

# Passeo-14 Championing the challenge

Up to 73 % faster deflation time<sup>2</sup> due to state of the art catheter shaft design that creates a large balloon lumen facilitating rapid inflation and deflation. A faster approach to treat long lesions.

“Impressive deflation time!”

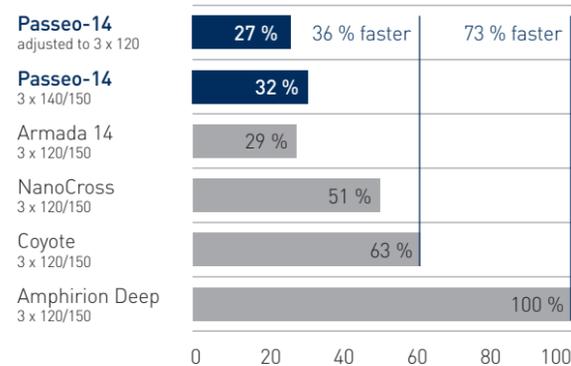
(Dr. M. A. De Gregorio Ariza, Saragossa, Spain, during initial product testing)

## Fast deflation times

Passeo-14<sup>3</sup> deflates:

- 73 % faster than Amphirion Deep
- 36 % faster than Coyote
- 24 % faster than NanoCross

Deflation time [%]



Delivering you the only forefront dedicated pedal design of:

- ø 1.5 - 2.0 mm, with
- 150 mm flexible distal shaft and
- tailored stiffening wire



Pre-treatment



Dilatation pedal arch



Dilatation plantar arch



Post dilatation

Courtesy of Dr. L. Steffanon, Vicenza, Italy

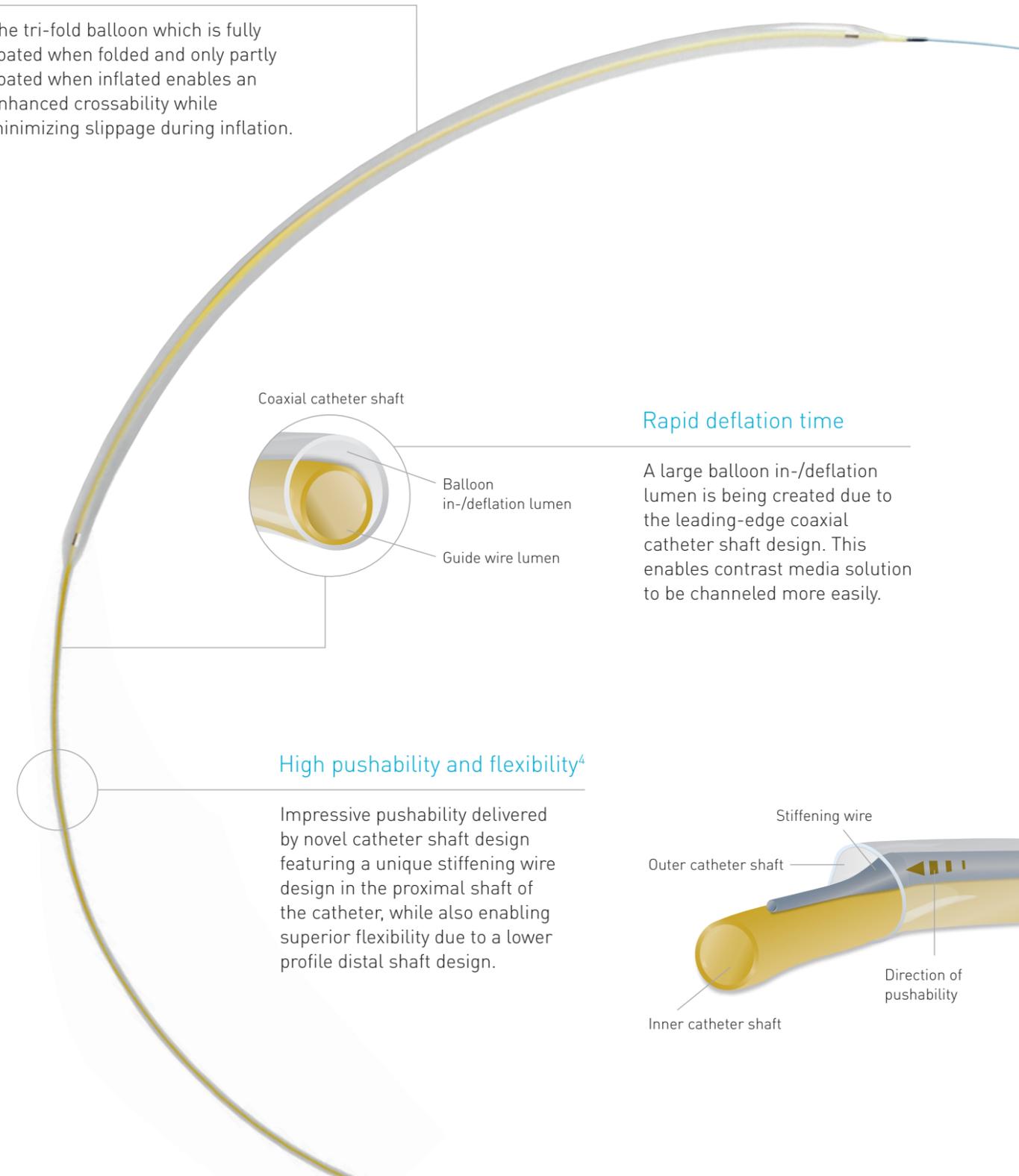
<sup>2,4</sup> BIOTRONIK data on file (IIB report 65/2012)

