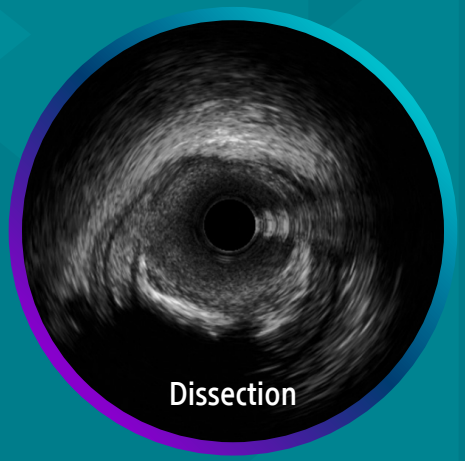
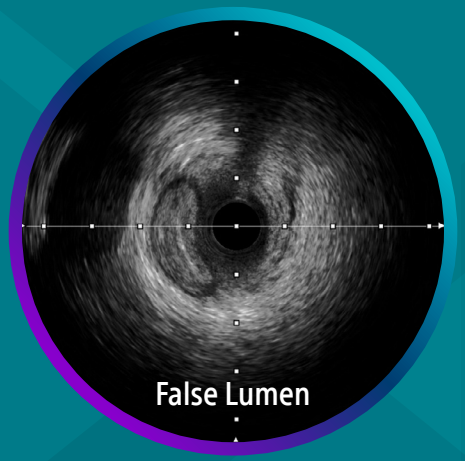
Boston Scientific
Advancing science for life™

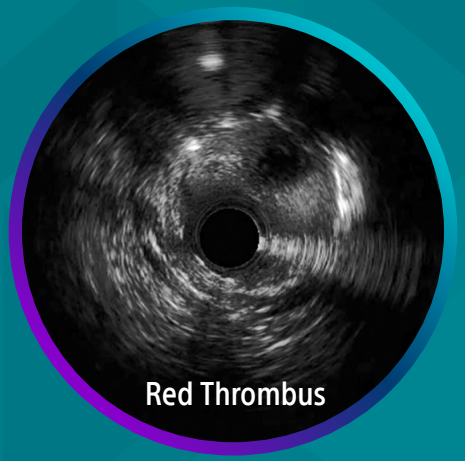
OPTICROSS™ HD
60 MHz Coronary Imaging Catheter

OPTICROSS™ 6 HD
60 MHz Coronary Imaging Catheter

High definition 5F and 6F imaging catheters with clear images and exceptional deliverability to guide confident treatment decisions



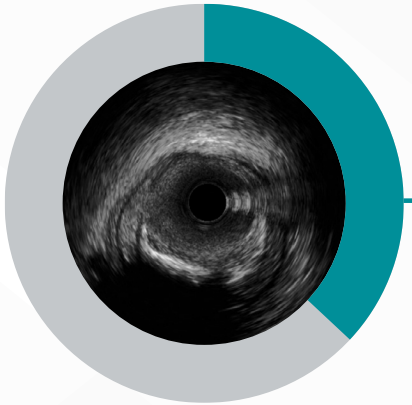




The Data is Clear

Imaging elevates PCI outcomes.

- Clearer treatment decisions.
- Fewer future complications.
- Better long-term outcomes.



Imaging-guided PCI led to a

37%

REDUCTION

in event rates* than angiography-guided PCI alone[1]

Intravascular imaging (IVI) is a Class 1A recommendation in the 2025 ACC/AHA/ACEP/NAEMSP/SCAI Guideline for the Management of Patients with Acute Coronary Syndromes (ACS) for guiding PCI in patients with ACS involving complex coronary lesions.[2] High-definition IVUS is the more flexible IVI option, and is the one that can be utilized in almost all clinical scenarios.[3]

* Primary endpoint of cardiac death, target vessel-related MI, or clinically driven target vessel revascularization.

1. Lee JM, Choi KH, Song YB, et al. Intravascular Imaging–Guided or Angiography–Guided Complex PCI. *N Engl J Med.* 2023;388(18):1668-1679. doi:10.1056/NEJMoa2216607.
2. Rao SV, O'Donoghue ML, Ruel M, et al. 2025 ACC/AHA/ACEP/NAEMSP/SCAI guideline for the management of patients with acute coronary syndromes: a report of the American College of Cardiology/Heart Association Joint Committee on Clinical Practice Guidelines. JACC. Published online February 27, 2025. https://doi.org/10.1016/j.jacc.2024.11.009
3. Truesdell AG et al. *J Am Coll Cardiol.* 2023;81(6):590–605. doi:10.1016/j.jacc.2022.11.045.

