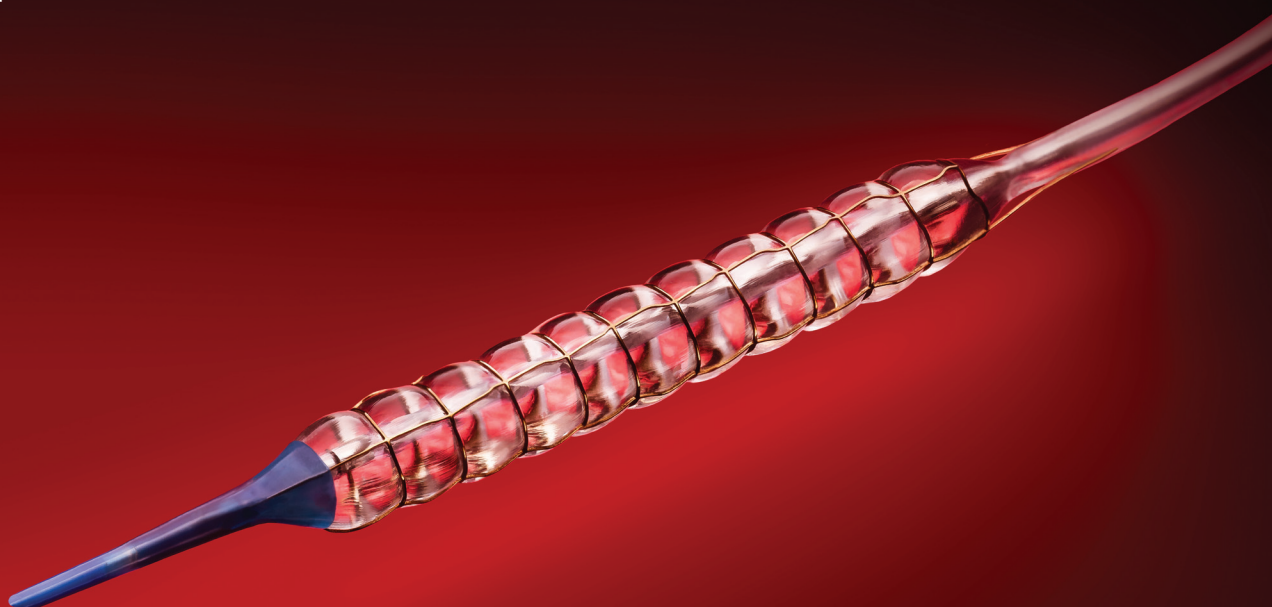


Chocolate

PTA Balloon Catheter

CE
0124



Designed to Perform

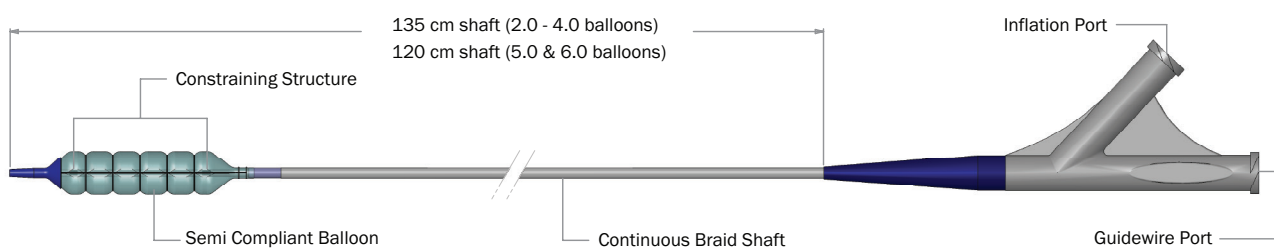
Designed to minimize vessel trauma and improve acute outcomes, Chocolate PTA Balloon Catheter represents the newest breakthrough in technology for interventionalists to treat complex peripheral vascular disease above and below the knee.

