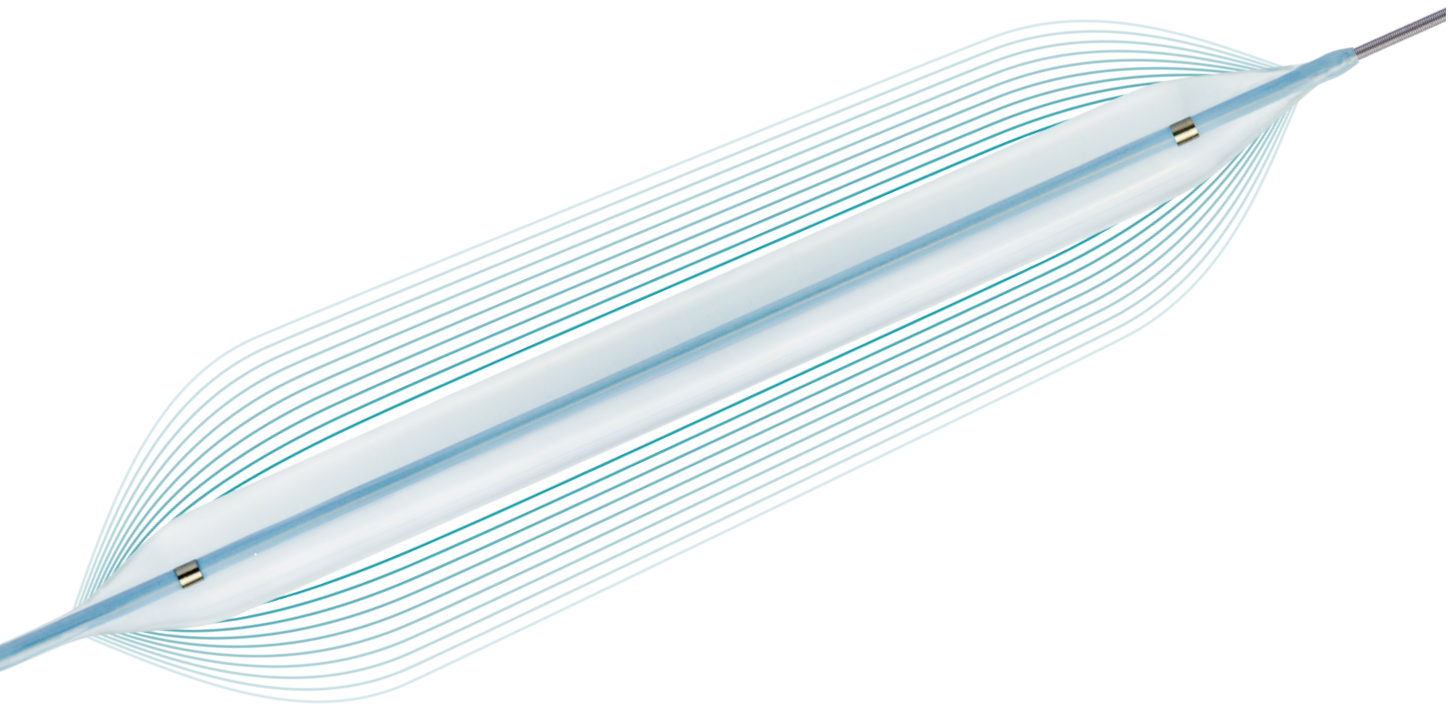


Vascular Intervention // **Peripheral**  
High Pressure PTA Balloon Catheter  
0.035"/OTW

# Passeo-35 HP



# Passeo-35 HP

## Cracking the most difficult challenge

Arterio-venous dialysis fistulae commonly require high pressure dilatation<sup>1</sup> due to the fibrotic-like morphology of these hemodialysis 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)

