

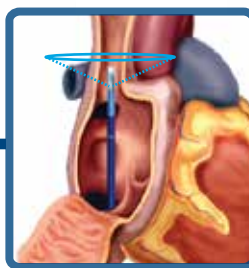
Transseptal Imaging with the ULTRA ICE™ PLUS Ultrasound Imaging Catheter

Four Images You Need to Know

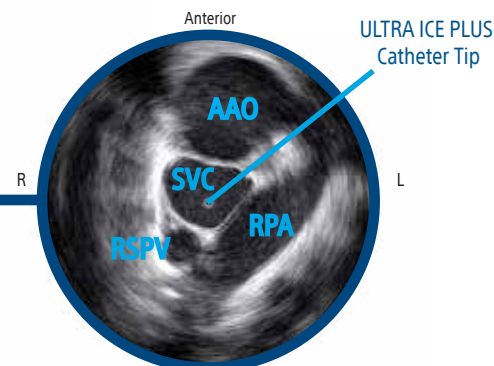
The four ultrasound images shown below are images commonly seen when using the Boston Scientific ULTRA ICE PLUS Imaging System in a transseptal procedure. The corresponding procedural information is reflective of how experienced physicians might typically respond when each of these images is observed.

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).

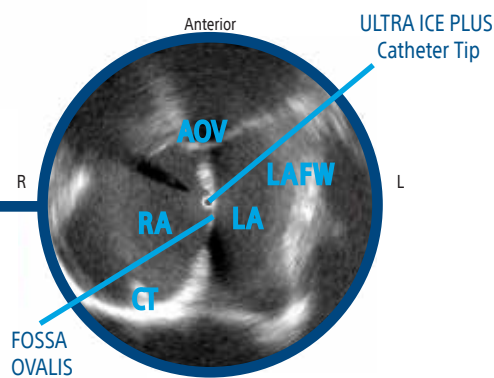
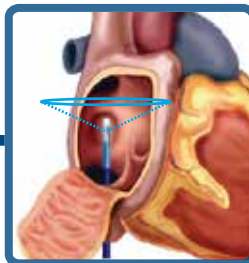


* View from patients feet.



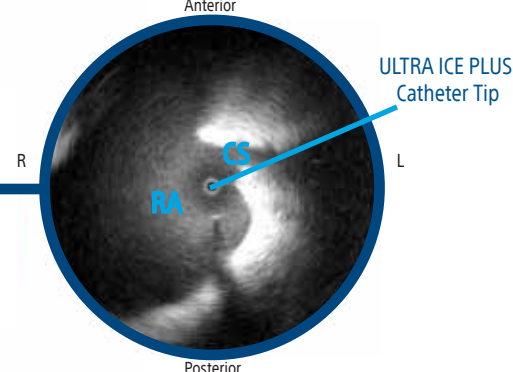
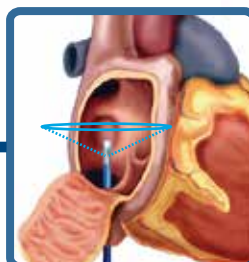
Pull Back to the mid RA / Next to FO

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).



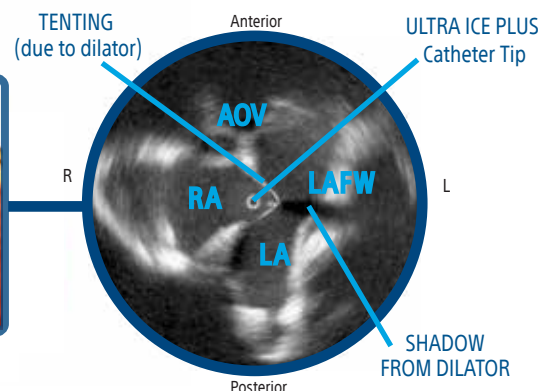
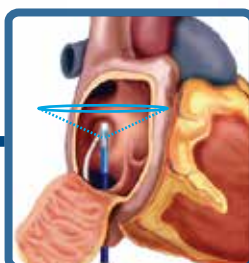
Too Far: RA Floor

If the ICE images show the RA floor, Coronary Sinus (CS), or Inferior Vena Cava (IVC), you have withdrawn too far and need to reverse course.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 9 MHz IntraCardiac Echo Catheter & MDU5 PLUS™ Sterile Bag Sterile Bag for MDU5 PLUS Motordrive Unit

INTENDED USE/INDICATIONS FOR USE

Ultra ICE™ Plus 9 MHz IntraCardiac Echo Catheter The Ultra ICE Plus rounded tip catheter is indicated for enhanced ultrasonic visualization of intracardiac structures.

MDU5 PLUS™ Sterile Bag Sterile Bag for MDU5 PLUS Motordrive Unit 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

Ultra ICE™ Plus 9 MHz IntraCardiac Echo Catheter 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.

MDU5 PLUS™ Sterile Bag Sterile Bag for MDU5 PLUS Motordrive Unit No additional information is required for the section in the BSD.

WARNINGS

Ultra ICE™ Plus 9 MHz IntraCardiac Echo Catheter • 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 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.

MDU5 PLUS™ Sterile Bag Sterile Bag for MDU5 PLUS Motordrive Unit No additional information is required for the section in the BSD.

PRECAUTIONS

Ultra ICE™ Plus 9 MHz IntraCardiac Echo Catheter Do not kink or sharply bend the catheter at any time, as this can lead to drive cable failure. An insertion angle greater than 45° is considered excessive. Please turn the MDU5 PLUS “OFF” before withdrawing the imaging catheter or when advancing the catheter within the body.

MDU5 PLUS™ Sterile Bag: Sterile Bag for MDU5 PLUS Motordrive Unit No additional information is needed for the section in the BSD.

POTENTIAL ADVERSE EVENTS

Ultra ICE™ Plus 9 MHz IntraCardiac Echo Catheter 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. • Allergic reaction to contrast media, anesthetic or medications • Arrhythmia • Cardiac tamponade and pericardial effusion • Cardiac trauma • Cerebrovascular accident and transient ischemic attack • Death • Device Entrapment requiring surgical intervention • Embolism (air, foreign body, tissue or thrombus) • Hematoma • Hemorrhage • Hypotension/Hypertension • Infection • Myocardial infarction • Radiation injury • Thrombosis including deep vein thrombosis and pulmonary embolism • Vessel trauma including perforation and arteriovenous fistula

MDU5 PLUS™ Sterile Bag Sterile Bag for MDU5 PLUS Motordrive Unit No additional information is required for the section in the BSD.

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CAUTION: Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner. Prior to use, please refer to all applicable “Instructions for Use” for more information on Intended Use/Indications for Use, Contraindications, Warnings, Precautions, Potential Adverse Events, and Operator’s Instructions.

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