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IVUS Imaging Catheters

Reference Guide

	Peripheral Catheter OptiCross™ 18	Coronary Catheter OptiCross 6	Coronary Catheter OptiCross	Intracardiac Catheter Ultra ICE™
Transducer Frequency	30 MHz	40 MHz	40 MHz	9 MHz
Order Number	H7493932800180	H7495181160	H749518110	M00499000
Typical Use	SFA, Popliteal, Tibial, Renal	Coronary	Coronary	Intracardiac
Maximum Diameter Penetration	12 mm	6 mm	6 mm	50 mm
Prep Location	Proximal	Proximal	Proximal	Distal
Catheter Telescoping Length	15 cm	15 cm	15 cm	n/a
Sled Pullback Length	10 cm	10 cm	10 cm	n/a
Distance from Transducer to Tip	2.0 cm	2.0 cm	2.0 cm	1.0 cm
Guidewire Lumen Length	1.6 cm	1.6 cm	1.6 cm	n/a
Guidewire Compatibility	≤ 0.018"	≤ 0.014"	≤ 0.014"	n/a
Sheath Compatibility (with max wire)	6 F	6 F	5 F	9 F
Guide Catheter Compatibility	6 F (ID ≥ 0.068")	6 F (ID ≥ 0.064")	5 F (ID ≥ 0.058")	n/a
Crossing Profile	3.5 F	3.1 F	3.1 F	n/a
Imaging Window Profile	2.9 F	2.9 F	2.6 F	9.0 F
Entry Profile	1.6 F	1.3 F	2.0 F	9.0 F
Working Length	135 cm	135 cm	135 cm	110 cm

OPTICROSS™ 18 CATHETER AND MDU5 PLUS BAG

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.

INTENDED USE/INDICATIONS FOR USE: OptiCross 18 Catheter: This catheter is intended for intravascular ultrasound examination of peripheral vessels only. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal interventional procedures. **MDU5 PLUS Sterile Bag:** 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:** Use of this product is contraindicated in the presence of conditions which create unacceptable risk during catheterization. **WARNINGS:** • Intravascular ultrasound examination of vascular anatomy should be performed only by physicians fully trained in interventional radiology and in the techniques of intravascular ultrasound, and in the specific approach to be used, in a fully-equipped cardiac catheterization lab. • The catheter has no user serviceable parts. Do not attempt to repair or to alter any component of the catheter assembly as provided. Using an altered catheter can result in poor image quality or patient complications. • No modification of this equipment is allowed. • Do not pinch, crush, kink or sharply bend the catheter at any time. An insertion angle greater than 45° is considered excessive. • Do not manipulate, advance and/or withdraw the coated device through a metal cannula or needle. Manipulation, advancement and/or withdrawal through such a metal device may result in destruction and/or separation of the outer hydrophilic coating, resulting in coating material remaining in the vasculature, which may cause adverse events and require additional intervention. • 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. • When advancing the catheter through a stented vessel, catheters that do not completely encapsulate the guidewire may engage the stent between the junction of the catheter and guidewire, resulting in entrapment of catheter/guidewire, catheter tip separation, and/or stent dislocation. • If resistance is met upon withdrawal of the catheter, verify resistance using fluoroscopy, then remove the entire system simultaneously. • When readvancing a catheter after deployment of stent(s), at no time should a catheter be advanced across a guidewire that may be passing between one or more stent struts. A guidewire may exit between one or more stent struts when recrossing stent(s). Subsequent advancement of the catheter could cause entanglement between the catheter and the stent(s), resulting in entrapment of catheter/guidewire, catheter tip separation and/or stent dislocation. Use caution when removing the catheter from a stented vessel. • Inadequately apposed stents, overlapping stents, and/or small stented vessels with distal angulation may lead to entrapment of the catheter with the stent upon retraction. When retracting the catheter, separation of a guidewire from an imaging catheter or bending of the guidewire may result in kinking of the guidewire, damage to the catheter distal tip, and/or vessel injury. The looped guidewire or damaged tip may catch on the stent strut resulting in entrapment. **PRECAUTIONS:** • 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. • If difficulty is encountered when backloading the guidewire into the distal end of the catheter, inspect the guidewire exit port for damage before inserting the catheter into the vasculature. • Never advance the imaging catheter without guidewire support. • Never advance the distal tip of the imaging catheter near the very floppy end of the guidewire. • Never advance or withdraw the imaging catheter without the imaging core assembly being positioned at the most distal portion of the imaging window. • During and after the procedure, inspect the catheter carefully for any damage which may have occurred during use. Multiple insertions may lead to catheter exit port dimension change/distortion which could increase the chance of the catheter catching on the stent. Care should be taken when re-inserting and/or retracting catheter to prevent exit port damage. • Turn the MDU5 PLUS™ "OFF" before withdrawing the imaging catheter. **ADVERSE EVENTS:** The risks and discomforts involved in vascular imaging include those associated with all catheterization procedures. These risks or discomforts may occur at any time with varying frequency or severity. Additionally, these complications may necessitate additional medical treatment including surgical intervention and, in rare instances, result in death. • Allergic reaction • Device entrapment requiring surgical intervention • Embolism (air, foreign body, tissue or thrombus) • End organ infarction • Hemorrhage/Hematoma • Hypotension and/or bradycardia (vasovagal syndrome) • Infection • Peripheral ischemia • Stroke and Transient Ischemic Attack • Thrombosis • Vessel occlusion and abrupt closure • Vessel trauma including, but not limited to dissection and perforation.

