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By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM – ISO 13485:2016

This is to certify that:

BIOTRONIK AG
Ackerstrasse 6
8180 Bülach
Switzerland

DUNS Number: 48-086-2817

Holds certificate No: **MDSAP 688646**

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure [if design controls are part of the certification]; Brasil RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009; Canada - Medical Devices Regulations - Part 1- SOR 98/282; Japan - MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D

Design, development, manufacture, distribution and sterilization of PTCA balloon catheters, PTA balloon catheters, drugreleasing PTCA balloon catheters, drug-releasing PTA balloon catheters, coronary stents and stent systems, peripheral stents and stent systems, drugeluting coronary stents and stent systems, coronary guidewires, peripheral guidewires, drug-eluting resorbable coronary scaffolds and scaffold systems.

For and on behalf of BSI:

Carlos Pitanga, Chief Operating Officer Assurance - Americas

Original Registration Date: 2018-10-11 Effective Date: 2018-10-11 Expiry date: 2021-10-10

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MEDICAL DEVICE SINGLE AUDIT PROGRAM
BSI Group America Inc. is an MDSAP authorized auditing organization

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 608280**

Issued To: **BIOTRONIK AG**
Ackerstrasse 6
8180 Bülach
Switzerland

In respect of:

Design and manufacture of PTCA balloon catheters, PTA balloon catheters, drug-releasing PTCA balloon catheters, drug-releasing PTA balloon catheters, coronary stent systems, peripheral vascular stent systems, drug-eluting coronary stent systems, drug-eluting resorbable coronary scaffold systems, coronary guidewires and peripheral guidewires

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2014-04-01** Date: **2019-10-30** Expiry Date: **2024-05-26**

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EC Certificate - Full Quality Assurance System

Supplementary Information to CE 608280

Issued To:

BIOTRONIK AG
Ackerstrasse 6
8180 Bülach
Switzerland

Number	Device Name	Intended purpose per IFU
Class III		
---	Magmaris Sirolimus-Eluting Resorbable Coronary Magnesium Scaffold System	See CE 608221
	PRO-Kinetic Energy Coronary Stent System	See CE 608282
	Pantera LEO Fast-Exchange PTCA catheter	See CE 608283
	Orsiro Sirolimus-Eluting Coronary Stent System	See CE 608284
	Pantera Lux Paclitaxel releasing PTCA Balloon Catheter	See CE 608285
	PK Papyrus Covered Coronary Stent System	See CE 608286
	Synsiro Sirolimus-Eluting Coronary Stent System	See CE 608289
	Passeo-18 Lux Paclitaxel releasing PTA Balloon Catheter	See CE 610590
	Cruiser and Cruiser Hydro coronary and peripheral artery guidewires	See CE 619676
	Pantera Pro Coronary Dilatation Catheter	See CE 620197
	Orsiro Mission Sirolimus Eluting Coronary Stent System	See CE 704680
	Synsiro Pro Sirolimus Eluting Coronary Stent System	See CE 708283

First Issued: **2014-04-01** Date: **2019-10-30** Expiry Date: **2024-05-26**

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 608280

Issued To:

BIOTRONIK AG
Ackerstrasse 6
8180 Bülach
Switzerland

Number	Device Name	Intended purpose per IFU
Class IIb		
47932	Self-expanding NiTi peripheral stents	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.
		For use in patients with atherosclerotic disease of the femoral and infrapopliteal arteries and for the treatment of insufficient results after percutaneous transluminal angioplasty (PTA), e.g residual stenosis and dissection.
		For use in patients with atherosclerotic disease of the superficial femoral, proximal popliteal and infrapopliteal arteries and for the treatment of insufficient results after percutaneous transluminal angioplasty (PTA), e.g. residual stenosis and dissection.

First Issued: **2014-04-01** Date: **2019-10-30** Expiry Date: **2024-05-26**

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 608280

Issued To:

BIOTRONIK AG
Ackerstrasse 6
8180 Bülach
Switzerland

Number	Device Name	Intended purpose per IFU
Class IIb		
47932	Balloon-expandable Cobalt Chromium peripheral stents	To improve sub-optimal angiographic results (≥ 50% residual stenosis) and/or flow-limiting dissections after PTA of atherosclerotic lesions in the infrapopliteal arteries.
44279	Iliac artery stents	For the treatment of de novo or restenotic atherosclerotic lesions in iliac arteries.
45852	Renal artery stents	For improving arterial luminal diameter in patients with clinical symptoms attributable to atherosclerotic stenosis of the renal arteries.
Class IIa		
MD 0106	PTA balloon catheters	---

