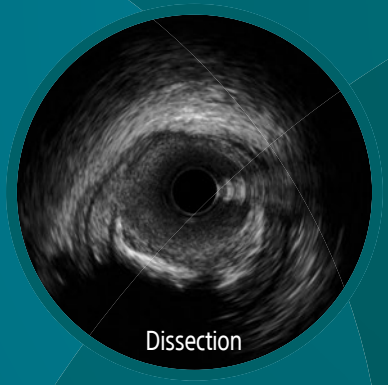
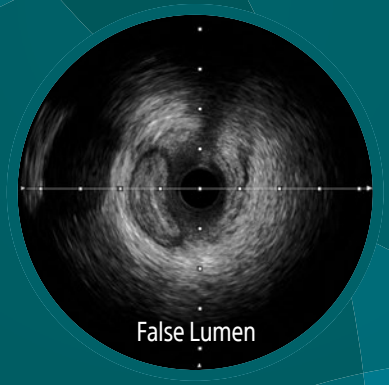
Boston Scientific
Advancing science for life™

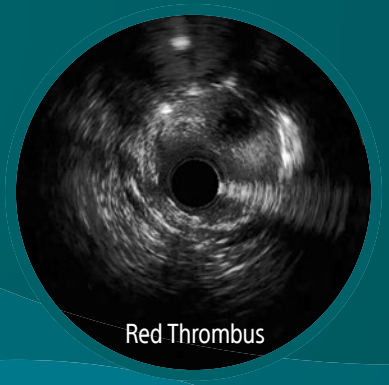
# OPTICROSS™ HD
60 MHz Coronary Imaging Catheter

# OPTICROSS™ 6 HD
60 MHz Coronary Imaging Catheter

New high definition imaging catheters with clear images and exceptional deliverability to guide confident treatment decisions



