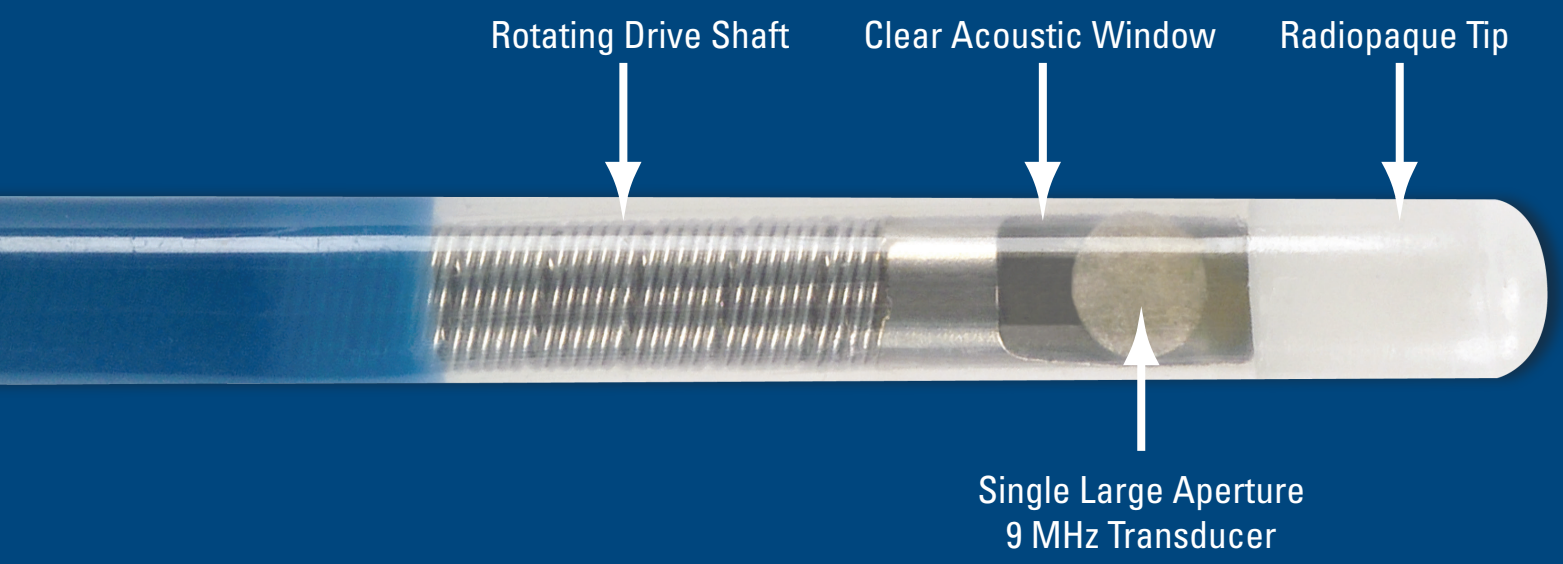


The ULTRA ICE™ PLUS Ultrasound Imaging Catheter

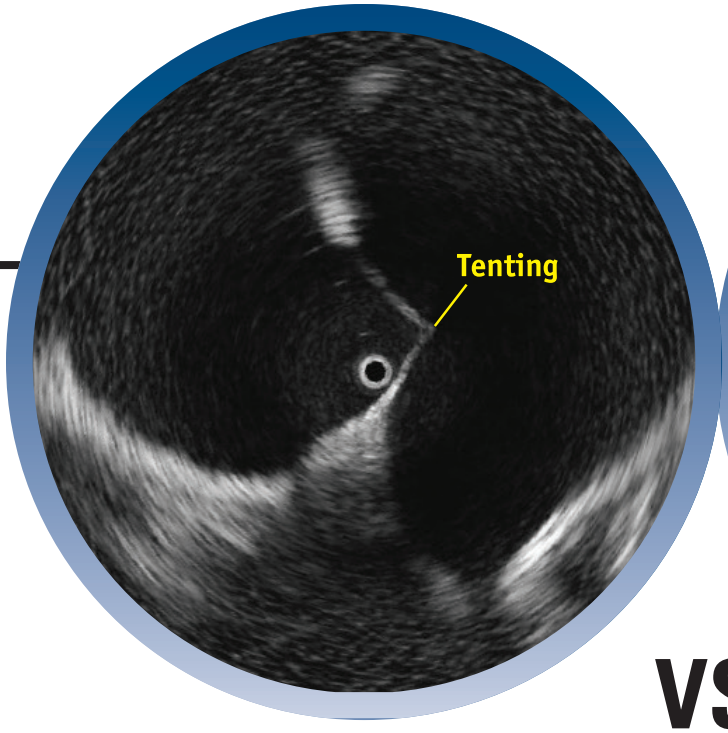
Excellent near-field detail. Stable positioning. Intuitive interpretation.