First Issued: **2014-04-01** Date: **2019-10-30** Expiry Date: **2024-05-26**

Lowest crossability in tight lesions

43% less friction during kissing balloon technique

38% more push to reach target lesion

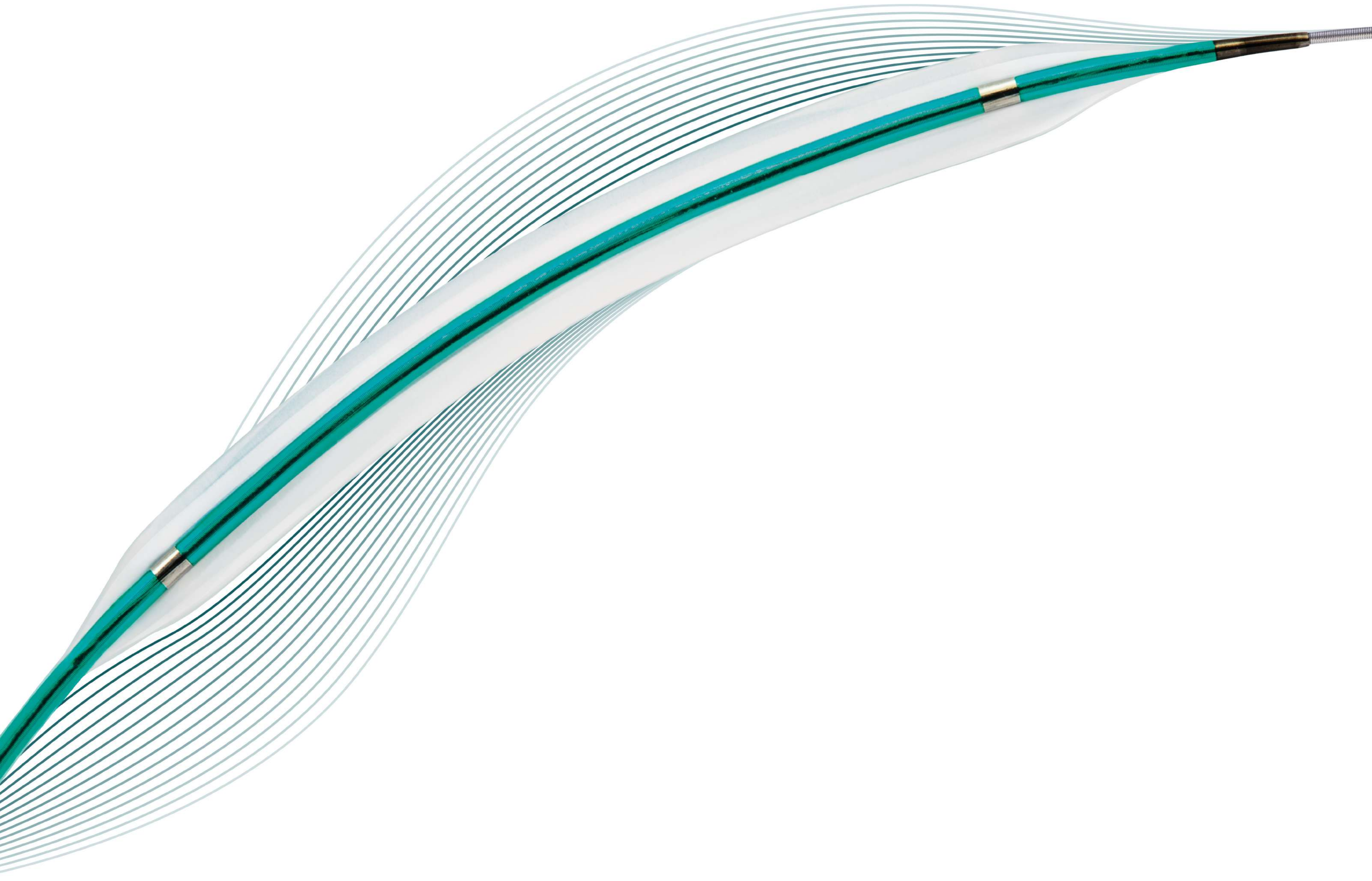
Technical data / ordering info

Vascular Intervention // Coronary

Semi-Compliant Workhorse Balloon Catheter

BIOTRONIK
