Boston Scientific
Advancing science for life™

POLARIS Multi-Modality Guidance System

Guidance *at* EVERY STEP

The complete solution for IVUS and FFR to help guide confident treatment decisions.

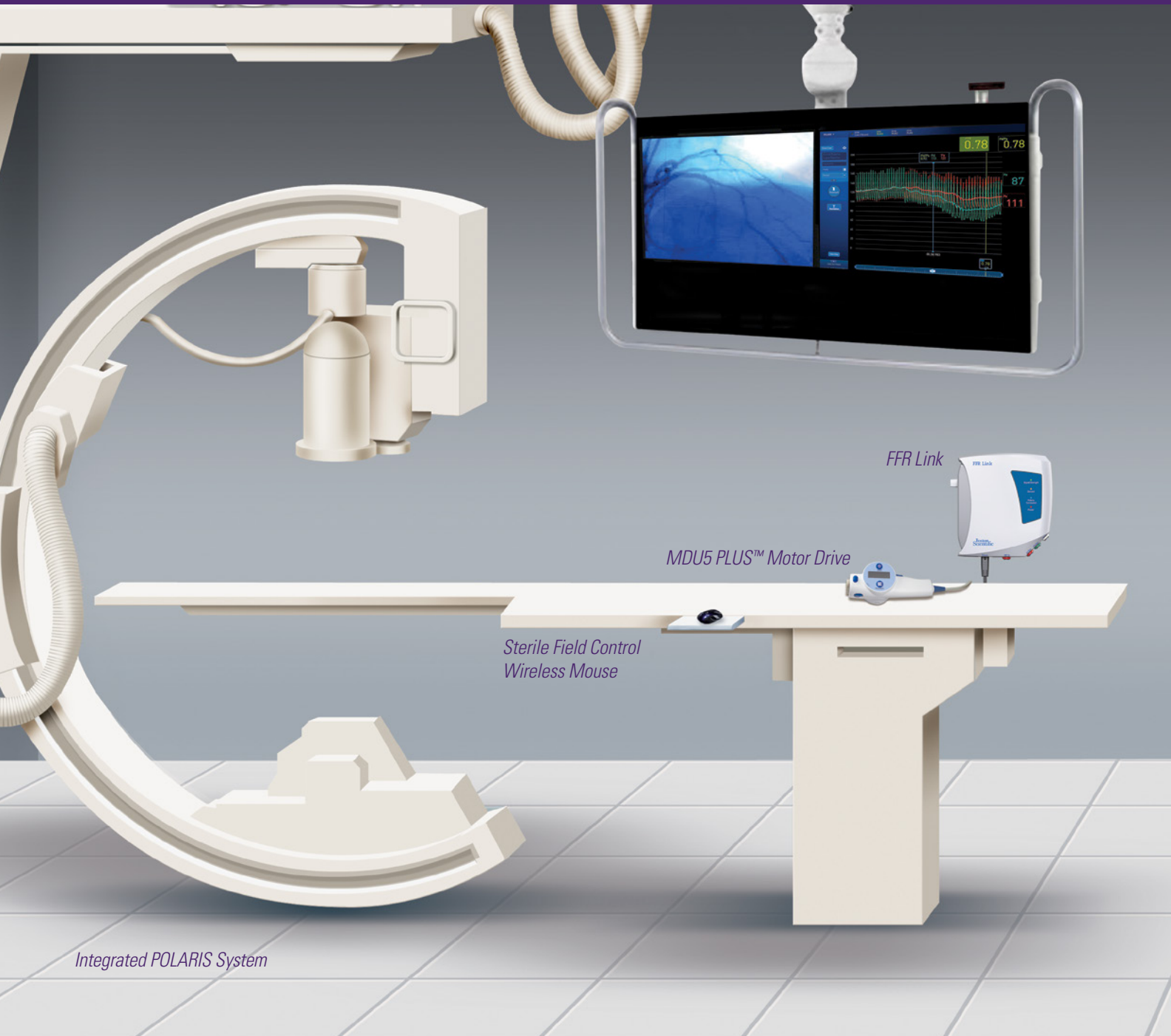

Smart


Fast


Accurate

Learn more at **www.bostonscientific.com/POLARIS**

POLARIS Multi-Modality Guidance System



Integrated POLARIS System

One partner

Boston Scientific has the tools and technology you need for IVUS and FFR. Through our partnership, you have access to an impressive cadence of innovative products and programs to make smart, fast, and accurate treatment decisions.

