

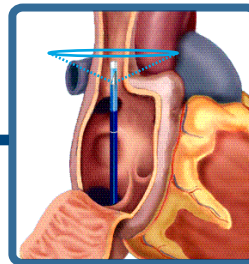
Transseptal Imaging with the ULTRA ICE™ PLUS Ultrasound Imaging Catheter

Four Images You Need to Know

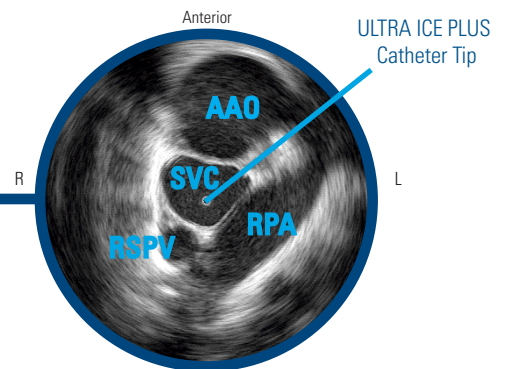
The four ultrasound images shown below are images commonly seen when using the Boston Scientific ULTRA ICE PLUS Imaging System in a transseptal procedure. The corresponding procedural information is reflective of how experienced physicians might typically respond when each of these images is observed.

Start in the SVC

Place the ULTRA ICE PLUS Catheter in the Superior Vena Cava (SVC). Typical structures visible in this plane are the Ascending Aorta (AAO), Right Pulmonary Artery (RPA), and the Right Superior Pulmonary Vein (RSPV).

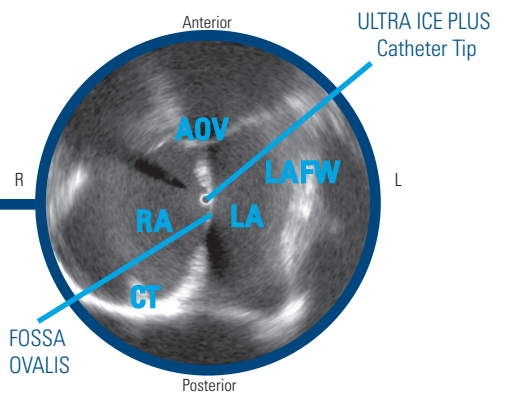
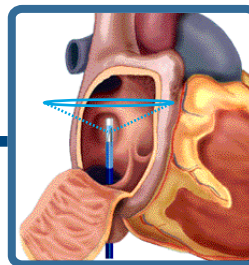


* View from patients feet.



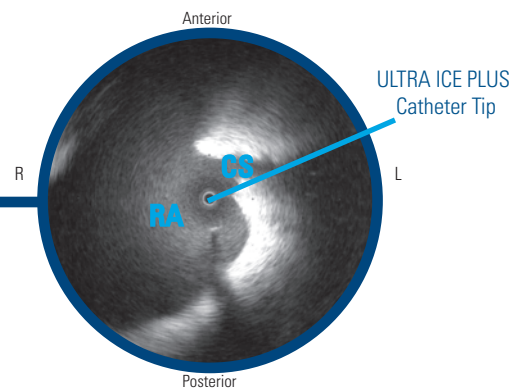
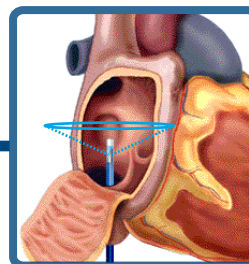
Pull Back to the mid RA / Next to FO

Continue withdrawing into the Right Atrium (RA) until the center of the Fossa Ovalis (FO) is clearly seen in the ICE image. Typical structures visible in this plane are the Left Atrium (LA), Left Atrial Free Wall (LAFW), Aortic Valve (AOV) and the Crista Terminalis (CT).



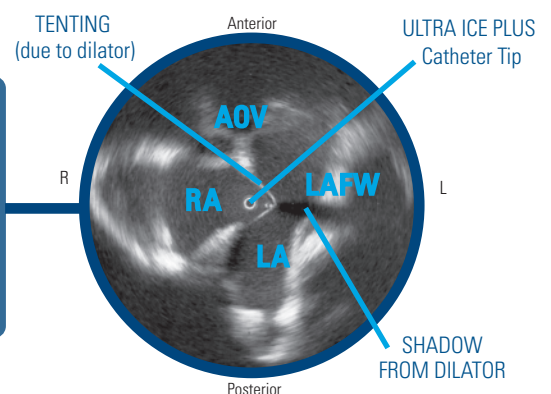
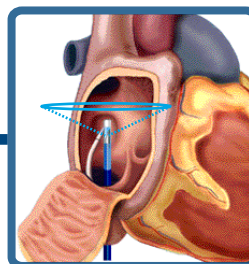
Too Far: RA Floor

If the ICE images show the RA floor, Coronary Sinus (CS), or Inferior Vena Cava (IVC), you have withdrawn too far and need to reverse course.



Advance Back to the proper Transseptal Position (mid RA/FO) and position Dilator.

When the ICE image shows the center of the fossa, use fluoro to guide the transseptal dilator to the ULTRA ICE PLUS Catheter Tip, and advance the dilator along the septal wall until tenting of the fossa is observed on the ICE image.



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 motor drive 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 an e-beam radiation 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 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.

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