excellence for life

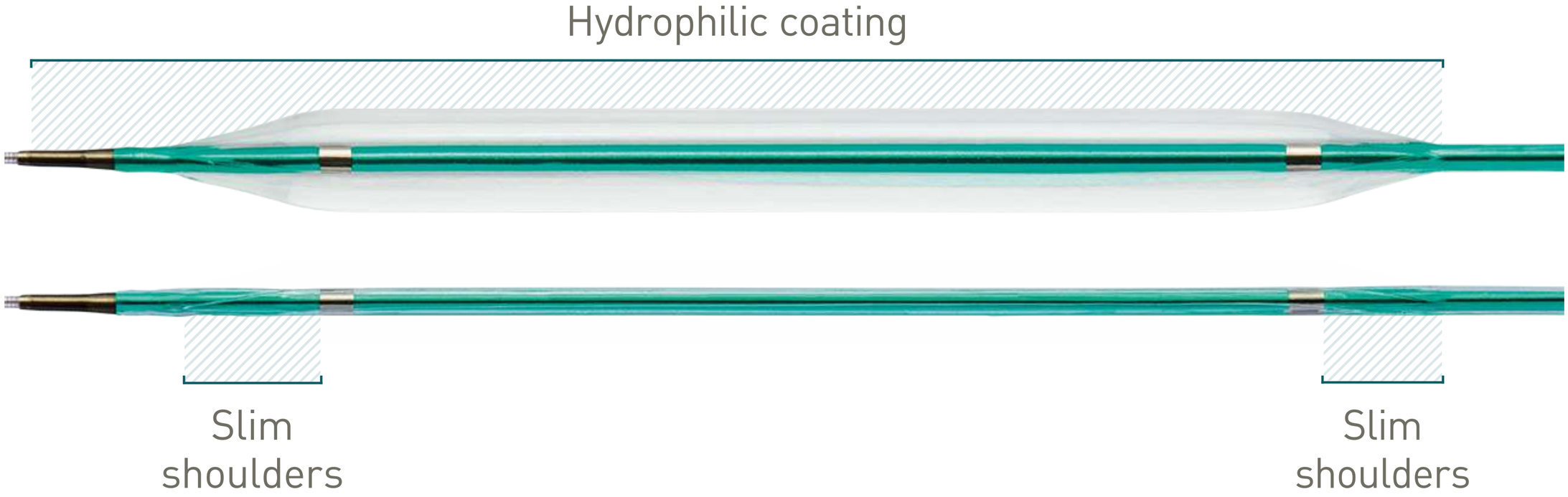
Pantera Pro

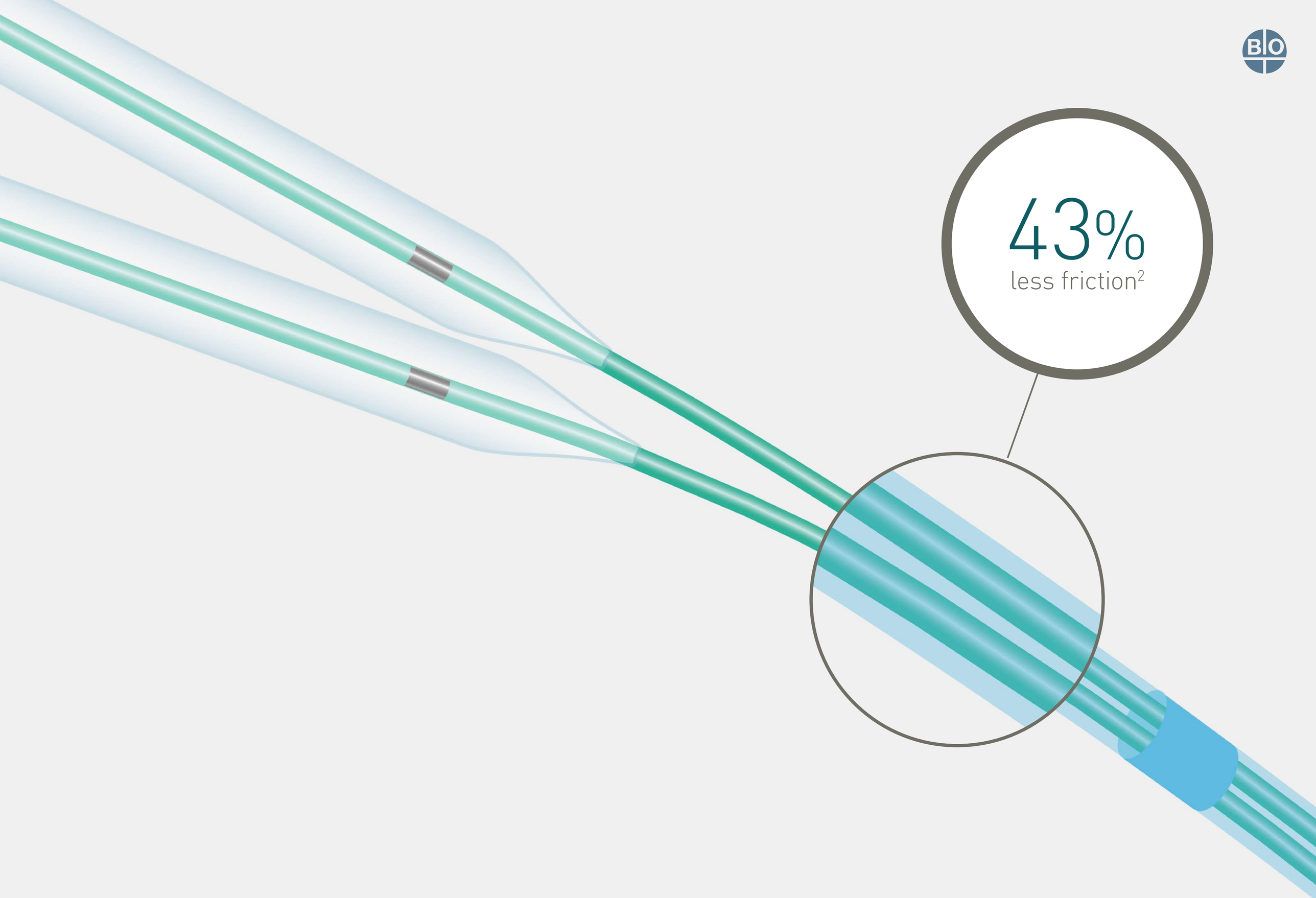


Lowest crossability in tight lesions[1]

Slim shoulders and hydrophilic coating

Proprietary balloon material for small sizes allows for slim shoulders while maintaining durability. Coupled with hydrophilic balloon coating, Pantera Pro excels in tight lesions.