## Exceptional Deliverability

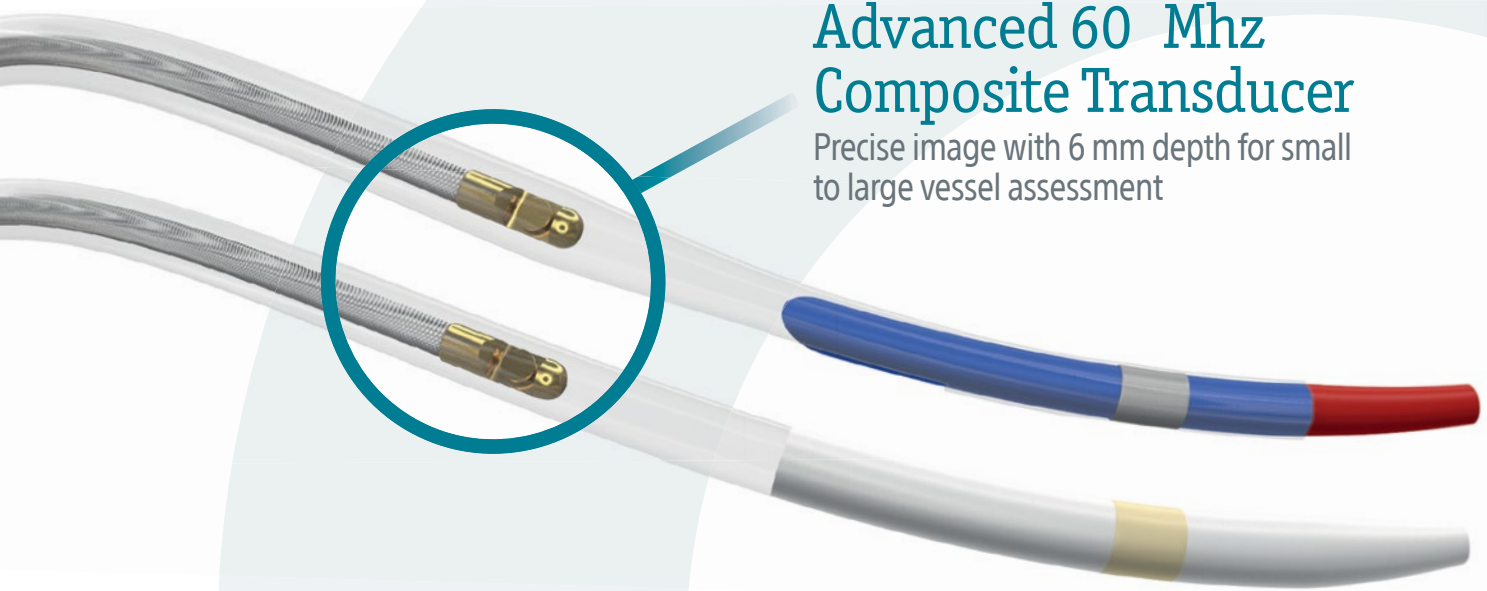
Well-balanced engineering design

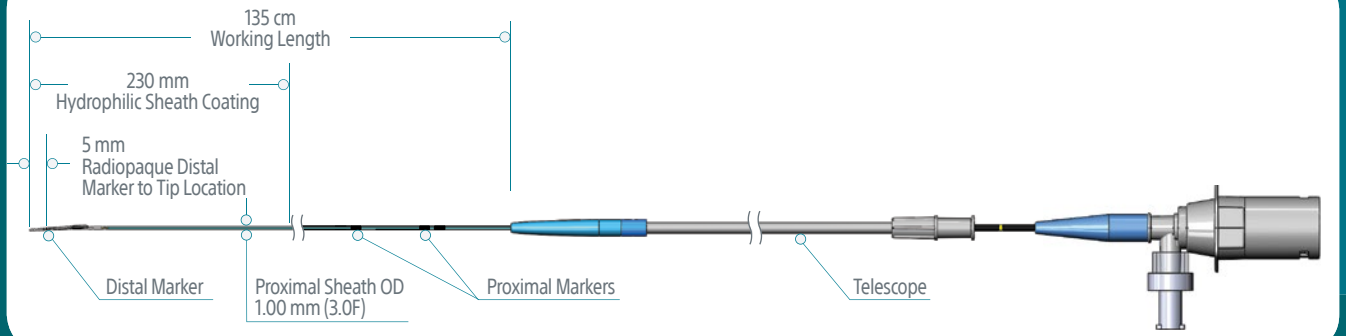
## 5F and 6F Compatible

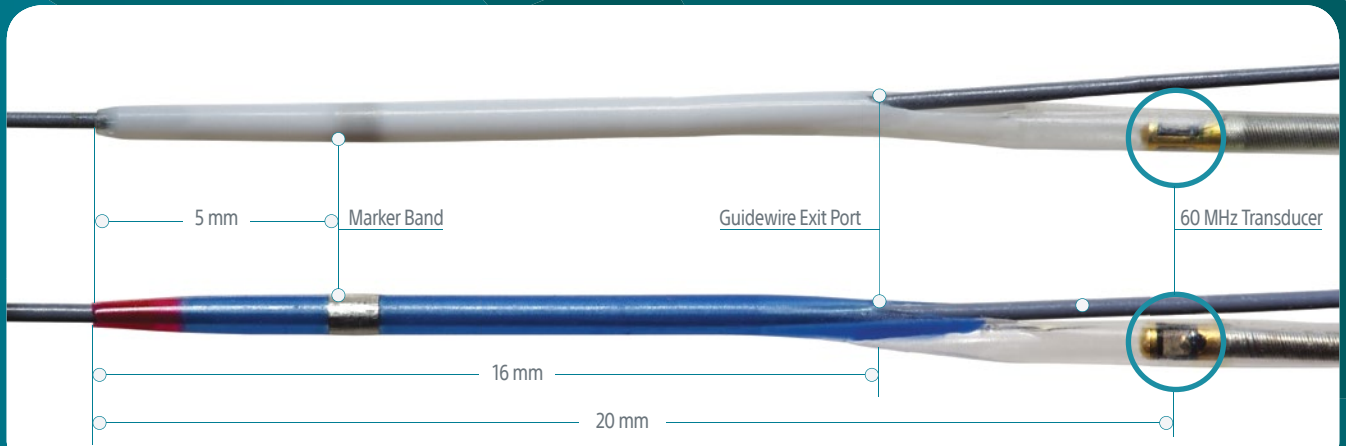
Assist in more cases

## Advanced 60 Mhz Composite Transducer

Precise image with 6 mm depth for small to large vessel assessment




135 cm
Working Length
230 mm
Hydrophilic Sheath Coating
5 mm
Radiopaque Distal
Marker to Tip Location
Distal Marker
Proximal Sheath OD
1.00 mm (3.0F)
Proximal Markers
Telescope


