Boston Scientific
Advancing science for life™

POLARIS
Multi-Modality Guidance System

NAVIGATE TO BETTER OUTCOMES

Use a single system to inform treatment decisions with high-definition IVUS and coronary physiology

www.bostonscientific.com/polaris

POLARIS MULTI-MODALITY GUIDANCE SYSTEM

Mobile POLARIS System

HIGH-PERFORMANCE PRODUCT PORTFOLIO

A full suite of imaging catheters and a true workhorse pressure guidewire offer best-in-class deliverability

INTUITIVE SOFTWARE

User friendly software features an easy workflow and specialized tools for IVUS and coronary physiology

FLEXIBLE INTEGRATION

Mobile option available to fit seamlessly in any facility

OFFERING FFR, DFR™, AND Pd/Pa MEASUREMENTS

Cutoff

FFR

Fractional Flow Reserve (FFR) calculates Pd/Pa during maximal hyperemia.

≤ 0.80

DFR

Diastolic hyperemia-Free Ratio (DFR) calculates a diastolic portion of the cardiac cycle at rest.

≤ 0.89

Pd/Pa

Pd/Pa calculates the entire cardiac cycle at rest.

≤ 0.91

DEVELOPED WITH ASAHI FOR TRUE WORKHORSE PERFORMANCE

- Free-spinning handle for minimal resistance steering
- Shapeable, atraumatic tip for challenging cases
- Precision cut body for 1:1 torque experience

ONE WIRE FOR THE ENTIRE PROCEDURE

- Optical technology provides reliable signal connection for diagnosis and post-PCI assessment
- Optimized rail support for device delivery (compatible with 0.014" devices)

COMET™
Pressure Guidewire

ASAHI TECHNOLOGY

VISUALIZE BETTER OUTCOMES WITH IVUS

OPTICROSS™ HD

60 MHz Coronary Imaging Catheters

HIGH-RESOLUTION IMAGING

- A 60 MHz wideband transducer increases lateral and axial resolution for superior image quality
- Enhances visualization of all three vessel layers and plaque morphology
- Improves stent strut visibility for better optimization

UNMATCHED VERSATILITY

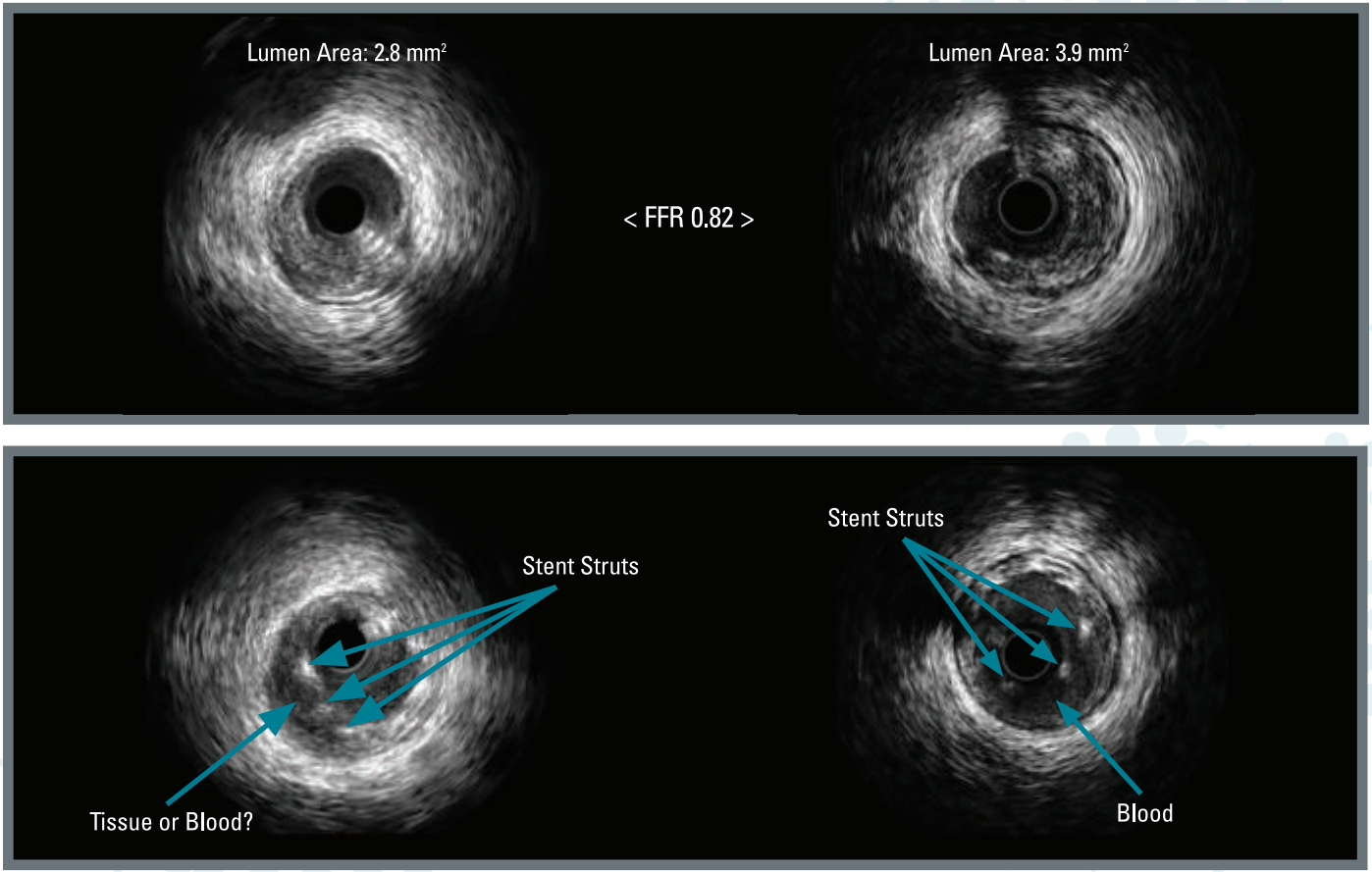
- Expect exceptional near-field visibility for small vessel imaging as well as penetration depth of 6 mm for large vessel assessment

