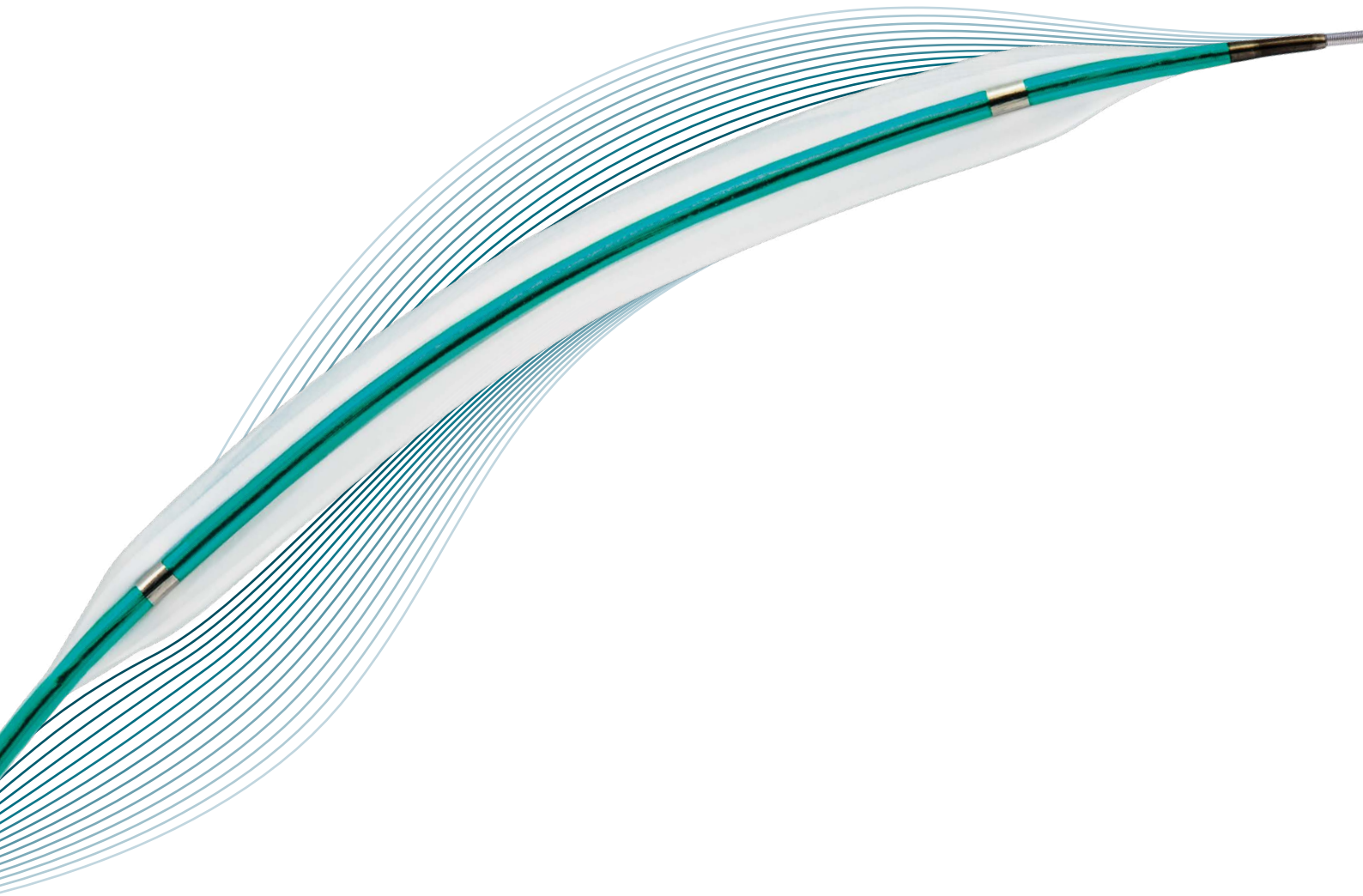




VI Product Catalogue

May 2020

Pantera[®] Pro



Lowest crossability in tight lesions



43% less friction during kissing
balloon technique



38% more push to reach target lesion

Pantera[®] Pro

Indicated for dilatation of coronary artery or bypass graft stenosis.*

Vascular
Intervention
Coronary



Technical Data	Proximal shaft
	Design Hypotube design
	Diameter 2.0F
	Shaft markers 92 cm and 102 cm from tip
Distal shaft	
	Guiding catheter 5F (min. I.D. 0.056" / 1.42 mm)
	Guide wire diameter 0.014"
	Lesion entry profile 0.017"
	Usable length 140 cm
	Balloon material Semi Crystalline Co-Polymer
	Balloon folding \varnothing 1.25 - 1.5 mm: Two-fold; \varnothing 2.0 - 4.0 mm: Tri-fold
	Balloon markers Platinum-Iridium: \varnothing 1.25 - 1.5 mm one marker; \varnothing 2.0 - 4.0 mm two markers
	Coating distal shaft Hydrophilic (end of balloon to Guide Wire (GW) exit port)
	Balloon and tip coating \varnothing 1.25 - 2.0 mm: Hydrophilic \varnothing 2.50 - 4.0 mm: Hydrophobic
	Kissing balloon technique 6F guiding catheter (min. I.D. 0.070" / 1.78 mm), up to \varnothing 3.5 mm
	Diameter 2.6F (\varnothing 1.25 - 2.0 mm); 2.7F (\varnothing 2.5 - 3.5 mm); 2.9F (\varnothing 4.0 mm)

Compliance Chart		Balloon diameter x length (mm)						
		\varnothing 1.25 x 6-20	\varnothing 1.50 x 6-20	\varnothing 2.00 x 10-30	\varnothing 2.50 x 10-30	\varnothing 3.00 x 10-30	\varnothing 3.50 x 10-30	\varnothing 4.00 x 10-30
Nominal Pressure (NP)	atm**	7	7	7	7	7	7	7
	\varnothing (mm)	1.24	1.49	2.01	2.49	3.08	3.62	3.95
Rated Burst Pressure (RBP)	atm**	14	14	14	14	14	14	14
	\varnothing (mm)	1.37	1.72	2.23	2.93	3.50	4.06	4.55

**1 atm = 1.013 bar

Ordering Information	Balloon \varnothing (mm)	Catheter length 140 cm Balloon length (mm)					
		6	10	15	20	25	30
	1.25	393289	393291	393298	393305	-	-
	1.50	393290	393292	393299	393306	-	-
	2.00	-	393293	393300	393307	393312	393317
	2.50	-	393294	393301	393308	393313	393318
	3.00	-	393295	393302	393309	393314	393319
	3.50	-	393296	393303	393310	393315	393320
	4.00	-	393297	393304	393311	393316	393321

5F

*Indication as per IFU.

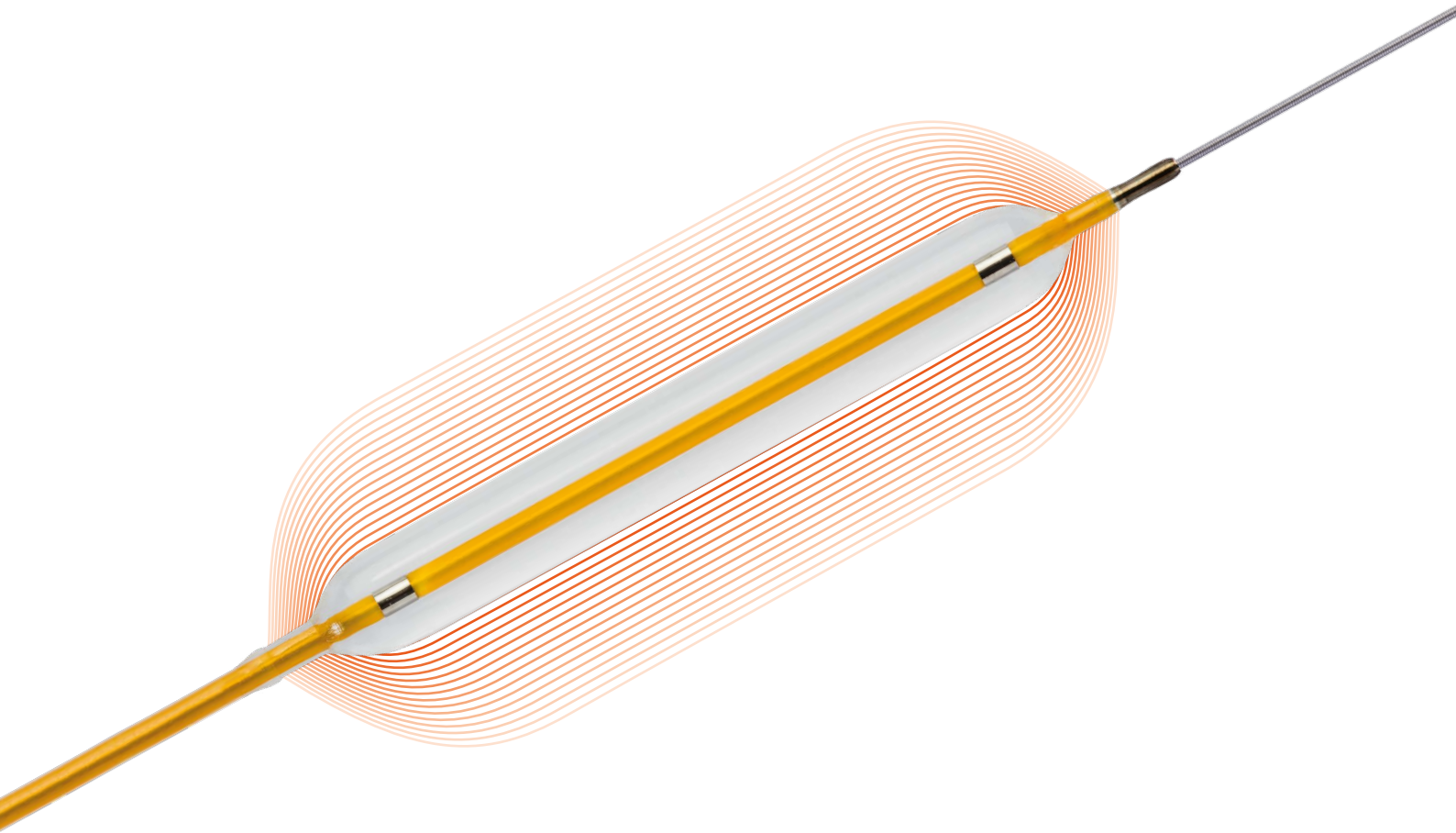
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Pantera[®] LE0



Lowest compliance in class
avoiding dog-bone effect



Precise dilatation



Enhanced crossability
and accurate placement

Pantera® LEO

Vascular
Intervention
Coronary



Indicated for stent post-dilatation and dilatation of a coronary artery or bypass graft stenosis.*

