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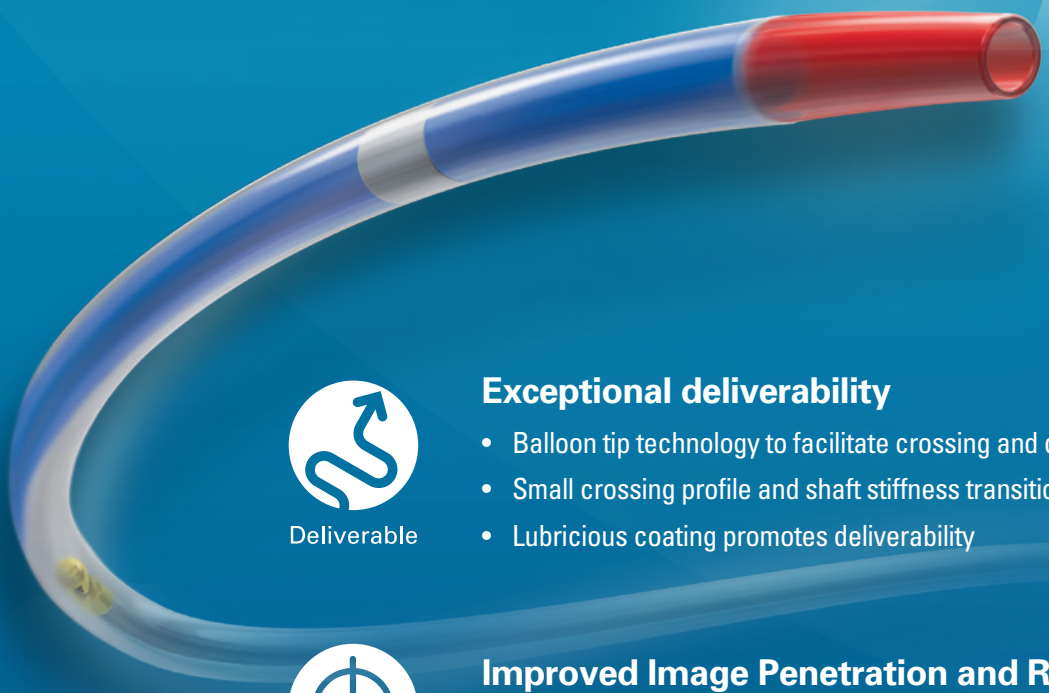
OPTICROSS™ 18 Peripheral Imaging Catheter

CONFIDENCE DELIVERED

18



Deliverable

Exceptional deliverability

- Balloon tip technology to facilitate crossing and deliverability
- Small crossing profile and shaft stiffness transitions for excellent deliverability
- Lubricious coating promotes deliverability

Accurate

Improved Image Penetration and Resolution

- 30 MHz transducer frequency allows for deeper ultrasound penetration than a 40 MHz transducer frequency
- Ability to visualize larger vessel sizes with higher image resolution than a 20 MHz transducer frequency

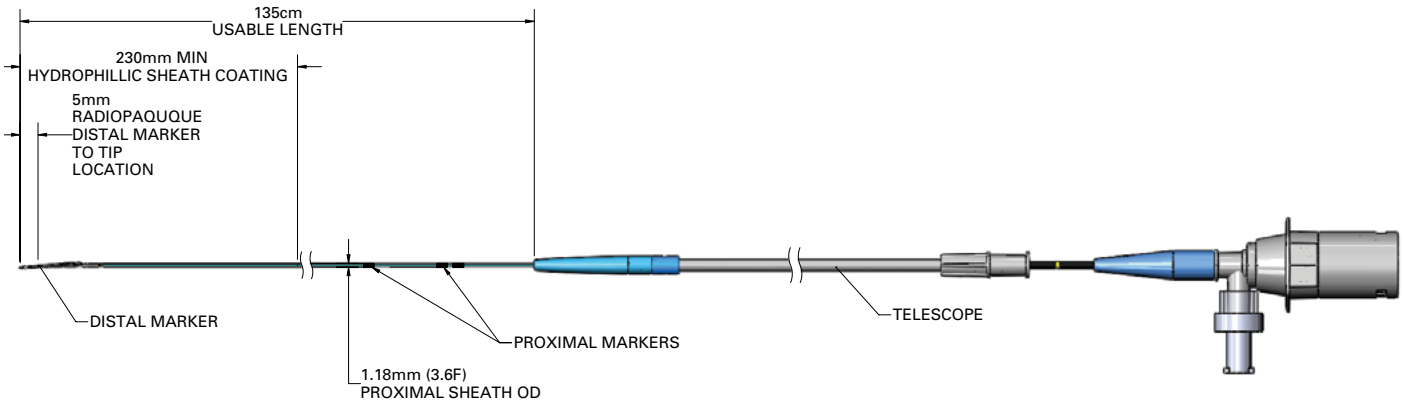
Easy

Confidence with advanced design

- Stronger proximal shaft for great pushability
- Ease of flush for quick prep
- Compatible with iLab™ POLARIS Multi-Modality Guidance System

POLARIS Multi-Modality Guidance System

OPTICROSS™ 18 Peripheral Imaging Catheter Specifications



Product Code	Catalog Number	Material Description	GTIN
H7493932800180	390590018	OPTICROSS 18	08714729904366

Necessary Equipment

The following are required for use of the OPTICROSS 18 Peripheral Imaging Catheter:

- iLab POLARIS Multi-Modality Guidance System
- MDU5 Plus Motor Drive Unit

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

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Peripheral Interventions
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www.bostonscientific.com

To order product or for more information contact customer service at 1.888.272.1001.

