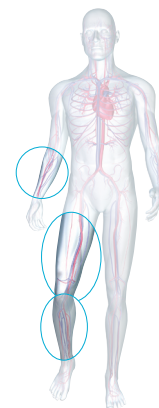


Passeo-18

PTA Balloon/0.018"/OTW

Indicated to dilate stenosis in the femoral, popliteal and infrapopliteal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae



- Highly pushable coaxial shaft design for access to distal lesions
- Predictable balloon expansion (controlled compliance)
- Low profile, wide size range: \varnothing 2 - 7 mm and 20 - 200 mm balloon lengths
- Patchwork coating designed to facilitate crossing

Passeo-18

The Passeo-18 features a coaxial shaft design with a strong inner shaft to support pushability and a flexible outer shaft to facilitate deliverability. Its wide array of available sizes enables treatment of both femoral and infrapopliteal disease.

Highly pushable coaxial shaft design

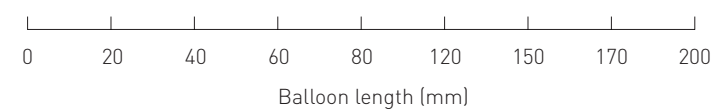
The available low profile 3.8F coaxial catheter shaft design facilitates access to distal lesions and allows reduction of access site complications¹ through the ability to use a 4F access sheath.

Low profile and wide array of sizes

Available balloon diameters/lengths
 ø 2.0 - 5.0 mm

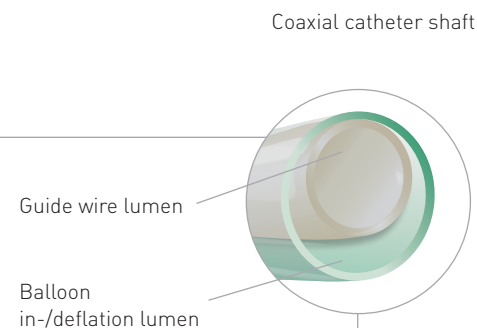


ø 6.0 mm - 7.0 mm



Tip

Smooth tapered tip entry profile promotes lesion crossing.



A versatile PTA Balloon to treat a broad range of vascular disease

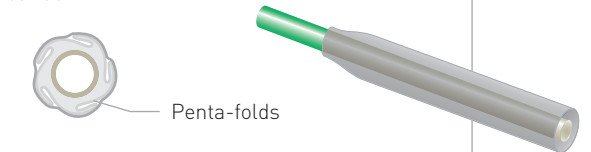
Controlled compliance

The innovative balloon design and semi-crystalline polymer (SCP) material enable a predictable balloon compliance rate. This controlled compliance is designed to minimize the risk of dissection due to balloon over-dilatation.

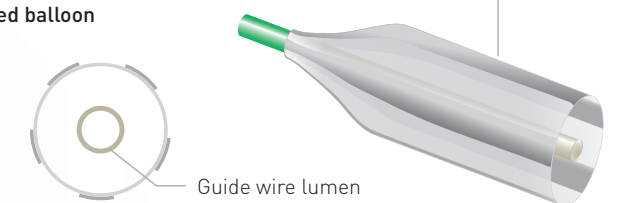
Patchwork coating

The penta-fold balloon is coated in a folded state, exposing uncoated balloon sections when inflated. This is intended to facilitate crossing while minimizing slippage during inflation.

Deflated balloon



Inflated balloon



■ Hydrophobic coating
 ■ Uncoated

¹ Bosiers M, Deloose K, Callaert J, et al. 4-French-compatible endovascular material is safe and effective in the treatment of femoropopliteal occlusive disease: results of the 4-EVER trial. J Endovasc Ther. 2013; 20(6): 746-756.

Passeo-18 – PTA Balloon/0.018"/OTW

| Technical Data | Balloon catheter |
|------------------------|---|
| Catheter type | OTW |
| Recommended guide wire | 0.018" |
| Tip | Short and tapered, colored |
| Balloon material | SCP (Semi-Crystalline Polymer), controlled compliance (4 - 8 %) |
| Balloon folding | 5-fold |
| Balloon coating | Hydrophobic patchwork coating |
| Balloon markers | 2 swaged markers (zero profile) |
| Sizes | ø 2.0 - 7.0 mm; L: 20 - 200 mm |
| Shaft | 3.8F, 3.9F (ø 6.0/7.0 mm x 170 - 200 mm); coaxial design |
| Usable length | 90, 130 and 150 cm |