Technical Data		Proximal shaft	
Design		Hypotube design	
Diameter		2.0F	
Shaft markers		92 cm and 102 cm from tip	
Coating		Hydrophobic	
		Distal shaft	
Guiding catheter		5F (min. I.D. 0.056")	
Guide wire diameter		0.014"	
Lesion entry profile		0.018"	
Usable length		145 cm	
Distal shaft length		34 cm	
Balloon material		SCP (Semi Crystalline Polymer)	
Balloon folding		3-fold	
Balloon markers		Platinum-Iridium	
Coating		Hydrophilic (end of balloon to GW exit port); hydrophobic (balloon and tip)	
Diameter		2.6F (ø 2.0 - 3.75 mm); 2.7F (ø 4.0 - 5.0 mm)	

Compliance Chart		Balloon diameter x length (mm)										
		ø 2.00 x 8-30	ø 2.25 x 8-30	ø 2.50 x 8-30	ø 2.75 x 8-30	ø 3.00 x 8-30	ø 3.25 x 8-30	ø 3.50 x 8-30	ø 3.75 x 8-30	ø 4.00 x 8-30	ø 4.50 x 8-30	ø 5.00 x 8-30
Nominal Pressure (NP)	atm**	14	14	14	14	14	14	14	14	14	14	14
	ø (mm)	2.00	2.25	2.50	2.75	3.00	3.25	3.50	3.75	4.00	4.50	5.00
Rated Burst Pressure (RBP)	atm**	20	20	20	20	20	20	20	20	20	18	18
	ø (mm)	2.05	2.32	2.57	2.83	3.09	3.35	3.61	3.89	4.12	4.56	5.07

**1 atm = 1.013 bar

Ordering Information	Balloon ø (mm)	Catheter length 145 cm Balloon length (mm)				
		8	12	15	20	30
5F	2.00	366991	367002	367013	367024	367035
	2.25	366992	367003	367014	367025	367036
	2.50	366993	367004	367015	367026	367037
	2.75	366994	367005	367016	367027	367038
	3.00	366995	367006	367017	367028	367039
	3.25	366996	367007	367018	367029	367040
	3.50	366997	367008	367019	367030	367041
	3.75	366998	367009	367020	367031	367042
	4.00	366999	367010	367021	367032	367043
	4.50	367000	367011	367022	367033	367044
5.00	367001	367012	367023	367034	367045	

*Indication as per IFU.

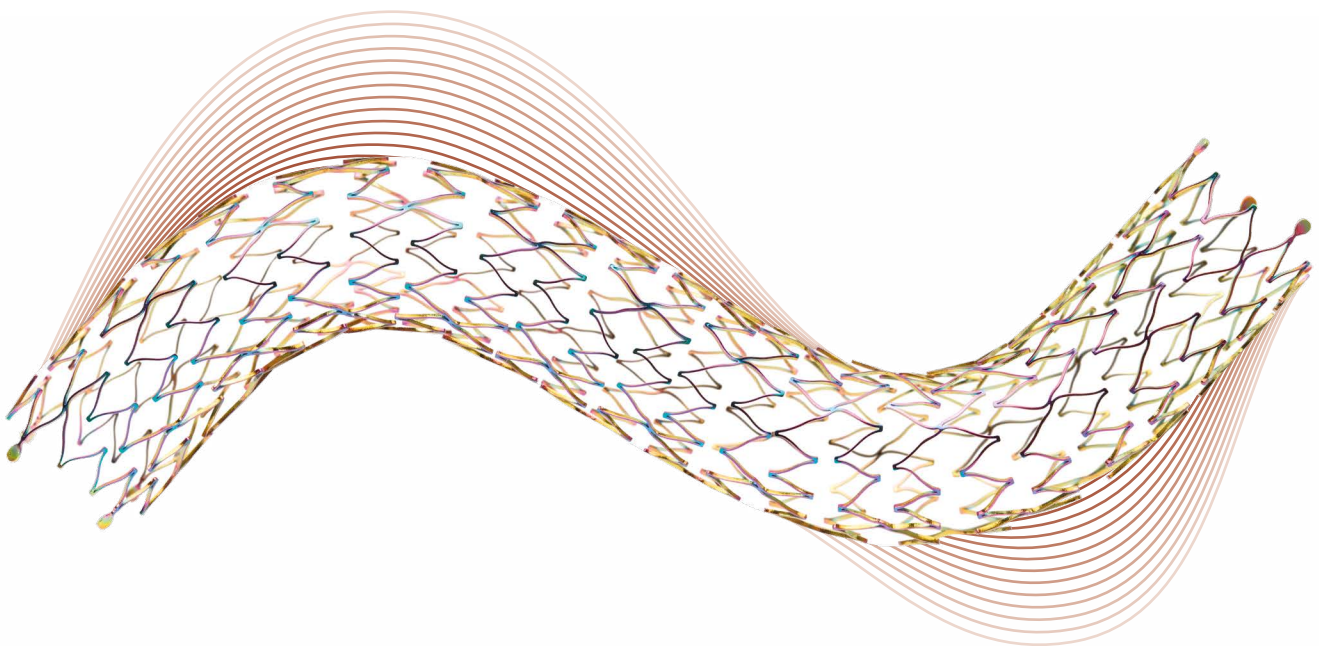
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excellence for life

Astron[®]



Clinically proven stent for the treatment of iliac disease



Pull-back delivery system for simple stent deployment



5.2F proximal shaft for contrast injection with device in sheath

Astron[®]

Vascular
Intervention
Peripheral



Indicated for use in patients with atherosclerotic disease of the iliac arteries and for the treatment of insufficient results after percutaneous transluminal angioplasty (PTA), e.g. residual stenosis and dissection.

Technical Data	Stent
Catheter type	OTW
Recommended guide wire	0.035"
Stent material	Nitinol
Strut thickness	225 µm (ø 10 mm = 230 µm)
Stent coating	proBIO [®] (Amorphous Silicon Carbide)
Stent markers	4 gold markers each end
Sizes	ø 7 - 10 mm; L: 30 - 80 mm
Proximal shaft	5.2F, hydrophobic coating
Usable length	70 and 120 cm

Ordering Information	Stent ø (mm)	Catheter length 70 cm Stent length (mm)			
		30	40	60	80
6F	7.0	343773	343774	343775	343776
	8.0	343777	343778	343779	343780
	9.0	343781	343782	343783	343784
	10.0	-	349214	349215	349216
6F	Stent ø (mm)	Catheter length 120 cm Stent length (mm)			
		30	40	60	80
	7.0	343785	343786	343787	343788
	8.0	343789	343790	343791	343792
9.0	343793	343794	343795	343796	

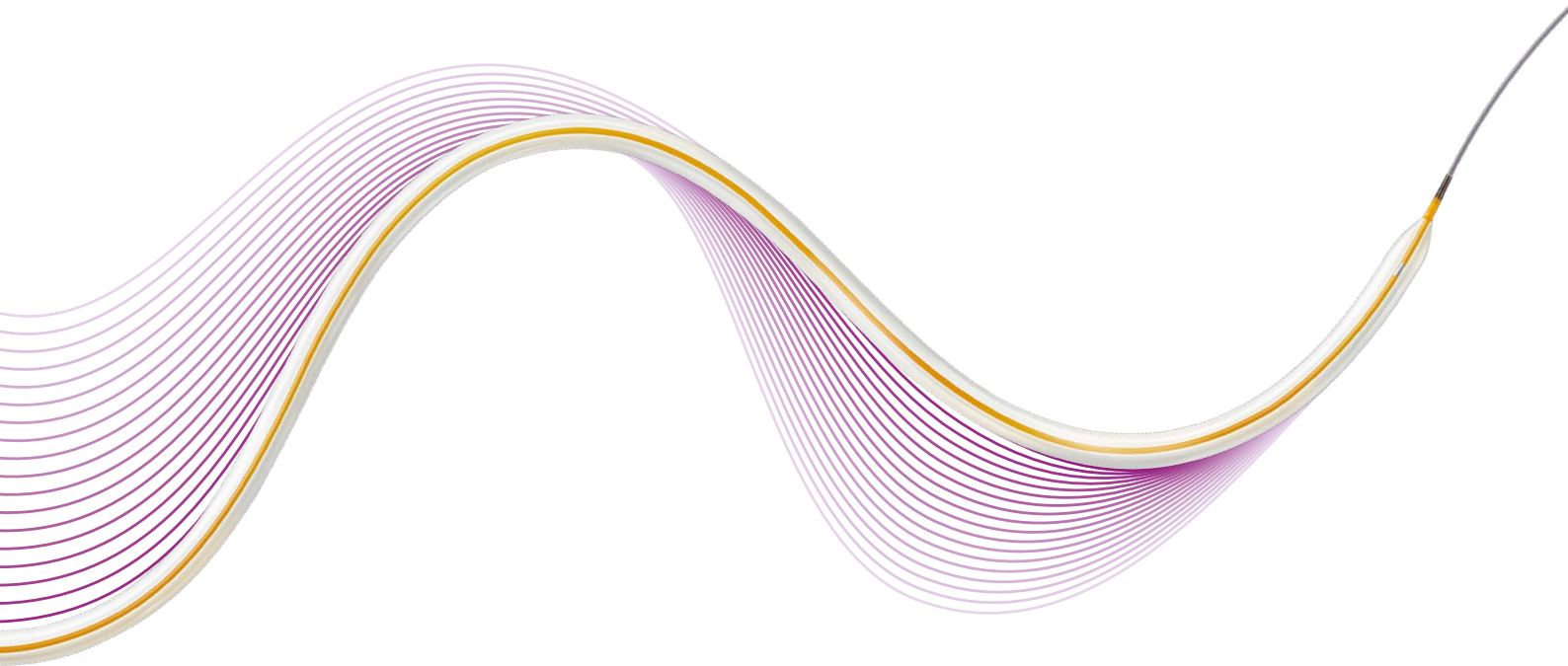
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Passeo[®]-14



Up to 3.8 x faster deflation times



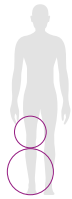
Enhanced crossability



High pushability and flexibility

Passeo[®]-14

Vascular
Intervention
Peripheral



Indicated for balloon dilatation of the stenotic portion of a lower limb artery for the purpose of improving perfusion.

