OPTICROSS™
CORONARY IMAGING CATHETER

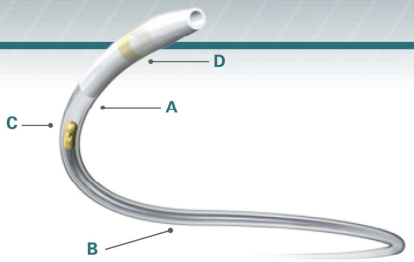
Boston Scientific
Advancing science for life™

Experience OPTICROSS — The IVUS Catheter that Delivers Confidently

With OPTICROSS, Boston Scientific has raised its best-in-class IVUS image quality to a new level. This catheter's 3.15 F crossing profile, enhanced trackability and pushability, and tapered imaging window contribute to smooth, sure deliverability. A beveled tip design is intended to ease lesion entry, decrease stent catch, and provide peace of mind.

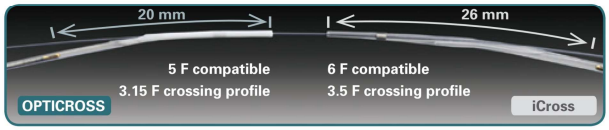
Construction Overview

A Superior Deliverability
B 5 F Guide Catheter Compatible
C Enhanced Image Quality
D Improved Ease of Use



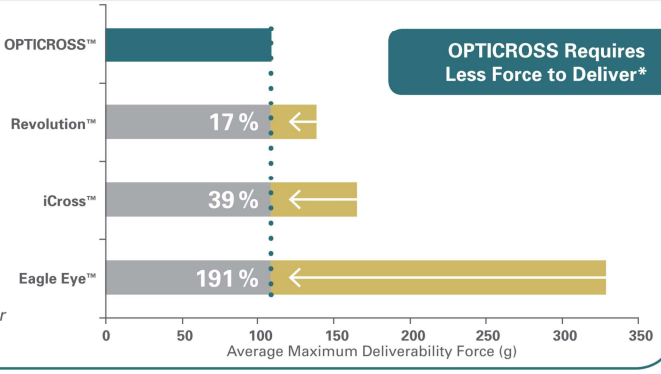
COMPATIBLE 5F

Superior Deliverability



- 23% shorter tip to transducer length†
- Smallest crossing profile†
  (20% smaller diameter than iCross)
- More robust monorail material

More robust monorail material + New monorail design = Less force to deliver

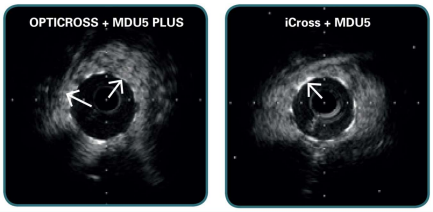


OPTICROSS Requires Less Force to Deliver*

Enhanced Image Quality

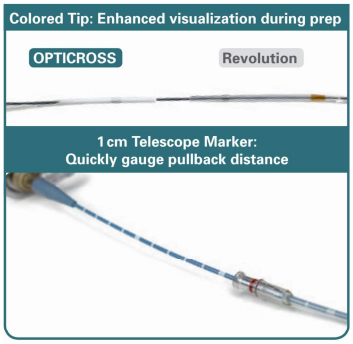
Axial Resolution *12% improved†*

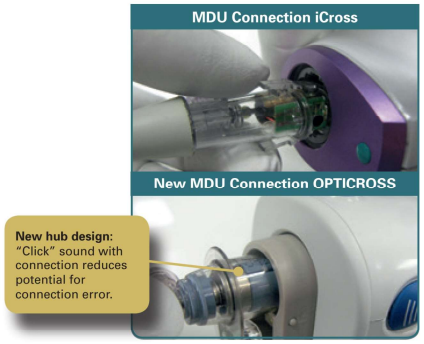
OPTICROSS	38 micron
iCross	43 micron
Revolution	50 micron
Eagle Eye	<170 micron

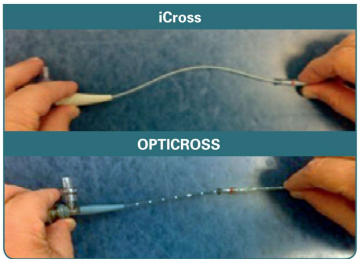


- Improved Axial Resolution
- Darker, more apparent lumen
- More visible stent struts

Improved Ease of Use







TELESCOPE IMPROVEMENTS:
- **Extended Proximal Shaft** — Extended proximal shaft covers drive cable inside to reduce entanglement.
- **Stiffer Telescope** — Reduce likelihood of kinking during imaging core advancement.

OPTICROSS™

CORONARY IMAGING CATHETER

OPTICROSS Ordering Information

Product Code	Description
51811	OPTICROSS Catheter
H749MDU5PLUS0	MDU5+ Motor Drive
H749MDU5PLUSBAG0	MDU5 PLUS sterile bag
H749A70200	Sterile pullback sled

All photographs taken by Boston Scientific Corporation.

Testing completed by Boston Scientific Corporation. Bench test results may not be indicative of clinical performance. Data on File.

*Tortuous deliverability model bench test (n = 5).

†Comparisons are made against the iCross Coronary Imaging Catheter.

OPTICROSS MDU5 PLUS Sterile Bag

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.

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.

REVAA

iCross Coronary Imaging Catheter

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: • Severe hemodynamic instability or shock • Patients diagnosed with coronary artery spasm • Total occlusion • Bacteremia or sepsis • Major coagulation system abnormalities • Patients disqualified for CABG surgery • Patients disqualified for PTCA.

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. • Air entrapped in the catheter and flushing accessories can cause potential injury or death. Always verify that the catheter and flushing accessories have been properly cleared of air prior to inserting the catheter into the vasculature. • **Do not 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. • If resistance is met upon withdrawal of the catheter, verify resistance using fluoroscopy, then remove the entire system simultaneously. • 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. • When readvancing a guidewire 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 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, ensure that the short rail distal tip is parallel to the guidewire. Separation 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. • No modification of this equipment is allowed.

Precautions: Note: This product contains (Bis(2-ethylhexyl)phthalate) DEHP. BSC has conducted a Chemical Safety Assessment of DEHP in this device based on currently known acceptable exposure limits for sensitive populations (children and pregnant/nursing women) and has determined that the potential exposure is below that of the known acceptable exposure limits for the device when used in accordance with the indications and instructions for use. • 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 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 MDU "OFF" before withdrawing the imaging.

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