PROVEN DELIVERABILITY

- Available in 5F compatibility, a trusted, well-balanced design that ensures better deliverability than competitive devices

OPTICROSS™
40 MHz Coronary Imaging Catheters

OPTICROSS™ HD
60 MHz Coronary Imaging Catheters



Images provided courtesy of Yannis Chatzizisis, MD, PhD, University of Nebraska Medical Center

ADVANCED SOFTWARE FEATURES

SmartMinimum™

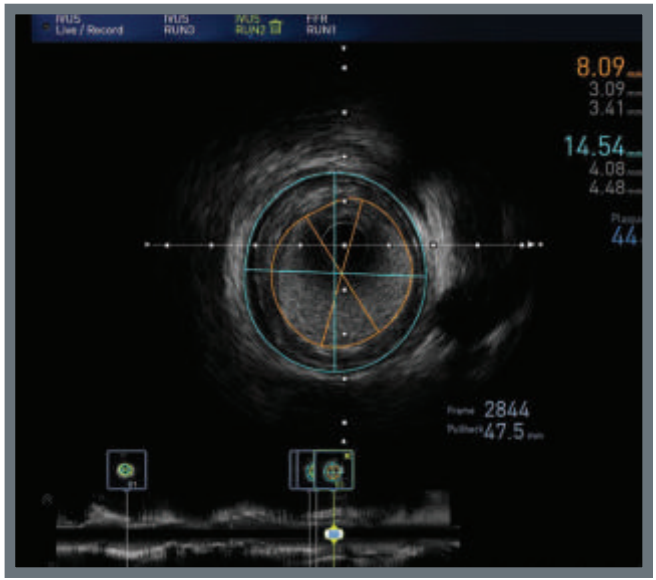
Automatically removes artifacts to quickly identify the true FFR value

SmartMinimum algorithm developed & clinically validated by the University of Texas