Technical Data	Balloon catheter
Catheter type	OTW
Recommended guide wire	0.014"
Tip	Optimized entry profile and colored
Balloon material	SCP (Semi-Crystalline Polymer), controlled compliance (4 - 6%)
Balloon folding	3-fold
Balloon coating	Hydrophilic patchwork coating
Balloon 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		Balloon diameter x length (mm)					
		ø 1.5 x 20-70	ø 2.0 x 40-220	ø 2.5 x 40-220	ø 3.0 x 40-220	ø 3.5 x 40-140	ø 4.0 x 40-140
Nominal Pressure (NP)	atm*	7	7	7	7	7	7
	ø (mm)	1.5	2.0	2.5	3.0	3.5	4.0
Rated Burst Pressure (RBP)	atm*	14	14	14	14	14	14
	ø (mm)	1.57	2.08	2.61	3.18	3.63	4.16

*1 atm = 1.013 bar

Ordering Information		Catheter Length (cm)	Balloon ø (mm)	Balloon Length (mm)						
				20	40	70	100	140	180	220
4F Antegrade approach	120	1.5	380271 ^a	380277	380283	-	-	-	-	-
	120	2.0	-	380278	380284	380290	380296	380302	380308	
	90	2.5	-	380279	380285	380291	380297	380303	380309	
	90	3.0	-	380280	380286	380292	380298	380304	380310	
	90	3.5	-	380281 ^a	380287 ^a	380293 ^a	380299 ^a	-	-	
	90	4.0	-	380282	380288	380294	380300	-	-	
	90	4.0	-	380282	380288	380294	380300	-	-	
4F Crossover approach	150	1.5	380313 ^a	380319	380325	-	-	-	-	
	150	2.0	-	380320	380326	380332	380338	380344	380350	
	150	2.5	-	380321	380327	380333	380339	380345	380351	
	150	3.0	-	380322	380328	380334	380340	380346	380352	
	150	3.5	-	380323 ^a	380329 ^a	380335 ^a	380341 ^a	-	-	
	150	4.0	-	380324	380330	380336	380342	-	-	
	150	4.0	-	380324	380330	380336	380342	-	-	

^a8 weeks pre-order only

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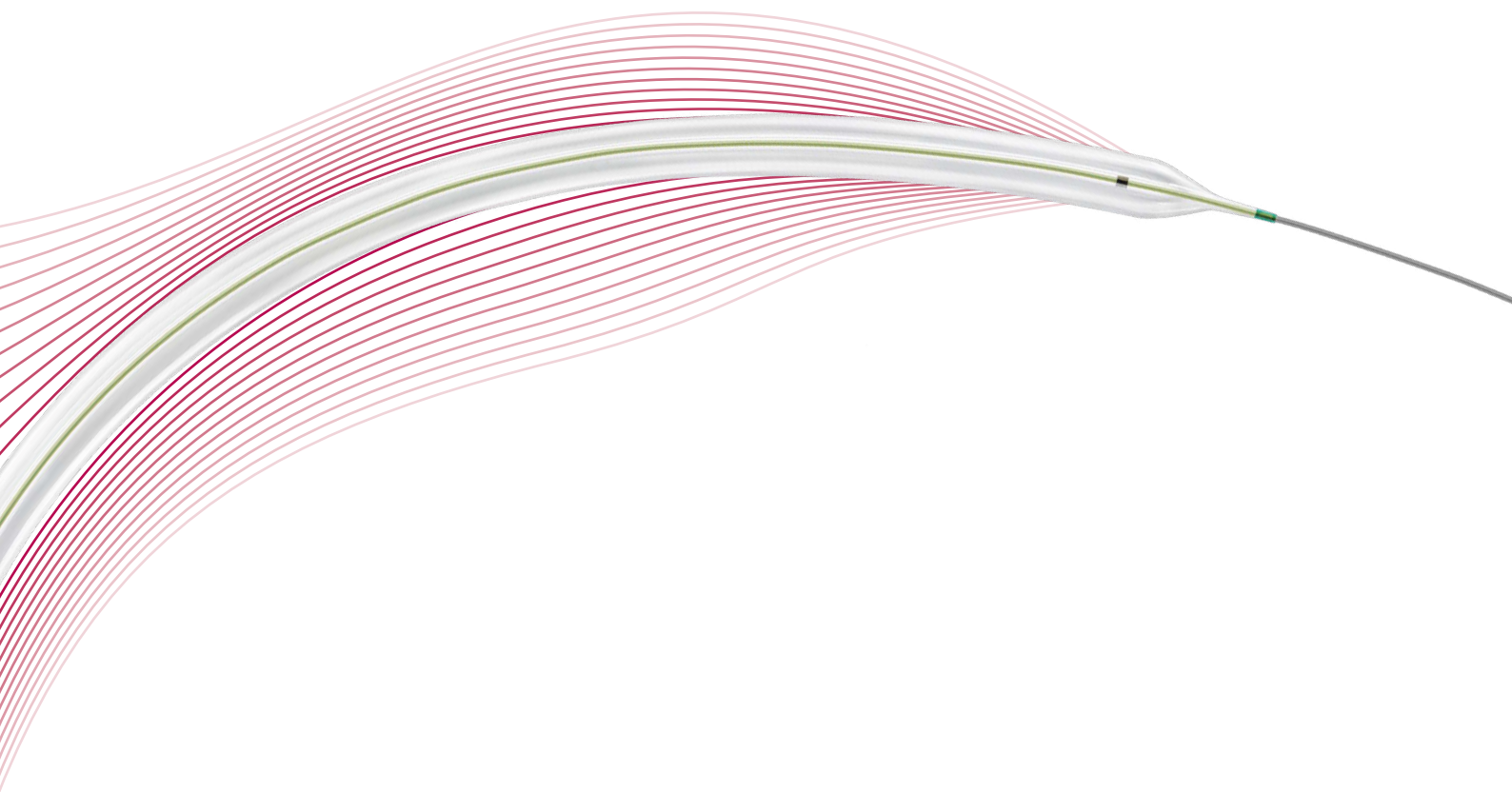
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Passeo[®]-18

Low profile PTA balloon with high pushability in a wide range of sizes.



High pushability



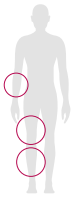
Controlled compliance



Low profile and wide range of sizes

Passeo[®]-18

Vascular
Intervention
Peripheral



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.

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	

Compliance Chart		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*	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*	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

*1 atm = 1.013 bar

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

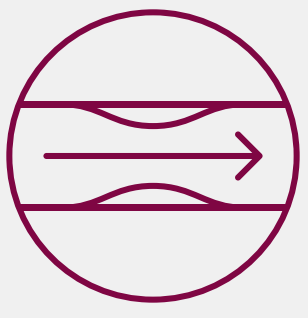
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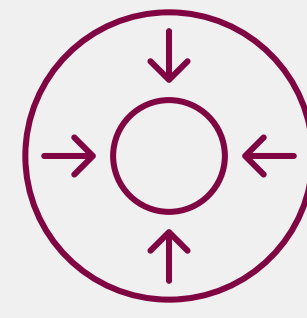
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excellence for life



Improved
crossability



Excellent
deliverability



Low profile, wide
range of sizes



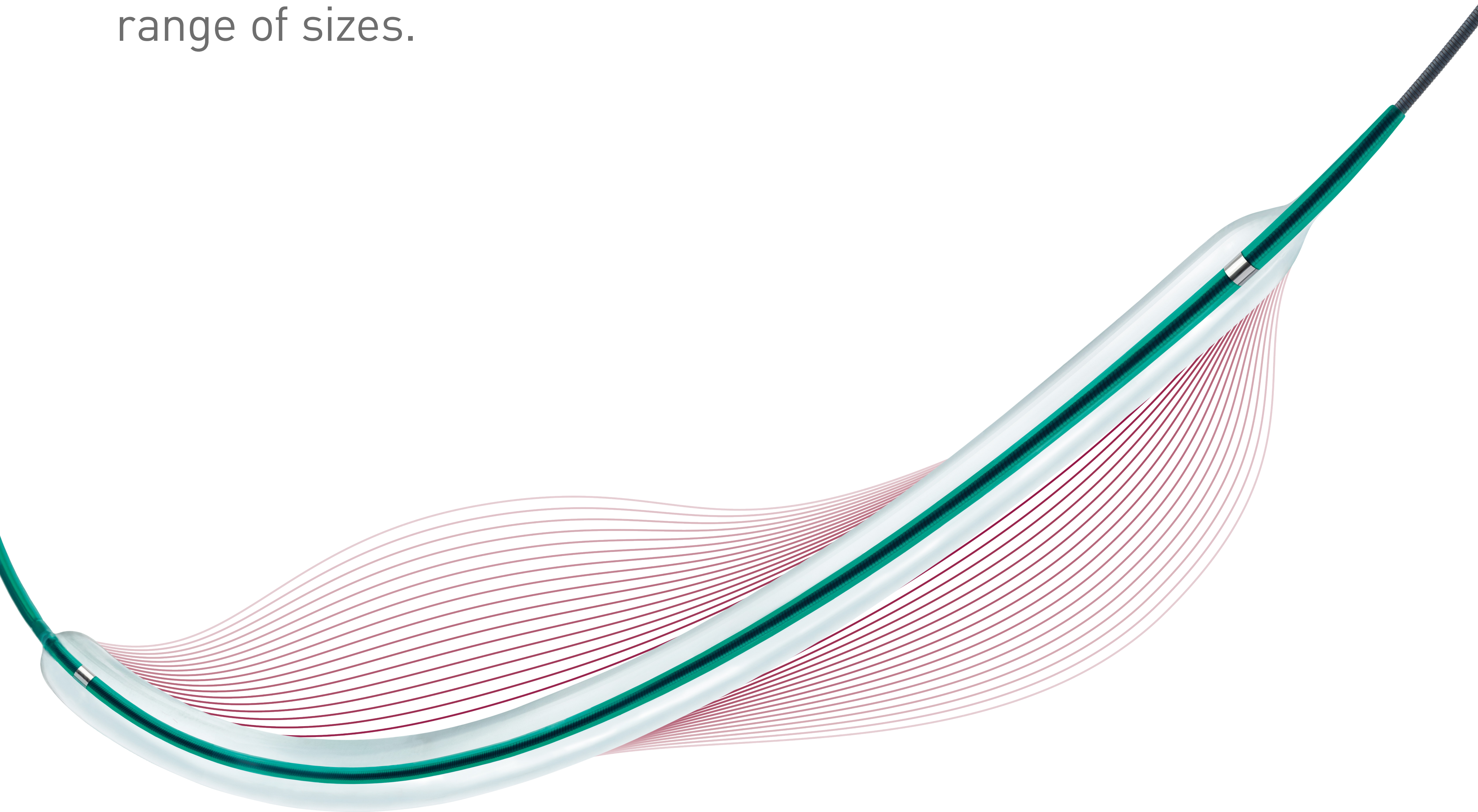
Technical data /
ordering info

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

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Passeo[®]-35 Xeo

Low profile PTA balloon with
excellent deliverability in a wide
range of sizes.