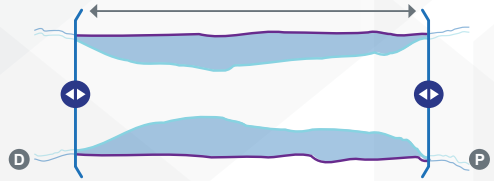
How to leverage IVUS in your PCI workflow

IVUS 123 ESSENTIALS

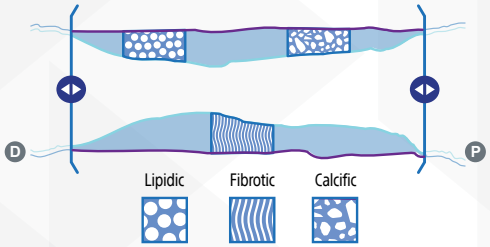
Clinical data consistently shows the benefits of IVUS to determine treatment strategy, guide stent placement, and assess procedural results. We developed IVUS 123 Essentials in partnership with physicians to simplify IVUS workflow and help improve outcomes for patients.

Pre-PCI workflow

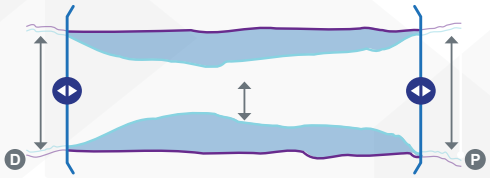
1 Determine lesion length



2 Study plaque morphology

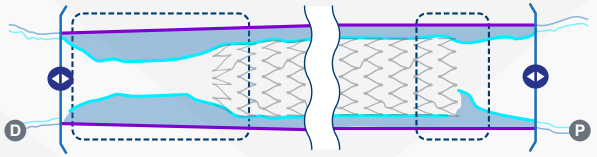


3 Analyze vessel diameter

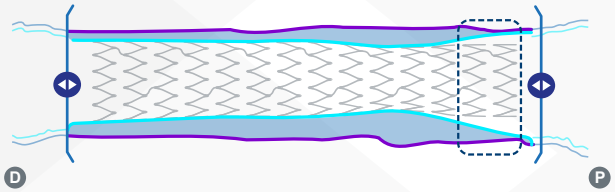


Post-stent workflow

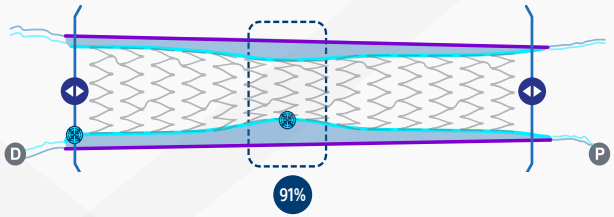
1 Examine stent edges



2 Review stent apposition



3 Assess stent expansion



ULTIMATE criteria:[4] Aim to achieve ≥ 90% of distal lumen reference area or an absolute MSA > 5.0 mm^2

4. Zhang J, Gao X, Kan J, et al. Intravascular Ultrasound Versus Angiography-Guided Drug-Eluting Stent Implantation: The ULTIMATE Trial. J Am Coll Cardiol Intv. 2018;72(24):3126-3137. doi: 10.1016/j.jacc.2018.09.013