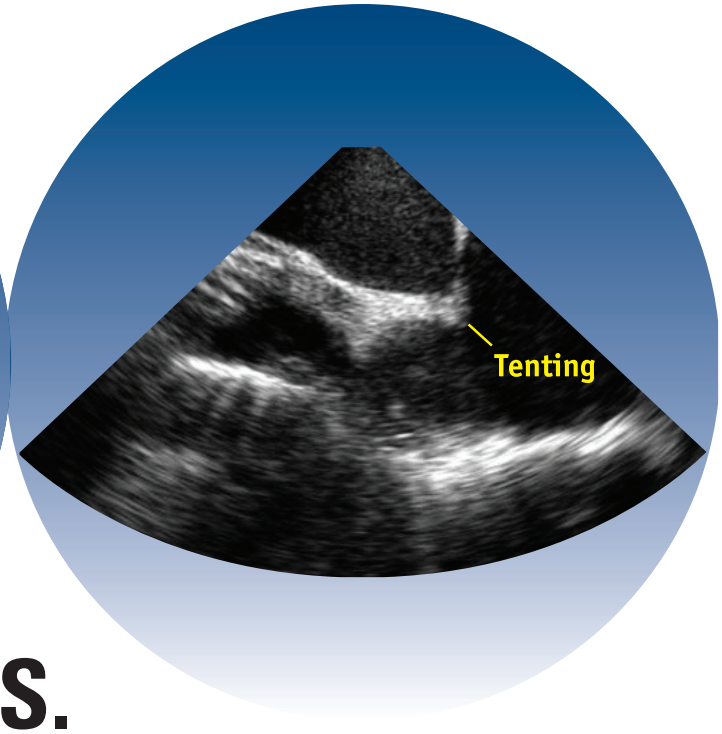
Unique Vision:

360° view of the world



The radiopaque tip of the ULTRA ICE PLUS Catheter facilitates placement and serves as a fluoroscopic marker during the procedure. The area of interest is the central point in the ultrasound image, providing a clear panorama of what you want to visualize.





VS.

ULTRA ICE™ PLUS Catheter
360° view

Phased Array Catheter
Pie-Shaped Wedge View

Stable Positioning

The radiopaque tip of the ULTRA ICE PLUS Catheter can be positioned *directly adjacent* to the area of interest (in this case the fossa) under fluoroscopic guidance. A phased array catheter must be positioned at a distance from the area of interest, then steered to bring the area into view.

This requires coordination of (a) catheter advancement within the atrium, (b) distance from the septum, (c) array rotation around the catheter's axis, and (d) angle of the array relative to the septum.

Detailed Near-Field Resolution; Wide Field of View

The ULTRA ICE PLUS Catheter generates a panoramic 360° image perpendicular to the catheter, with the tip as a central reference point. This allows the user to visualize structures (such as the fossa) directly adjacent to the catheter tip and still see a detailed cross-section of the entire septum.