One system

One system that combines ease of use with best in class IVUS image quality and FFR wire performance to save time, cost, and space.

Mobile POLARIS System

- **Available in both integrated and mobile system options**
- **Intuitive, user friendly software designed in partnership with clinicians**

COMET™ Pressure Guidewire

Deliverable

Developed with Asahi for true workhorse performance

Smart

Optical technology provides reliable disconnection and reconnection

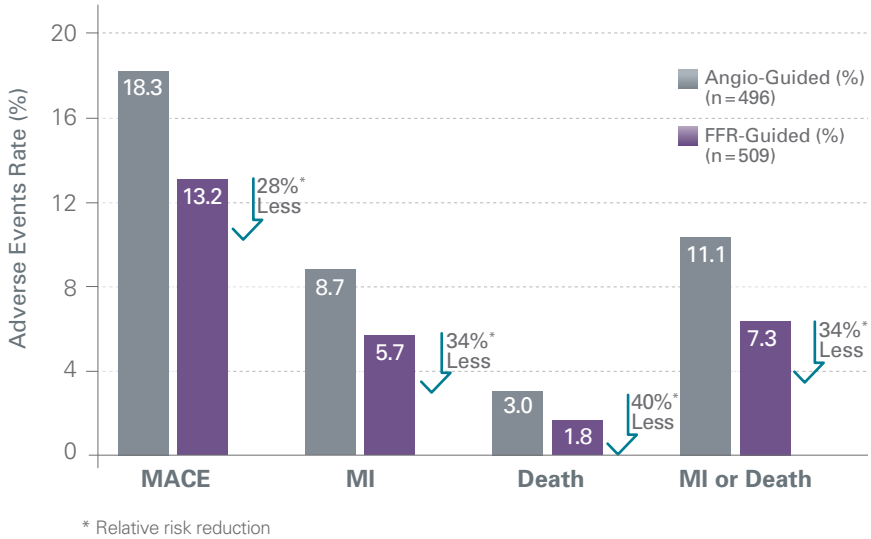
Fast

Optimized rail support for device delivery

For full product specifications, see information in back of brochure.

Improve outcomes and reduce costs with FFR

FFR use demonstrated improved overall health outcomes at one year with less MACE, MI, and death.[1]