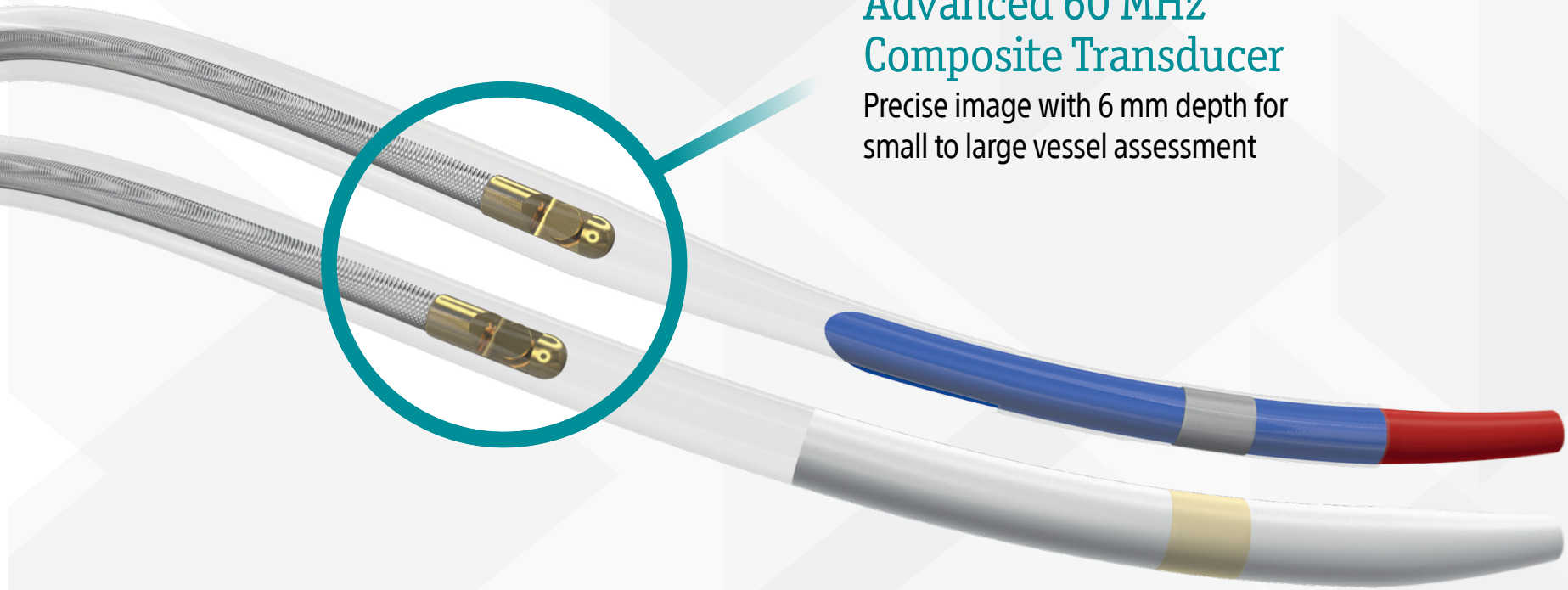
OPTICROSS™ HD
60 MHz Coronary Imaging Catheter

OPTICROSS™ 6 HD
60 MHz Coronary Imaging Catheter

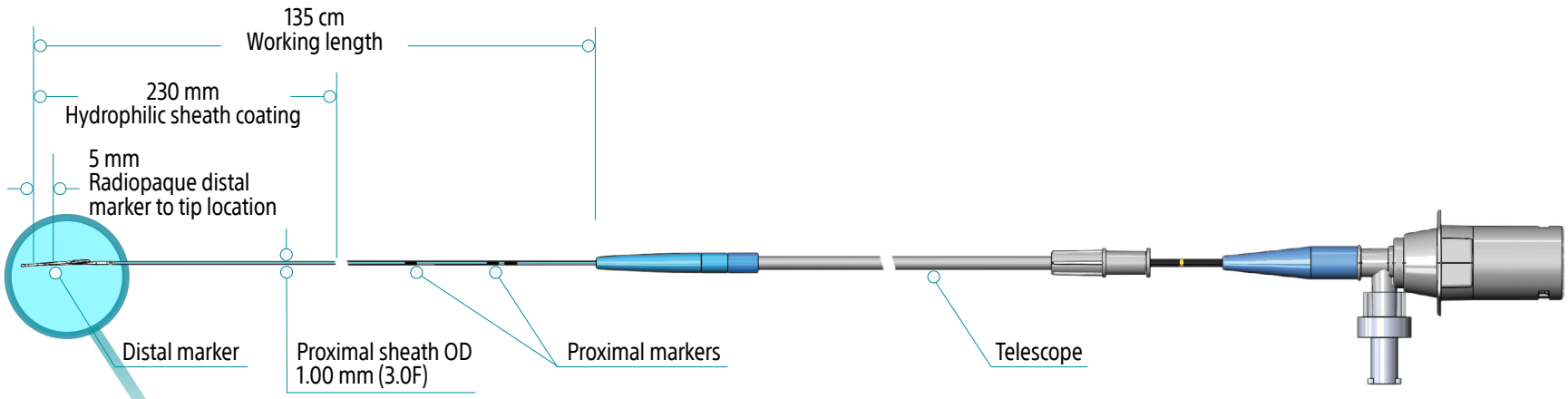
Exceptional Deliverability
Well-balanced engineering design

