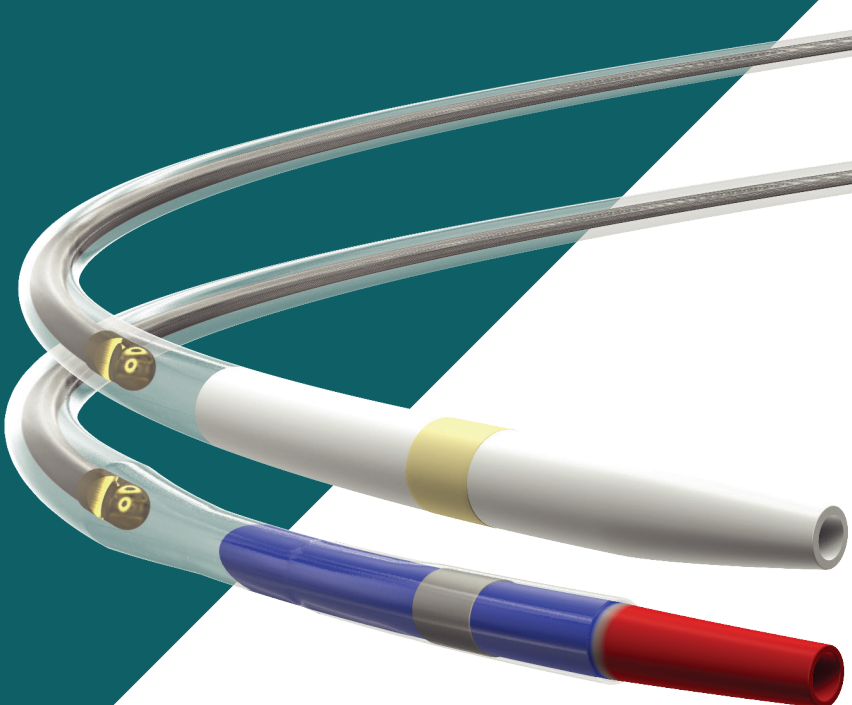

AVVIGO™ +
Multi-Modality Guidance System
Boston Scientific
Advancing science for life™
Fast. Intuitive. Accurate.
A Leap Forward in PCI Guidance Technology

OPTICROSS™ HD

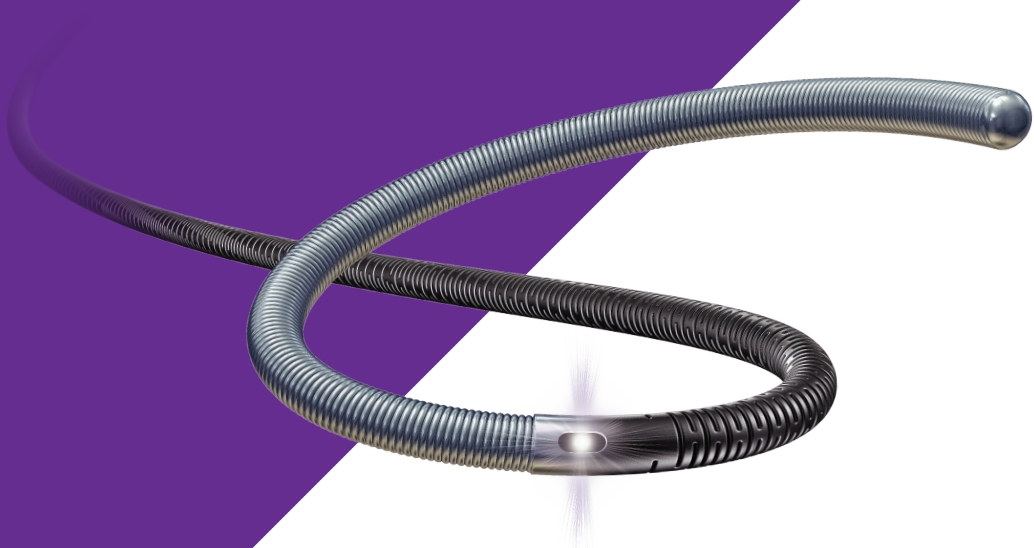
60 MHz Coronary Imaging Catheter



OPTICROSS™ HD Imaging Catheter

Visualize better outcomes with IVUS.

COMET™ II
Pressure Guidewire



COMET™ II Pressure Guidewire:
Total Confidence in Your Treatment Decision.