5 mm
Marker Band
Guidewire Exit Port
60 MHz Transducer
16 mm
20 mm

# Product Specifications

| | OPTICROSS HD | OPTICROSS 6 HD |
|---|---|---|
| Transducer Frequency | 60 MHz | |
| Maximum Diameter Penetration | 6 mm | |
| Crossing Profile | 3.1F | |
| Tip to Transducer Distance | 20 mm | |
| Distal Marker to Transducer | 15 mm | |
| Working Length | 135 cm | |
| Guidewire Compatibility | ≤ 0.014" | |
| Entry Profile | 0.026" | 0.017" |
| Guide Catheter Compatibility | 5F (≥ 0.058") | 6F (≥ 0.064") |
| Hydrophilic Sheath Coating | Bioslide™ | Z-Glide™ |

# Ordering Information

| | OPTICROSS HD | OPTICROSS 6 HD |
|---|---|---|
| Ref/Catalog Number | H749 3935204 0 | H749 3935408 0 |
| Order Number (GTIN) | 08714729960737 | 8714729960775 |
| Description | HD IVUS eDFU | HD IVUS 6F eDFU |

The C-Code used for the OPTICROSS™ HD and OPTICROSS 6 HD Coronary Imaging Catheters is C1753. C-Codes are used for hospital outpatient device reporting for Medicare and some private payers. Note: Boston Scientific Corporation is not responsible for correct use of C-Codes on submitted claims; this information does not constitute reimbursement or legal advice

# Necessary Equipment

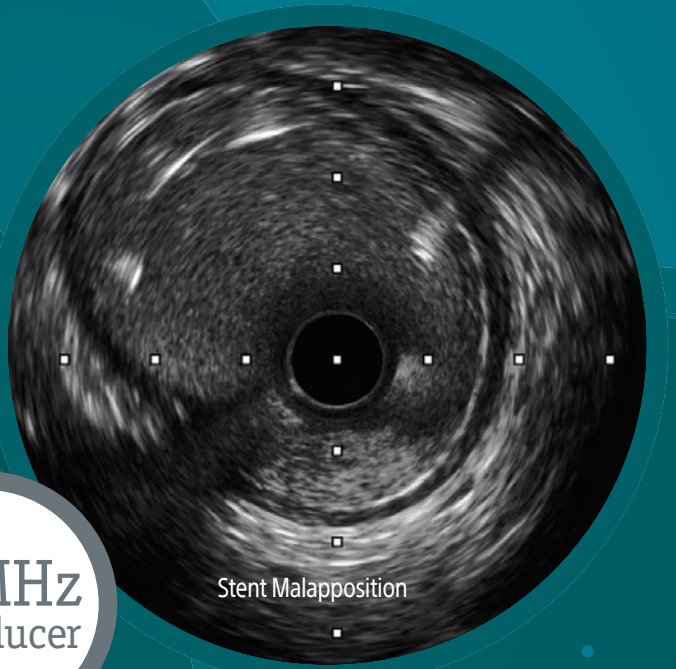
The following are required for use of the OPTICROSS HD and OPTICROSS 6 HD Coronary Imaging Catheters:

- iLab™ POLARIS Multi-Modality Guidance System
- MDU5 PLUS™ Motor Drive
- Automatic Pullback Sled (optional)

# Easier To Read Images

with the depth to image small to large vessels provided by a new advanced composite transducer

60 MHz Transducer



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**OPTICROSS HD, 6 HD 60 MHz Coronary Imaging Catheters and MDU5 PLUS™ Sterile Bag**

**Intended Use/Indications for Use: OPTICROSS HD, 6 HD:** 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. **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 imaging catheter is contraindicated where introduction of any catheter would constitute a threat to patient safety. The contraindications also include the following: • 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 • Use of the imaging catheter to cross a 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. 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 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 position 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 • 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 (air, foreign body, tissue or thrombus) • 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.

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Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary.

Dissection image provided courtesy of Boston Scientific.
False Lumen image provided courtesy of Wilson Ginete, MD, Essentia Health.
Red Thrombus image provided courtesy of Michael Kim, MD, FACC, FSCAI, North Colorado Medical Center.

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**Interventional Cardiology**
300 Boston Scientific Way
Marlborough, MA 01752-1234
**www.bostonscientific.com**

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IC-546709-AA