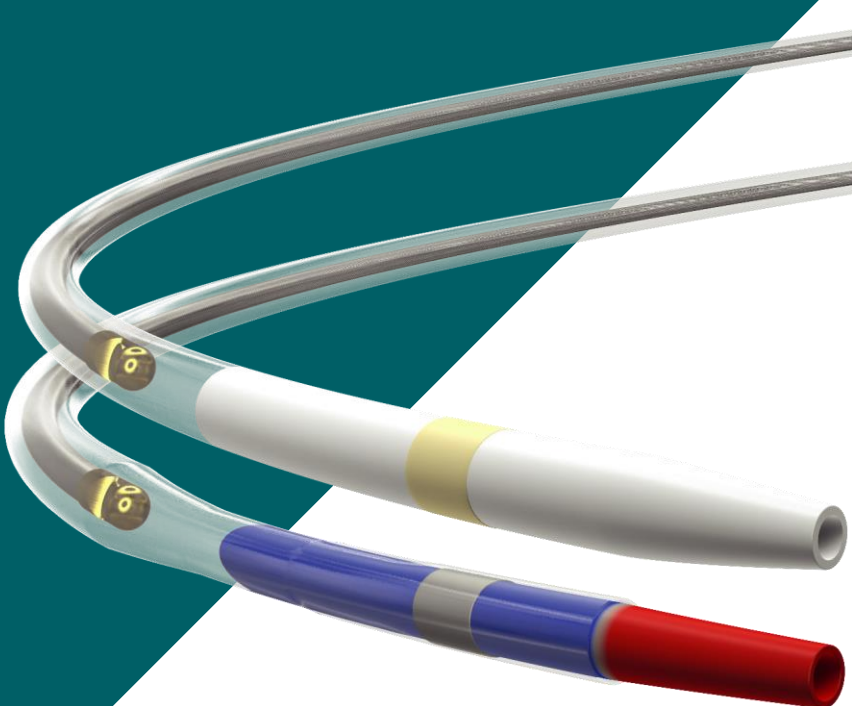

AVVIGO™ +
Multi-Modality Guidance System
Boston Scientific
Advancing science for life™
Rápido. Intuitivo. Preciso.
Um passo a frente na tecnologia de PCI Guidance

OPTICROSS™ HD

60 MHz Coronary Imaging Catheter



OPTICROSS™ HD Cateter de Imagem

Visualize melhores resultados com IVUS.

COMET™ II
Pressure Guidewire

COMET™ II Fio Guia de Pressão:
Total confiança na sua decisão de tratamento.

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PhysioMap™

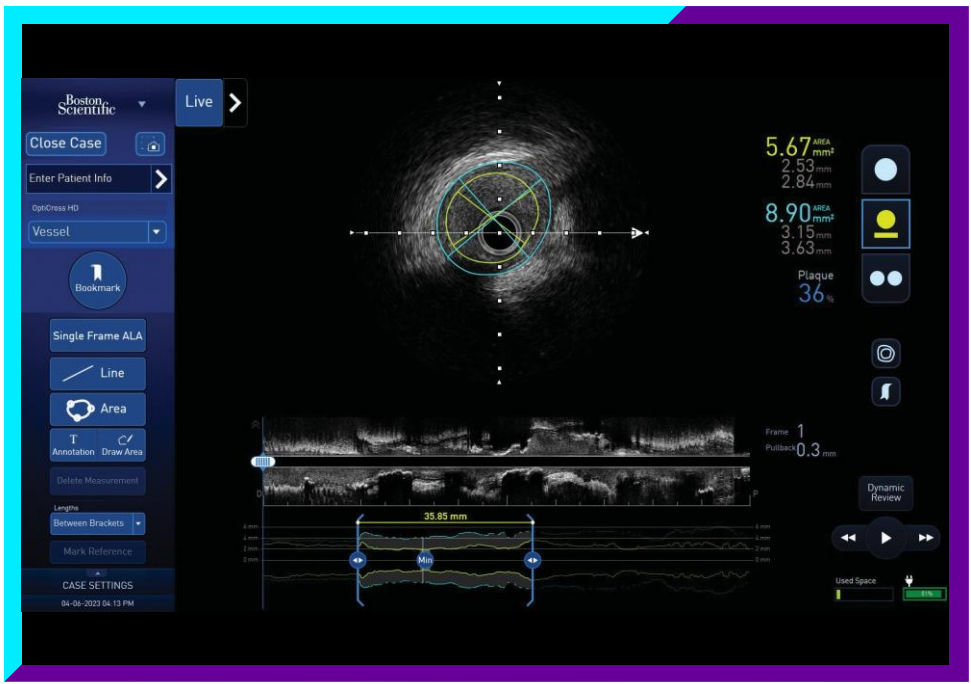
+ Orientação DFR aprimorada

Otimize suas decisões de tratamento localizando rapidamente regiões de mudança de pressão durante o pullback.

*DFR ou Índice fisiológico livre de hiperemia diastólica é um tipo de índice fisiológico livre de hiperemia.

Avaliação Automatizada de Lesão (ALA™)

- Medições precisas nos vasos
  - Limites precisos de lúmen e vasos Perfil
  - do vaso
  - Marcadores automáticos na lesão



Fast Pullback

+ Imagens de alta qualidade na velocidade do pullback que você escolher:

O recuo automático agora inclui velocidades mais rápidas, de até 8mm/s, permitindo uma aquisição de imagens do vaso mais rápidas.

Velocidades de recuo, incluem: 0.5, 1, 2, 3, 4, 6, or 8 mm/s

Equipamentos necessários

- AVVIGO™+ Sistema de orientação Multimodal
- MDU – Fast Pullback (Recuo rápido)
- FFR Link (Incluso kit de cabos hemodinâmicos)
- Trenó permanente (Permanent Sled)
- Bolsa para trenó permanente
- OPTICROSS™ Cateter de imagem
- COMET™ II - Fio guia de pressão

Informações para pedido

Número de Ref/Catálogo	Descrição
H7492493320C0	AVVIGO + MOB SYSTEM
H7495551000	FFR Link
H749MDU5PLUSF0	MDU Fast Pullback
H749393160100	Permanent Sled
H749393150100	Permanent Sled Sterile Bag
H74939352060	OPTICROSS HD BAGLESS
H749518140	OPTICROSS 5 BAGLESS
H74939359310	COMET™ II Pressure Guidewire

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.

CUIDADO: A lei restringe estes dispositivos a venda por ordem de um médico. Indicações, contraindicações, advertências e as instruções de uso podem ser encontradas na rotulagem do produto fornecida com cada dispositivo ou em www.IFU-BSCI.com. Produtos mostrados apenas para fins de INFORMAÇÃO e pode não ser aprovada venda em determinados países. Este material não se destina ao uso na França.

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