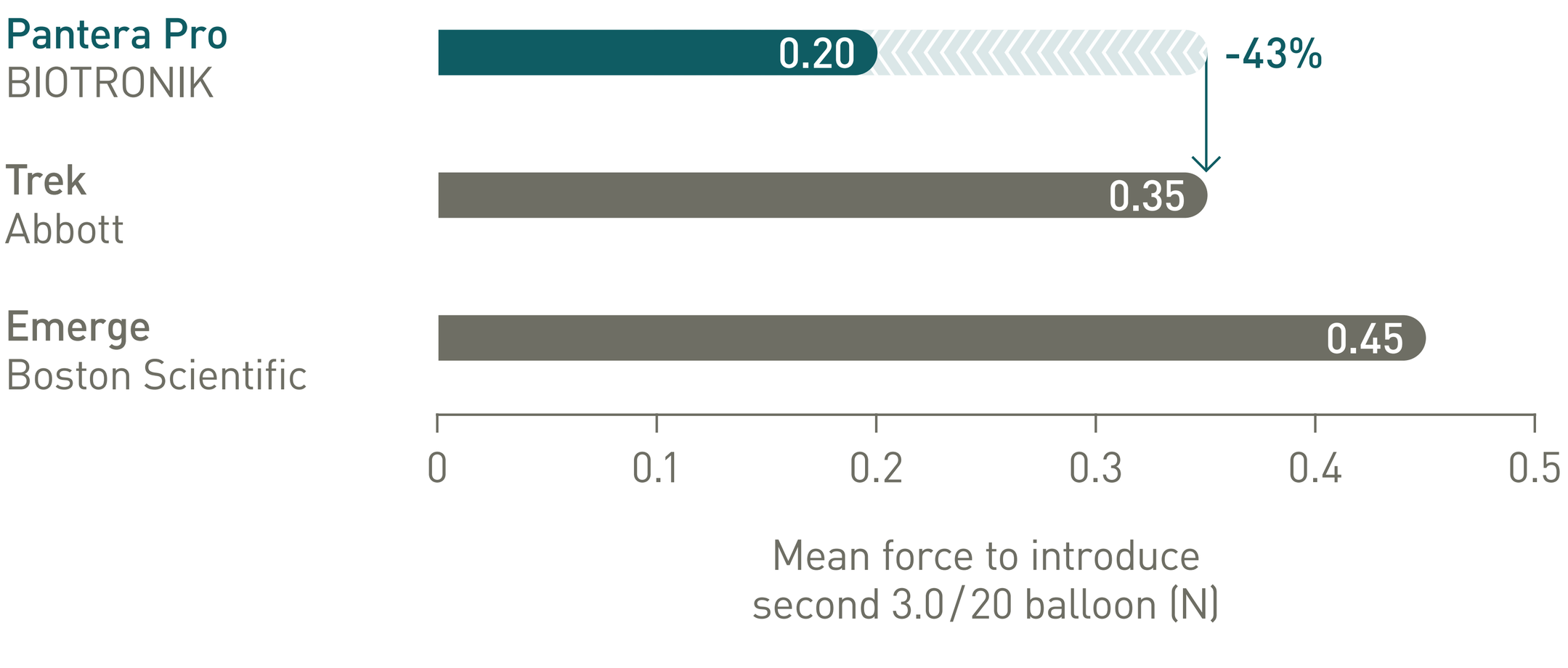


43% less friction[2] during kissing balloon technique

Reduced distal shaft profile

The reduced distal shaft profile lowers friction when using two balloons in a 6F guiding catheter.*

Lowest friction during kissing balloon technique compared to main competitors



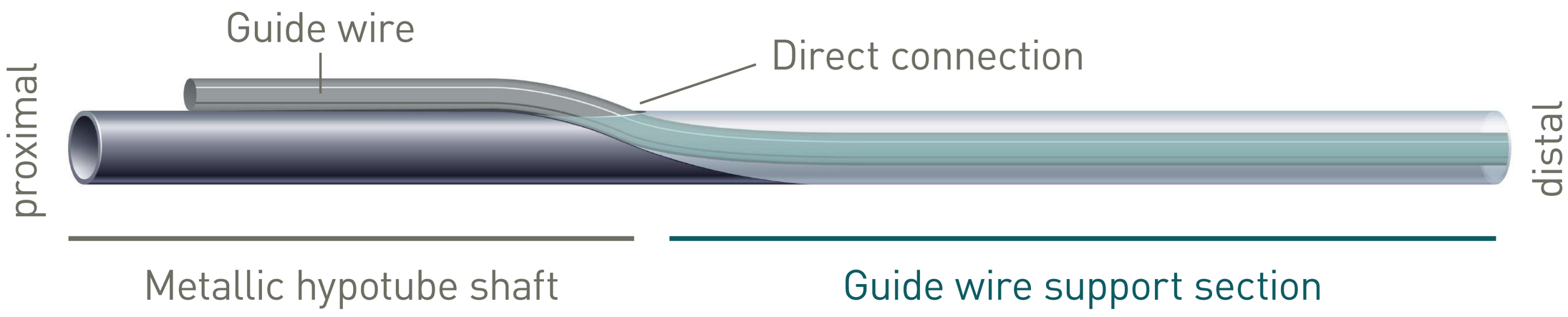
*Any combination of two diameters not larger than 3.5 mm within a 6F guiding catheter with a minimal inner diameter of 0.070”/1.78 mm.

38% more push[3] to reach target lesion

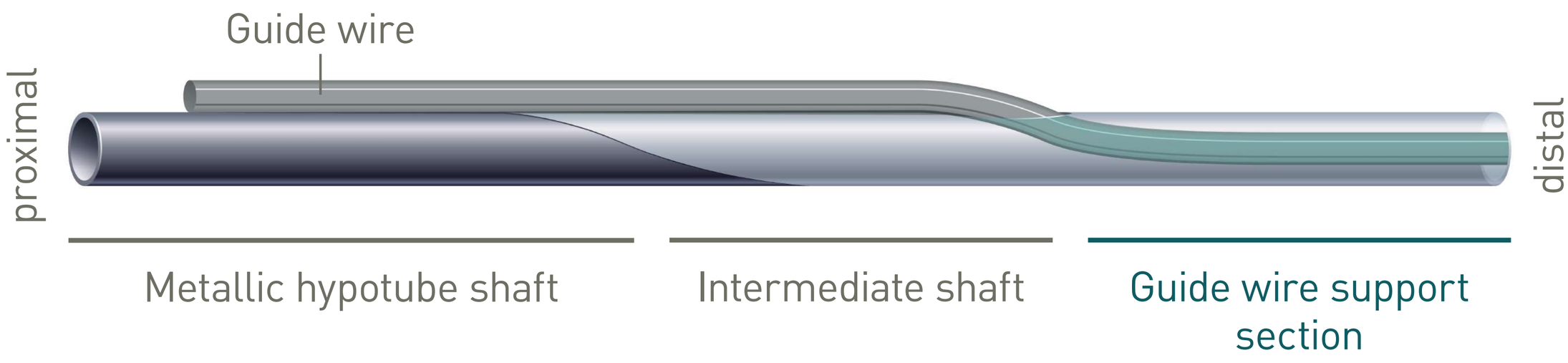
Enhanced Force Transmission shaft

BIOTRONIK's unique Enhanced Force Transmission shaft results in optimal pushability due to the direct transition from proximal metallic hypotube to distal guide wire support section.