* Relative risk reduction

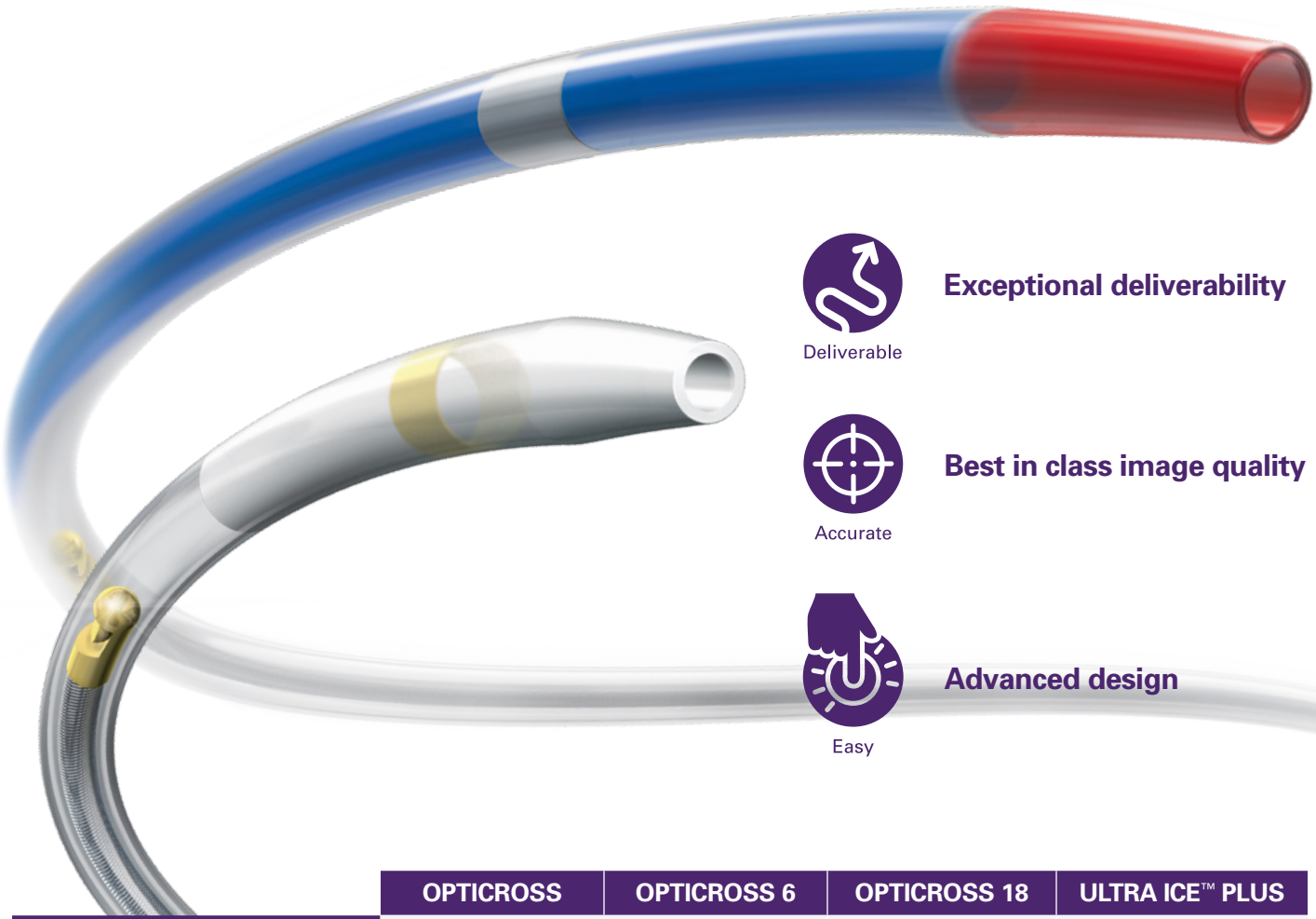
$2,385

savings/patient per year over one year in patients with multi-vessel disease.[2]

1. Tonino, et al. *New Engl J Med.* 2009;360:213-24. MACE: death, MI, repeat revascularization. n = 1,005 patients

2. Fearon WF, Bomschein B, Tonino PA, et al. Economic evaluation of fractional flow reserve-guided percutaneous coronary intervention in patients with multivessel disease. *Circulation.* 2010;122(24):2545 50.

OPTICROSS™ Coronary Imaging Catheters



Deliverable

Exceptional deliverability

Accurate

Best in class image quality

Easy

Advanced design

	OPTICROSS	OPTICROSS 6	OPTICROSS 18	ULTRA ICE™ PLUS
Typical Use	Coronary		SFA, Popliteal, Tibial, Renal	Intracardiac
Transducer Frequency	40 MHz		30 MHz	9 MHz
Maximum Diameter Penetration	6 mm		12 mm	60 mm
Guidewire Compatibility	≤ 0.014"		≤ 0.018"	n/a
Guide Catheter Compatibility	5F (≥ 0.058" ID)	6F (≥ 0.064" ID)	6F (≥ 0.068" ID)	n/a

For full product specifications, see information in back of brochure.

