96% success rate opening arterio-venous dialysis fistulae

Controlled compliance at high pressure

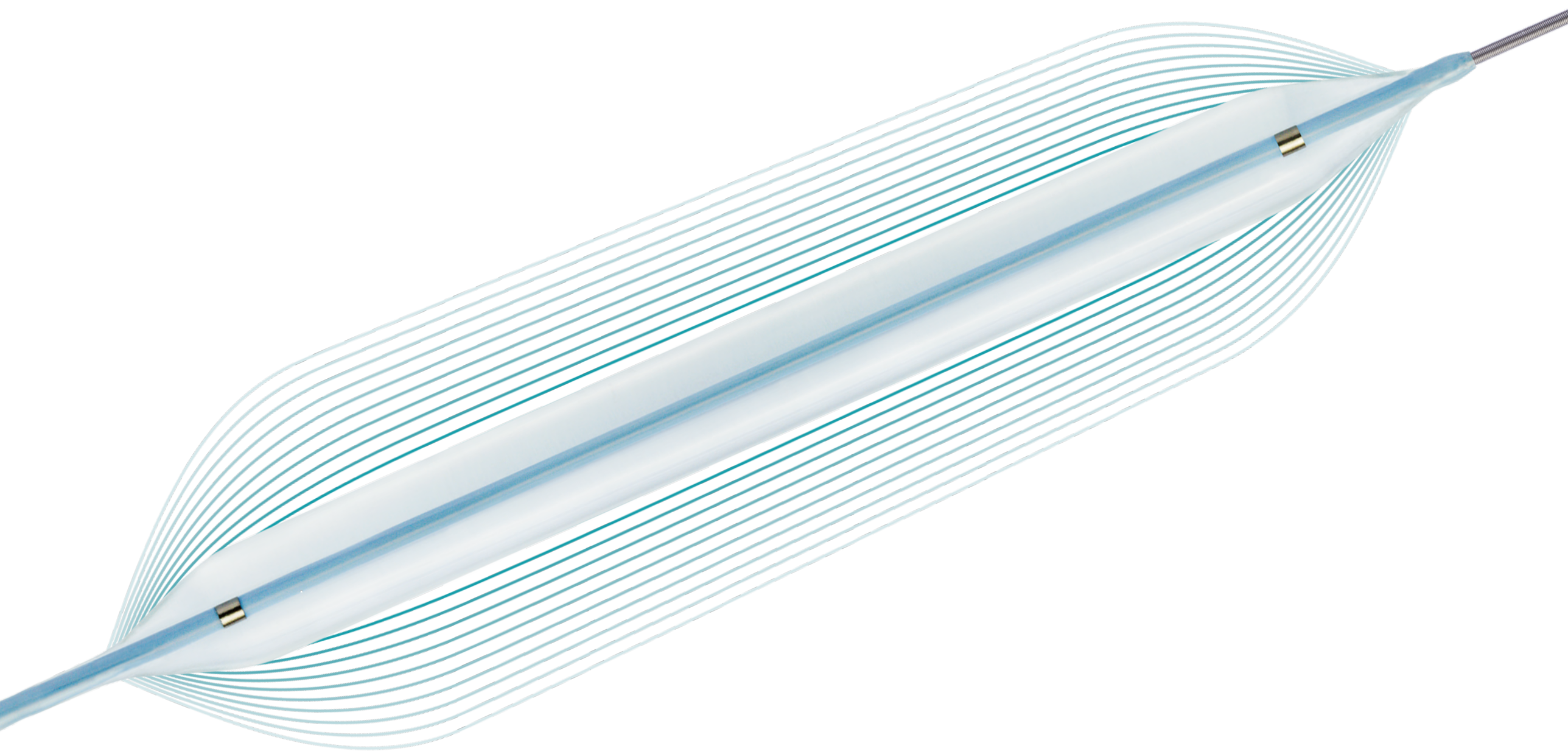
Minimizing vessel straightening

Technical data / ordering info

Vascular Intervention // Peripheral
High Pressure PTA Balloon Catheter/0.035”/OTW

