

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	2.5	40	150	0.014"	5	9	14		
CB1415025080OTW		80							
CB1415025120OTW		120							
CB1415030040OTW	3.0	40							
CB1415030080OTW		80							
CB1415030120OTW		120							
CB1413535040OTW	3.5	40	135						
CB1413535080OTW		80							
CB1413535120OTW		120							
CB1413540040OTW	4.0	40	120						
CB1413540080OTW		80							
CB1413540120OTW		120							
CB1812050040OTW	5.0	40		120	0.018"	6	6	12	
CB1812050080OTW		80							
CB1812050120OTW		120							
CB1812060040OTW	6.0	40							120
CB1812060080OTW		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.

# CHOCOLATE BAR CLINICAL REFERENCE GUIDE




Chocolate™  
PTA Balloon

# CHOCOLATE BAR STUDY DESIGN

33 sites

488  
Patients  
Enrolled



## ALL-COMERS

### ATK Cohort

262 subjects ■ 12-month follow-up

LESION LENGTH **8.35 cm**    DIABETES **50.4%**

CLI **32.1%**    TOTAL OCCLUSION **23%**

### BTK Cohort

226 subjects ■ 6-month follow-up

LESION LENGTH **6.6 cm**    DIABETES **58.8%**

CLI **55.8%**    TOTAL OCCLUSION **41.1%**

### Baseline Clinical Characteristics

Characteristic	ATK <sup>†</sup> 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	0% (0/262)	0.4% (1/226)
1	0.4% (1/262)	0.4% (1/226)
2	21.0% (55/262)	12.4% (28/226)
3	46.6% (122/262)	31.0% (70/226)

### Rutherford Classification (CLI subjects)

4	13.0% (34/262)	18.1% (41/226)
5	19.1% (50/262)	33.6% (76/226)
6	0% (0/262)	4.0% (9/226)

### Lesion Characteristics

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

# CHOCOLATE BAR CLINICAL OUTCOMES

Predictable, Uniform and Atraumatic Dilatation



0%  
Flow-limiting Dissections

< 2%  
ATK/BTK  
Bailout Stenting

### Chocolate Bar Registry Outcomes<sup>1</sup>

Primary Study Endpoint	ATK	BTK
Achieved ≤ 30% Diameter Stenosis <sup>**††</sup>	85.1% <sup>***</sup>	84.6% <sup>***</sup>
Procedural Success <sup>††</sup>	ATK	BTK
Flow-limiting Dissections		
Type E	0% <sup>***</sup>	0% <sup>***</sup>
Type F	0% <sup>***</sup>	0% <sup>***</sup>
Per Protocol Bailout Stents	1.6% <sup>†††</sup>	0.9% <sup>†††</sup>

### Clinical Outcomes<sup>1</sup> (Kaplan Meier)

	ATK <sup>†</sup> 12 months	BTK 6 months
Freedom from TLR	78.5% <sup>†††</sup>	88.9% <sup>†††</sup>
Freedom from Major Unplanned Amputation	97.2% <sup>†††</sup>	96.7% <sup>†††</sup>
Freedom from All-cause Mortality	93.3% <sup>†††</sup>	97.1% <sup>†††</sup>

<sup>†</sup>Many ATK patients had concurrent BTK disease.

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

<sup>††</sup>Core lab-adjudicated.

<sup>\*\*\*</sup>Based on lesion data.

<sup>†††</sup>Based on subject data.

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