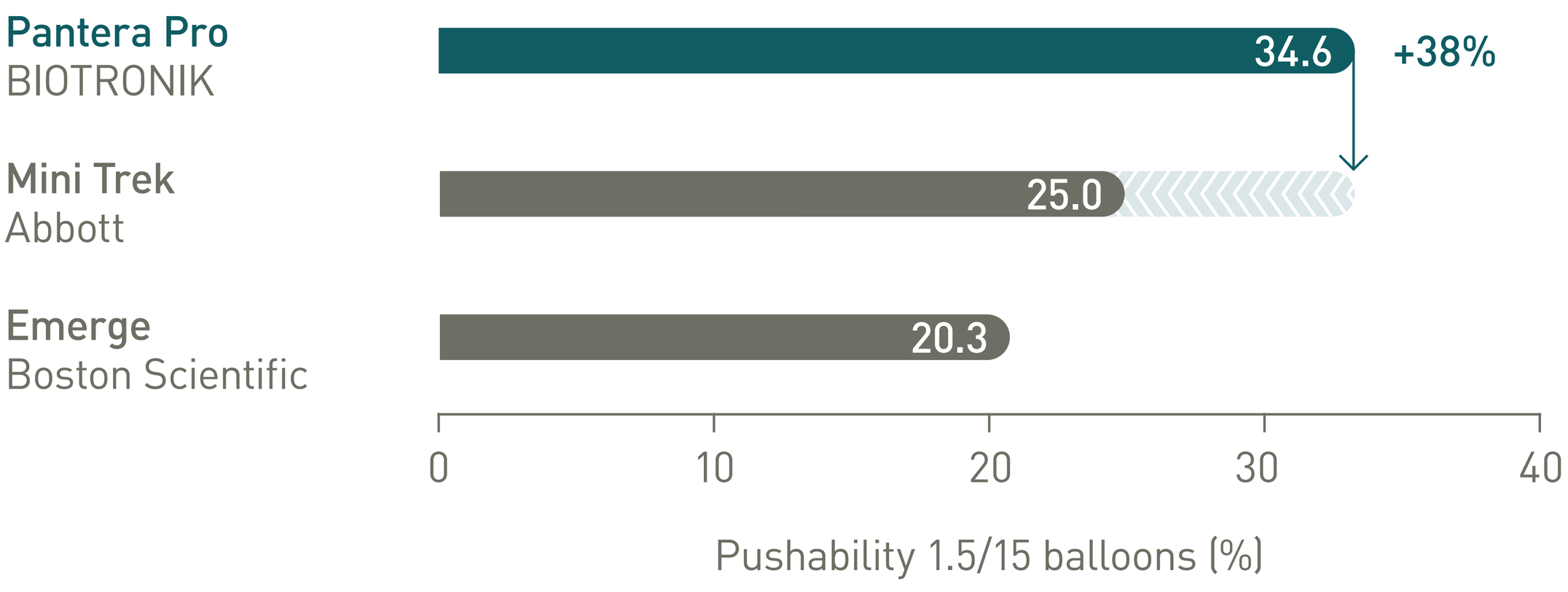
Pantera Pro

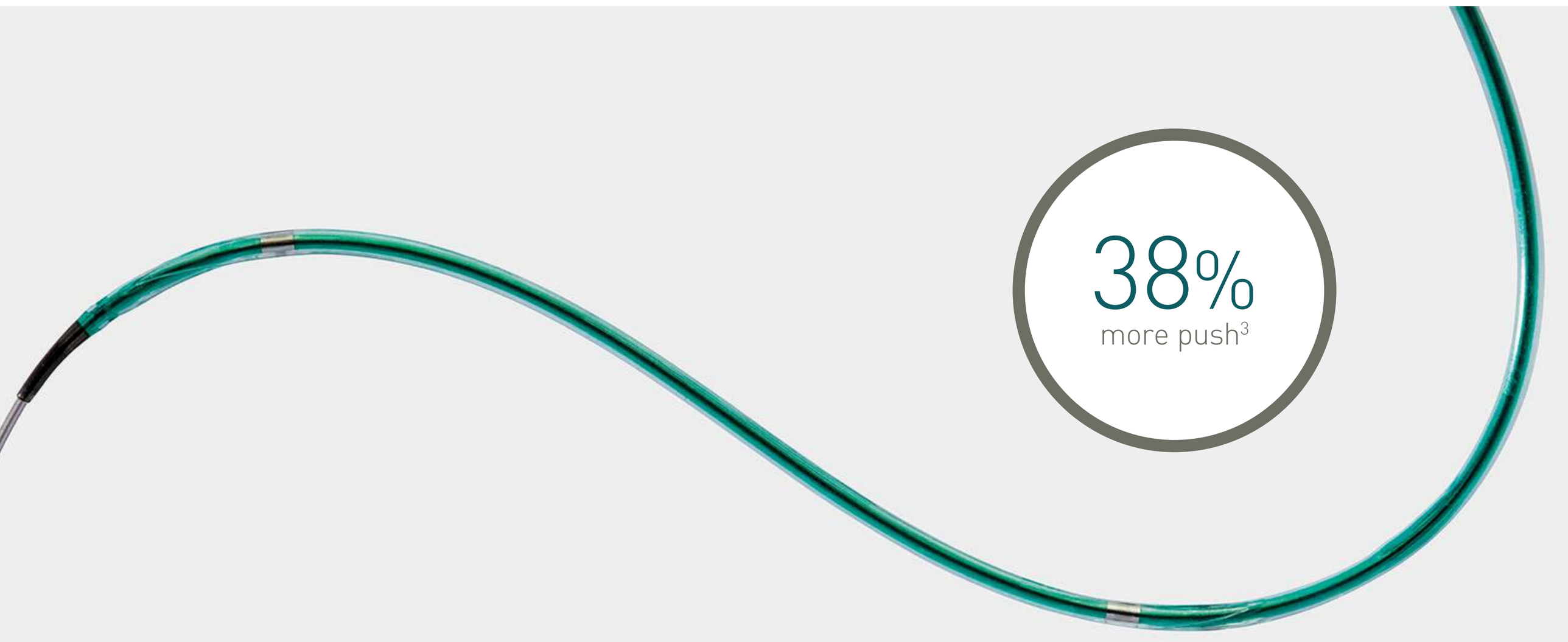


Competitors



Pushability comparison





Pantera Pro

Indicated for dilation 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	ø 1.25 - 1.5 mm: Two-fold; ø 2.0 - 4.0 mm: Tri-fold
Balloon markers	Platinum-Iridium: ø 1.25 - 1.5 mm one marker; ø 2.0 - 4.0 mm two markers
Coating distal shaft	Hydrophilic (end of balloon to Guide Wire (GW) exit port)
Balloon and tip coating	ø 1.25 - 2.0 mm: Hydrophilic ø 2.50 - 4.0 mm: Hydrophobic
Kissing balloon technique	6F guiding catheter (min. I.D. 0.070”/1.78 mm), up to ø 3.5 mm
Diameter	2.6F (ø 1.25 - 2.0 mm); 2.7F (ø 2.5 - 3.5 mm); 2.9F (ø 4.0 mm)

Compliance Chart

Balloon diameter x length (mm)		ø 1.25 x 6-20	ø 1.50 x 6-20	ø 2.00 x 10-30	ø 2.50 x 10-30	ø 3.00 x 10-30	ø 3.50 x 10-30	ø 4.00 x 10-30
Nominal Pressure (NP)	atm**	7	7	7	7	7	7	7
	ø (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
	ø (mm)	1.37	1.72	2.23	2.93	3.50	4.06	4.55

**1 atm = 1.013 bar

Ordering Information

Balloon ø (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

1. 1.25-2.0 mm diameter, bench test when compared to key competitors, BIOTRONIK data on file; 2. vs Trek (Abbott), BIOTRONIK data on file; 3. vs Mini Trek (Abbott), BIOTRONIK data on file.

Trek and Mini Trek are registered trademarks of Abbott; Emerge is a registered trademark of Boston Scientific.

*Indication as per IFU.

413275/B/Jan_2018_DV

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BIOTRONIK
excellence for life