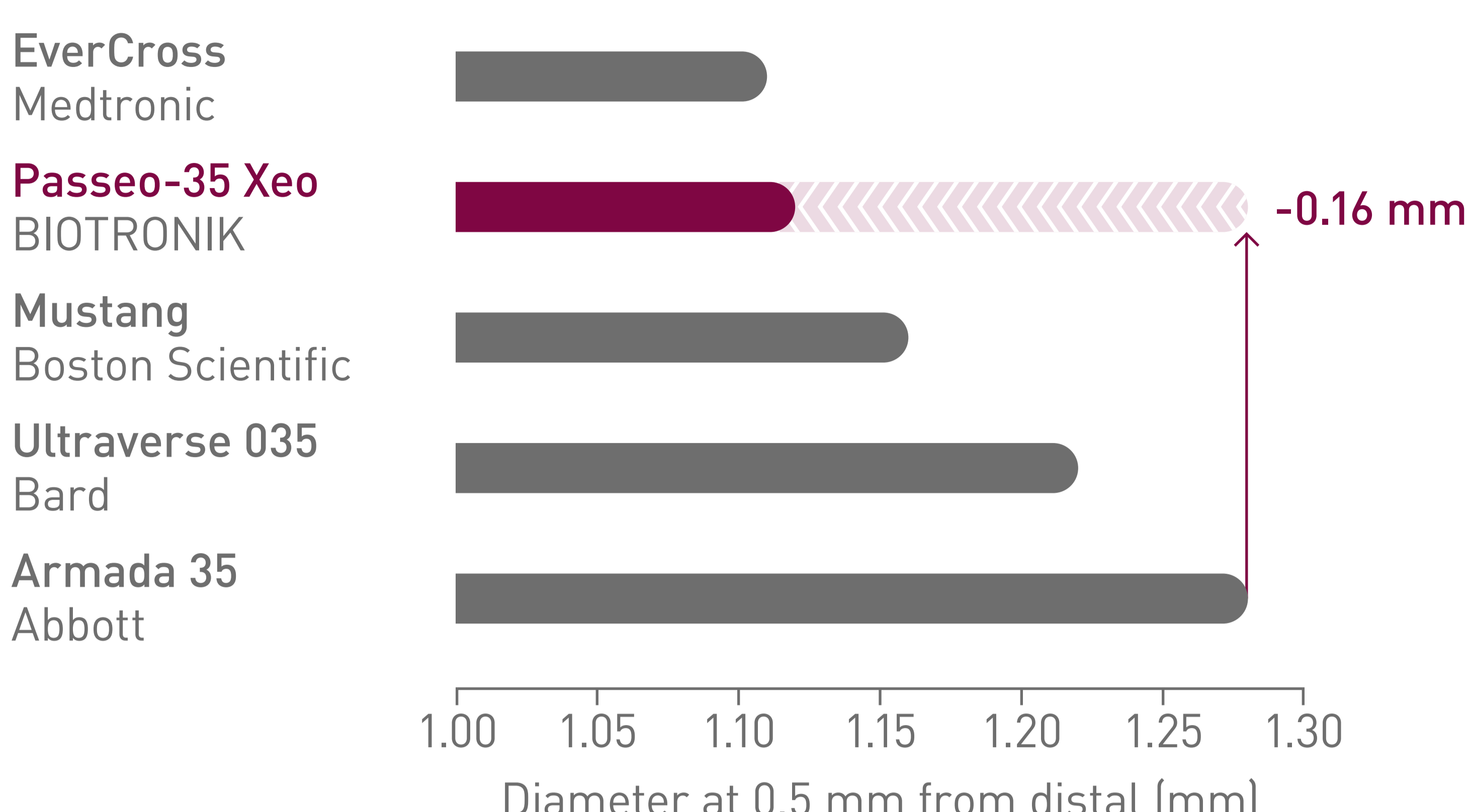


Passeo-35 Xeo

Low profile PTA balloon with excellent deliverability in a wide range of sizes.

Improved crossability

Up to 0.16 mm lower tip entry profile compared to leading competitors.¹



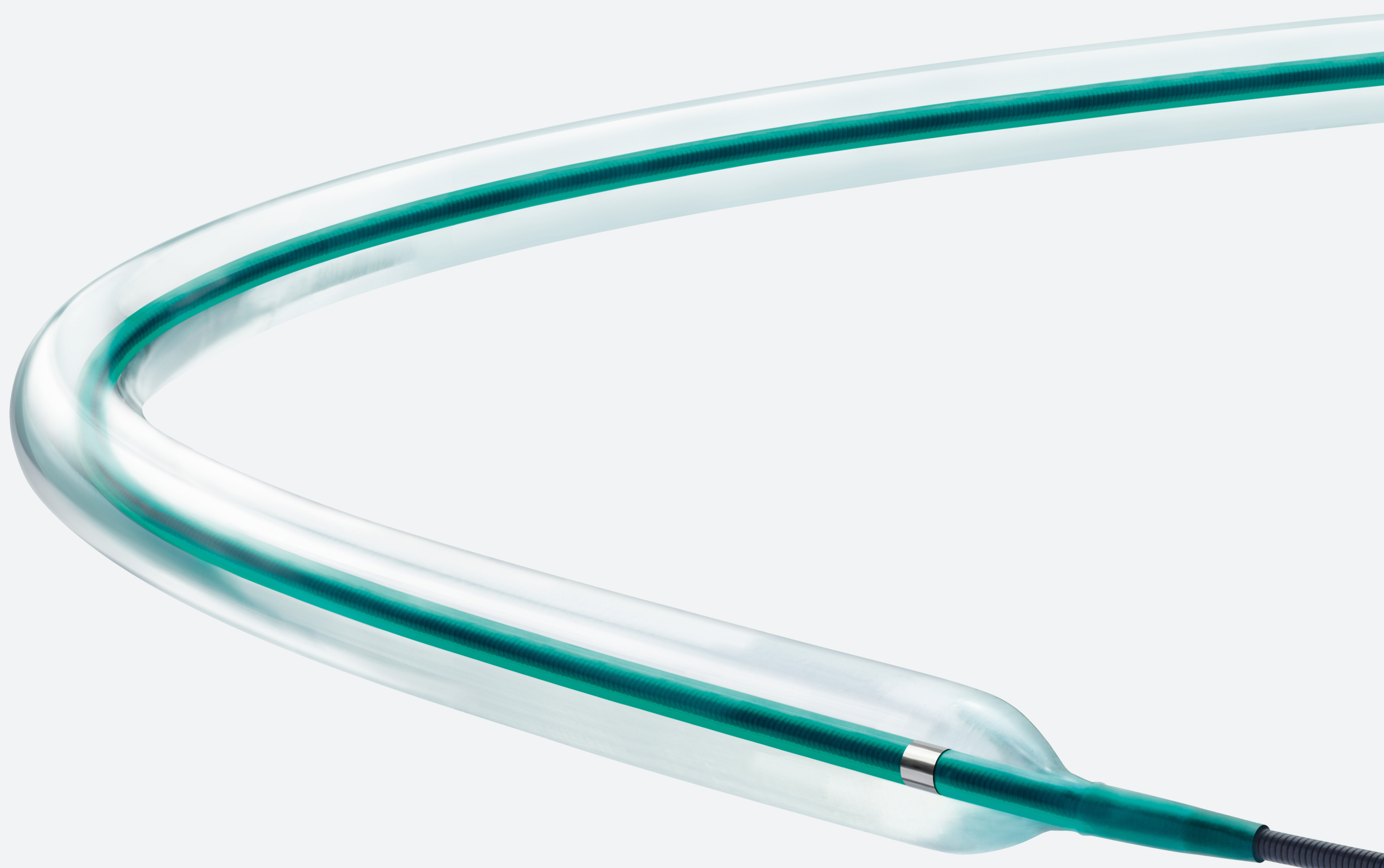
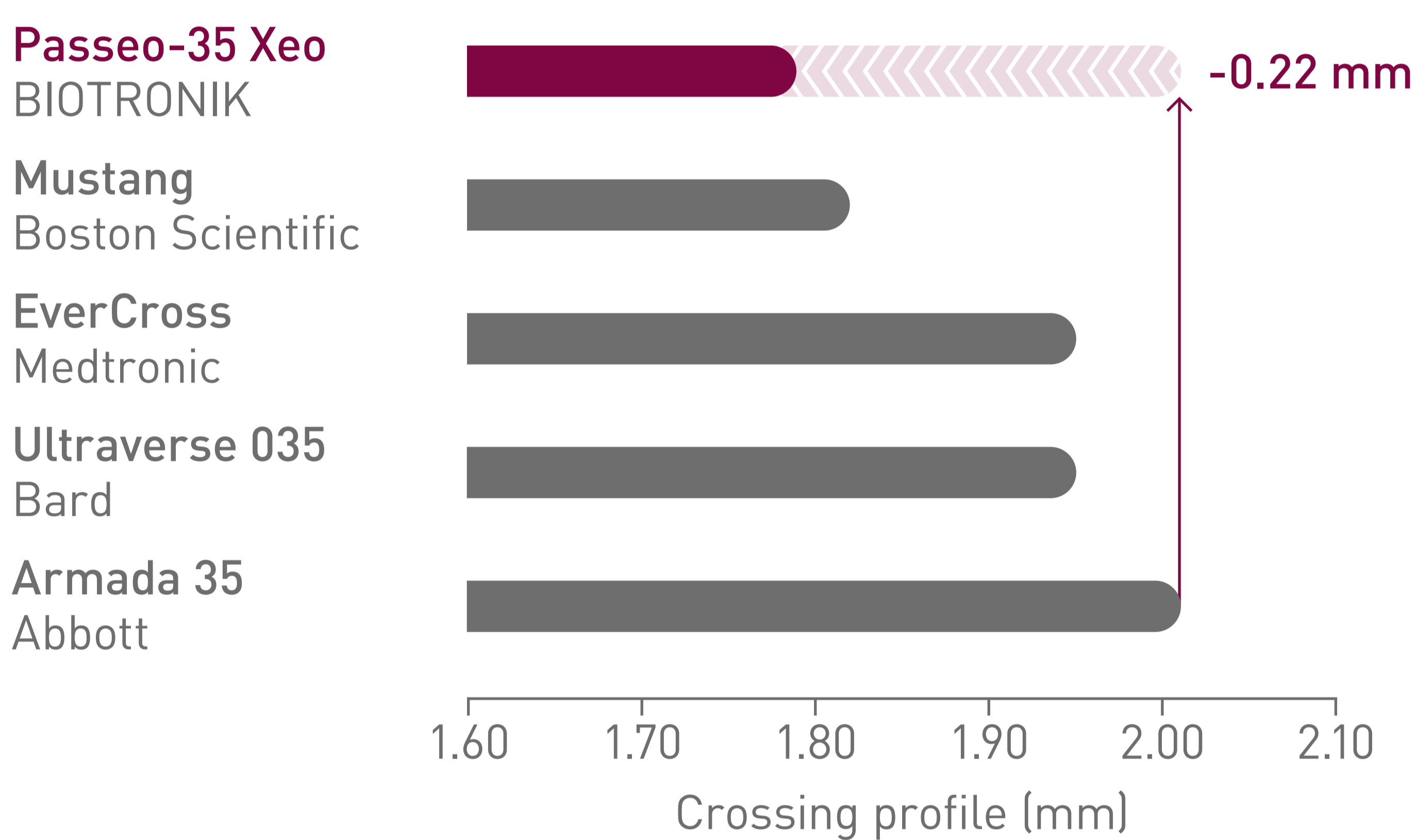
Advanced tip profile

The low tip entry profile and smooth tapered tip of Passeo-35 Xeo facilitates crossing.