Necessary Equipment

- AVVIGO™+ Multi-Modality Guidance System (Integrated or Mobile)
- MDU – Fast Pullback
- Tableside Control (For Integrated system only)
- FFR Link (Includes Hemodynamic Cable Kit)
- Permanent Sled
- Permanent Sled Bag
- OPTICROSS™ Imaging Catheter
- COMET™ II Pressure Guidewire

Ordering Information

Ref/Catalog Number	Description
H749 2493120C 0	AVVIGO + Mob System, US
H749 2493120I 0	AVVIGO + Integrated System, US
H749 555111 0	COMET™ II Pressure Guidewire
H749 3935204 0	OPTICROSS™ HD Imaging Catheter
H749 3935408 0	OPTICROSS 6 HD Imaging Catheter
H749 51811 0	OPTICROSS Imaging Catheter
H749 518116 0	OPTICROSS 6 Imaging Catheter
H749 393280018 0	OPTICROSS 18 Imaging Catheter
H749 393280035 0	OPTICROSS 35 Imaging Catheter
M004 9912 0	ULTRA ICE™ PLUS Imaging Catheter
H749 MDU5PLUSF 0	MDU - Fast pullback
H749 555100 0	FFR Link
H749 39316010 0	Permanent Sled
H749 39315010 0	Permanent Sled Bag

AVVIGO™+

Multi-Modality Guidance System

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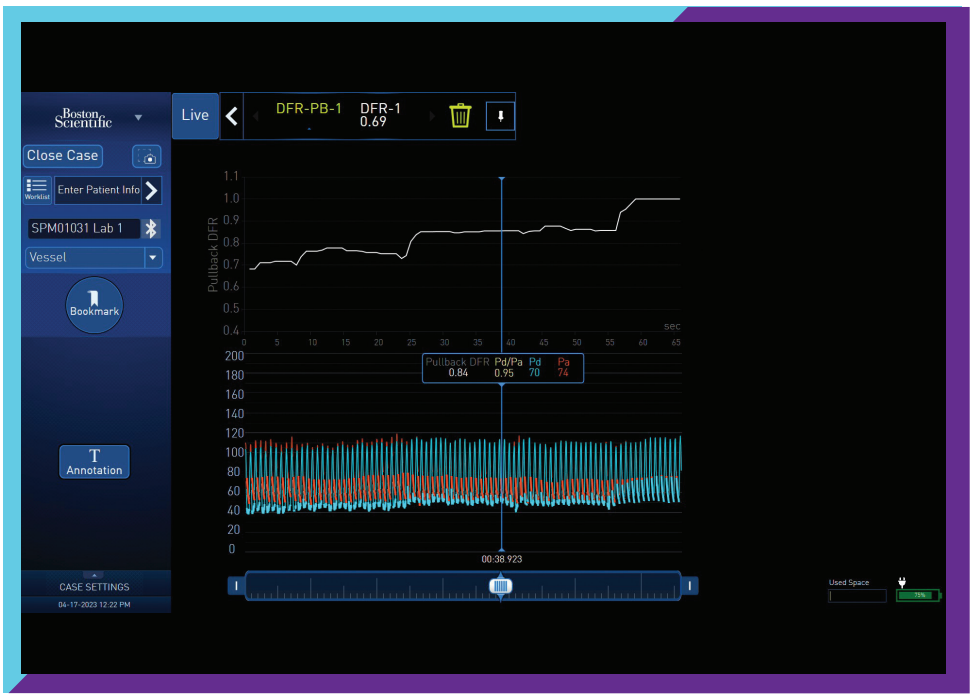
PhysioMap™

+ Enhanced DFR guidance

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



*DFR or Diastolic hyperemia free ratio is a type of hyperemia free physiologic index