BIOTRONIK
excellence for life

Passeo-35 HP

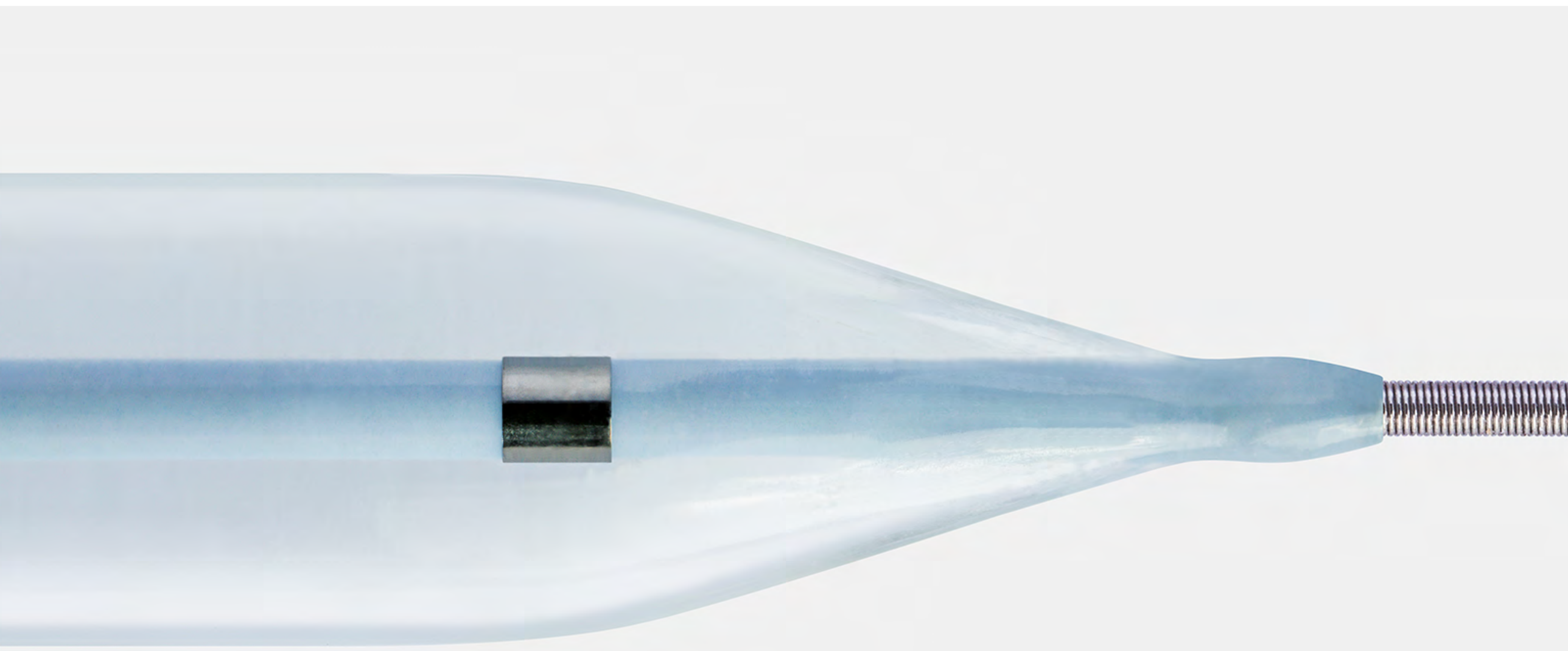


96% success rate opening arterio-venous dialysis fistulae[1]

Arterio-venous Dialysis Fistulae commonly require high pressure dilatations[2] due to the fibrotic-like morphology of these hemodialyses shunts. With a Rated Burst Pressure (RBP) of up to 27 atm, the highly flexible and conformable Passeo-35 HP reliably dilates these resistant lesions.