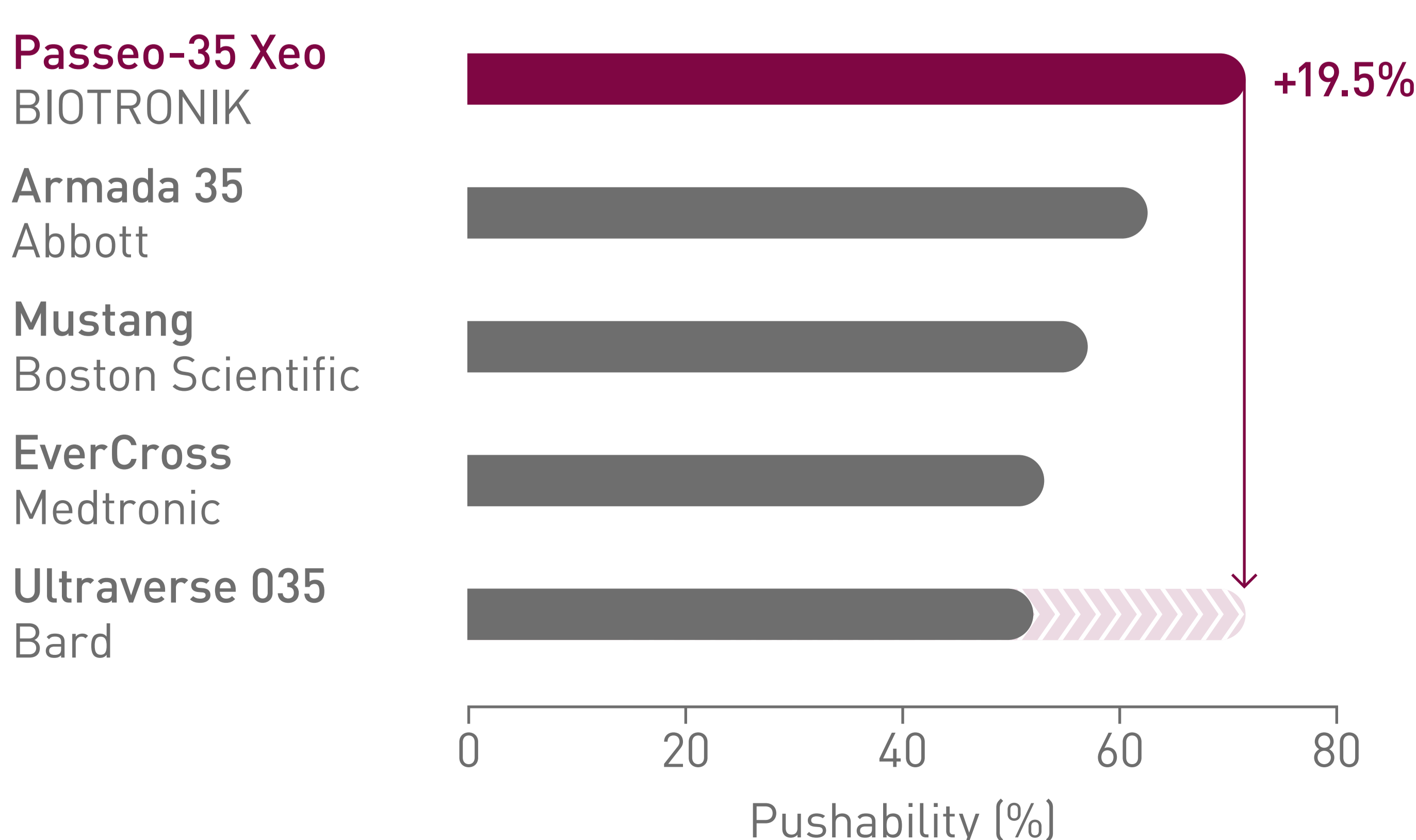
Lowest crossing profile

Up to 0.22 mm lower crossing profile compared to leading competitors.¹



Excellent deliverability

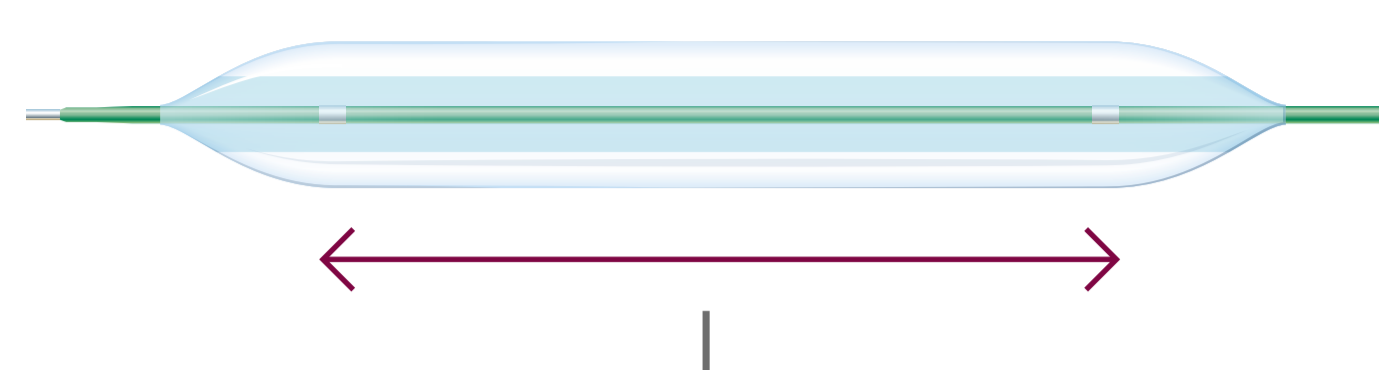
The Passeo-35 Xeo catheter offers excellent trackability and pushability compared to competitive 0.035" PTA balloon catheters.²



Low profile, wide range of sizes

Passeo-35 Xeo features a low profile design with a full 5F compatibility up to 7.0 mm balloon diameter and 250 mm balloon length, 6F up to 10.0 mm and 7F up to 12.0 mm diameter.

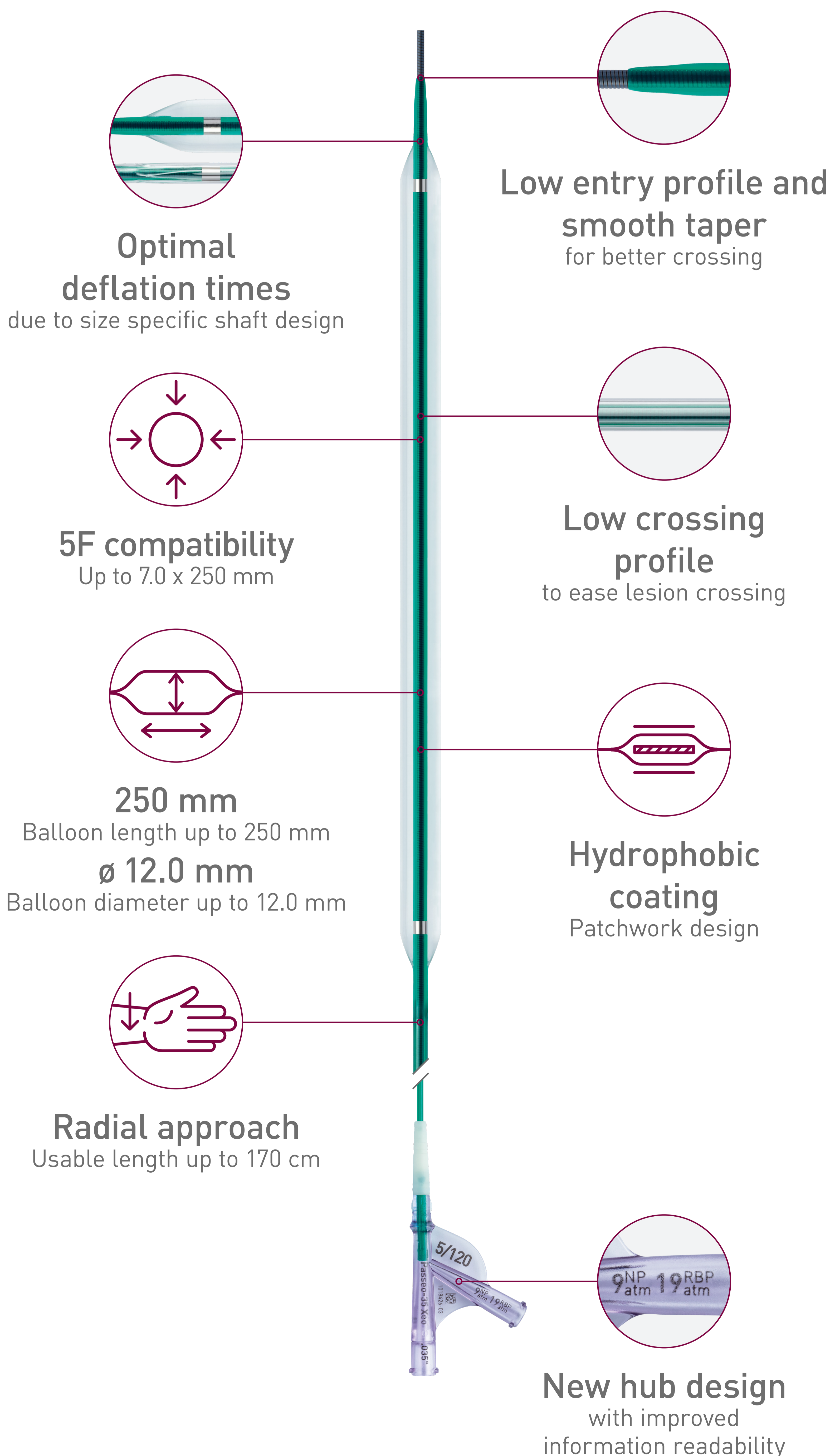
5F \varnothing 3.0 – 7.0 mm
L 20 – 250 mm



6F \varnothing 8.0 – 10.0 mm
L 20 – 120 mm

Passeo-35 Xeo

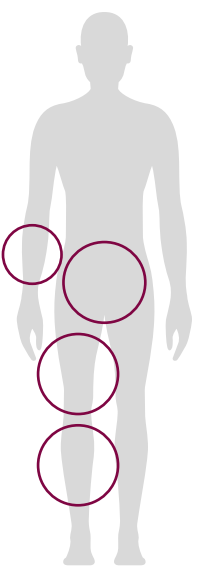
Low profile PTA balloon designed to cross





Passeo-35 Xeo

Vascular
Intervention
Peripheral



The Passeo-35 Xeo is indicated to dilate stenosis in the iliac*, femoral, popliteal and infrapopliteal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. Passeo-35 Xeo is also recommended for post-dilation of balloon expandable and self-expanding stents in the peripheral vasculature.**

Technical Data - Balloon Catheter

Catheter type	OTW	Balloon markers	2 swaged markers
Recommended guide wire	0.035"	Sizes	ø 3.0-12.0 mm; L: 20-250 mm
Tip	Low entry profile, colored	Shaft	5.1-5.4F, dual-lumen, hydrophobic coating
Balloon material	SCP (Semi-Crystalline Polymer), controlled compliance	Usable length	90, 130 and 170 cm
Balloon coating	Hydrophobic patchwork coating	Guide wire lumen	Hydrophobic coating