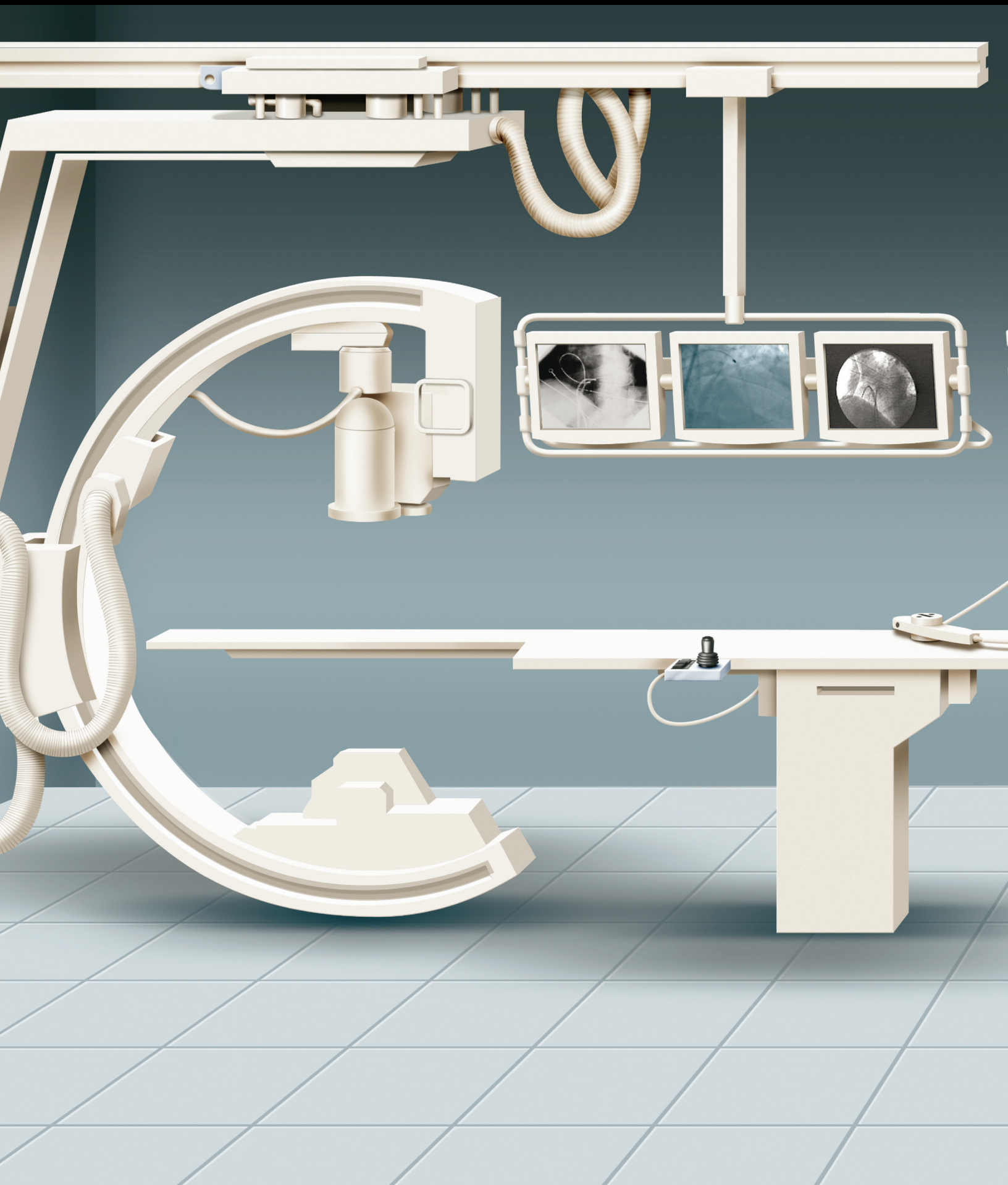
Near-field detail is dependant on the position of the catheter head relative to the area of interest and the orientation of the imaging plane. The far-field image is constrained to a narrow, pie-shaped wedge view.

Intuitive Interpretation

The close proximity between the catheter tip and area of interest (such as the fossa) is designed to allow intuitive interpretation of the ULTRA ICE PLUS image. The tip also serves as a fluoroscopic marker to guide the placement of the transseptal dilator tip at the fossa.

The distance required between the tip and the area of interest may effect the correlation between the catheter tip and anatomic structures. It may also prohibit the tip from serving as a marker for placement of other catheters.

The iLAB™ Ultrasound Imaging System



Total lab integration. *Always there, always available.*

iLAB™ Ultrasound Imaging System transformed visualization during EP procedures as the first intracardiac ultrasound system customized for the EP lab. It offers an easy user -interface and automatic enhancement of ICE images. The Modular hardware design comes either installed or on a cart allowing flexibility to upgrade. The iLAB system is compatible with all Boston Scientific ultrasound catheters: Intracardiac (ICE), Intravascular (IVUS) and Peripheral (PI).

- New, intuitive user interface
- Large high definition monitor
- Convenient touchpad interface
- Automatic enhancement of ULTRA ICE™ PLUS images
- Modular hardware design easy to upgrade

Ordering Information

Description	UPN
ULTRA ICE™ PLUS Catheter	M004 9912 0
Fluid Dock™ Filling Device	M004 9915 1
MDU5 PLUS Motor Drive	H749MDU5PLUS0
MDU5 PLUS Sterile Bag	H749MDU5PLUSBAG0
iLAB Ultrasound Imaging System (Integrated)	H749ILAB120N2710
iLAB Ultrasound Imaging System (Cart)	H749ILAB120C2710

ULTRA ICE™ PLUS Ultrasound Imaging Catheter from Boston Scientific

INDICATIONS FOR USE

Ultra ICE Plus Catheter: This rounded tip catheter is indicated for enhanced ultrasonic visualization of intracardiac structures. MDU5 PLUS Sterile Bag: The MDU5 PLUS Sterile Bag is intended to cover the motordrive during intravascular ultrasound procedures to maintain the sterile field and prevent transfer of microorganisms, body fluids and particulate material to the patient and healthcare worker.

