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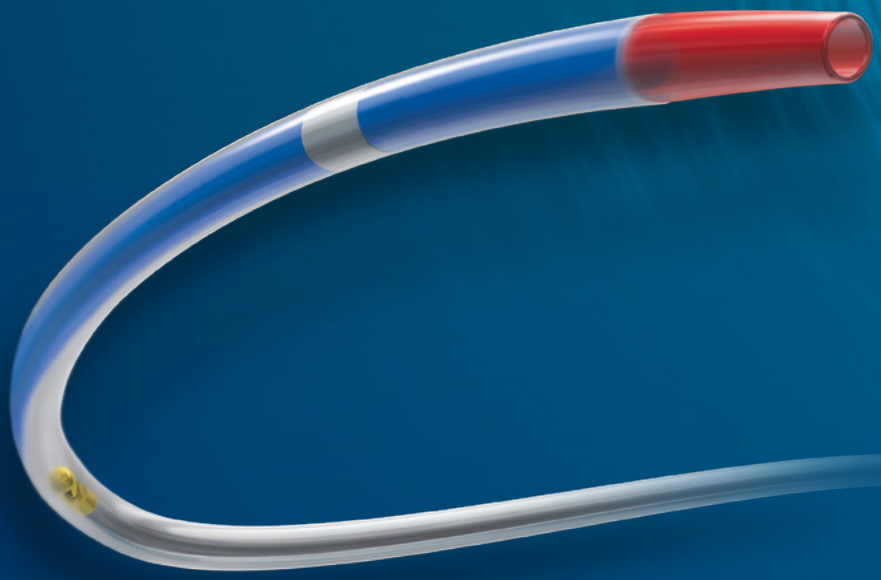
OPTICROSS™ 18 Peripheral Imaging Catheter

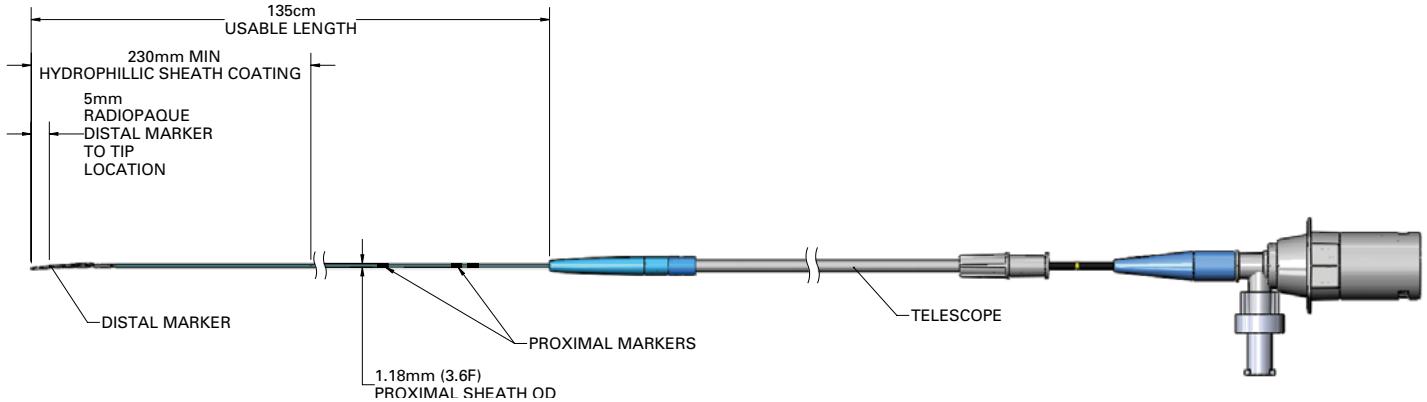
VISUALIZE SUCCESS



360 **Intraluminal Views**

PI **Robust Peripheral Portfolio**

OPTICROSS™ 18 Peripheral Imaging Catheter Specifications



Transducer Frequency	Imaging diameter (up to)	Catheter Telescoping Length	Distance from Transducer to Tip	Guidewire Lumen Length	Guidewire Compatibility	Sheath Compatibility (with max wire)	Working Length
30 MHz	22 mm*	15 cm	2.0 cm	1.6 cm	≤.018	4 F	135 cm

Ordering Information

Description	iLab™ System (Cart Version)	OptiCross™18 IVUS Catheter	MDU5+ Motor Drive	MDU5+ Sterile Bag	Sterile Pullback Sled	Sterile Sled Bag
UPN	H749ILAB120C2710	H7493932800180	H749MDU5PLUS0	H749MDU5PLUSBAG0	H749A70200	H749A70170
GTIN	08714729847885	08714729904366	08714729842279	08714729842255	08714729228684	08714729263074

IVUS CPT™ Codes

Important Information

- Add-on code (+) must be performed in addition to a primary procedure; (i.e., stent, PTA, atherectomy, embolization, thrombolysis, thrombectomy)
- Add-on codes are exempt from multiple procedure reduction
- Coding is per vessel evaluated; however, contiguous vessel abnormalities (i.e., DVT, diffuse atherosclerotic disease) are described by a single code
- Check your payer guidelines closely, as there may be limitations for the use of these codes- contractors will define **SPECIFIC PRIMARY CODES**

CPT Code	Description
+ 37252	Intravascular ultrasound (noncoronary vessel) during diagnostic evaluation and/or therapeutic intervention, including radiological supervision and interpretation; initial noncoronary vessel (List separately in addition to code for primary procedure)
+ 37253	Intravascular ultrasound (noncoronary vessel) during diagnostic evaluation and/or therapeutic intervention, including radiological supervision and interpretation; each additional noncoronary vessel (List separately in addition to code for primary procedure)

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

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