Balloon ø (mm)	NP ^a	RBP ^a	Catheter length 90 cm									
			Balloon length (mm)									
			20	40	60	80	100	120	150	170	200	250
5F			428777	428786	428795	428804	-	-	-	-	-	-
			428778	428787	428796	428805	428814	428823	-	-	-	-
			428779	428788	428797	428806	428815	428824	428833	-	428843	428848
			428780	428789	428798	428807	428816	428825	428834	-	428844	428849
			428781	428790	428799	428808	428817	-	-	-	-	-
6F			428782	428791	428800	428809	428818	-	-	-	-	-
			428783	428792	428801	428810	428819	-	-	-	-	-
			428784	428793	428802	428811	428820	-	-	-	-	-
7F			-	428794	428803	428812	428821	-	-	-	-	-

Balloon ø (mm)	NP ^a	RBP ^a	Catheter length 130 cm									
			Balloon length (mm)									
			20	40	60	80	100	120	150	170	200	250
5F			428851	428860	428869	428878	428887	428896	428905	428910	428915	428920
			428852	428861	428870	428879	428888	428897	428906	428911	428916	428921
			428853	428862	428871	428880	428889	428898	428907	428912	428917	428922
			428854	428863	428872	428881	428890	428899	428908	428913	428918	428923
			428855	428864	428873	428882	428891	428900	428909	428914	428919	428924
6F			428856	428865	428874	428883	428892	428901	-	-	-	-
			428857	428866	428875	428884	428893	428902 ^b	-	-	-	-
			428858	428867	428876	428885	428894	428903 ^b	-	-	-	-
7F			-	428868	428877	428886	428895	428904 ^b	-	-	-	-

Balloon ø (mm)	NP ^a	RBP ^a	Catheter length 170 cm										
			Balloon length (mm)										
			20	40	60	80	100	120	150	170	200	250	
5F			-	428935 ^b	428944 ^b	428953 ^b	-	-	428971 ^b	428980 ^b	-	428990 ^b	428995 ^b
			428927 ^b	428936 ^b	428945 ^b	428954 ^b	-	-	428972 ^b	428981 ^b	-	428991 ^b	428996 ^b
			428928 ^b	428937 ^b	428946 ^b	428955 ^b	-	-	428973 ^b	428982 ^b	-	428992 ^b	428997 ^b
			428929 ^b	428938 ^b	428947 ^b	428956 ^b	-	-	-	-	-	-	-
			428930 ^b	428939 ^b	428948 ^b	428957 ^b	-	-	-	-	-	-	-
6F			-	428940 ^b	428949 ^b	428958 ^b	-	-	-	-	-	-	
			-	428941 ^b	428950 ^b	428959 ^b	-	-	-	-	-	-	

^aNP = Nominal Pressure and RBP = Rated Burst Pressure in atm (1 atm = 1.013 bar)
^b8 weeks pre-order only

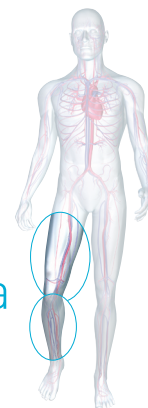
1. BIOTRONIK data on file. Compared to leading competitors 6.0 mm diameter balloon size. IIB(P) 39/217; 2. BIOTRONIK data on file. Compared to leading competitors 6.0x200 mm balloon size. *Note for Australia: Passeo-35 Xeo not approved by Therapeutic Goods Administration for use in the common iliac arteries.**Indication as per IFU. Passeo and Xeo are trademarks or registered trademarks of the BIOTRONIK Group of Companies. EverCross is a trademark or registered trademark of the Medtronic Group of companies. Mustang is a trademark or registered trademark of the Boston Scientific Group of companies. Ultraverse is a trademark or registered trademark of Becton, Dickinson and Company or its affiliates. Armada is a trademark or registered trademark of the Abbott Group of companies.



Passeo-14

PTA Balloon/0.014"/OTW

Indicated for balloon dilatation of the stenotic portion of a lower limb artery for the purpose of improving perfusion



- Up to 73 % faster deflation times¹
- Offering dedicated pedal sizes
- Patchwork coating designed to facilitate crossing
- High pushability and flexibility

Passeo-14 PTA Balloon/0.014"/OTW

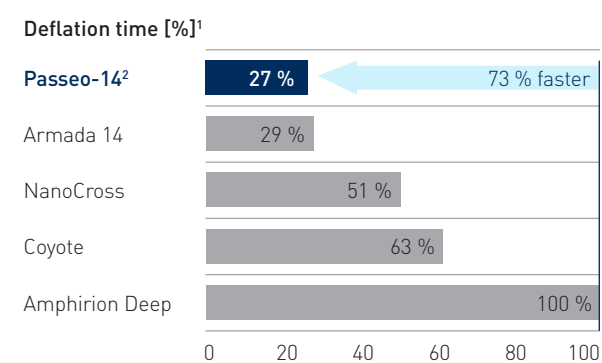
Up to 73 % faster deflation times¹ due to the catheter shaft design featuring a large balloon inflation lumen to facilitate rapid inflation and deflation.

“Impressive deflation time!”
[Dr. M. A. De Gregorio Ariza, Saragossa, Spain, during initial product testing]

Fast deflation times

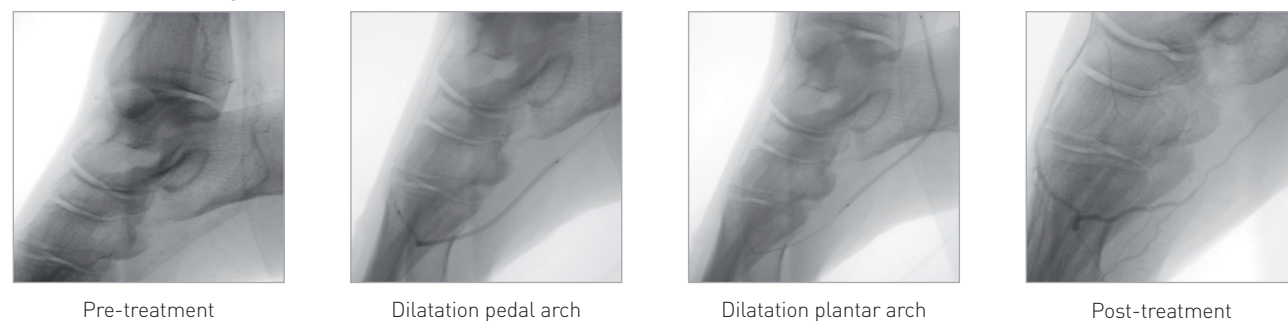
Passeo-14² deflates:

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



Providing dedicated pedal design:

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



Pre-treatment

Dilatation pedal arch

Dilatation plantar arch

Post-treatment

Courtesy of Dr. L. Steffanon, Vicenza, Italy

¹ Measurements taken by IIB (Institut für Implant-Technologie und Biomaterialien) [Passeo-14 balloon 3 mm x 140 mm] and competitor devices (3 mm x 120 mm balloons), all with 150 cm usable catheter lengths. Data on file at BIOTRONIK. Bench test results not necessarily indicative of clinical performance.

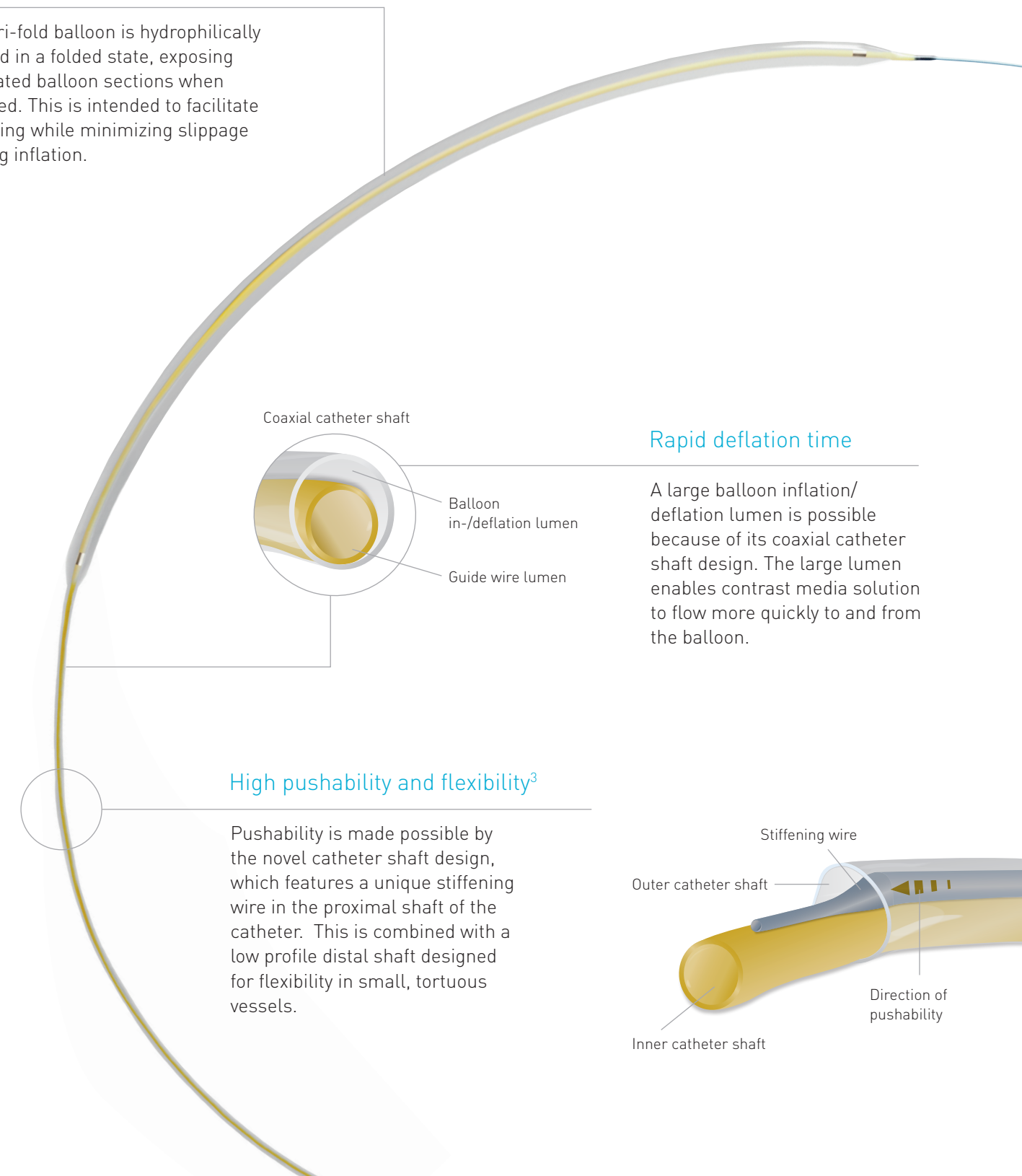
² Volume adjustment: A 3 mm x 120 mm contains 15 % less contrast media volume than a 3 mm x 140 mm balloon. The measured deflation time of a 3 mm x 140 mm balloon was adjusted by 15 % to make a direct competitive comparison.