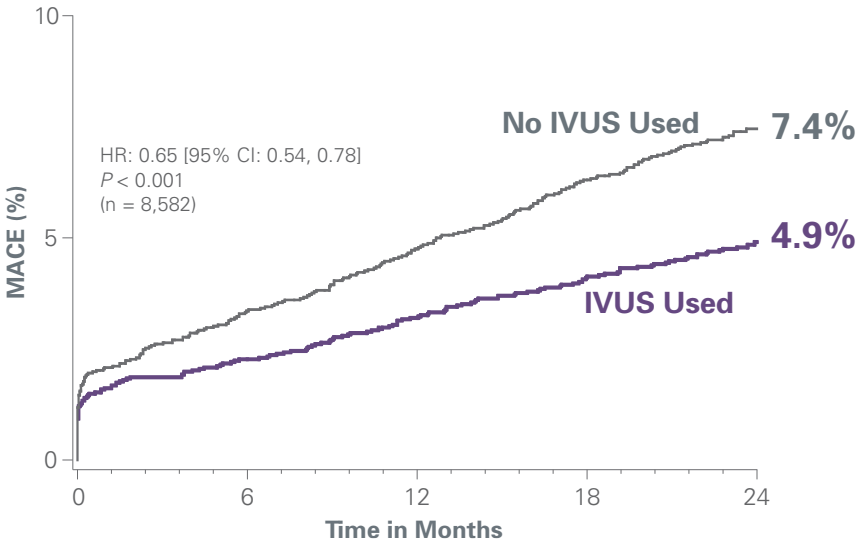
Optimize outcomes and reduce costs with IVUS

IVUS changed clinical decision making

74%

of the time according to ADAPT-DES 2-Year results[1]

IVUS led to use of larger stents and balloons, more post-dilation, additional stents, or higher pressures.[1]



IVUS-guided PCI was more cost effective than angio-guided PCI in studies.

$2,142 savings/patient over lifetime[2]

The potential patients savings are even higher in complex cases[2]

1. Maehara A. ADAPT-DES IVUS Substudy: Utility of IVUS in Delineating the Mechanism of and Preventing Stent Thrombosis. Cardiovascular Research Foundation/Columbia University Medical Center, NY.

2. Ahn JM, Kang SJ, Yoon SH, et al. Meta-analysis of outcomes after intravascular ultrasound-guided versus angiography-guided drug-eluting stent implantation in 26,503 patients enrolled in three randomized trials and 14 observational studies. *Am J Cardiol*. 2014;113(8), 1,338-47.

POLARIS *ExpertCare* Service Programs

Enhance your investment

Ensure you have the latest technology and maximize performance with our POLARIS *ExpertCare* Service Programs.

	Total Care*	Essential Care	Biomed Care*
POLARIS hardware upgrade	●		
Software updates	●	●	●
100% Coverage on replacement parts (up to $10,000 per part)	●	●	●
100% Coverage on labor and travel expenses (up to $3,000 savings per service visit)	●	●	
One preventative maintenance per year ($5,250 value)	●	●	
Unlimited 24/7/365 phone support	●	●	
Unlimited service repair visits	●	●	
Basic user training during preventative maintenance	●	●	
48 Hour in-person response	●	●	
Certified biomed training			●

* Requires 3-year commitment

Contact: **POLARIS *ExpertCare***

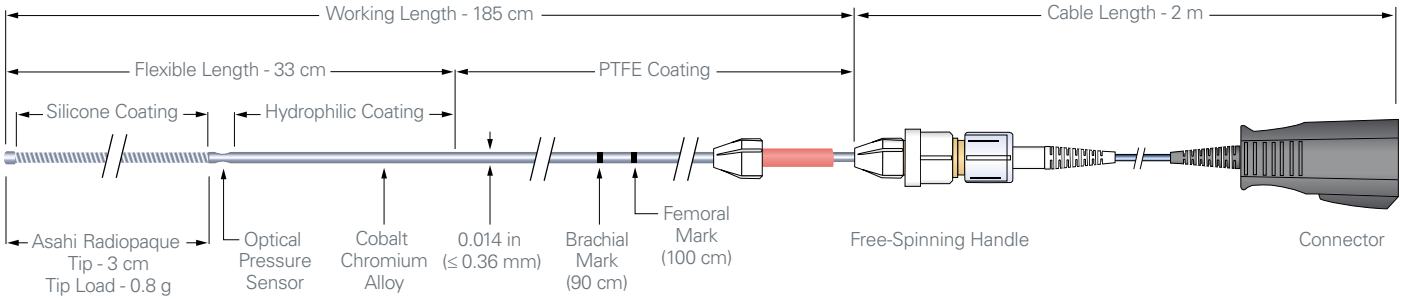
24 HR

Technical Support 24/7/365 at:
1-800-949-6708

Visit bostonscientific.com/POLARIS or contact your sales representative for more information