Lowest compliance in class avoiding dog-bone effect

Precise dilatation

Enhanced crossability and accurate placement

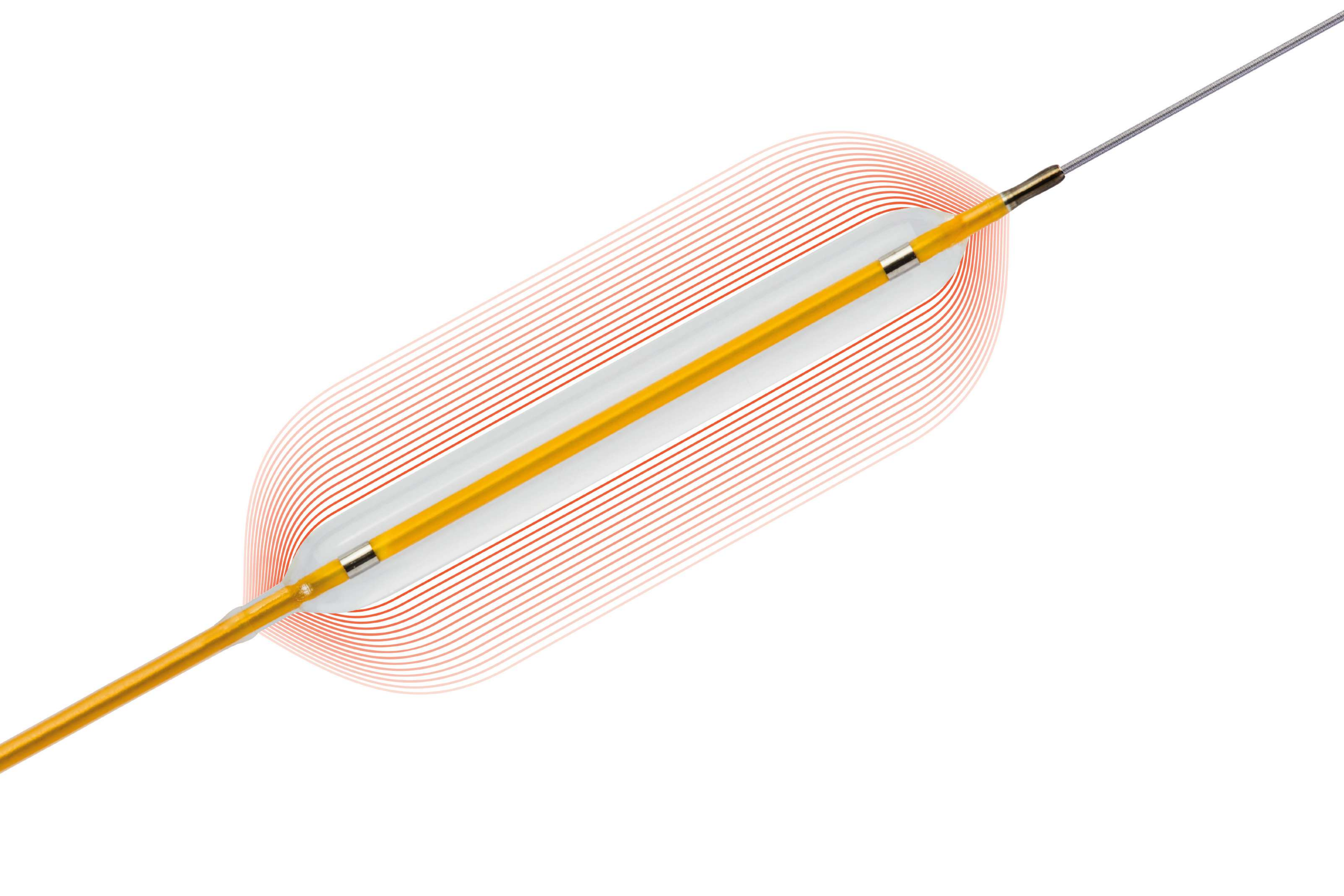
Technical data / ordering info

Vascular Intervention // Coronary

Non-Compliant High Pressure Balloon Catheter

BIOTRONIK
excellence for life

Pantera LEO