<sup>3</sup> Volume correction: the volume of a 3 x 120 mm balloon is 15 % less than the volume of the 3 x 140 mm balloon which can be directly correlated to the deflation time. Therefore the measured deflation time of 32 % can be reduced by 15 % which results in a volume corrected deflation time of 27 %.

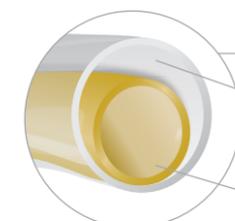
# A superb PTA Balloon to treat most complex lower limb lesions

## Enhanced crossability

The tri-fold balloon which is fully coated when folded and only partly coated when inflated enables an enhanced crossability while minimizing slippage during inflation.



Coaxial catheter shaft



Balloon in-/deflation lumen

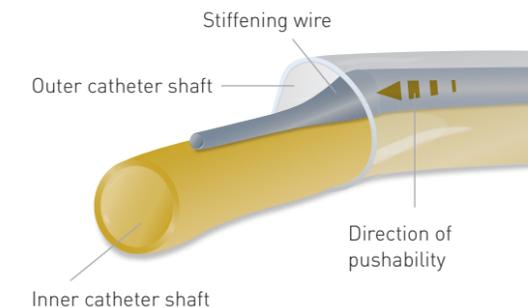
Guide wire lumen

## Rapid deflation time

A large balloon in-/deflation lumen is being created due to the leading-edge coaxial catheter shaft design. This enables contrast media solution to be channeled more easily.

## High pushability and flexibility<sup>4</sup>

Impressive pushability delivered by novel catheter shaft design featuring a unique stiffening wire design in the proximal shaft of the catheter, while also enabling superior flexibility due to a lower profile distal shaft design.



Stiffening wire

Outer catheter shaft

Inner catheter shaft

Direction of pushability

# Passéo-14

PTA Balloon/0.014"/OTW

## Technical Data

Ballon catheter	OTW
Catheter type	OTW
Recommended guide wire	0.014"
Tip	Optimized entry profile and colored
Ballon material	SCP (Semi-Crystalline Polymer), controlled compliance (4 - 6%)
Ballon folding	3-fold
Ballon coating	Hydrophilic patchwork coating
Ballon markers	2 swaged markers (zero profile)
Sizes	ø 1.5 - 4.0 mm; L: 20 - 220 mm
Distal shaft	3.1F, hydrophilic coating, coaxial design; 150 mm length (ø 1.5/2.0 x 20 - 100 mm); 75 mm length (ø 2.0 x 140 - 220 mm and ø 2.5 - 4.0 mm)
Proximal shaft	3.9F, hydrophobic coating, coaxial design; stiffening wire
Usable length	150 cm (ø 1.5 - 4.0 mm); 120 cm (ø 1.5 - 2.0 mm); 90 cm (ø 2.5 - 4.0 mm)