| | | Balloon diameter x length (mm) | | | | | | | | | | | | | | | |
|----------------------------|------------------|--------------------------------|-------------|----------------|-------------|----------------|-------------|----------------|-------------|----------------|-----------------|----------------|-------------|-----------------|----------------|----------------|--|
| | | ø 2.0 x 20-170 | ø 2.0 x 200 | ø 2.5 x 20-170 | ø 2.5 x 200 | ø 3.0 x 20-170 | ø 3.0 x 200 | ø 3.5 x 20-170 | ø 3.5 x 200 | ø 4.0 x 20-150 | ø 4.0 x 170-200 | ø 5.0 x 20-120 | ø 5.0 x 150 | ø 5.0 x 170-200 | ø 6.0 x 20-200 | ø 7.0 x 20-200 | |
| Nominal Pressure (NP) | atm ² | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | |
| | ø (mm) | 2.0 | 2.0 | 2.5 | 2.5 | 3.0 | 3.0 | 3.5 | 3.5 | 4.0 | 4.0 | 5.0 | 5.0 | 5.0 | 6.0 | 7.0 | |
| Rated Burst Pressure (RBP) | atm ² | 15 | 14 | 15 | 14 | 15 | 14 | 15 | 14 | 15 | 13 | 15 | 12 | 13 | 12 | 12 | |
| | ø (mm) | 2.1 | 2.1 | 2.6 | 2.6 | 3.2 | 3.2 | 3.7 | 3.7 | 4.3 | 4.2 | 5.3 | 5.2 | 5.2 | 6.2 | 7.3 | |

² 1 atm = 1.013 bar

| Ordering Information | Catheter Length (cm) | Balloon ø (mm) | Balloon Length (mm) | | | | | | | | | |
|----------------------|----------------------|----------------|---------------------|---------------------|---------------------|---------------------|---------------------|---------------------|---------------------|---------------------|---------------------|---------------------|
| | | | 20 | 40 | 60 | 80 | 120 | 150 | 170 | 200 | | |
| Antegrade approach | 4F | 90 | 2.0 | 366098 ³ | 366099 ³ | 366100 ³ | 366104 ³ | 366105 ³ | 366106 ³ | 366114 ³ | 376276 ³ | |
| | | 90 | 2.5 | 357451 | 357458 | 366101 ³ | 357469 | 357476 | 366107 ³ | 357483 | 376277 ³ | |
| | 5F | 90 | 3.0 | 357452 | 357459 | 366102 | 357470 | 357477 | 366108 ³ | 357484 | 376278 ³ | |
| | | 90 | 3.5 | 357453 ³ | 357460 | 366103 ³ | 357471 ³ | 357478 ³ | 366109 ³ | 357485 ³ | 376279 ³ | |
| | 90 | 4.0 | 357454 | 357461 | 357465 | 357472 | 357479 | 366110 ³ | 376272 ³ | 376280 ³ | | |
| | | 90 | 5.0 | 357455 | 357462 | 357466 | 357473 | 357480 | 366111 ³ | 376273 ³ | 376281 | |
| | 90 | 6.0 | 357456 | 357463 | 357467 | 357474 | 357481 ³ | 366112 ³ | 376274 ³ | 376282 ³ | | |
| | | 90 | 7.0 | 357457 ³ | 357464 | 357468 ³ | 357475 ³ | 357482 ³ | 366113 ³ | 376275 ³ | 376283 ³ | |
| | Retrograde approach | 4F | 150 | 2.0 | 366115 ³ | 366118 | 366119 ³ | 366123 | 366126 | 366129 | 366137 | 376296 ³ |
| | | | 130 | 2.5 | 357486 ³ | 357491 | 366120 ³ | 357502 | 357507 | 366130 | 357512 | 376297 |
| 5F | | 130 | 3.0 | 357487 ³ | 357492 | 366121 | 357503 | 357508 | 366131 | 357513 | 376298 | |
| | | 130 | 3.5 | 357488 ³ | 357493 ³ | 366122 ³ | 357504 ³ | 357509 ³ | 366132 ³ | 357514 ³ | 376299 ³ | |
| 130 | | 4.0 | 357489 ³ | 357494 | 357498 | 357505 | 357510 | 366133 | 376292 ³ | 376300 ³ | | |
| | | 130 | 5.0 | 357490 | 357495 | 357499 | 357506 | 357511 | 366134 | 376293 ³ | 376301 | |
| 130 | | 6.0 | 366116 ³ | 357496 | 357500 | 366124 | 366127 | 366135 ³ | 376294 ³ | 376302 ³ | | |
| | | 130 | 7.0 | 366117 ³ | 357497 | 357501 ³ | 366125 ³ | 366128 ³ | 366136 ³ | 376295 ³ | 376303 ³ | |

³ Size available upon special request

Passeo-18 is part of the BIOTRONIK **4F** Solutions portfolio, including:

- Introducer Sheath: **Fortress** ■ Balloons: **Passeo-14**

Manufacturer:
BIOTRONIK AG
Ackerstrasse 6
8180 Bülach · Switzerland
Tel +41 (0)44 8645111
Fax +41 (0)44 8645005
info.vi@biotronik.com
www.biotronik.com

Distributed in the US by:

MAQUET
GETINGE GROUP

Maquet Medical Systems USA
45 Barbour Pond Drive
Wayne, NJ 07470 USA
www.maquetusa.com

MCV00039790 REVA

BIOTRONIK
excellence for life