Passeo-35 HP

High Pressure PTA Balloon/0.035"/OTW Indicated for arterio-venous dialysis fistulae Treatment of femoral, iliac¹ and renal¹ arteries





- Up to 27 atm to dilate resistant lesions in complex anatomy
- 96 % success rate opening arterio-venous dialysis fistulae²
- Controlled compliance for excellent stability during inflation
- Flexible and conformable minimizing vessel straightening
- ¹ Australia: Not TGA approved for use within the renal and common iliac arteries
- ² BIOTRONIK data on file (PME report, 2013)





Passeo-35 HP Cracking the most difficult challenge

A unique High Pressure PTA Balloon to dilate most resistant lesions in complex anatomy

Guide wire lumen

in-/deflation lumen

Balloon

Arterio-venous Dialysis Fistulae commonly require high pressure dilatations³ 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:

96 % success rate of opening Arterio-venous Dialysis Fistulae.²

Dilation of resistant lesions in complex anatomy

High pressure balloon in atm* (NP/RBP)

	Balloon ø (mm)		length 40 length (mn	*		
		20	40	60	80	100
•	3.0	-	14/27	-	-	-
	4.0	14/27	14/27	-	-	-
	5.0	14/27	14/27	14/27	-	-
	6.0	14/25	14/25	14/25	-	14/25
	7.0	14/23	14/23	14/23	-	14/23
	8.0	14/22	14/22	14/22	14/22	-
	9.0	-	12/20	-	-	-
	10.0	-	12/20	-	-	-
•	12.0	-	12/18	-	-	-

^{* 1} atm = 1.013 bar; NP = Normal Pressure; RBP = Rated Burst Pressure



Extraordinary one-piece molded hub delivering secure high-pressure fitting designed to support actual burst pressure up to 45 atm⁴.

Easy re-insertion

Coaxial catheter shaft

Balloon re-wrap tool, pre-loaded on shaft, facilitating easy re-insertion.

Controlled compliance for excellent stability

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.



Image showing deployed balloon in silicone tubing.⁵

Precise positioning

Two radiopaque markers at balloon shoulders quarantee precise balloon positioning.

³ Prospective study of balloon inflation pressures and other technical aspects of hemodialysis access angiopla Trerotola SO, Kwak A, Clark TW, et al. J Vasc Interv Radiol. 2005 Dec; 16(12): 1613-8.

Refer to compliance chart for RI

Passeo-35 HP

High Pressure PTA Balloon/0.035"/OTW

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 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	atm*	14	14	14	14	14	14	12	12	12
(NP)	ø (mm)	3.11	4.01	5.01	6.05	6.93	7.98	8.96	10.02	11.86
Rated Burst Pressure	atm*	27	27	27	25	23	22	20	20	18
(RBP)	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
	3.0	-	399077	-	-	-	-
	4.0	399078	399079	-	-	-	-
6F	5.0	399080	399081	399082	-	-	-
OF .	6.0	399083	399084	399085	-	399086	399063
	7.0	399087	399088	399089	-	399090	399067
	8.0	399091	399092	399093	399094	-	399071
7 E	9.0	-	399095	-	-	-	-
	10.0	-	399096	-	-	-	-
8F	12.0	-	399097	-	-	-	-

Passeo-35 HP is part of the BIOTRONIK 6F Solutions portfolio, including:

■ Introducer Sheath: Fortress ■ Balloons: Passeo-35 ■ Stents: Dynamic, Astron, Pulsar-35

For ordering please contact your local sales representative

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