## Compliance Chart

Ballon diameter x length (mm)	atm*	NP] ø (mm)	Rated Burst Pressure atm	[RBP] ø (mm)
ø 1.5 x 20-70	7	1.5	14	1.57
ø 2.0 x 40-220	7	2.0	14	2.08
ø 2.5 x 40-220	7	2.5	14	2.61
ø 3.0 x 40-220	7	3.0	14	3.18
ø 3.5 x 40-140	7	3.5	14	3.63
ø 4.0 x 40-140	7	4.0	14	4.16

\* 1 atm = 1.013 bar

## Ordering Information

Catheter Length (cm)	Ballon ø (mm)	Ballon Length (mm)
120	1.5	380271s
120	2.0	380278
120	2.5	380279
120	3.0	380280
120	3.5	380281s
120	4.0	380282
90	1.5	380271s
90	2.0	380278
90	2.5	380279
90	3.0	380280
90	3.5	380281s
90	4.0	380282

## Antegrade approach

Catheter Length (cm)	Ballon ø (mm)	Ballon Length (mm)
150	1.5	380319s
150	2.0	380320
150	2.5	380321
150	3.0	380322
150	3.5	380323s
150	4.0	380324

## Crossover approach

Catheter Length (cm)	Ballon ø (mm)	Ballon Length (mm)
150	1.5	380342
150	2.0	380343
150	2.5	380344
150	3.0	380345
150	3.5	380346
150	4.0	380347

Passéo-14 is part of the BIOTRONIK 4F Solutions portfolio, including:

- Introducer Sheath: Fortress ■ Guide Wires: Cruiser, Cruiser-18 ■ Balloons: Passéo-18
- Stents: PRO-Kinetic Energy Explorer, Pulsar-18

For ordering please contact your local sales representative

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Vascular Intervention // Peripheral

# Passéo-14

PTA Balloon/0.014"/OTW  
 Indicated for lower limb arteries

LEVBEETH MEDICAL+



- Up to 73 % faster deflation times<sup>1</sup>
- The only forefront solution offering dedicated pedal sizes
- Enhanced crossability
- High pushability and flexibility

<sup>1</sup> vs. Amphion Deep

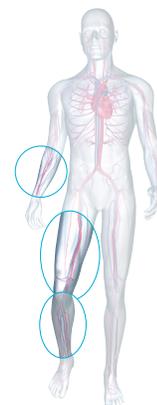
BIOTRONIK excellence for life

4F Solutions

# 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

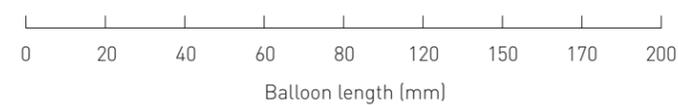
The available low profile 3.8F coaxial catheter shaft design facilitates access to distal lesions and allows reduction of access site complications<sup>1</sup> through the ability to use a 4F access sheath.

## Low profile and wide array of sizes

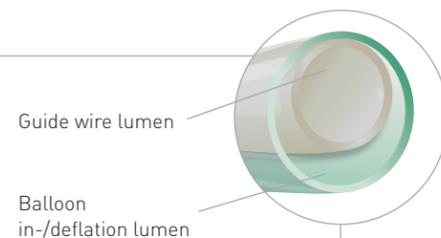
Available balloon diameters/lengths  
 ø 2.0 - 5.0 mm



ø 6.0 mm - 7.0 mm



Coaxial catheter shaft



# 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

## Tip

Smooth tapered tip entry profile promotes lesion crossing.



