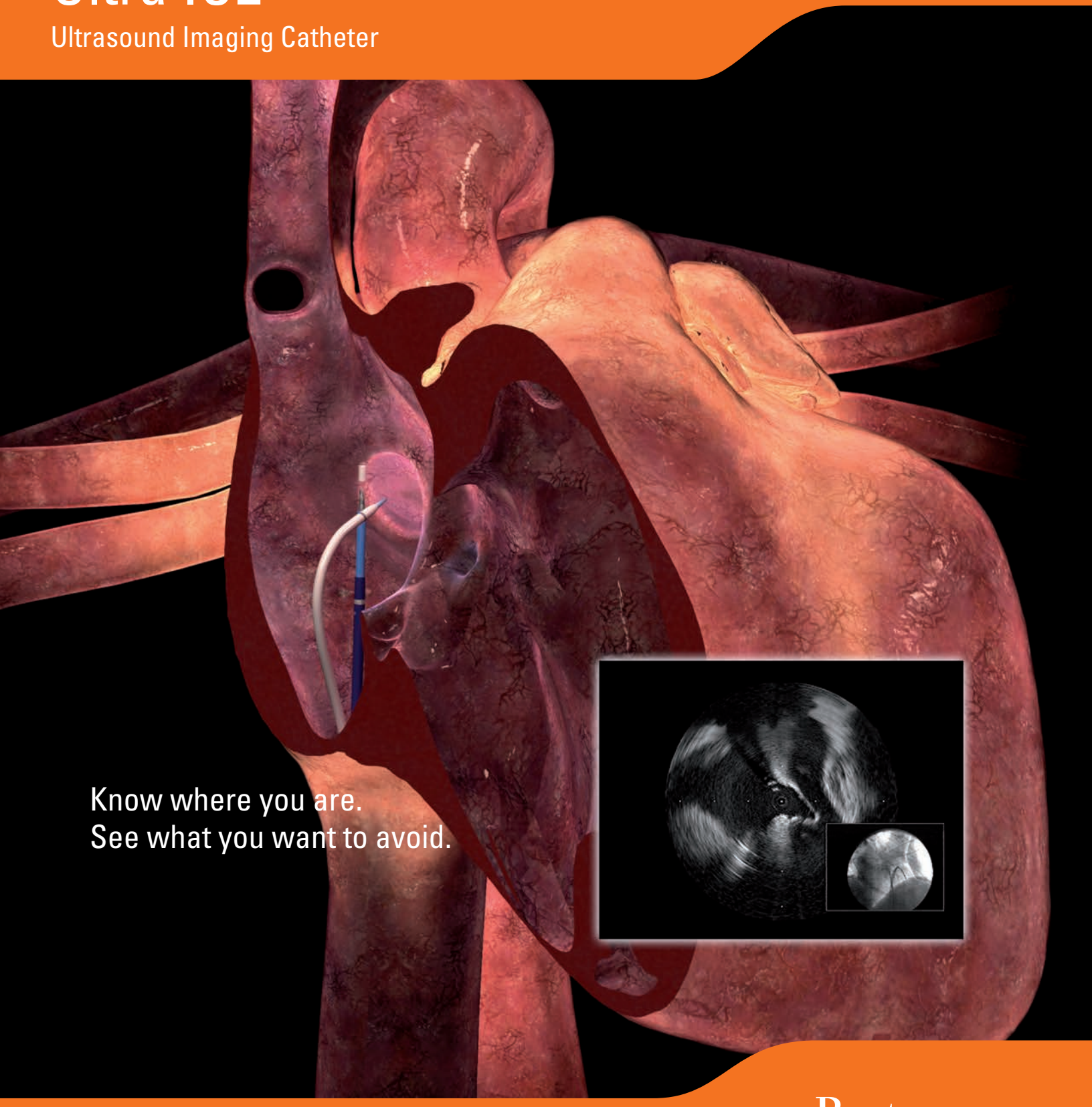
Ultra ICE™

Ultrasound Imaging Catheter



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

Boston Scientific

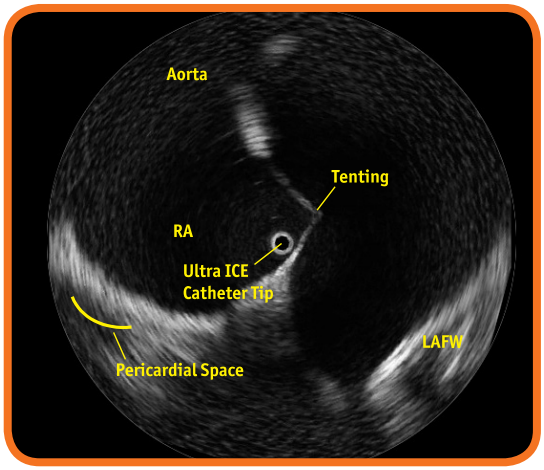
Advancing science for life™

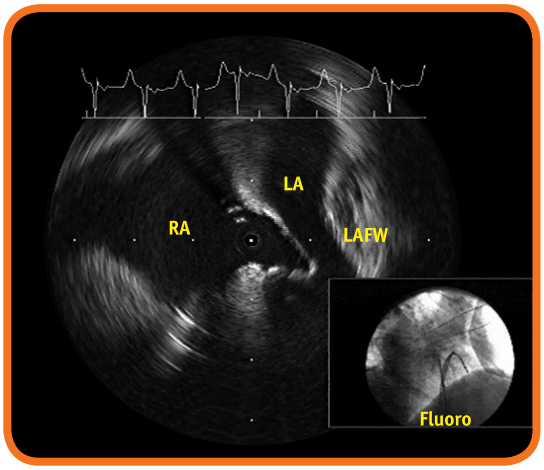
Ultra ICE™ for Transseptal Puncture

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 Ultrasound Imaging Catheter is designed to provide precise, real-time visualization of both Intracardiac anatomy and devices positioned within the heart. Not only does