ULTRA ICE™ PLUS
ULTRASOUND IMAGING CATHETER

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.
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
- 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

Rotating Drive Shaft   Clear Acoustic Window   Radiopaque Tip

Single Large Aperture
9 MHz Transducer

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.
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.

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.

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.

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.

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.
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

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

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<thead>
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<th>Description</th>
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<tbody>
<tr>
<td>ULTRA ICE™ PLUS Catheter</td>
<td>M00499120</td>
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<tr>
<td>Fluid Dock™ Filling Device</td>
<td>M00499151</td>
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<tr>
<td>MDU5 PLUS Motor Drive</td>
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<td>MDU5 PLUS Sterile Bag</td>
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<tr>
<td>iLAB Ultrasound Imaging System (Integrated)</td>
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<tr>
<td>iLAB Ultrasound Imaging System (Cart)</td>
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INTENDED USE/INDICATIONS FOR 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 Catheters are tested and approved by Multidisciplinary Catheter Testing Laboratory (MDT) for use with the iLab System. 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 cardiomyopathy • 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 Catheter Directions for Use packaged with each Imaging Catheter.

WARNINGs, CAUTIONs, AND PRECAUTIONS LISTs

- INAPPROPRIATE USE OF THE ILAB SYSTEM MAY LEAD TO PATIENT INJURY OR DEATH. DO NOT ATTEMPT TO OPERATE THE SYSTEM WITHOUT COMPLETING THE TRAINING PROGRAM PROVIDED BY BOSTON SCIENTIFIC.
- USE WITH iLAB SYSTEM ONLY. THIS DEVICE IS DESIGNED TO BE OPERATED WITH THE iLAB SYSTEM.
- THIS DEVICE IS NOT INTENDED FOR USE WITH ANY OTHER SYSTEMS OR DEVICES.
- USE WITH система for IMAGING ONLY. THIS DEVICE IS NOT INTENDED FOR USE WITH ANY OTHER PROCEDURES OR PROCEDURAL NAMEs.
- USE WITH CAUTION. THIS DEVICE IS NOT INTENDED FOR USE WITH ANY OTHER DEVICES OR SYSTEMs.
- USE WITH PRECAUTIONS. THIS DEVICE IS NOT INTENDED FOR USE WITH ANY OTHER PROCEDURES OR PROCEDURAL NAMEs.
- USE WITH OPERATOR’S INSTRUCTIONS. THIS DEVICE IS NOT INTENDED FOR USE WITH ANY OTHER OPERATIONAL PROCEDURES OR PROCEDURAL NAMEs.
- USE WITH CAUTION. THIS DEVICE IS NOT INTENDED FOR USE WITH ANY OTHER DEVICES OR SYSTEMs.
- USE WITH OPERATOR’S INSTRUCTIONS. THIS DEVICE IS NOT INTENDED FOR USE WITH ANY OTHER OPERATIONAL PROCEDURES OR PROCEDURAL NAMEs.

Potential System Usage Complications

The potential 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) • Infection • Myocardial infarction • Myocardial ischemia • Myocardial perforation • Infected arterial puncture tract • Shock (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.