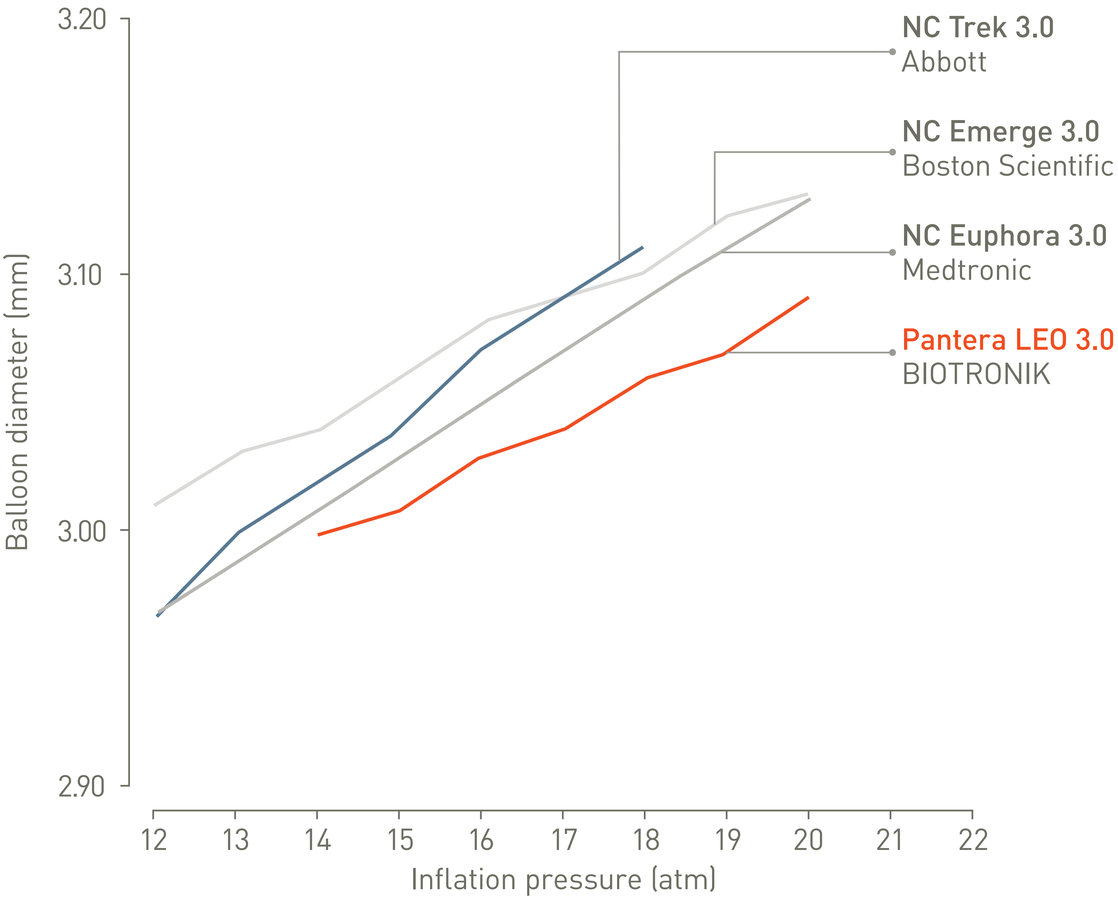


Lowest compliance in class[1] avoiding dog-bone effect

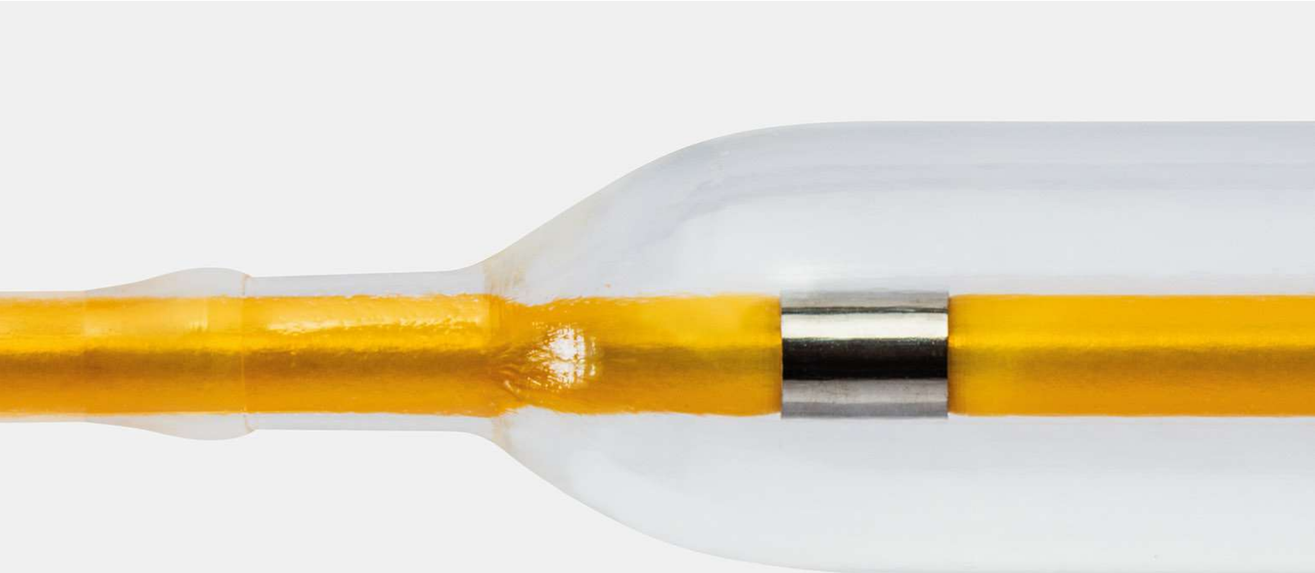
The Pantera LEO high pressure balloon has the lowest compliance in class[1] which ensures controlled minimal growth up to Rated Burst Pressure (RBP) without any dog-bone effect.