it help you in identifying anatomical structures, it also helps you in visualizing where your devices are relative to those structures.

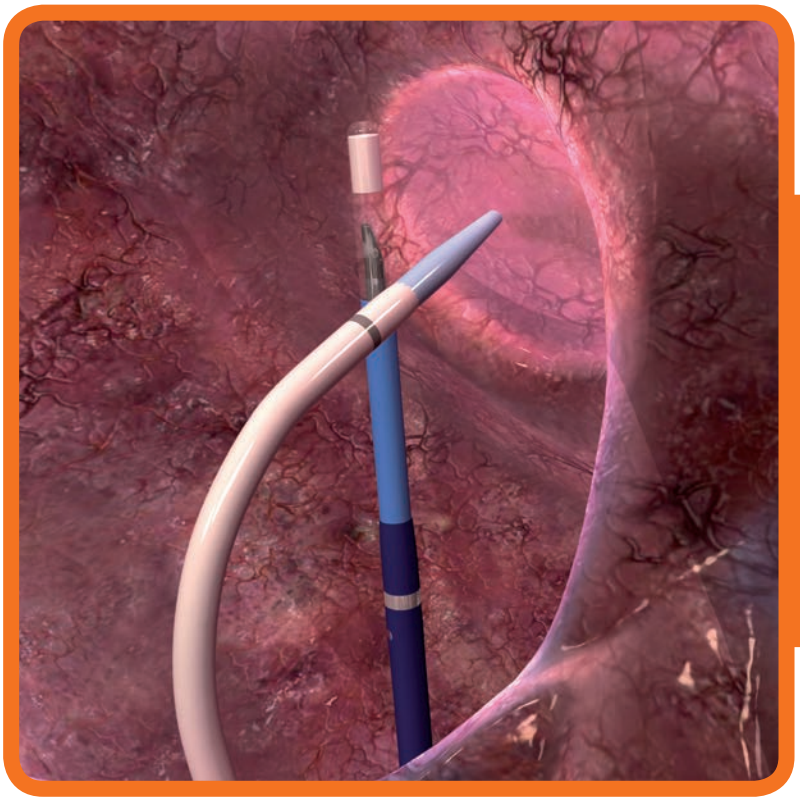
The images above show an Ultra ICE Catheter positioned in the right atrium, adjacent to the fossa ovalis, visualizing the structures critical to successful transseptal puncture: the septum, aorta, needle position, tenting, and the LAFW.*

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 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.