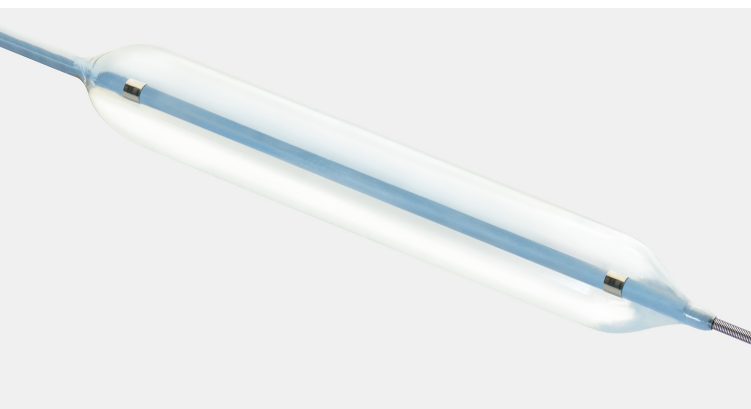
	Balloon ø (mm)	Catheter length 40, 75 cm Balloon length (mm)				
		20	40	60	80	100
	3.0	-	14/27	-	-	-
	4.0	14/27	14/27	-	-	-
6F	5.0	14/27	14/27	14/27	-	-
	6.0	14/25	14/25	14/25	-	14/25
	7.0	14/23	14/23	14/23	-	14/23
	8.0	14/22	14/22	14/22	14/22	-
7F	9.0	-	12/20	-	-	-
	10.0	-	12/20	-	-	-
8F	12.0	-	12/20	-	-	-

\*1 atm = 1.013 bar; NP = normal pressure; RBP = rated burst pressure



### Precise positioning

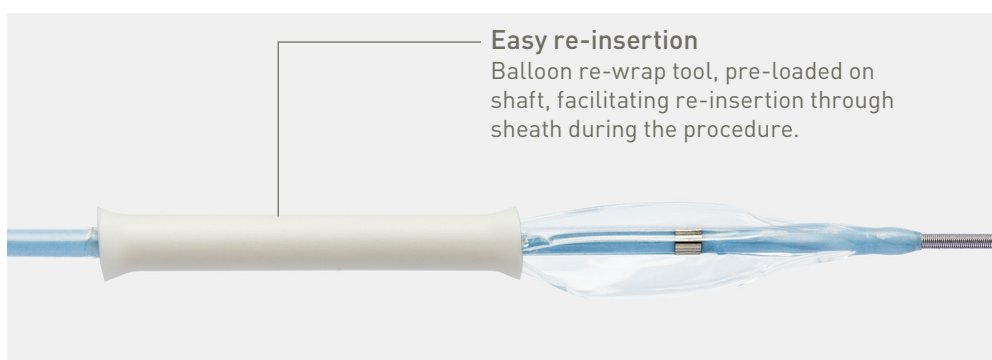
Two radiopaque markers at balloon shoulders enable precise balloon positioning.



# A unique high-pressure PTA balloon to dilate most resistant lesions in complex anatomy

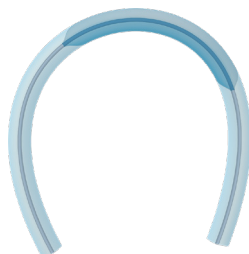
## Coaxial catheter shaft design

The coaxial catheter shaft is designed to offer advanced flexibility at high strength while supporting rapid balloon deflation. The coaxial design allows for a large lumen to enable contrast media solution to flow more quickly to and from the balloon.



## 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

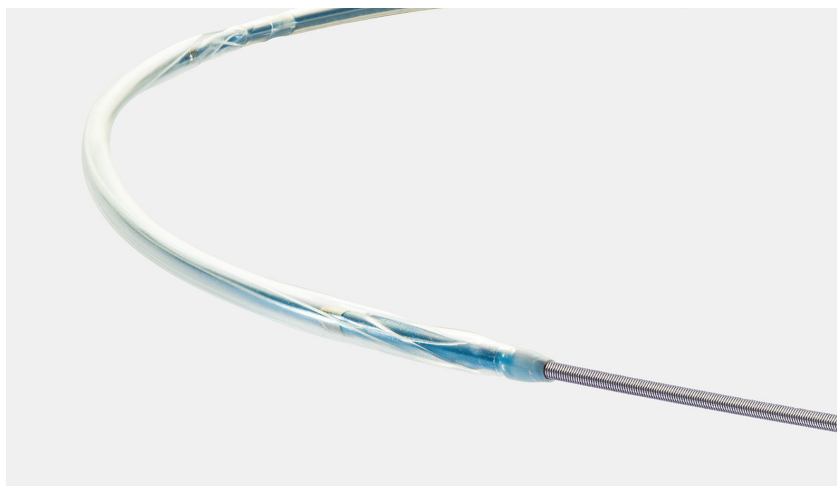


Image showing deployed balloon in silicone tubing.<sup>3</sup>

\* Conquest is a registered trademark of Bard Peripheral Vascular, Inc.

# Passeo-35 HP

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 arterio-venous dialysis fistulae

Vascular  
Intervention  
Peripheral



## 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. 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.
2. Successful dilatation defined as full balloon dilation during treatment - BIOTRONIK data on file (PME report, 2013);
3. Data on file at Creagh Medical



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