5F and 6F Compatible
Assist in more cases

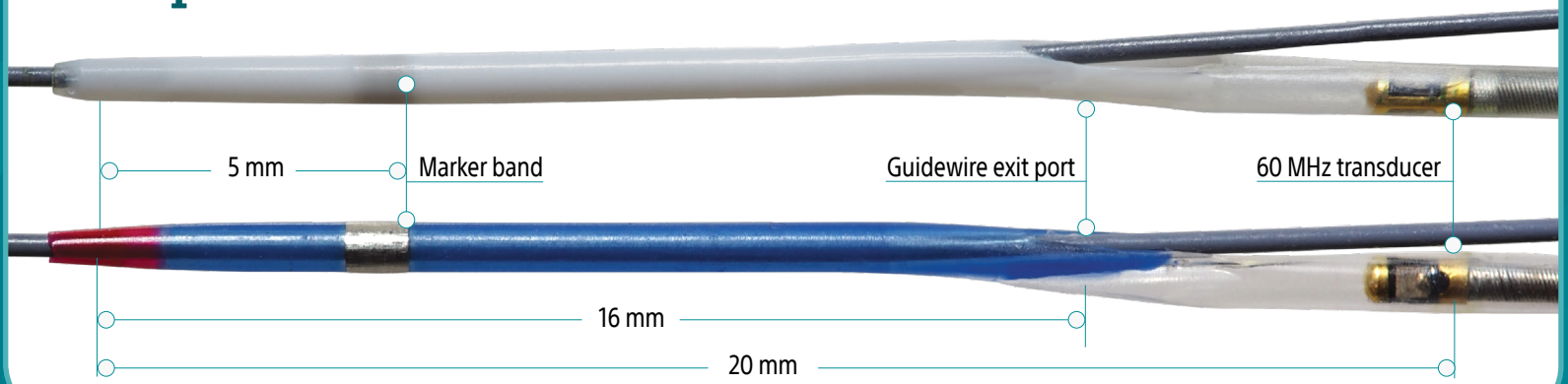
Advanced 60 MHz Composite Transducer
Precise image with 6 mm depth for small to large vessel assessment



OPTICROSS™ Imaging Catheter Design

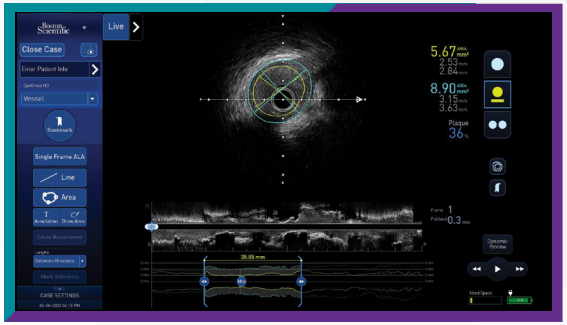


Tip to Transducer



OPTICROSS™ HD is compatible with the AVVIGO+ Multi-Modality Guidance System

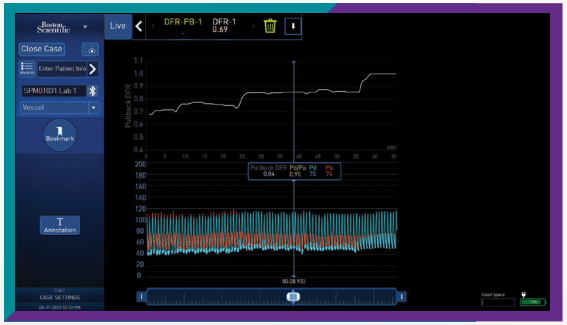
Automated Lesion Assessment (ALA™)



Precise vessel measurements

- Accurate lumen and vessel borders
- Vessel profile
- Key frame markers

PhysioMap™

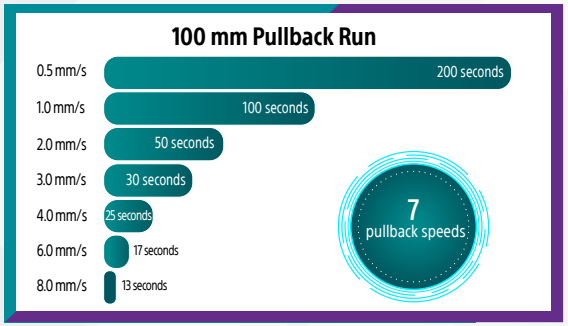


Enhanced DFR* guidance

- Optimize your treatment decisions by quickly locating regions of pressure change during a pullback