Product Specifications

COMET™ Pressure Guidewire



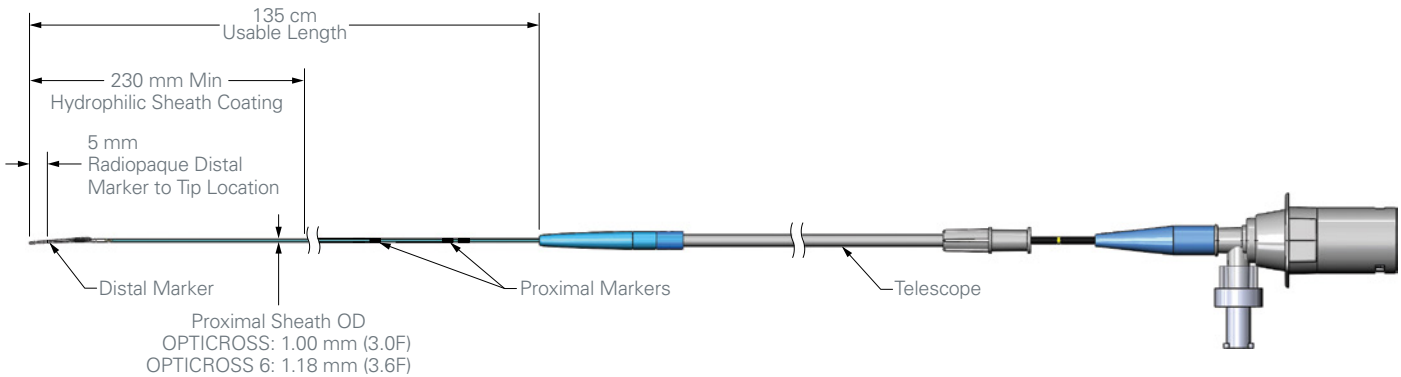
ASAHI TECHNOLOGY

Pressure Guidewire

Torque Device

Optical Cable

OPTICROSS™ Coronary Imaging Catheters



Hardware and Software

FFR workflow	Guided step-by-step instructions displayed on monitor
FFR Link power requirements and consumption	Power requirement: 100–240 VAC, 50/60 Hz Power consumption: 20 VA nominal at all voltages
IVUS pullback options	Manual pullback and auto-pullback with disposable sled
IVUS auto-pullback speed	Two options: 0.5 mm/sec and 1.0 mm/sec
IVUS maximum run length	Manual pullback: 18,000 frames max Auto pullback: 3000 frames @ 1 mm/sec or 6000 frames @ 0.5 mm/sec
IVUS image views	Manual pullback: Cross sectional and DualView displays Auto pullback adds LongView™
IVUS image processing optimization	Optimized blood speckle filtering and optimized image brightness
IVUS measurements	Manual area and distance measurement options on the cross section; length measurement option on LongView
IVUS TraceAssist™	Auto trace for suggested lumen and vessel. Provides suggested minimum and maximum diagonals, areas, and % stenosis (operator assisted).
Worklist	Auto patient data entry from modality worklist server
Digital storage/retrieval	Cases may be stored on local hard drive, space permitting. Cases may also be archived as DICOM studies to CD, DVD, removable hard drive, and to the network (PACS).
DICOM	Modalities supported: US, IVUS. SOP Class used for IVUS frames: Ultrasound Multi-frame Image Storage. SOP Class used for Screenshots: Ultrasound Multi-frame Image Storage. Compression schemes supported: JPEG Baseline and JPEG NH-Lossless.
Operating system	Windows™ 7
Digital archiving options	CD: 650 MB, DVD: 4.7 GB, Removable HD: up to 2 TB
LAN in/out	10/100/1000 Base-T

Ordering Information

Ref/Catalog Number	Order Number (GTIN)	Description
H749 **555111** 0	08714729875758	COMET™ Pressure Guidewire
H749 **51811** 0	08714729847878	OPTICROSS™ Imaging Catheter
H749 **518116** 0	08714729904762	OPTICROSS 6 Imaging Catheter
H749 **393280018** 0	08714729904366	OPTICROSS 18 Imaging Catheter
M004 **9912** 0	08714729904380	ULTRA ICE™ PLUS Imaging Catheter
H749 **A7020** 0	08714729339328	Automatic Pullback Sled

The C-Code used for the OPTICROSS Coronary Imaging Catheters is C1753 and the C-Code used for the COMET Pressure Guidewire is C1769. 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 codes on submitted claims; this information does not constitute reimbursement or legal advice.