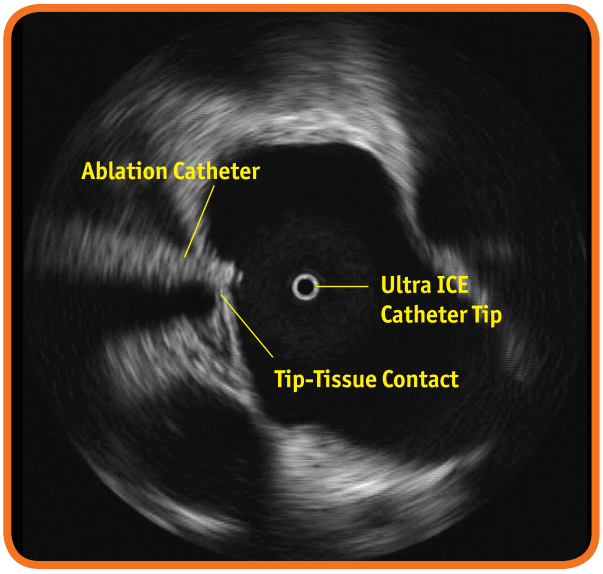
By using Ultra ICE™ to visualize soft tissue in real-time, the user can observe catheter movement, monitor the interactions between devices and the tissue (e.g., tenting and puncture of the fossa ovalis), and guide devices into position relative to the anatomy.

Advanced Applications: *Crossing to the left side*

Ultra ICE 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 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 Catheter involves crossing the septum and then monitoring and helping to guide left-sided procedures. In this setting, Ultra ICE 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

