Boston Scientific
Advancing science for life™

PERIPHERAL CUTTING BALLOON™

Microsurgical Dilatation Device For Hemodialysis Access Management

THE PROVEN SOLUTION FOR RESISTANT AV FISTULAE

Peripheral Cutting Balloon (PCB) is designed to minimize vessel trauma with its unique mechanism of action.

Non-compliant balloon material

- Designed for predictable, controlled dilatation
- Designed to ensure secure atherotome fixation

Tapered Tip

- Laser-formed design built to facilitate lesion entry and crossing

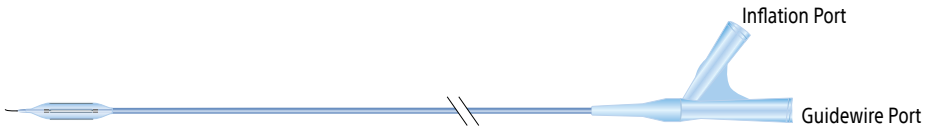
Atherotomes

- Microsurgical blades designed to create precise incisions and provide predictable hoop stress relief

PCB

- 2 cm length
- 5–8 mm diameters
- 0.018" guidewire compatible
- 50 cm, 90 cm, and 135 cm lengths
- Available in OTW

Product Information



Over-the-Wire PCB 2 cm Balloon Catheter

UPN	Catalog	Diameter	Usable Length
M001PCB5020500	PCB502050	5 mm	50 cm
M001PCB6020500	PCB602050	6 mm	50 cm
M001PCB7020500	PCB702050	7 mm	50 cm
M001PCB8020500	PCB802050	8 mm	50 cm
M001PCB5020900	PCB502090	5 mm	90 cm
M001PCB6020900	PCB602090	6 mm	90 cm
M001PCB7020900	PCB702090	7 mm	90 cm
M001PCB8020900	PCB802090	8 mm	90 cm
M001PCB50201350	PCB5020135	5 mm	135 cm
M001PCB60201350	PCB6020135	6 mm	135 cm
M001PCB70201350	PCB7020135	7 mm	135 cm
M001PCB80201350	PCB8020135	8 mm	135 cm

2CM PERIPHERAL CUTTING BALLOON
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:** The Peripheral Cutting Balloon catheters are indicated for Percutaneous Transluminal Angioplasty (PTA) of obstructive lesions of synthetic or native arteriovenous dialysis fistulae. **CONTRAINDICATIONS:** • Use of the Cutting Balloon Device is contraindicated in situations where the Cutting Balloon Device would be passed through the struts of a previously placed stent as the deflated Cutting Balloon Device could become entangled in the stent. • The Peripheral Cutting Balloon Device is not for use in the coronary arteries or carotid arteries. • The Peripheral Cutting Balloon Device is not intended for the expansion or delivery of stents. **WARNINGS:** • The Cutting Balloon Device should be used before new stent placement. Exercise extreme care when treating a lesion distal to a previously placed stent. If the guidewire has passed through the stent cell rather than down the axis of the stent, the deflated Cutting Balloon Device could become entangled in the stent. Confirm wire position in two views before advancing the Cutting Balloon Device if crossing a previously placed stent. Excessive withdrawal pressure against resistance can damage the Device and potentially require surgery for retrieval. When treating lesions at a bifurcation, the Cutting Balloon Device can be used prior to placing a stent, but should not be taken through the side cell of a stent to treat the side branch of a lesion at a bifurcation where a stent has been previously placed. • Angioplasty with the Peripheral Cutting Balloon Device, because of its mechanism of action, may pose a greater risk of perforation than that observed with conventional PTA. Oversizing increases the risk of perforation. To reduce the potential for vessel damage the inflated diameter of the Peripheral Cutting Balloon Device should not exceed a 1.1:1 ratio of the diameter of the vessel just proximal and distal to the stenosis. • Balloon pressure should not exceed the rated burst pressure. The rated burst pressure is based on the results of in vitro testing. At least 99.9% of the balloons, (with a 95% confidence) will not burst at or below their rated burst pressure. Use of a pressure monitoring device is recommended to prevent over pressurization. • Use only the recommended balloon inflation medium (e.g. - contrast medium). Never use air or any gaseous medium to inflate the balloon. • Do not use in a kinked or buckled introducer sheath or if resistance is encountered. Resistance, kinking, or buckling in the introducer sheath may damage the atherotomes or balloon. If any of these occur, immediately withdraw both devices. • When the catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum. If resistance is met during manipulation, determine the cause of the resistance before proceeding. **PRECAUTIONS:** Prior to angioplasty, the catheter should be examined to verify functionality and ensure that its size and shape are suitable for the specific procedure for which it is to be used. Only physicians who have received the appropriate training should use the Peripheral Cutting Balloon Device. During the Peripheral Cutting Balloon Device procedure, appropriate anticoagulant therapy should be provided to the patient. Anticoagulant therapy should be continued after the procedure for a period of time to be determined by the physician. The Peripheral Cutting Balloon Device is not designed for, and therefore, cannot be used to monitor in vivo arterial pressures. **POTENTIAL ADVERSE EVENTS:** Risks associated with interventional treatment of stenosis with the Peripheral Cutting Balloon Device are similar to those of conventional PTA. Potential risks include, but are not limited to: • Allergic or drug reaction (device material, contrast medium and medications) • Amputation • Arteriovenous fistula • Death • Embolism • Hematoma • Hemorrhage • Hypotension/hypertension • Infection/Sepsis • Ischemia/infarction of tissue/organ • Pain • Pseudoaneurysm • Restenosis • Surgical intervention • Swelling • Thrombosis • Vessel injury (dissection, perforation, or rupture) • Vessel occlusion • Vessel spasm
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