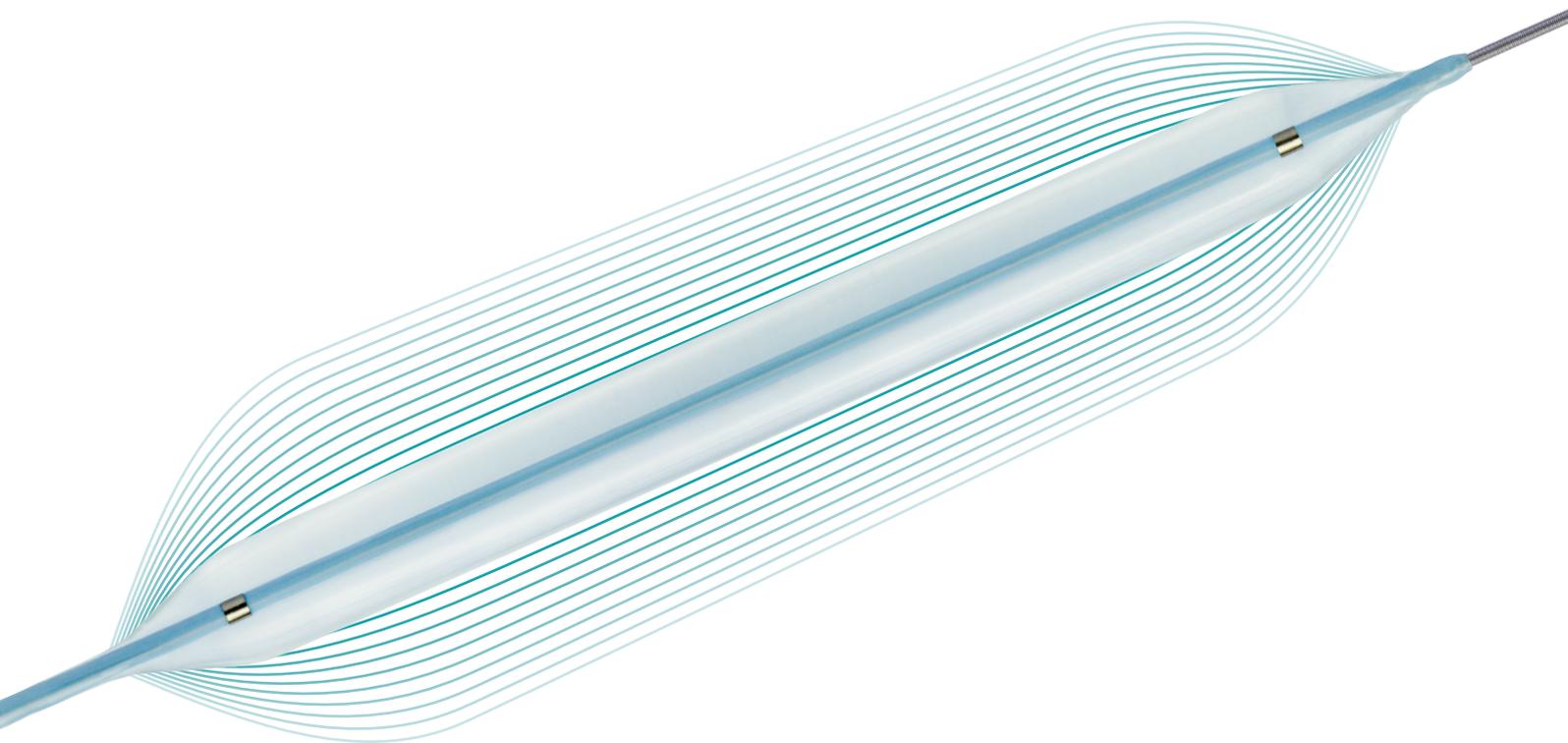


Vascular Intervention // **Peripheral**
High Pressure PTA Balloon Catheter / 0.035" / OTW