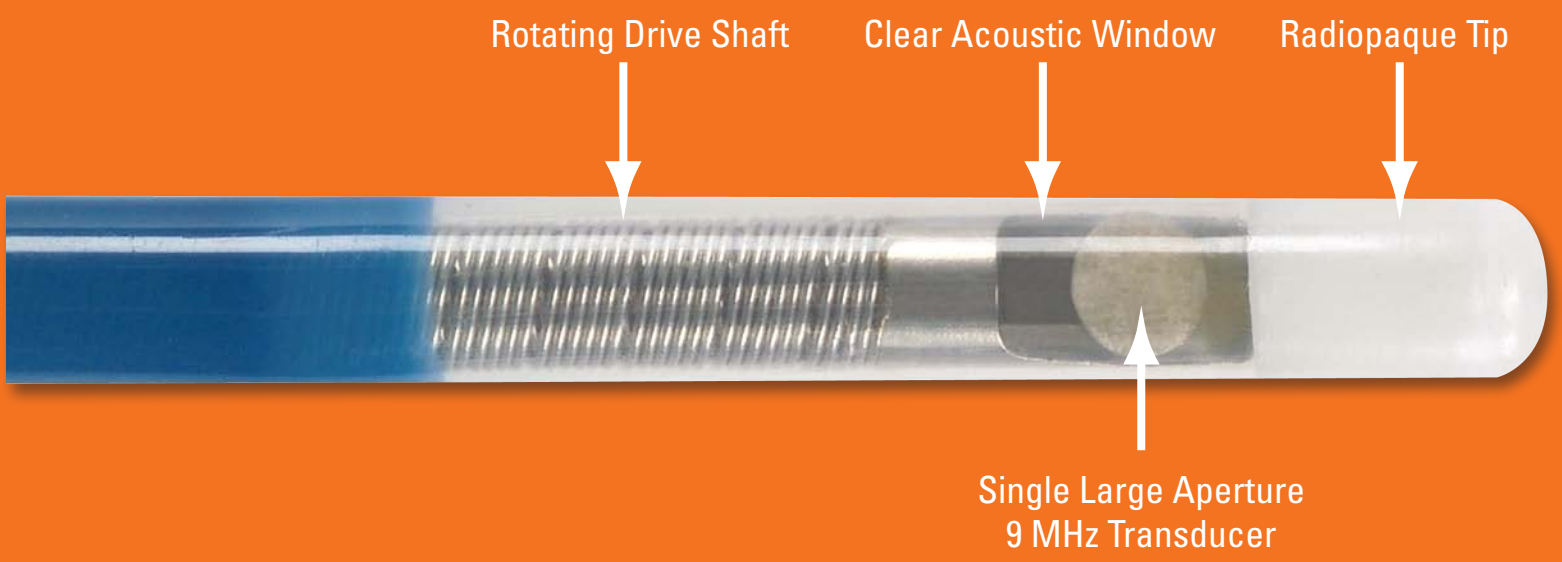


The Ultra ICE™ Ultrasound Imaging Catheter

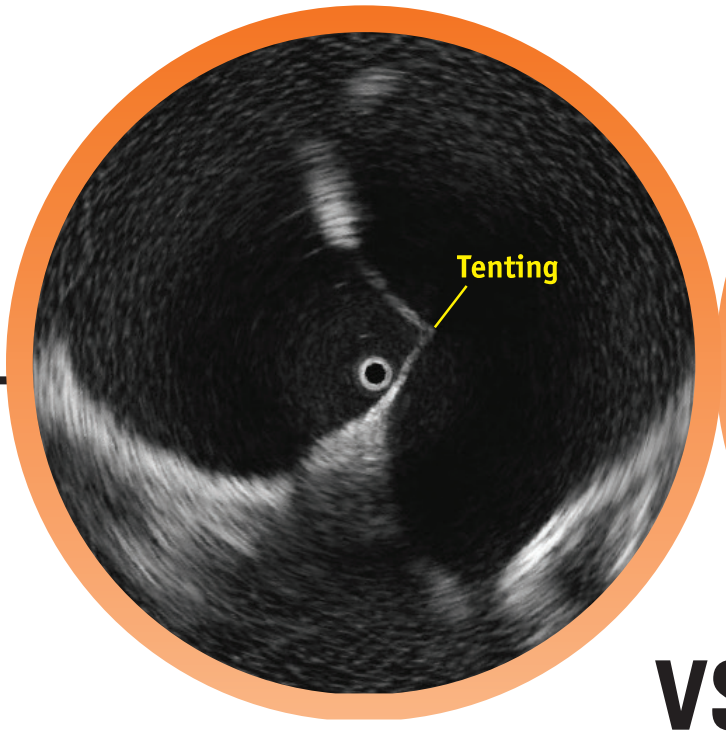
Excellent near-field detail. Stable positioning. Intuitive interpretation.

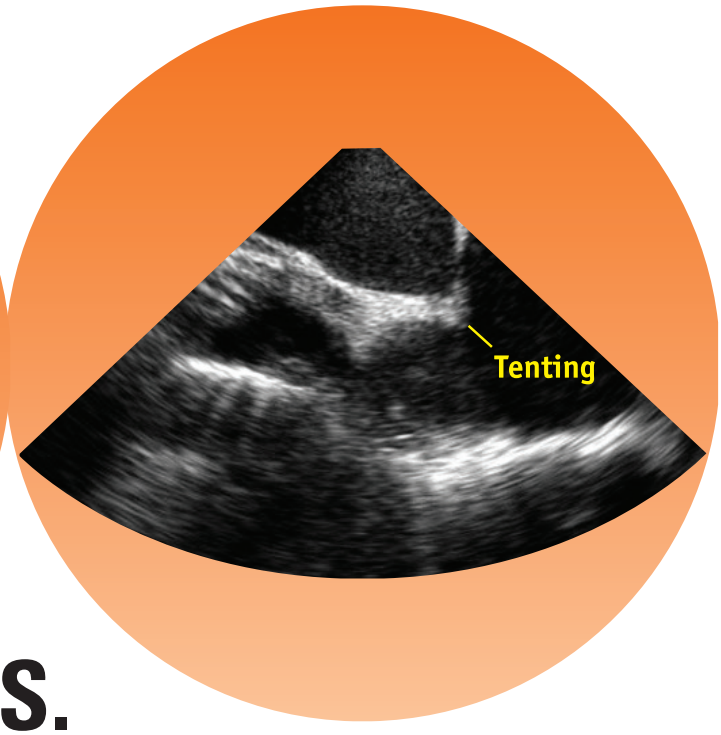
Unique Vision:

360° view of the world



The radiopaque tip of the Ultra ICE 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™ Catheter

360° view

Phased Array Catheter

Pie-Shaped Wedge View

Stable Positioning

The radiopaque tip of the Ultra ICE 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 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.

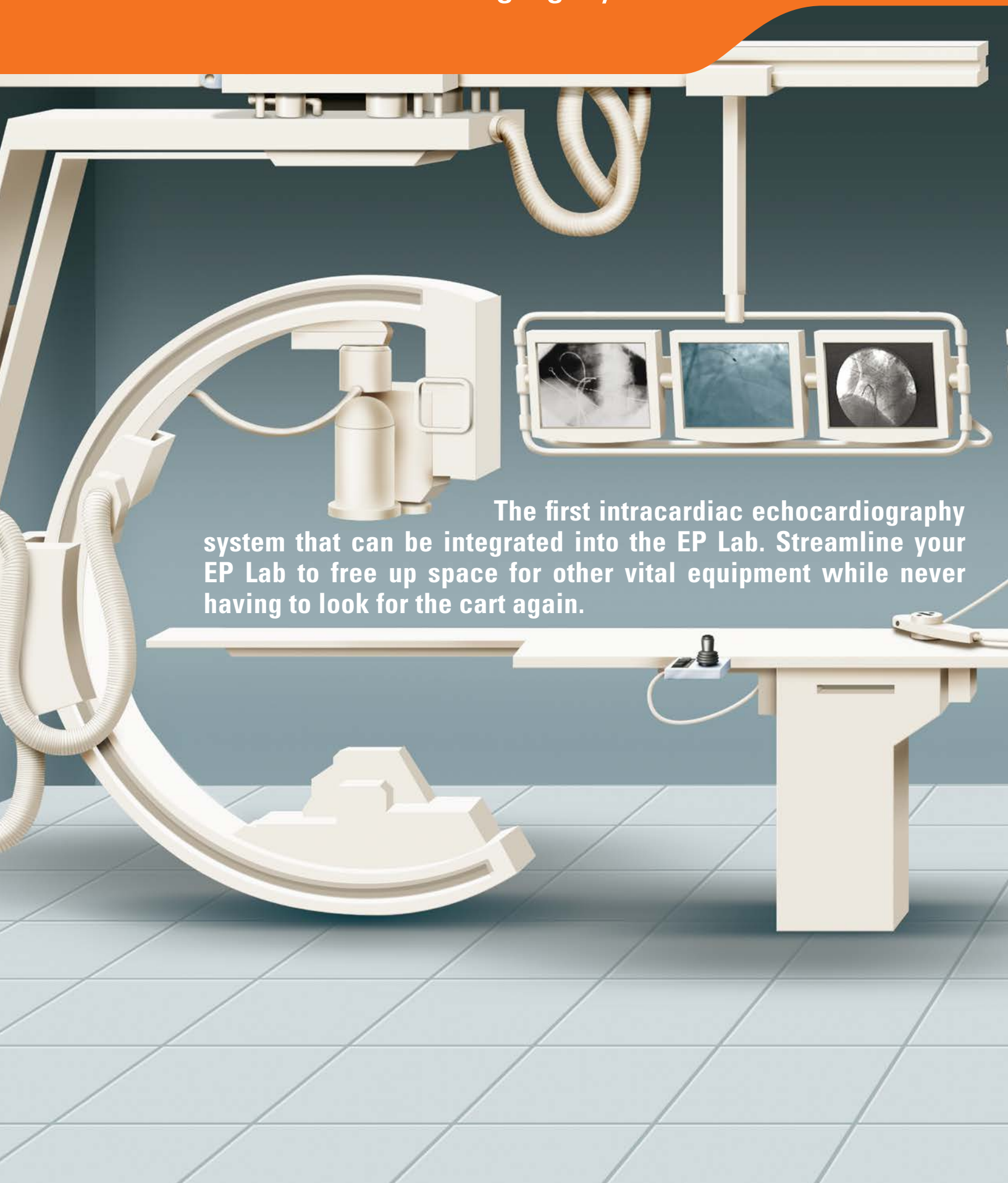
Near-field detail is dependant on the position of the catheter head relative to the area of interest and the orientation of the imaging plane. The far-field image is constrained to a narrow, pie-shaped wedge view.