³ BIOTRONIK data on file (IIB report 65/2012)

Designed to treat complex lower limb lesions

Patchwork coating designed to facilitate crossing

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

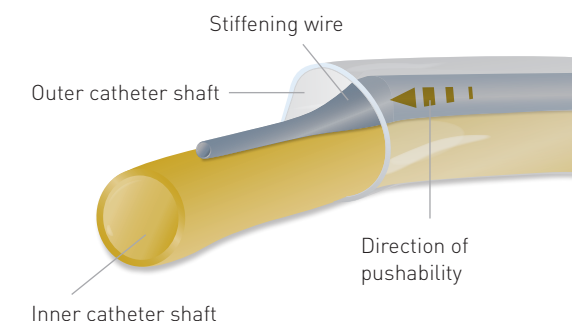


Rapid deflation time

A large balloon inflation/deflation lumen is possible because of its coaxial catheter shaft design. The large lumen enables contrast media solution to flow more quickly to and from the balloon.

High pushability and flexibility³

Pushability is made possible by the novel catheter shaft design, which features a unique stiffening wire in the proximal shaft of the catheter. This is combined with a low profile distal shaft designed for flexibility in small, tortuous vessels.



Passeo-14 – PTA Balloon/0.014"/OTW

Technical Data		Balloon catheter
Catheter type		OTW
Recommended guide wire		0.014"
Tip		Optimized entry profile and colored
Balloon material		SCP (Semi-Crystalline Polymer), controlled compliance (4 - 6 %)
Balloon folding		3-fold
Balloon coating		Hydrophilic patchwork coating
Balloon 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		Balloon diameter x length (mm)					
		ø 1.5 x 20-70	ø 2.0 x 40-220	ø 2.5 x 40-220	ø 3.0 x 40-220	ø 3.5 x 40-140	ø 4.0 x 40-140
Nominal Pressure (NP)	atm*	7	7	7	7	7	7
	ø (mm)	1.5	2.0	2.5	3.0	3.5	4.0
Rated Burst Pressure (RBP)	atm*	14	14	14	14	14	14
	ø (mm)	1.57	2.08	2.61	3.18	3.63	4.16

* 1 atm = 1.013 bar

Ordering Information		Catheter Length (cm)	Balloon ø (mm)	Balloon Length (mm)						
				20	40	70	100	140	180	220
Antegrade approach	4F	120	1.5	380271 ⁴	380277 ⁴	380283	-	-	-	-
		120	2.0	-	380278	380284	380290	380296	380302 ⁴	380308 ⁴
		90	2.5	-	380279	380285	380291	380297	380303 ⁴	380309
		90	3.0	-	380280	380286 ⁴	380292	380298 ⁴	380304 ⁴	380310 ⁴
		90	3.5	-	380281 ⁴	380287 ⁴	380293 ⁴	380299 ⁴	-	-
		90	4.0	-	380282 ⁴	380288 ⁴	380294 ⁴	380300 ⁴	-	-

Ordering Information		Catheter Length (cm)	Balloon ø (mm)	Balloon Length (mm)						
				20	40	70	100	140	180	220
Crossover approach	4F	150	1.5	380313	380319	380325	-	-	-	-
		150	2.0	-	380320	380326	380332	380338	380344	380350
		150	2.5	-	380321	380327	380333	380339	380345 ⁴	380351
		150	3.0	-	380322	380328	380334	380340	380346	380352
		150	3.5	-	380323 ⁴	380329 ⁴	380335 ⁴	380341 ⁴	-	-
		150	4.0	-	380324	380330 ⁴	380336	380342 ⁴	-	-

⁴ Size available upon special request

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

- Introducer Sheath: **Fortress** ■ Balloons: **Passeo-18**

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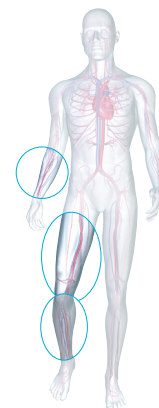
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Passeo-18

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

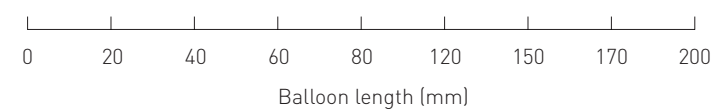
The available low profile 3.8F coaxial catheter shaft design facilitates access to distal lesions and allows reduction of access site complications¹ through the ability to use a 4F access sheath.

Low profile and wide array of sizes

Available balloon diameters/lengths
 ø 2.0 - 5.0 mm

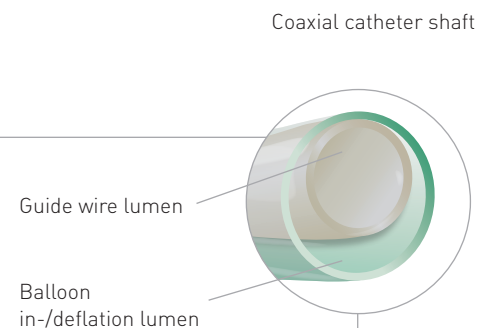


ø 6.0 mm - 7.0 mm



Tip

Smooth tapered tip entry profile promotes lesion crossing.



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

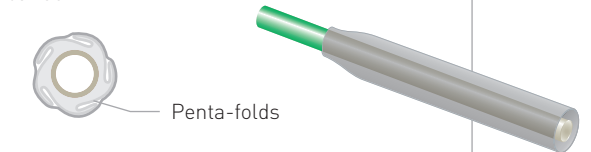
Controlled compliance

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.

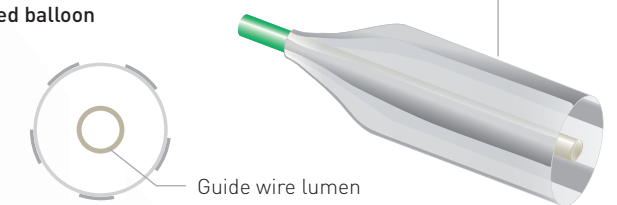
Patchwork coating

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	
	4F	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	
	5F	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	
4F		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	
5F		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**

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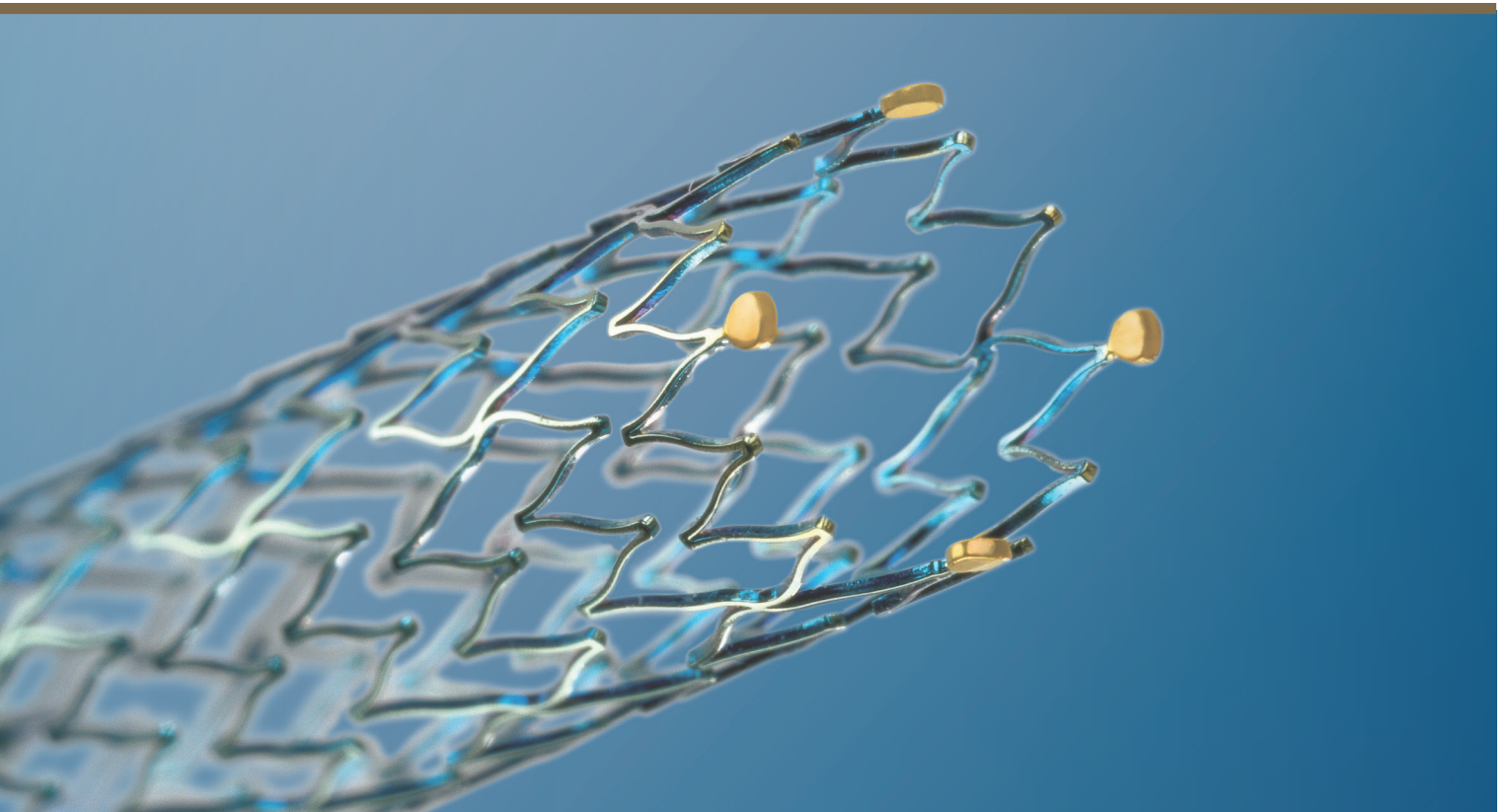
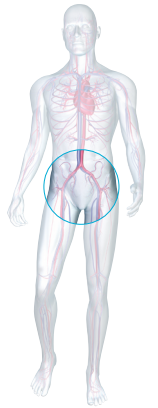
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Astron

Self-Expanding Stent/0.035"/OTW

Indicated for atherosclerotic disease of iliac arteries



- Pull-back delivery system for simple stent deployment
- 5.2F proximal shaft for contrast injection with device in sheath
- Segmented stent design and thick struts for sufficient chronic outward force
- S-articulating connecting bars and peak-to-valley design for multi-directional flexibility

Astron Strength with flexibility

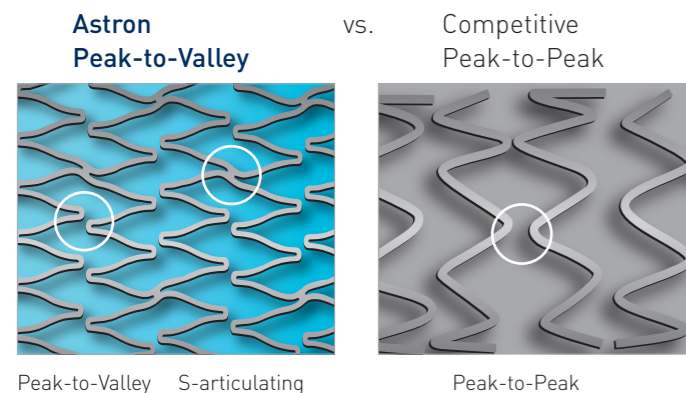
A stent designed for iliac artery lesions which are often calcified and occluded. Both stent and markers are completely coated with **proBIO**. Unique “S-articulations” to allow stent conformability. The particular design respects the vessel movement without compromising the needed strength.