REV AA

ULTRA ICE 9 MHZ INTRACARDIAC ECHO CATHETER

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

INTENDED USE/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 rightsided 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 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 or 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. **REV AA**

OPTICROSS 6 40 MHZ CORONARY IMAGING CATHETER

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.

INTENDED USE/INDICATIONS FOR USE: This catheter is intended for ultrasound examination of coronary intravascular pathology only. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal coronary interventional procedures. **CONTRAINDICATIONS:** Use of this Imaging Catheter is contraindicated where introduction of any catheter would constitute a threat to patient safety. The contraindications also include the following patient characteristics: • Bacteremia or sepsis • Major coagulation system abnormalities • Patients diagnosed with coronary artery spasm • Patients disqualified for CABG surgery • Patients disqualified for PTCA • Severe hemodynamic instability or shock • Total occlusion. **WARNINGS:** • Intravascular ultrasound examination of coronary anatomy should be performed only by physicians fully trained in interventional cardiology or interventional radiology and in the techniques of intravascular ultrasound, and in the specific approach to be used, in a fully-equipped cardiac catheterization lab. • The catheter has no user serviceable parts. Do not attempt to repair or to alter any component of the catheter assembly as provided. • No modification of this equipment is allowed. • Do not pinch, crush, kink or sharply bend the catheter at any time. An insertion angle greater than 45° is considered excessive. • 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. • When advancing the catheter through a stented vessel, catheters that do not completely encapsulate the guidewire may engage the stent between the junction of the catheter and guidewire, resulting in entrapment of catheter/guidewire, catheter tip separation, and/or stent dislocation. • If resistance is met upon withdrawal of the catheter, verify resistance using fluoroscopy, then remove the entire system simultaneously. A catheter that is forcibly removed may cause vessel injury or patient complications. • When readvancing a catheter after deployment of stent(s), at no time should a catheter be advanced across a guidewire that may be passing between one or more stent struts. A guidewire may exit between one or more stent struts when recrossing stent(s). Subsequent advancement of the catheter could cause entanglement between the catheter and the stent(s), resulting in entrapment of catheter/guidewire, catheter tip separation and/or stent dislocation. Use caution when removing the catheter from a stented vessel. • Inadequately apposed stents, overlapping stents, and/or small stented vessels with distal angulation may lead to entrapment of the catheter with the stent upon retraction. When retracting the catheter, separation of a guidewire from an Imaging Catheter or bending of the guidewire may result in kinking of the guidewire, damage to the catheter distal tip, and/or vessel injury. The looped guidewire or damaged tip may catch on the stent strut resulting in entrapment. **PRECAUTIONS:** • 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. • During and after the procedure, inspect the catheter carefully for any damage which may have occurred during use. Multiple insertions may lead to catheter exit port dimension change/distortion which could increase the chance of the catheter catching on the stent. Care should be taken when re-inserting and/or retracting catheter to prevent exit port damage. • Turn the MDU5 PLUS™ "OFF" before withdrawing the Imaging. **ADVERSE EVENTS:** The risks and discomforts involved in vascular imaging include those associated with all catheterization procedures. These risks or discomforts may occur at any time with varying frequency or severity. Additionally, these complications may necessitate additional medical treatment including surgical intervention and, in rare instances, result in death. • Allergic reaction • Angina • Cardiac arrest • Cardiac arrhythmias including, but not limited to ventricular tachycardia, atrial/ventricular fibrillation and complete heart block • Cardiac tamponade/Pericardial effusion • Death • Device entrapment requiring surgical intervention • Embolism • Hemorrhage/Hematoma • Hypotension • Infection • Myocardial infarction • Myocardial Ischemia • Stroke and Transient Ischemic Attack • Thrombosis • Vessel occlusion and abrupt closure • Vessel trauma including, but not limited to dissection and perforation. **REV AA**

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PI-388805-AA MAY2016