Tableside Control

+ Complete control from the sterile field

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

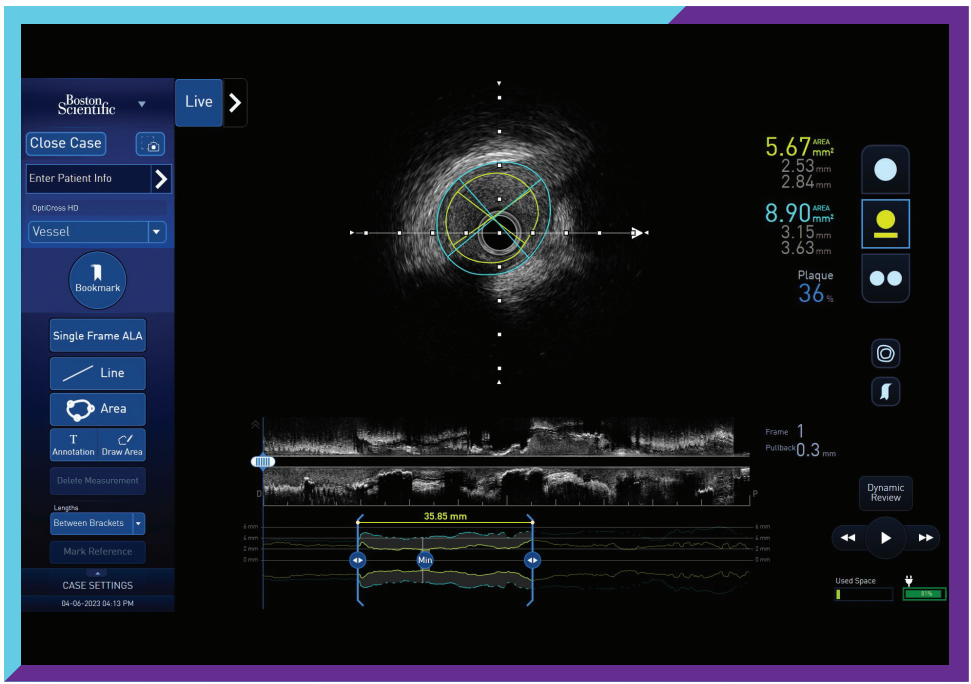
+ Cath Lab

Tableside Control is available on integrated systems only

+ Control Room

Automated Lesion Assessment (ALA™)

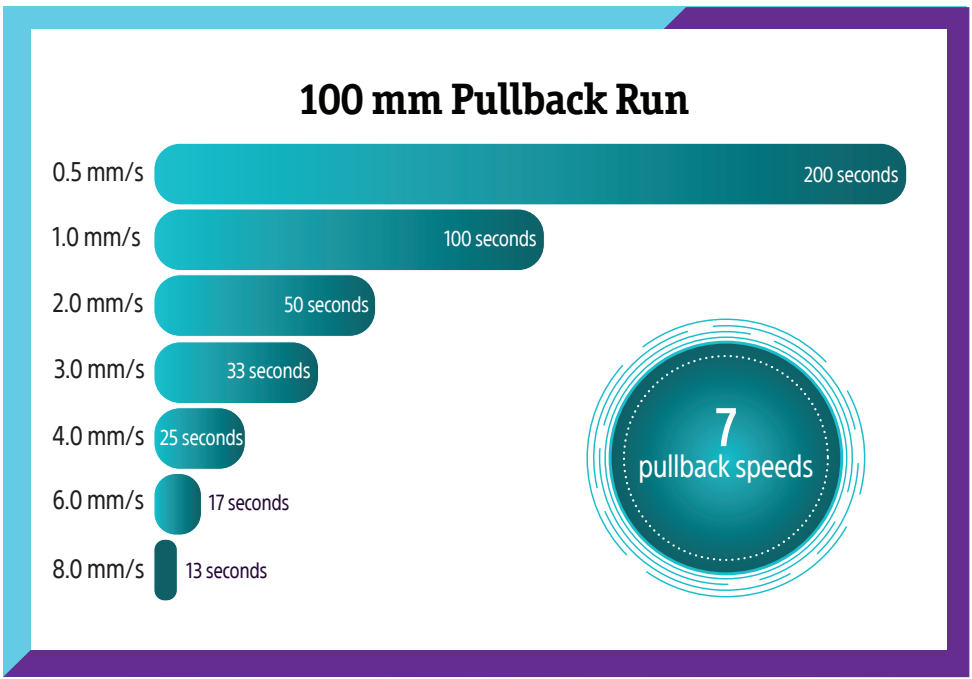
- Precise Vessel Measurements
  - Accurate lumen and vessel borders
  - Vessel profile
  - Key frame markers



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



Fast pullback includes 0.5, 1, 2, 3, 4, 6, or 8 mm/s

AVVIGO™+
Multi-Modality Guidance System

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 Catheters 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.

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 "Instructions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

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