CONTRAINDICATIONS

This product is contraindicated in the presence of conditions which create unacceptable risk during catheterization. This device is not intended to be used in the coronary arteries. This device is not intended for fetal use.

WARNINGS

DO NOT advance the catheter if resistance is encountered. The catheter should never be forcibly inserted into lumens narrower than the catheter body or forced through a tight stenosis. If resistance is met upon withdrawal of the catheter, verify resistance using fluoroscopy, then remove the entire system simultaneously. When utilizing a steerable guide sheath, it is not recommended to articulate the sheath tip beyond 55 degrees. Utilizing a fixed curve guide sheath with an angle greater than 55 degrees is not recommended. A guide sheath with an inner diameter less than 2.84 mm must never be utilized. When utilizing the ICE catheter, it is not recommended to place the transducer assembly within the curve of the guide sheath while imaging.

PRECAUTIONS

Contents supplied STERILE using a gamma radiation (Cobalt 60) process. Do not use if sterile barrier is damaged. For single 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. This device should be used by physicians thoroughly trained in the techniques of invasive cardiology and in the specific approach to be used. After the procedure, inspect the catheter carefully for any damage which may have occurred during use. The catheter has no user serviceable parts. Do not attempt to repair or to alter any component of the catheter assembly as provided. Do not attempt to connect the catheter to electronic equipment other than the designated systems. Never attempt to attach or detach the catheter while the motor is running. Throughout the procedure anticoagulant therapy is recommended for patients undergoing left-sided and transseptal cardiac procedures and should be considered for selected patients undergoing right-sided procedures. Avoid any sharp bends, pinching or crushing of the catheter. **Do not kink or sharply bend the catheter at any time.** An insertion angle greater than 45° is considered excessive. Turn the MDU5 PLUS "OFF" before withdrawing the imaging catheter, or when advancing the catheter in the body. Prior to utilizing the ICE catheter, verify there are not kinks in either the ICE catheter or guide sheath.

COMPLICATIONS

The risks and discomforts involved in imaging cardiac structures include those associated with similar types of diagnostic procedures in the heart. However, any of these risks or discomforts may occur with greater frequency or severity than previously reported. Additionally, these complications may necessitate additional medical treatment including surgical intervention. Abnormal heart rhythms, cardiac wall injury including perforation, damage to cardiac valvular structures, death, endocarditis, hematoma, hypotension/hypertension, infection/discomfort, myocardial infarction, stroke/embolism, thrombosis, vascular wall injury including perforation. As with all procedures that utilize the Seldinger Technique for introducing a catheter into an artery, the following complications have been reported: infection and pain in the region of the insertion site, hemorrhage, arteriovenous fistula.

91161596 (Rev AA)

iLAB™ Ultrasound Imaging System from Boston Scientific

INDICATIONS AND CONTRAINDICATIONS FOR SYSTEM USE

The iLab™ Ultrasound Imaging System is intended for ultrasound examinations of intravascular pathology. Intravascular ultrasound is indicated in patients who are candidates for transluminal interventional procedures such as angioplasty and atherectomy. Refer to the Catheter Directions for Use provided with all Boston Scientific Ultrasound Imaging Catheters to determine compatibility with the iLab System. All Ultrasound Imaging Catheters will be referred to as Imaging Catheters throughout the remainder of this user's guide. The Imaging Catheters generate ultrasound images and are intended for ultrasound examination of vascular and cardiac pathology. Boston Scientific manufactures a wide variety of catheters for different applications. The recommended use of each of these catheters may vary depending on the size and type of the catheter. Please refer to Imaging Catheter Directions for Use, packaged with each catheter.

CONTRAINDICATIONS FOR SYSTEM USE

Use of the Imaging Catheter is contraindicated where introduction of any catheter would constitute a threat to patient safety. This instrument is contraindicated for fetal imaging. The contraindications include the following patient characteristics: General • Bacteremia or sepsis • Major coagulation system abnormalities • Unsuitability for coronary artery bypass surgery • Unsuitability for balloon angioplasty (PTCA) • Total occlusion • Severe hemodynamic instability or shock • Coronary artery spasm • Myocardial infarction • Intra-arterial or intra-ventricle thrombosis • Life-threatening rhythmic disorders • Mechanical heart valves that would be crossed by the imaging catheter

INDICATIONS FOR AUTO PULLBACK USE

Automatic Pullback is indicated when the following occurs: • The physician/operator wants to standardize the method in which intravascular ultrasound images are obtained and documented: procedure-to-procedure, operator-to-operator. • The physician/operator wants to make linear distance determinations post-procedurally, which requires the imaging core of a catheter to be pulled back at a known uniform speed. • Two-dimensional, longitudinal reconstruction of the anatomy is desired.

