

Chocolate Touch[®]

Changing the Landscape
of Drug-Coated Balloons

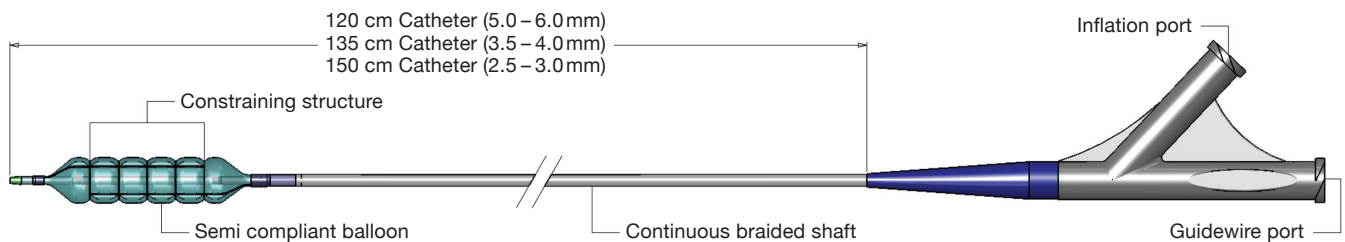
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The pillows and grooves of the Chocolate[®] platform were designed to minimize vessel wall trauma. This unique platform has been demonstrated to reduce flow limiting dissections and bail-out stenting*. Chocolate Touch[®] is coated with the drug paclitaxel for improved long-term outcomes. It is indicated to treat peripheral vascular disease and does not require pre-dilatation.

Features & Specifications	
Platform	Chocolate
Balloon Material	Nylon, semi-compliant
Constraining Structure	Nitinol
Drug	Paclitaxel
Delivery System	Over the wire
Catheter Length	150 cm (2.5 – 3.0 mm) 135 cm (3.5 – 4.0 mm) 120 cm (5.0 – 6.0 mm)
Entry Profile	0.020"

Ordering Information

Balloon Diameter	Balloon Length	Guidewire	Introducer Sheath	Nominal Pressure	Rated Burst Pressure	Reference Number
2.5 mm	40 mm	0.014"	5F	10 atm	14 atm	CN14-150-25040 OTW
2.5 mm	80 mm	0.014"	5F	10 atm	14 atm	CN14-150-25080 OTW
2.5 mm	120 mm	0.014"	5F	10 atm	14 atm	CN14-150-25120 OTW
3.0 mm	40 mm	0.014"	5F	10 atm	14 atm	CN14-150-30040 OTW
3.0 mm	80 mm	0.014"	5F	10 atm	14 atm	CN14-150-30080 OTW
3.0 mm	120 mm	0.014"	5F	10 atm	14 atm	CN14-150-30120 OTW
3.5 mm	40 mm	0.014"	5F	10 atm	14 atm	CN14-135-35040 OTW
3.5 mm	80 mm	0.014"	5F	10 atm	14 atm	CN14-135-35080 OTW
3.5 mm	120 mm	0.014"	5F	10 atm	14 atm	CN14-135-35120 OTW
4.0 mm	40 mm	0.014"	6F	9 atm	14 atm	CN14-135-40040 OTW
4.0 mm	80 mm	0.014"	6F	9 atm	14 atm	CN14-135-40080 OTW
4.0 mm	120 mm	0.014"	6F	9 atm	14 atm	CN14-135-40120 OTW
5.0 mm	40 mm	0.018"	6F	8 atm	12 atm	CN18-120-50040 OTW
5.0 mm	80 mm	0.018"	6F	8 atm	12 atm	CN18-120-50080 OTW
5.0 mm	120 mm	0.018"	6F	8 atm	12 atm	CN18-120-50120 OTW
6.0 mm	40 mm	0.018"	7F	8 atm	12 atm	CN18-120-60040 OTW
6.0 mm	80 mm	0.018"	7F	8 atm	12 atm	CN18-120-60080 OTW
6.0 mm	120 mm	0.018"	7F	8 atm	12 atm	CN18-120-60120 OTW



Indications for use

The Chocolate Touch® Paclitaxel Drug-Coated PTA Balloon Catheter is coated with the anti-restenotic drug paclitaxel and 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
- Pregnant or breast feeding women or patients with known hypersensitivity to Paclitaxel

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 Chocolate Touch® Paclitaxel Drug-Coated 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.

* Data on file at TriReme Medical, LLC

Manufactured and Distributed by:
 TriReme Medical LLC.
 7060 Koll Center Parkway, Suite 300
 Pleasanton, California 94566 USA
 Toll Free: +1 888 553 8555
 Fax: +1 925 931 1363
 Tel: +1 925 931 1300

info@trirememedical.com
www.trirememedical.com

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

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