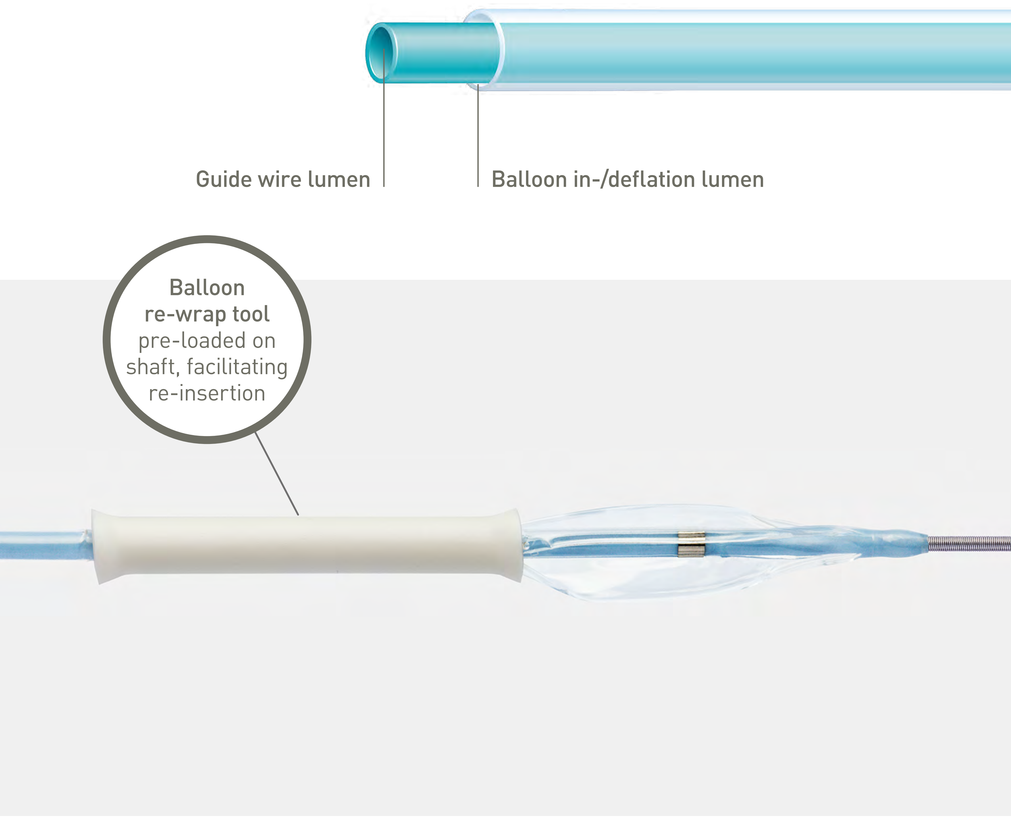
Controlled compliance at high pressure

Shape retention for precise dilatation.



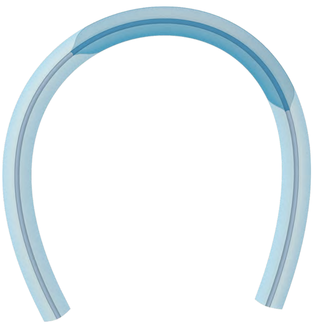
Coaxial catheter shaft designed for flexibility, strength and rapid deflation

Coaxial catheter shaft design offering advanced flexibility at high strength while supporting rapid deflation. A faster approach to treat long lesions.