AVVIGO™+
Multi-Modality Guidance System

Fast Pullback



High quality images at the pullback speed you want

- Automatic pullback now includes faster speeds, up to 8 mm/s, allowing for quicker vessel imaging

Tableside Control†

Complete control from the sterile field

- Operate IVUS and capture physiological measurements on your integrated system without leaving the sterile field

* DFR or Diastolic hyperemia free ratio is a type of hyperemia free physiologic index
† Tableside Control is available on integrated systems only

Product specifications and ordering information

	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"	
Guide catheter compatibility	5F (≥ 0.058")	6F (≥ 0.064")
Hydrophilic sheath coating	Bioslide™	Z-Glide™

Ref/Catalog Number	Description
H749 2493120C 0	AVVIGO™+ Mobile System, US
H749 2493120I 0	AVVIGO+ Integrated System, US
H749 MDU5PLUSF 0	MDU – Fast pullback
H749 39316010 0	Permanent Sled
H749 39315010 0	Permanent Sled Bag
H749 3935205 0	OPTICROSS HD Bagless NON-CE
H749 3935409 0	OPTICROSS HD 6 Bagless NON-CE
H749 555100 0	FFR Link
H749 3935911 0	COMET™ II Pressure Guidewire

OptiCrossTM HD and OptiCrossTM 6 HD 60 MHz Coronary Imaging Catheters & MDU5 PLUS Bag - eIFU 51706289, 51607117

INTENDED USE/INDICATIONS FOR USE OptiCrossTM HD and OptiCrossTM 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 OptiCrossTM HD and OptiCrossTM 6 HD: 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 **MDU5 PLUS Sterile Bag:** None known. **WARNINGS OptiCrossTM HD and OptiCrossTM 6 HD:** • Do not use device after indicated 'Use By' date. Use of an expired device could result in patient injury due to device degradation. • 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. • 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 pinch, crush, kink or sharply bend the catheter at anytime. This can cause poor catheter performance, vessel injury or patient complications. 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. • Never advance or withdraw the imaging catheter without fluoroscopic visualization because it may cause vessel injury or patient complications. • 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. A catheter that is forcibly advanced may cause catheter damage resulting in vessel injury or patient complications. • 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. • If multiple insertions are required, the catheter should not be disconnected from the MDU5 PLUS to avoid possible breach of catheter sterility. **MDU5 PLUS Sterile Bag:** None known. **PRECAUTIONS OptiCrossTM HD and OptiCrossTM 6 HD:** • Do not attempt to connect the catheter to electronic equipment other than the designated systems because the catheter may not function properly. • Never attempt to attach or detach the catheter while the motor is running. To do so may damage the connector. • 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. The use of a damaged guidewire exit port could increase the resistance of catheter advancement or withdrawal. • Never advance the imaging catheter without guidewire support because it can cause difficulty in reaching the intended region of interest or can cause the distal catheter tip to kink. • Never advance the distal tip of the imaging catheter near the very floppy end of the guidewire. This part of the guidewire will not adequately support the catheter. A catheter advanced to this position may not follow the guidewire when it is retracted and cause the guidewire to buckle into a loop which the catheter may drag along the inside of the vessel and catch on the guide catheter tip. If this occurs, it may be necessary to remove the catheter assembly, guidewire and the guide catheter together. If the catheter is advanced too near the end of the guidewire, advance the guidewire while holding the imaging catheter steady. If this fails, withdraw the catheter and guidewire together. • Never advance or withdraw the imaging catheter without the imaging core assembly being positioned at the most distal position of the imaging window because it may cause the catheter to kink. • 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 because it could cause the motor drive to overload. **MDU5 PLUS Sterile Bag:** None known. **ADVERSE EVENTS OptiCrossTM HD and OptiCrossTM 6 HD:** 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. • Potential adverse events which may be associated with vascular imaging include but are not limited to: • 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 • Need for additional intervention or surgery • Radiation injury • Stroke and Transient Ischemic Attack • Thrombosis • Vessel occlusion and abrupt closure • Vessel trauma including, but not limited to dissection and perforation **MDU5 PLUS Sterile Bag:** None known.

