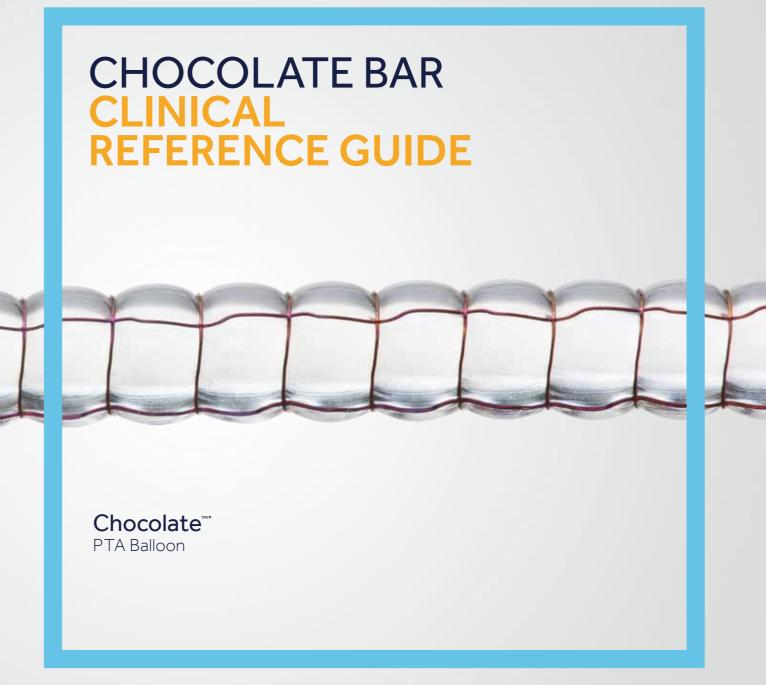
Chocolate^{™*} PTA Balloon

ORDERING INFORMATION							
Product code	Balloon diameter (mm)	Balloon length (mm)	Shaft length (cm)	Guidewire (in)	Introducer sheath (F)	Nominal pressure (atm)	Rated burst pressure (atm)
CB1415025040OTW		40					
CB1415025080OTW	2.5	80					
CB1415025120OTW		120	150				
CB1415030040OTW		40	150				
CB1415030080OTW	3.0	80					
CB1415030120OTW		120		0.014"	5	9	14
CB1413535040OTW		40		0.014	5	5	14
CB1413535080OTW	3.5	80					
CB1413535120OTW		120	135				
CB1413540040OTW		40	155				
CB1413540080OTW	4.0	80					
CB1413540120OTW		120					
CB1812050040OTW		40					
CB1812050080OTW	5.0	80					
CB1812050120OTW		120	120	0.018"	6	6	12
CB1812060040OTW		40	120	0.018	0	0	12
CB1812060080OTW	6.0	80					
CB1812060120OTW		120					

Important Information: Indications, contraindications, warnings, and instructions for use can be found in the product labeling supplied with each device.

Indications for Use: The Chocolate[™] PTA Balloon Catheter is intended for balloon dilatation of lesions in the peripheral vasculature, including the iliac, femoral, iliofemoral, popliteal, infrapopliteal, and renal arteries.

CLINICAL



Medtronic

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medtronic.com/peripheral Bench test data on file at TriReme Medical. Data not indicative of clinical performance.



CHOCOLATE BAR STUDY DESIGN

CHOCOLATE BAR CLINICAL OUTCOMES

33 sites

ALL-COMERS

ATK Cohort 262 subjects • 12-month follow-up

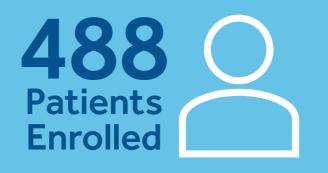


TOTAL OCCLUSION

BTK Cohort

226 subjects = 6-month follow-up





Baseline Clinical Characteristics

Characteristic	ATK[†] subjects (N = 262)	BTK subjects (N = 226)		
Age (yrs)	69.7	71.5		
Male	61.1% (160)	65.9% (149)		
Diabetes	50.4% (132)	58.8% (133)		
Rutherford Classification				
0 1 2 3	0% (0/262) 0.4% (1/262) 21.0% (55/262) 46.6% (122/262)	0.4% (1/226) 0.4% (1/226) 12.4% (28/226) 31.0% (70/226)		
Putherford Classification (CLL subjects)				

Rutherford Classification (CLI subjects)

4 13.070 (34/202) 10.170 (47/220) 5 19.1% (50/262) 33.6% (76/226) 6 0% (0/262) 4.0% (9/226)	4 5 6		. ,
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Lesion Characteristics

Characteristic	ATK[†] lesions (N = 265)	BTK lesions (N = 245)
Lesion Length (mm)	83.5	66.0
сто	23.0% (60/261)	41.1% (99/241)
Calcification None/Mild Moderate Severe	36.5% (93/255) 43.5% (111/255) 20.0% (51/255)	67.7% (155/229) 30.1% (69/229) 2.2% (5/229)



)% **Flow-limiting Dissections**

Chocolate Bar Registry Outcomes¹

Primary Study Endpoint	ATK	втк
Achieved ≤ 30% Diameter Stenosis ^{**,††}	85.1%***	84.6%***
Procedural Success ^{tt}	ATK	BTK
Flow-limiting Dissections Type E Type F	0%*** 0%***	0%*** 0%***
Per Protocol Bailout Stents	1.6% ^{†††}	0.9% ^{†††}

[†]Many ATK patients had concurrent BTK disease

**Achievement of Optimal PTA Outcome: Percentage of cases in which < 30% diameter stenosis without a flow-limiting dissection is achieved.

⁺⁺Core lab-adjudicated.

**Based on lesion data. ⁺⁺Based on subject data.

¹ Data on file with Medtronic — CLR782: Final Study Report: The Chocolate BAR by TriReme Medical, LLC.



Predictable, Uniform and Atraumatic Dilatation



Clinical Outcomes¹ (Kaplan Meier)

	ATK [†] 12 months	BTK 6 months
Freedom from TLR	78.5%†††	88.9%†††
Freedom from Major Unplanned Amputation	97.2%†††	96.7%†††
Freedom from All-cause Mortality	93.3% ^{†††}	97.1%†††