<sup>1</sup> 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 <sup>2</sup>	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 <sup>2</sup>	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	

<sup>2</sup> 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 <sup>3</sup>	366099 <sup>3</sup>	366100 <sup>3</sup>	366104 <sup>3</sup>	366105 <sup>3</sup>	366106 <sup>3</sup>	366114 <sup>3</sup>	376276 <sup>3</sup>
		90	2.5	357451	357458	366101 <sup>3</sup>	357469	357476	366107 <sup>3</sup>	357483	376277 <sup>3</sup>
		90	3.0	357452	357459	366102	357470	357477	366108 <sup>3</sup>	357484	376278 <sup>3</sup>
		90	3.5	357453 <sup>3</sup>	357460	366103 <sup>3</sup>	357471 <sup>3</sup>	357478 <sup>3</sup>	366109 <sup>3</sup>	357485 <sup>3</sup>	376279 <sup>3</sup>
		90	4.0	357454	357461	357465	357472	357479	366110 <sup>3</sup>	376272 <sup>3</sup>	376280 <sup>3</sup>
		90	5.0	357455	357462	357466	357473	357480	366111 <sup>3</sup>	376273 <sup>3</sup>	376281
		90	6.0	357456	357463	357467	357474	357481 <sup>3</sup>	366112 <sup>3</sup>	376274 <sup>3</sup>	376282 <sup>3</sup>
		90	7.0	357457 <sup>3</sup>	357464	357468 <sup>3</sup>	357475 <sup>3</sup>	357482 <sup>3</sup>	366113 <sup>3</sup>	376275 <sup>3</sup>	376283 <sup>3</sup>
		Retrograde approach	5F	150	2.0	366115 <sup>3</sup>	366118	366119 <sup>3</sup>	366123	366126	366129
130	2.5			357486 <sup>3</sup>	357491	366120 <sup>3</sup>	357502	357507	366130	357512	376297
130	3.0			357487 <sup>3</sup>	357492	366121	357503	357508	366131	357513	376298
130	3.5			357488 <sup>3</sup>	357493 <sup>3</sup>	366122 <sup>3</sup>	357504 <sup>3</sup>	357509 <sup>3</sup>	366132 <sup>3</sup>	357514 <sup>3</sup>	376299 <sup>3</sup>
130	4.0			357489 <sup>3</sup>	357494	357498	357505	357510	366133	376292 <sup>3</sup>	376300 <sup>3</sup>
130	5.0			357490	357495	357499	357506	357511	366134	376293 <sup>3</sup>	376301
130	6.0			366116 <sup>3</sup>	357496	357500	366124	366127	366135 <sup>3</sup>	376294 <sup>3</sup>	376302 <sup>3</sup>
130	7.0			366117 <sup>3</sup>	357497	357501 <sup>3</sup>	366125 <sup>3</sup>	366128 <sup>3</sup>	366136 <sup>3</sup>	376295 <sup>3</sup>	376303 <sup>3</sup>

<sup>3</sup> Size available upon special request

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

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

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417922/B/603/US

# Passeo-35

## Engineered excellence

Passeo-35 features a low profile design for 5F and 6F Sheath compatibility, a wide range of balloon diameters (3 - 10 mm) and lengths of up to 200 mm. Above all, with its puncture resistant balloon material, Passeo-35 competes in most calcified lesions.

### Low profile and wide range – as best in class

A comprehensive choice of 5F and 6F configurations.

Catheter 80, 90 and 130 cm

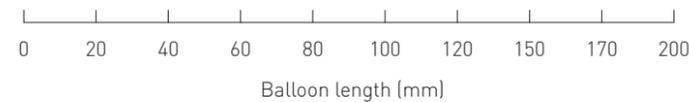
ø 3.0 - 7.0 mm



ø 8.0 mm



ø 9.0 - 10.0 mm



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

### Puncture resistant balloon material

A robustly engineered balloon that provides effective dilation; suitable for most calcified lesions.

Deflated balloon



Penta-folds



Inflated balloon



Guide wire lumen



■ Hydrophobic coating  
■ Uncoated

### Patchwork coating for enhanced crossability

The penta-fold balloon is fully coated when folded and only partly coated when inflated. This enables enhanced crossability while minimizing slippage during inflation of most calcified lesions.

### Shaft design

5F shaft for uncompromised flush capability and angiographic quality.