Easy release

Relieves friction of introducer valve on the retractable shaft during stent deployment for a smoother action.

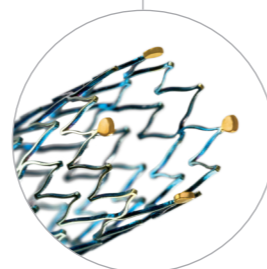
Segmented stent design for iliac artery

- Peak-to-valley design and S-articulating connecting bars provide multi-directional flexibility and avoid fish-scaling in tortuous arteries.
- Segmented design and strut thickness designed to provide sufficient chronic outward force.



Enhanced visibility

Four gold markers at each end of the stent enhance visibility.



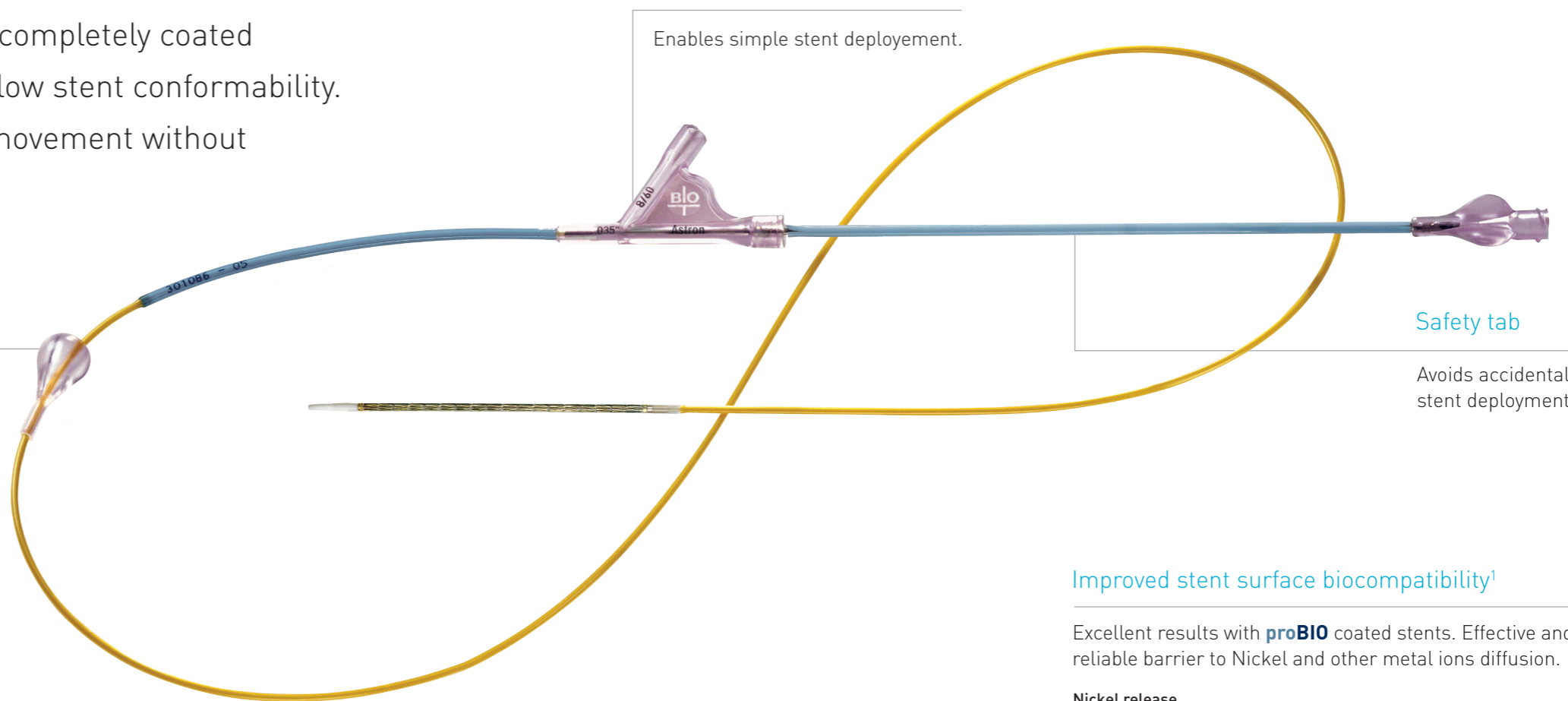
Stent designed to achieve radial force and flexibility in iliac arteries

Pull-back delivery system

Enables simple stent deployment.

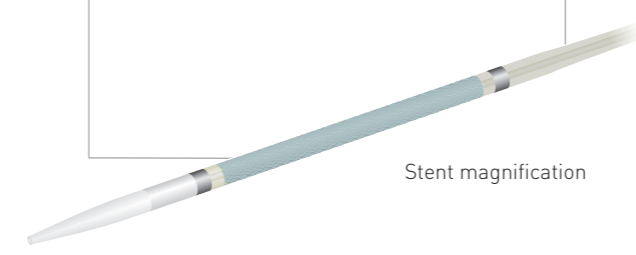
Safety tab

Avoids accidental stent deployment.



6F Introducer compatibility

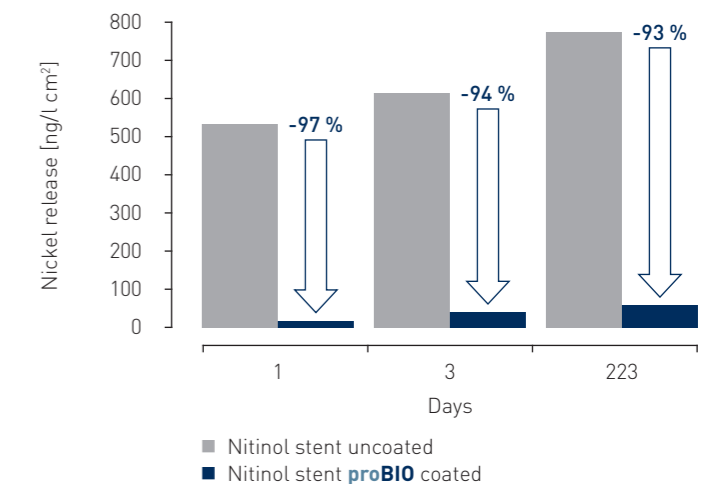
6F distal shaft with 5.2F proximal shaft for contrast injection with device positioned inside introducer and across lesion.



Improved stent surface biocompatibility¹

Excellent results with **proBIO** coated stents. Effective and reliable barrier to Nickel and other metal ions diffusion.

Nickel release



¹ Nickel release test results; BIOTRONIK Data on file

Astron

Self-Expanding Nitinol Stent/0.035"/OTW

Technical Data	Stent
Catheter type	OTW
Recommended guide wire	0.035"
Stent material	Nitinol
Strut thickness	225 µm (ø 10 mm = 230 µm)
Stent coating	proBIO (Amorphous Silicone Carbide)
Stent markers	4 gold markers each end
Sizes	ø 7 - 10 mm; L: 30 - 80 mm
Proximal shaft	5.2F, hydrophobic coating
Usable length	70 and 120 cm

Ordering Information	Stent ø (mm)	Catheter length 70 cm Stent length (mm)			
		30	40	60	80
	7.0	343773	343774	343775	343776
	8.0	343777	343778	343779	343780
6F	9.0	343781	343782	343783	343784
	10.0	-	349214	349215	349216

	Stent ø (mm)	Catheter length 120 cm Stent length (mm)			
		30	40	60	80
	7.0	343785	343786	343787	343788
6F	8.0	343789	343790	343791	343792
	9.0	343793	343794	343795	343796

Astron is part of the BIOTRONIK **6F** Solutions portfolio, including:

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

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Outstanding trackability
through the small and
tortuous arteries due to
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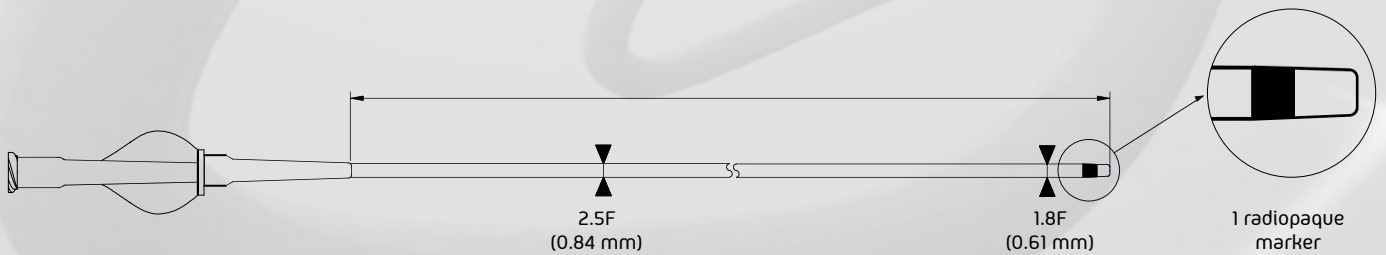
**Optimal flexibility,
pushability and resistance
to kinking** provided by a
full length variable braided
pattern

**Complete
guidewire control**
ensured by its
conical transition

**Superior crossability and
penetration capacity** due to
its optimized tip profile and
shape with double c-cut
radiopaque markers

navitian features

- > **Over the wire catheter (OTW)**
- > **Guidewire compatibility 0.014"**
- > **Usable catheter length 135 and 150 cm**
- > **Radiopaque markers**
- > **Internal PTFE layer**
- > **Hydrophilic coating: 70 and 90 cm**



Product with CE mark, certified by Notified Body 0318

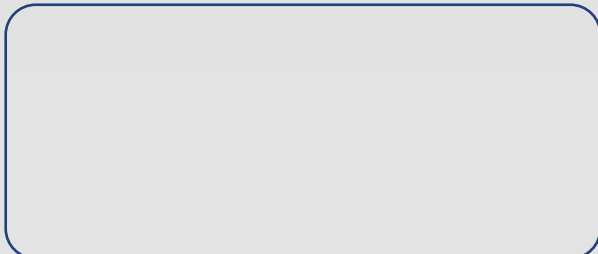
References

Usable length 135 cm
Usable length 150 cm

MCC C14 135 001
MCC C14 150 001

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