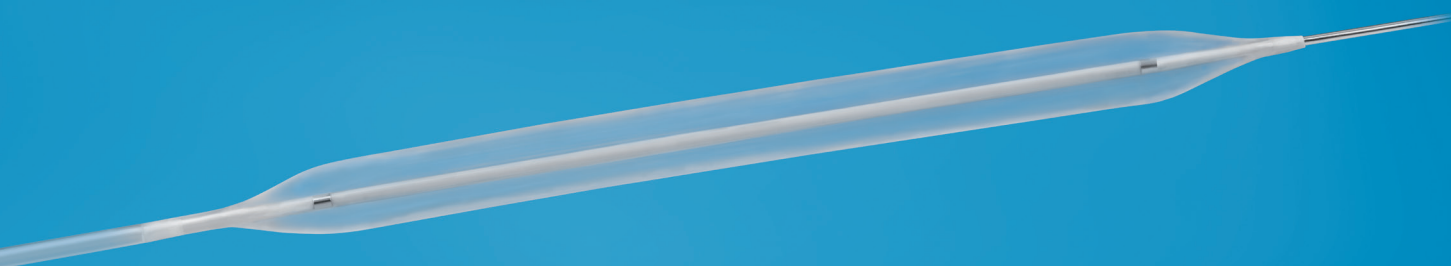
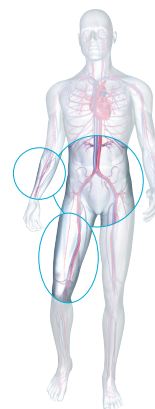


# Passeo-35 HP

High Pressure PTA Balloon/0.035"/OTW

Indicated for arterio-venous dialysis fistulae

Treatment of femoral, iliac<sup>1</sup> and renal<sup>1</sup> arteries



- Up to 27 atm to dilate resistant lesions in complex anatomy
- 96 % success rate opening arterio-venous dialysis fistulae<sup>2</sup>
- Controlled compliance for excellent stability during inflation
- Flexible and conformable minimizing vessel straightening

<sup>1</sup> Australia: Not TGA approved for use within the renal and common iliac arteries

<sup>2</sup> BIOTRONIK data on file (PME report, 2013)

# Passeo-35 HP

## Cracking the most difficult challenge

Arterio-venous Dialysis Fistulae commonly require high pressure dilatations<sup>3</sup> 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.<sup>2</sup>

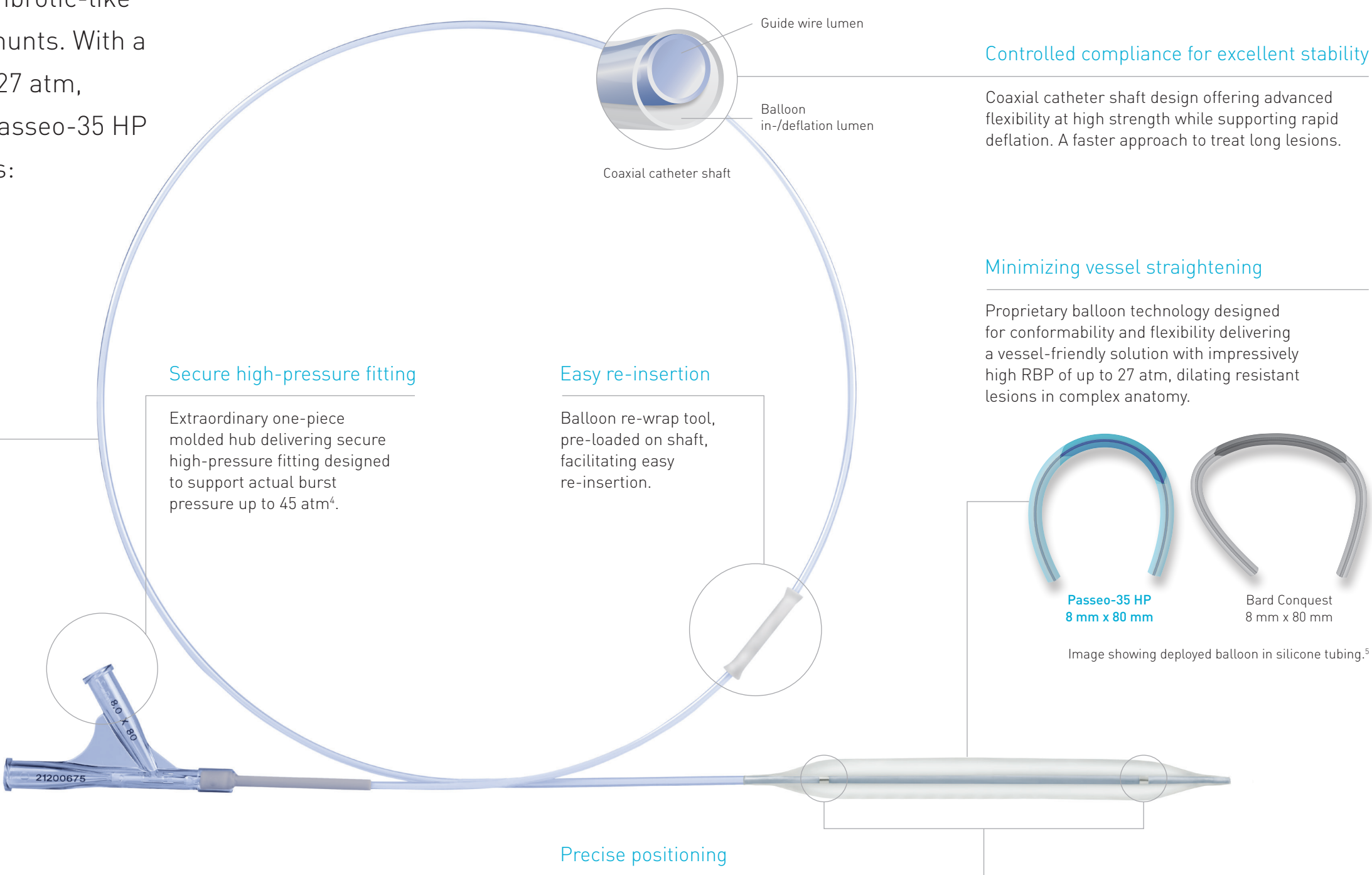
### Dilation of resistant lesions in complex anatomy

High pressure balloon in atm\* (NP/RBP)

Balloon ø (mm)	Catheter length 40, 75 cm Balloon length (mm)				
	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

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



<sup>3</sup> 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.

<sup>4</sup> Refer to compliance chart for RBP.

<sup>5</sup> Data on file at Creagh Medical

# 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 (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
		3.0	-	399077	-	-	-	-
		4.0	399078	399079	-	-	-	-
6F		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	-	-	-	-

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

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

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