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AVVIGO™+ Multi-Modality Guidance System Brief Summary

INTENDED USE/INDICATIONS FOR USE: The IVUS modality of the System is intended for ultrasound examinations of intravascular pathology. Intravascular ultrasound is indicated in patients who are candidates for transluminal interventional procedures such as angioplasty and atherectomy. FFR and DFR are intended for use in catheterization and related cardiovascular specialty laboratories to compute, and display various physiological parameters based on the output from one or more electrodes, transducers, or measuring devices. FFR and DFR are indicated to provide hemodynamic information for use in the diagnosis and treatment of patients that undergo measurement of physiological parameters. Refer to the Catheter Instructions for Use provided with all Boston Scientific Ultrasound Imaging Catheters to determine compatibility with the System. All Ultrasound Imaging Cat heters will be referred to as Imaging Catheters throughout the remainder of this User Guide. The Imaging Catheters generate ultrasound images and are intended for ultrasound examination of vascular and cardiac pathology. Boston Scientific manufactures a wide variety of catheters for different applications. The recommended use of each of these catheters may vary depending on the size and type of the catheter. Please refer to the Imaging Catheter Instructions for Use, packaged with each catheter. **INDICATIONS FOR AUTO PULLBACK USE (IVUS ONLY):** Automatic Pullback is indicated when the following occurs: • The physician/operator wants to standardize the method in which intravascular ultrasound images are obtained and documented: procedure-to-procedure, operator-to-operator. • The physician/operator wants to make linear distance determinations post-procedurally, which requires the imaging core of a catheter to be pulled back at a known uniform speed. • Two-dimensional, longitudinal reconstruction of the anatomy is desired. **CONTRAINDICATIONS:** The System has no patient alarm functions and should not be used for cardiac monitoring. Consult the Imaging Catheter, Guidewire, FFR Link, Motordrive Unit, and the Sled Instructions for Use for a complete list of Contraindications, Adverse Events, Warnings and Precautions. **WARNINGS:** • The ALA feature has not been evaluated in patients with coronary artery aneurysms or with aneurysmal coronary artery disease like Kawasaki's disease. • The AVVIGO+ System and FFR Link uses type CF (Cardiac Floating) defibrillator-proof connections with its applied parts. So that the defibrillator-proof function of the AVVIGO+ System and FFR Link is not compromised, only use the AVVIGO+ System and FFR Link with parts, accessories, applied parts and transducers approved by Boston Scientific. • Inappropriate use of the System may lead to patient illness, or injury. Please read this User Guide and the Instructions for Use for the FFR Link, Imaging Catheters, MDU, and pressure guidewires carefully and completely before attempting to use the System. • Inappropriate use of the System may lead to misinterpretation of patient data and subsequent misdiagnosis/mistreatment, potentially leading to injury. • The System can only be used with Boston Scientific specified accessories, imaging catheters, pressure guidewires and cables. The use of accessories and cables other than the items provided by Boston Scientific may result in increased emission or decreased immunity of the System. For questions regarding this matter, please contact Boston Scientific for technical assistance. • Refer to the Instructions for Use supplied with the specific Imaging Catheter to determine certification for use with the System. If the proper identification of a connected Imaging Catheter is not displayed on the Imaging Display, do not proceed with its use. **PRECAUTIONS:** • External defibrillation or cardioversion can potentially harm the patient or damage the AVVIGO+ System and FFR Link. Consider the following when using a defibrillator: - Avoid placing a pad (or paddle) directly over parts and accessories of the AVVIGO+ System and FFR Link. - Position the pads (or paddles) as far from the AVVIGO+ System and FFR Link as possible. - Set the energy output of external defibrillation equipment as low as clinically acceptable. • If an Imaging Catheter that has not been approved for use with the System is connected, or if an Imaging Catheter is not properly connected, the corresponding Imaging Catheter identification data and Displayed Depth will not be displayed. Imaging will be disabled. Resolve this issue before continuing use. • The System is intended for use in the electromagnetic environment as specified below. The user of the System should ensure that it is only used in such an environment. Note: Medical electrical equipment requires special precautions regarding (EMC). This equipment needs to be installed and put into service according to the EMC information contained within the accompanying documents. Portable and mobile RF communications equipment can affect medical electrical equipment. **ADVERSE EVENTS:** Please consult the Imaging Catheter and Pressure Guidewire Instructions for Use.

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CAUTION: Federal law (USA) restricts these devices 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

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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