Passeo-35 HP



96% success rate opening
arterio-venous dialysis fistulae



Controlled compliance at high pressure



Minimizing vessel straightening

Passeo-35 HP

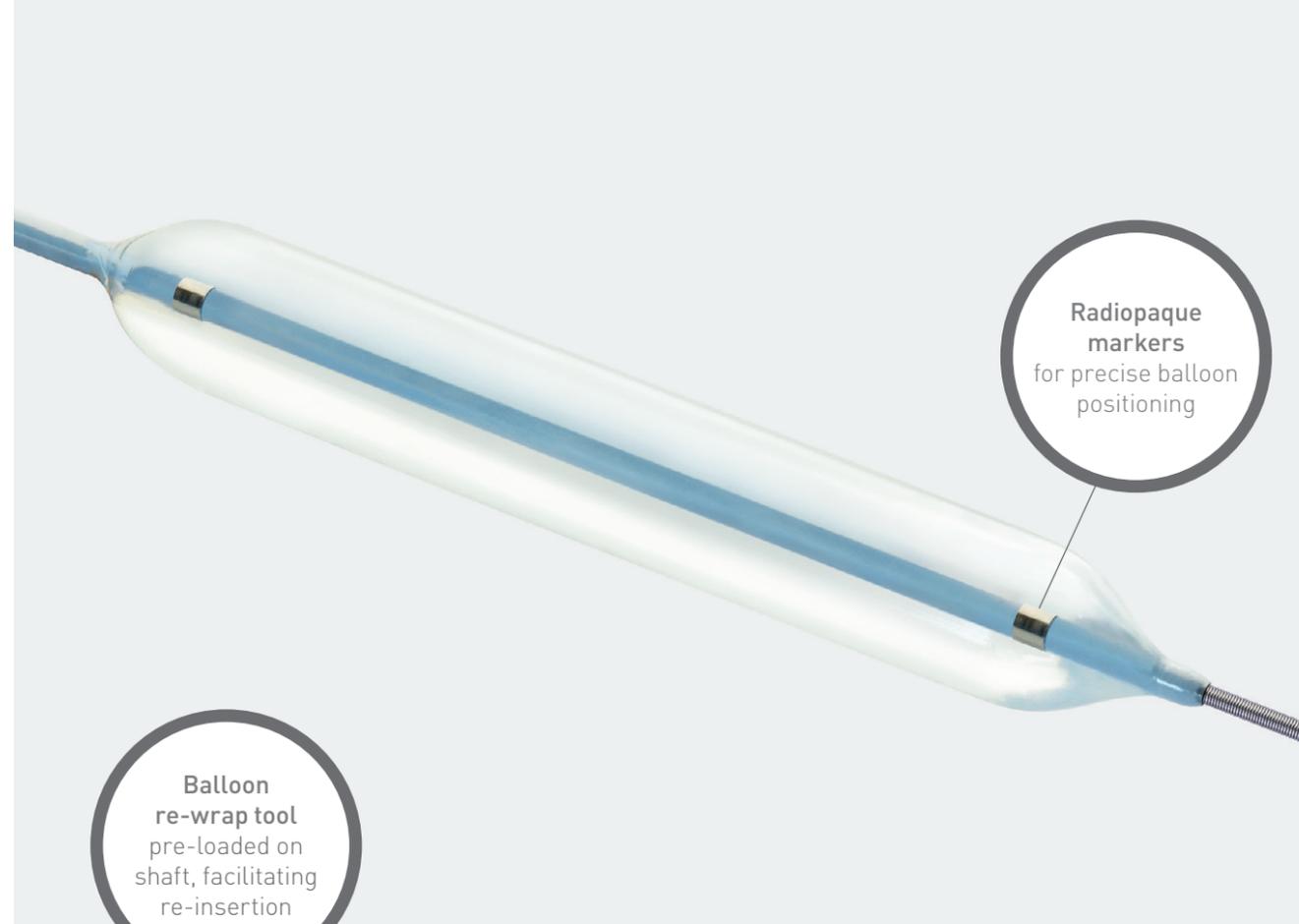
Controlled compliance with flexibility and conformability to minimize straightening.

96% success rate opening arterio-venous dialysis fistulae¹

Arterio-venous Dialysis Fistulae commonly require high pressure dilatations² 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.

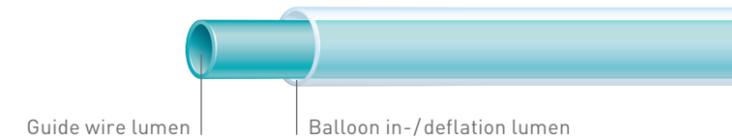
Controlled compliance at high pressure

Shape retention for precise dilatation.



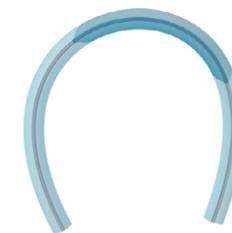
Coaxial catheter shaft designed for flexibility, strength and rapid deflation

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 |
| | 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 | - | - | - | - |

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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