CONTRAINDICATIONS FOR AUTO PULLBACK USE

Use of the Automatic Pullback is contraindicated where introduction of any catheter would constitute a threat to patient safety. For further information, please consult the Imaging Catheter Directions for Use packaged with each Imaging Catheter.

WARNINGS, CAUTIONS, AND PRECAUTIONS LISTS

Inappropriate use of the iLab System may lead to patient illness, injury, or death. Please read this User's Guide and the package inserts for the Imaging Catheters carefully and completely before attempting to use the System. .To avoid the risk of electrical shock, this equipment must only be connected to a supply mains with protective earth. Other than the fuses on the AC Power Isolation Transformer, the iLab System enclosures contain no operator-serviceable components. Refer servicing to Boston Scientific-authorized personnel only. Possible explosion hazard if used in the presence of flammable anesthetics. Use only Imaging Catheters that are specifically approved for the iLab System. For instructions on proper disposal methods for the following consumable items, please refer to the Directions for Use packaged with the item: • Disposable Sled • Motordrive Sterile Bag • Imaging Catheter (and packaged accessories) • Tableside Controller Drape

Care should also be exercised in adjusting all settings to avoid obscuring low-level signals that may have diagnostic value. Improper settings can seriously degrade image quality. Do not attempt to autoclave, immerse, or sterilize the Motordrive Unit. The user has the ultimate responsibility for any use of these measurements in the direction of interventions.

CAUTIONS LIST

Ensure that the Imaging Catheter is carefully inserted through the opening in the Motordrive Sterile Bag, without catching any part of the Bag between the Imaging Catheter and the Motordrive. Do not attempt to manually move the Motordrive in the Sled once it is installed in a Sled without first depressing the Release Lever. The AC Power Isolation Transformer is intended to be used only with iLab System equipment. Always begin powering off the system by first using the Control Panel and then turning off the main AC power switch. For more information, refer to "Powering Down the iLab System" in the chapter, *Using the iLab System* in the *User's Guide*.

PRECAUTIONS LIST

Verify that both latches on the Sled are fully engaged with the Motordrive. Observe the precautions provided from the manufacturer of the media regarding handling, labeling, and storage. If the iLab System does not produce a usable image when connected to a Catheter Simulator, please contact your Boston Scientific representative for technical assistance.

NOTE: Medical electrical equipment requires special precautions regarding EMC. This equipment needs to be installed and put into service according to the EMC information contained within the accompanying documents. Due to the unique nature of archived (DICOM) files on CD, DVD or Removable Hard Drive media should be labeled, handled, and stored according to individual manufacturer's recommendations to avoid data loss or corruption over time.

POTENTIAL SYSTEM USAGE COMPLICATIONS

The following complications may occur as a consequence of intravascular or intracardiac imaging: • Abrupt closure • Angina • Cardiac arrhythmias including but not limited to: ventricular tachycardia, ventricular fibrillation, and complete heart block • Catheter/Guidewire/Pressure wire entrapment • Embolism • Emergent Coronary Artery Bypass Graft (CABG) surgery • Infection• Myocardial infarction • Myocardial ischemia • Myocardial perforation • Stent strut damage • Stroke (including Cerebral Vascular Accident and Transient Ischemic Attack) • Thrombus formation • Total occlusion • Valvular injury • Vessel dissection, injury, or perforation • Vessel spasm

For further information, please consult the Catheter Directions for Use packaged with each Imaging Catheter.

myocardial perforation, stent strut damage, stroke (including Cerebral Vascular Accident and Transient Ischemic Attack), thrombus formation, total occlusion, valvular injury, vessel dissection, injury, or perforation, vessel spasm.

For further information, please consult the Catheter Directions for Use packaged with each Imaging Catheter.

90960359 (Rev AB)

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.

CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device. Information for the use only in countries with applicable health authority product registrations. Information not intended for use or distribution in France.

Boston Scientific

Advancing science for life™

Rhythm Management
300 Boston Scientific Way
Marlborough, MA 01752-1234
www.bostonscientific.com

Medical Professionals:
1.800.CARDIAC (227.3422)
Customer Service:
1.888.272.1001

EP-201314-AD