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OPTICROSS™ 35 Peripheral Imaging Catheter

CLEAR CONFIDENCE AT EVERY ANGLE

Exceptional 360° image quality and greater depth of field for IVUS

The OptiCross 35 peripheral imaging catheter delivers the IVUS image quality and depth of field required to detect and treat venous disease with confidence.

True 360° View

Unique Design

HQ

High Image Quality

Optimal Outcomes

Detect and Treat With Confidence

The OptiCross 35 peripheral imaging catheter provides exceptional image quality and deeper penetration of complex lesions, giving interventionalists a reliable choice for performing acute DVT, iliac vein compression, post-thrombotic and other venous interventions.

Unique Design

The OptiCross 35 uses an exclusive rotating transducer to provide true 360° images for IVUS.

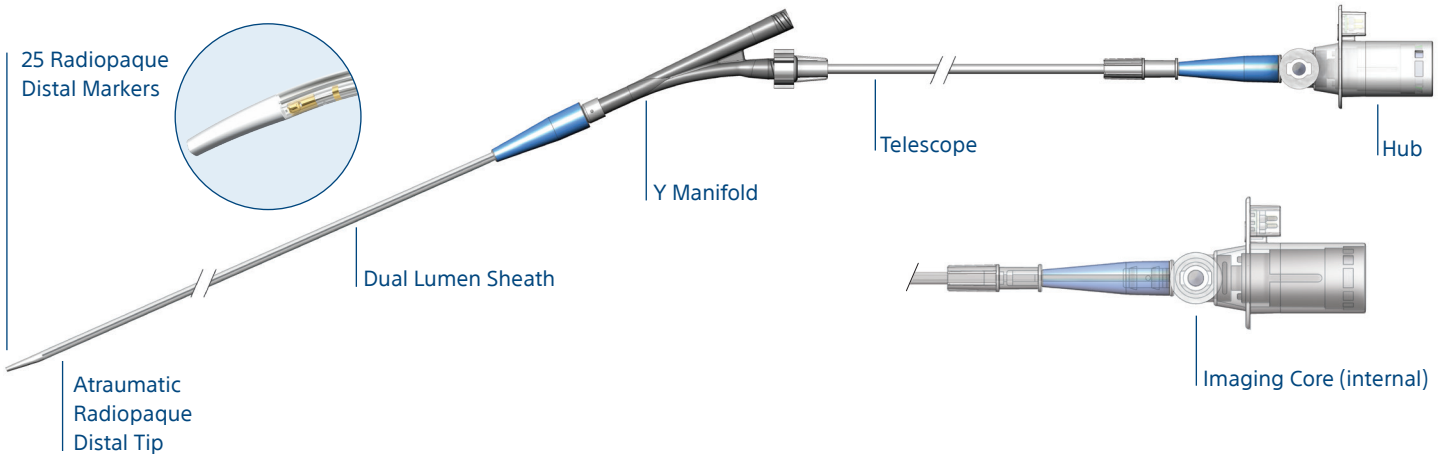
High Image Quality

IVUS images produced by the OptiCross 35 feature excellent clarity and a large depth of field.

Optimal Outcomes

Clear IVUS images help improve patient outcomes while reducing complications and readmissions.

OptiCross 35 Designed for 360° Clarity	15 MHz target operating frequency	70 mm target imaging diameter	0.035" guidewire compatible	8 F compatible



Ordering Information

Product Code	Catalog Number	Material Description	GTIN
H7493932800350	41010-50	OPTICROSS 35	8714729984542

For additional information please visit **www.bostonscientific.com/opticross-35** or contact your sales representative.

OptiCross 35 15 MHz Peripheral Imaging Catheter + MDU5 PLUS Sterile 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 35 15 MHz Catheter: This catheter is intended for ultrasound examination of peripheral pathology 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:** OptiCross 35 15 MHz 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. MDU5 PLUS Sterile Bag: None known. **WARNINGS:** Do not pinch, crush, kink or sharply bend the catheter at any time. This can cause poor catheter performance, vessel injury or patient complications. An insertion angle greater than 45° is considered excessive and can lead to device kinking which can cause difficult advancing/retracting the telescope shaft and poor image quality. • 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 or retracting the catheter through a stented vessel, the catheter tip may interact with the stent, resulting in entrapment of catheter/guidewire, catheter tip separation, and/or stent dislocation. • If resistance is met upon withdrawal of the catheter, assess the cause of resistance using fluoroscopy, and if necessary, remove the entire system as a unit. • Do not advance the catheter along a guidewire that may be passing between one or more stent struts. This could result in entrapment of catheter/guidewire, catheter tip separation and/or stent dislocation. Use caution when introducing or removing the catheter from a stented vessel. **PRECAUTIONS:** Do not advance the imaging core if resistance is encountered. MDU5 PLUS Sterile Bag: None known. **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. Complications may include: Allergic reaction (device, contrast or other) • Arrhythmia • Device entrapment requiring surgical intervention • Embolism (air, foreign body, tissue or thrombus) • Hemorrhage/Hematoma • Hepatic dysfunction • Hypotension/hypertension • Infection/sepsis • Ischemia • Renal insufficiency/failure • Stroke/cerebrovascular accident/transient ischemic attack • Thrombosis/thrombus • Vasospasm • Vessel injury (including perforation, trauma, rupture, dissection, and pseudoaneurysm) • Vessel occlusion. MDU5 PLUS Sterile Bag: None known. 92552184 A

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