Minimizing vessel straightening

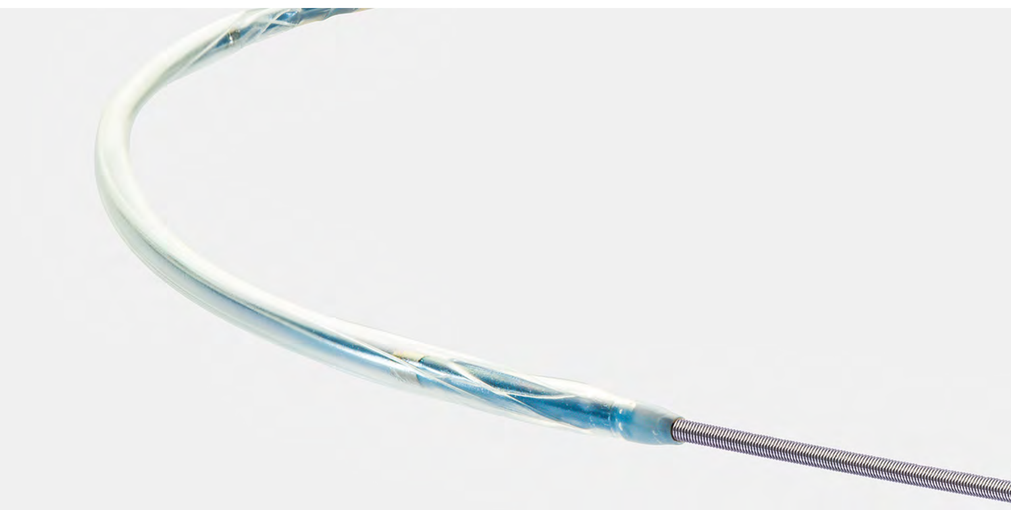
Proprietary balloon technology designed for conformability and flexibility. Delivering a vessel-friendly solution with impressively high RBP of up to 27 atm, dilating resistant lesions in complex anatomy.



Passeo-35 HP
8 mm x 80 mm

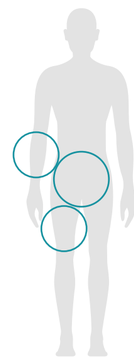
Bard Conquest
8 mm x 80 mm

Image showing deployed balloon in silicone tubing at 14 atm.[3]



Passeo-35 HP

Vascular Intervention Peripheral



Indicated for use in Percutaneous Transluminal Angioplasty of the femoral, iliac and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.*

Technical Data

Balloon catheter

Catheter type	OTW
Recommended guide wire	0.035”
Tip	Soft, short, tapered
Balloon material	Nylon/Pebax, controlled compliance
Balloon folding	3-fold (ø 3.0 - 9.0 mm); 5-fold (ø 10.0 - 12.0 mm)
Balloon markers	2 radiopaque markers
Sizes	ø 3.0 - 12.0 mm; L: 20 - 100 mm
Shaft	5.9F, coaxial
Usable length	40 cm and 75 cm

Compliance Chart

Balloon diameter x length (mm)

		ø 3.0 x 40	ø 4.0 x 20-40	ø 5.0 x 20-60	ø 6.0 x 20-100	ø 7.0 x 20-100	ø 8.0 x 20-80	ø 9.0 x 40	ø 10.0 x 40	ø 12.0 x 40
Nominal Pressure (NP)	atm**	14	14	14	14	14	14	12	12	12
	ø (mm)	3.11	4.01	5.01	6.05	6.93	7.98	8.96	10.02	11.86
Rated Burst Pressure (RBP)	atm**	27	27	27	25	23	22	20	20	18
	ø (mm)	3.42	4.41	5.46	6.56	7.45	8.50	9.66	10.78	12.41

**1 atm = 1.013 bar

Ordering Information

	Balloon ø (mm)	Catheter length 75 cm Balloon length (mm)					Catheter length 40 cm Balloon length (mm)
		20	40	60	80	100	40
6F	3.0	-	399077	-	-	-	-
	4.0	399078	399079	-	-	-	-
	5.0	399080	399081	399082	-	-	-
	6.0	399083	399084	399085	-	399086	399063
	7.0	399087	399088	399089	-	399090	399067
	8.0	399091	399092	399093	399094	-	399071
7F	9.0	-	399095	-	-	-	-
	10.0	-	399096	-	-	-	-
8F	12.0	-	399097	-	-	-	-

1. BIOTRONIK data on file. 2. Prospective study of balloon inflation pressures and other technical aspects of hemodialysis access angioplasty. Trerotola SO, Kwak A, Clark TW, et al. J Vasc Interv Radiol. 2005 Dec; 16(12): 1613-8. 3.Data on file at Creagh Medical.

*Australia: Not TGA approved for use within the renal and common iliac arteries.

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