Necessary Equipment

- iLab™ POLARIS Multi-Modality Guidance System (Integrated or Mobile)
- MDU5 PLUS™ Motor Drive
- FFR Link (includes Hemodynamic Cable Kit)
- Automatic Pullback Sled (optional)

All trademarks are the property of their respective owners.

FFR Link and COMET™ Pressure Guidewire

FFR Link: Intended Use/Indications for Use: The FFR modality of the iLab™ POLARIS Multi-Modality Guidance System is 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. This modality is indicated to provide hemodynamic information for use in the diagnosis and treatment of patients that undergo measurement of physiological parameters, Fractional Flow Reserve (FFR). **Contraindications:** The FFR modality of the iLab™ POLARIS Multi-Modality Guidance System has no patient alarm functions and should not be used for cardiac monitoring. **Warnings and Precautions:** Use only a Boston Scientific COMET Pressure Guidewire or other Boston Scientific pressure guidewire with the FFR Link. Use of pressure guidewires from other manufacturers will provide inaccurate pressure readings. The POLARIS System maintains a floating double-insulated patient isolation connection within the FFR Link. This connection is intended for defibrillator-proof direct cardiac application (type CF), and includes circuitry to limit the patient leakage current to the levels specified in UL2601-1, EN60601-1, and JIS-T-060101.

COMET Pressure Guidewire: Intended Use/Indications for Use: The COMET Pressure Guidewire measures blood pressure gradient across coronary and peripheral lesions during endovascular procedures. FFR (Fractional Flow Reserve) pressure guidewire may also be used as a coronary or peripheral guidewire for interventional treatments. The COMET Pressure Guidewire is indicated to direct a catheter through a blood vessel and to measure physiological parameters in the coronary and peripheral blood vessels. **Contraindications:** The COMET Pressure Guidewire is contraindicated for use in the cerebral vasculature. **Warnings:** • Resulting pressure guidewire fractures might require additional percutaneous intervention or surgery. • Use extreme caution and careful judgment in patients for whom anticoagulation is not indicated. • Severe reaction may occur in response to contrast agents that cannot be adequately premedicated. **Precautions:** Maintain diligent control of the distal tip at all times during an intervention to avoid vessel dissections and perforations. When crossing a stent, exercise care to avoid entanglement between the pressure guidewire and the stent. Avoid abrasion of the pressure guidewire coating. • To avoid damage to the hydrophilic coating, do not withdraw or manipulate the pressure guidewire in a metal cannula or sharp object. • Excessive tightening of the torque device onto the pressure guidewire may result in abrasion of the coating on the pressure guidewire. Use only the optical cable provided to connect the pressure guidewire to FFR Link. Use of a different optical cable will produce inaccurate pressure readings. The accuracy of the diagnostic information is affected by, but not limited to: • Failure to achieve maximum coronary and myocardial hyperemia. • Interventional devices, such as balloon catheters, which are positioned so as to affect the blood flow or guidewires that stretch the vessel. • Pressure wire positioning relative to the lesion. • Microvascular resistance. Carefully check and match therapeutic device compatibility to the pressure guidewire prior to use. Do not use the pressure guidewire in conjunction with atherectomy catheters. **Adverse Events:** Potential adverse events which may result from the use of the device include but are not limited to: • Abrupt closure • Allergic reaction • Embolism • Exposure to biohazardous material • Infection • Prolonged procedure • Restenosis (reocclusion) • Spasm • Stroke/cerebral vascular accident (CVA)/transient ischemic attack (TIA) • Vascular thrombus • Vessel trauma (dissection, perforation, rupture or injury). In addition, when used for interventional procedures: • Angina or unstable angina • Arrhythmias • Cardiac tamponade/pericardial effusion • Contrast induced renal insufficiency or renal failure • Death • Myocardial infarction or ischemia. Some of the above potential adverse events may require additional surgical intervention. **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.

Rev AA

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.

Rev AB

OPTICROSS 6 Catheter and 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. 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. • 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. To do so may damage the connector. • 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. • 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.

Rev AA

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