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 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



The first intracardiac echocardiography system that can be integrated into the EP Lab. Streamline your EP Lab to free up space for other vital equipment while never having to look for the cart again.

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

The Boston Scientific iLab™ System is the first intracardiac ultrasound system that allows you the option to fully integrate the hardware into your EP Lab. The integrated system is always there, and always available.

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

Or, if a portable version is a better fit for your hospital, the iLab System is also available in a cart-based configuration.

Whichever configuration you prefer, the iLab System suits your needs.

- Quickly learn basic imaging techniques
- Compatible with all Boston Scientific ultrasound catheter platforms: Intracardiac (ICE), Intravascular (IVUS) and Peripheral

Ultra ICE™ Imaging Catheter

Indications for Use, Contraindications, Warnings, Precautions, Potential Adverse Events

INDICATIONS FOR USE The Ultra ICE™ Rounded Tip Catheter is indicated for enhanced ultrasonic visualization of intracardiac structures. CONTRAINDICATIONS This product is contraindicated in the presence of conditions which create unacceptable risk during catheterization. This device is not 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. Over articulation may result in separation and/or embolization of device components that could lead to vessel obstruction or necessitate percutaneous or surgical intervention. In rare cases, stroke or death could result • Utilizing a fixed curve guide sheath with an angle greater than 55 degrees is not recommended. This could result in separation and/or embolization of device components that could lead to vessel obstruction or necessitate percutaneous or surgical intervention. In rare cases, stroke or death could result • A guide sheath with an inner diameter less than 2.84 mm must never be utilized. Utilization of such a guide sheath could cause separation and/or embolization of device components that could lead to vessel obstruction or necessitate percutaneous or surgical intervention. In rare cases, stroke or death could result • When utilizing the ICE catheter, it is not recommended to place the transducer assembly within the curve of the guide sheath while imaging. This could result in separation and/or embolization of device components that could lead to vessel obstruction or necessitate percutaneous or surgical intervention. In rare cases, stroke or death could result. PRECAUTIONS Contents supplied STERILE using a gamma radiation (Cobalt 60) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative • 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. Contamination of the device may lead to injury, illness or death of the patient • 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. To do so may damage the connector • 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. This can cause drive cable failure. An insertion angle greater than 45° is considered excessive • Turn the MDU "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. Utilization of a kinked ICE catheter and/or guide sheath could compromise the functionality of the ICE catheter, leading to a device failure. 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 for discomforts may occur with greater frequency or severity than previously reported. Additionally, these complications may necessitate additional medical treatment including surgical intervention. Myocardial infarction, Abnormal heart rhythms, Thrombosis, Hematoma, Cardiac wall injury including perforation, Vascular wall injury including perforation, Infection/discomfort, Damage to cardiac valvular structures, Hypotension/Hypertension, Endocarditis, Stroke/embolism, Death.

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.

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician. Carefully read all instructions prior to use. Observe all contraindications, warnings, and precautions noted in these instructions. Failure to do so may result in patient complications. Boston Scientific relies on the physician to determine, assess, and communicate to each patient all foreseeable risks of the procedure.

Boston Scientific

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