Features & Specifications	
Platform:	Over-the-Wire
Balloon Material:	Nylon, semi-compliant
Constraining Structure:	Nitinol
Shaft Length:	135 cm (2.0 – 4.0 mm) 120 cm (5.0 – 6.0 mm)
Shaft:	Hydrophilic coated braided shaft
Entry Profile:	0.020"
Crossing Profile:	0.045"

Ordering Information



Balloon Diameter	Balloon Length	Guidewire	Introducer Sheath	Rated Burst Pressure	Reference Number
2.5	20	0.014"	5F	14 atm	CF14-135-25020 OTW
2.5	40	0.014"	5F	14 atm	CF14-135-25040 OTW
2.5	80	0.014"	5F	14 atm	CF14-135-25080 OTW
2.5	120	0.014"	5F	14 atm	CF14-135-25120 OTW
3.0	20	0.014"	5F	14 atm	CF14-135-30020 OTW
3.0	40	0.014"	5F	14 atm	CF14-135-30040 OTW
3.0	80	0.014"	5F	14 atm	CF14-135-30080 OTW
3.0	120	0.014"	5F	14 atm	CF14-135-30120 OTW
3.5	20	0.014"	5F	14 atm	CF14-135-35020 OTW
3.5	40	0.014"	5F	14 atm	CF14-135-35040 OTW
3.5	80	0.014"	5F	14 atm	CF14-135-35080 OTW
3.5	120	0.014"	5F	14 atm	CF14-135-35120 OTW
4.0	20	0.014"	5F	14 atm	CF14-135-40020 OTW
4.0	40	0.014"	5F	14 atm	CF14-135-40040 OTW
4.0	80	0.014"	5F	14 atm	CF14-135-40080 OTW
4.0	120	0.014"	5F	14 atm	CF14-135-40120 OTW
5.0	20	0.018"	6F	12 atm	CF18-120-50020 OTW
5.0	40	0.018"	6F	12 atm	CF18-120-50040 OTW
5.0	80	0.018"	6F	12 atm	CF18-120-50080 OTW
5.0	120	0.018"	6F	12 atm	CF18-120-50120 OTW
6.0	20	0.018"	6F	12 atm	CF18-120-60020 OTW
6.0	40	0.018"	6F	12 atm	CF18-120-60040 OTW
6.0	80	0.018"	6F	12 atm	CF18-120-60080 OTW
6.0	120	0.018"	6F	12 atm	CF18-120-60120 OTW



EC REP

MPS Medical Product Service GmbH
Borngasse 20
D-35619 Braunfels, Germany
Tel: +49 6442 962073

Distributed by:

TriReme Medical Inc.
7060 Koll Center Parkway, Suite 300
Pleasanton
California 94566 USA
Tel: +1 925 931 1300
www.trirememedical.com

Developed by:

Quattro Vascular
ROC REG 201006397R

INDICATIONS FOR USE

The Chocolate PTA Balloon Catheter is intended for balloon dilatation of lesions in the peripheral vasculature, including the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries.

CONTRAINDICATIONS

- Use in the coronary and cerebral vasculature.
- Lesion is unable to be crossed with a guidewire.

WARNINGS

STERILE product, to be for one-time use only. Re-sterilizing or re-using may compromise the structural integrity of the device and may create a risk of contamination which, in turn, may result in health risks to patients. The inflated diameter of the balloon should correspond to the diameter of the vessel for treatment. The catheter should be used under fluoroscopic guidance. DO NOT advance or retract the catheter unless the balloon is fully deflated under vacuum. DO NOT advance against resistance without first determining the cause of the resistance and taking appropriate action. Balloon pressure should never exceed the rated burst pressure (RBP). Exceeding the RBP may result in balloon rupture and Constricting Structure failure. Use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon. Use the Chocolate PTA Balloon Catheter prior to the "Use By" date specified on the package. The Chocolate PTA Balloon Catheter has not been tested for post-dilatation of stents or advancement through stents, calcified lesions or synthetic vascular grafts. DO NOT use in the presence of a freshly deployed stent.