DFR™

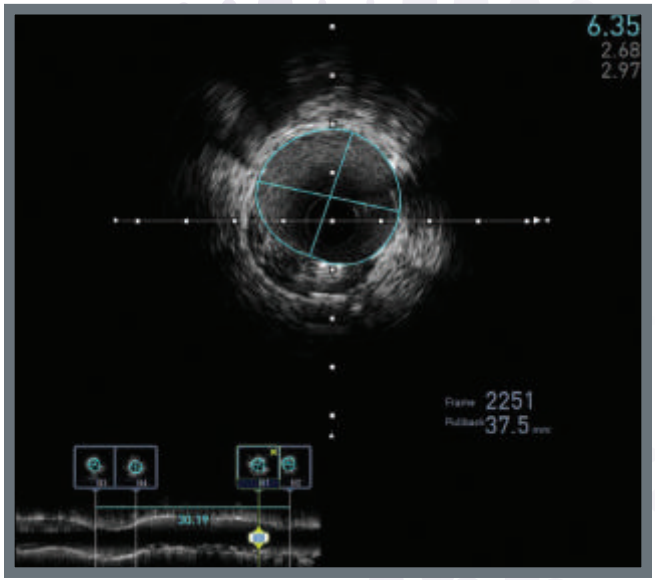
A new option in resting coronary physiology. Diastolic hyperemia-Free Ratio (DFR) calculates a diastolic portion of the cardiac cycle at rest.

Trace Assist™



An aid to automatically draw lumen and vessel borders

LongView™



IVUS LongView provides a user the ability to guide PCI with length measurements and visualization of bifurcations

ORDERING INFORMATION

Ref/Catalog Number	Description
H7493932430	COMET™ Pressure Guidewire
H74939352020	OPTICROSS™ HD 60 MHz Coronary Imaging Catheter
H749518120	OPTICROSS™ 40 MHz Coronary Imaging Catheter
H7495181260	OPTICROSS™ 6 40 MHz Coronary Imaging Catheter
H7493932700180	OPTICROSS™ 18 30 MHz Peripheral Imaging Catheter
M00499100	ULTRA ICE™ PLUS 9 Mhz IntraCardiac Echo Catheter
H749A70200	Automatic Pullback Sled

NECESSARY EQUIPMENT

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

FFR Link and COMET™ Pressure Guidewire

FFR Link Intended Use/indications For Use: The FFR Link is intended to condition physiological signals from measuring devices (BSC Pressure Guidewire or an external pressure transducer), transmit and receive via radiofrequency, and recondition the signals so they can be displayed on and/or recorded in a receiving device (iLab™ POLARIS Multi-Modality Guidance System or other monitoring device). The physiological signals can also be distributed by cable. Contraindications: The FFR Link has no patient alarm functions and should not be used for cardiac monitoring.

Comet™ Pressure Guidewire: INTENDED USE The Comet Pressure Guidewire measures blood pressure gradient across coronary lesions during endovascular procedures. FFR (Fractional Flow Reserve) pressure guidewire may also be used as a coronary guidewire for interventional treatments. **Indications For Use:** The Comet Pressure Guidewire is indicated to direct a catheter through a blood vessel and to measure physiological parameters in the coronary blood vessels.
Contraindications: The Comet™ Pressure Guidewire is contraindicated for use in the cerebral vasculature. Warnings: • The Comet Pressure Guidewire should be used only be physicians trained in angiography and percutaneous interventions including transluminal coronary angioplastry (PTCA). Vessel trauma (dissection, perforation, rupture or injury) may result from the improper use of this device. • Resulting pressure guidewire fractures migmt require additional percutaneous intervention or surgery. • Use extreme caution and careful judgment in patients for whom anticoagulation is not indicated. • Severe reation may occur in response to contrast agents that cannot be adequately premedicated.

OPTICROSS™ HD 60 MHz Coronary Imaging Catheter

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: • 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 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 hte 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 any time.** This can cause poor catheter performance, vessel injury or patient complications. An insertion angle greater than 45 degrees is considered excessive. • 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 stended 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 strusts. A guidewire may exit between one or more stent struts when recrossing stent(s). Subsequent advancement of the catheter could cause entrangement between the catheter and 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.

iLab™ POLARIS Multi-Modality Guidance System

The IVUS modality of the iLab™ Polaris Multi-Modality Guidance 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. 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.

• **Caution**: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions of use can be found in the product labeling supplied with each device. Information for the use only in countries with applicable health authority product registrations.

• The information presented in this document by Boston Scientific is intended for healthcare professionals in India. [The information presented in this document is intended to provide balanced, scientific, and evidence based answers to unsolicited medical questions.] The information should not be, however, treated as comprehensive and does not intend to provide diagnosis, treatment or any medical or health advice. For full information about the product, please refer to the appropriate product labeling. Responsibility for patient care resides with the healthcare professional on the basis of his or her professional licence, experience and knowledge of the patient. Healthcare professionals must rely on their judgment when deciding which treatments and procedures to use with patients.

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