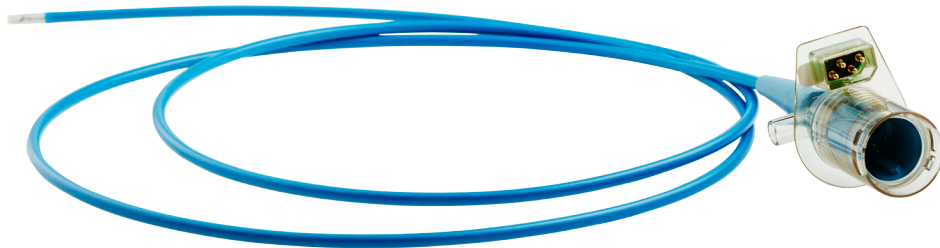


ULTRA ICE™ PLUS

ULTRASOUND IMAGING CATHETER



Technical Information

Description	Specifications
Shaft diameter	8.5 F
Usable length	110 cm
Imaging frequency	9 MHz
Ultrasound type	Mechanically rotating transducer
Distance from transducer to tip	9 mm
Image type	Panoramic 360° view
Imaging depth	>6 cm radius (>12 cm diameter)
Lateral resolution	≤1.23 mm
Axial resolution	≤0.29 mm
Shaft rotation speed	1800 RPM
Frame refresh rate	30 frame/sec
Ultrasound pulse rate	256 /rotation

Ordering Information

ULTRA ICE PLUS Catheter	M004 9912 0
Fluid Dock™ Filling Device	M004 9915 1

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 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.

(Rev A)

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

© 2016 by Boston Scientific Corporation
or its affiliates. All rights reserved.

EP-404002-AA AUG2016