Boston Scientific
Advancing science for life™

OPTICROSS™ 18 Cateter de Imagem Periférica

ENTREGUE CONFIANÇA

18

Entregável

Entrega excepcional

- Tecnologia de ponta de balão para fácil cruzamento e entrega
- Baixo perfil de cruzamento e rigidez do eixo para uma excelente entrega
- Revestimento hidrofílico para facilitar a entrega

Preciso

Penetração e Resolução de Imagem Melhorada

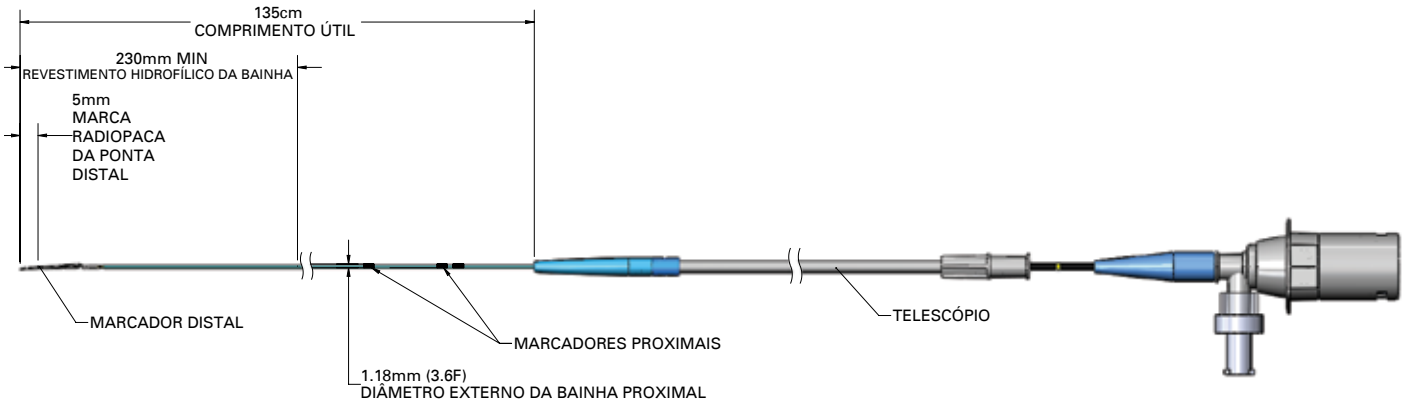
- Frequência do transdutor de 30 MHz permite uma penetração mais profunda que 40 MHz
- Habilidade de visualizar vasos maiores com mais resolução que 20 MHz

Fácil

Confiança com Desenho Avançado

- Eixo proximal mais forte para maior capacidade de empurrar
- Fácil lavagem para um preparo rápido
- Compatível com iLAB™ POLARIS

OPTICROSS™ 18 Cateter de Imagem Periférica - Especificações



Código do Produto	Número do Catalogo	Descrição do Material	GTIN
H74932700180	390590018	OPTICROSS 18	08714729904366

Equipamento Necessário

Os seguintes são requeridos para o uso do cateter de imagem periférica Opticross 18:

- Sistema iLAB™ POLARIS Multi-Modalidade
- Unidade MDU5 Plus Drive

OPTICROSS™ 18 CATHETER AND MDU5 PLUS BAG

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.

INTENDED USE/INDICATIONS FOR USE: OptiCross 18 Catheter: This catheter is intended for intravascular ultrasound examination of peripheral vessels only. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal interventional procedures. MDU5 PLUS Sterile Bag: The MDU5 PLUS Sterile Bag is intended to cover the motordrive during intravascular ultrasound procedures to maintain a sterile field and prevent transfer of microorganisms, body fluids and particulate material to the patient and healthcare worker. **CONTRAINDICATIONS:** This product is contraindicated in the presence of conditions which create unacceptable risk during catheterization. **WARNINGS:** • Intravascular ultrasound examination of vascular anatomy should be performed only by physicians fully trained in 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. • Do not pinch, crush, kink or sharply bend the catheter at any time. 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. • 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. • 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. • Never advance the imaging catheter without guidewire support. • Never advance the distal tip of the imaging catheter near the very floppy end of the guidewire. • Never advance or withdraw the imaging catheter without the imaging core assembly being positioned at the most distal portion of the imaging window. • 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 • Device entrapment requiring surgical intervention • Embolism (air, foreign body, tissue or thrombus) • End organ infarction • Hemorrhage/Hematoma • Hypotension and/or bradycardia (vasovagal syndrome) • Infection • Peripheral ischemia • Stroke and Transient Ischemic Attack • Thrombosis • Vessel occlusion and abrupt closure • Vessel trauma including, but not limited to dissection and perforation

FPO

Boston Scientific
Advancing science for life™

Peripheral Interventions
Boston Scientific - Brazil
Av. Das Nações Unidas, 14.171
Torre Marble 12º Andar, São Paulo - SP

www.bostonscientific.com

To order product or for more information contact customer service at 1.888.272.1001.

PI-392413-AA MAY2016
PI-757405-AA Mar2020