More controlled growth from Nominal Pressure (NP) to RBP[1]

Compliance curves 3.0 mm balloons (Values shown between NP and RBP)



Source: Product Labelling



Precise dilatation

Extra short balloooon shoulders

The extra short balloon shoulders reduce longitudinal balloon growth, minimizing the potential for vessel trauma outside the treatment area.

Longitudinal balloon growth between NP and RBP[2]

Pantera LEO
BIOTRONIK

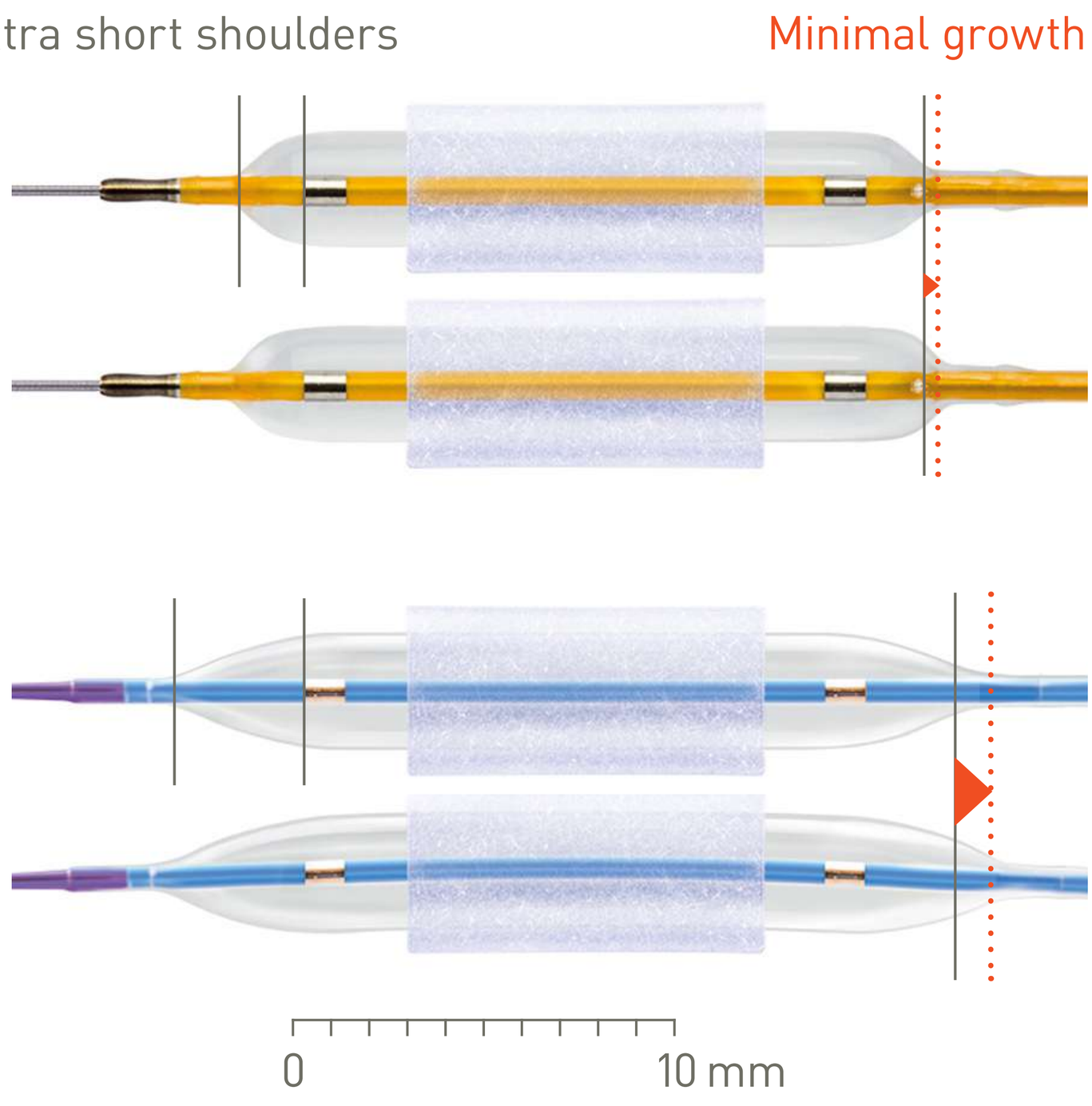
NP at 14 atm

RBP at 20 atm

NC Emerge
Boston Scientific

NP at 12 atm

RBP at 20 atm



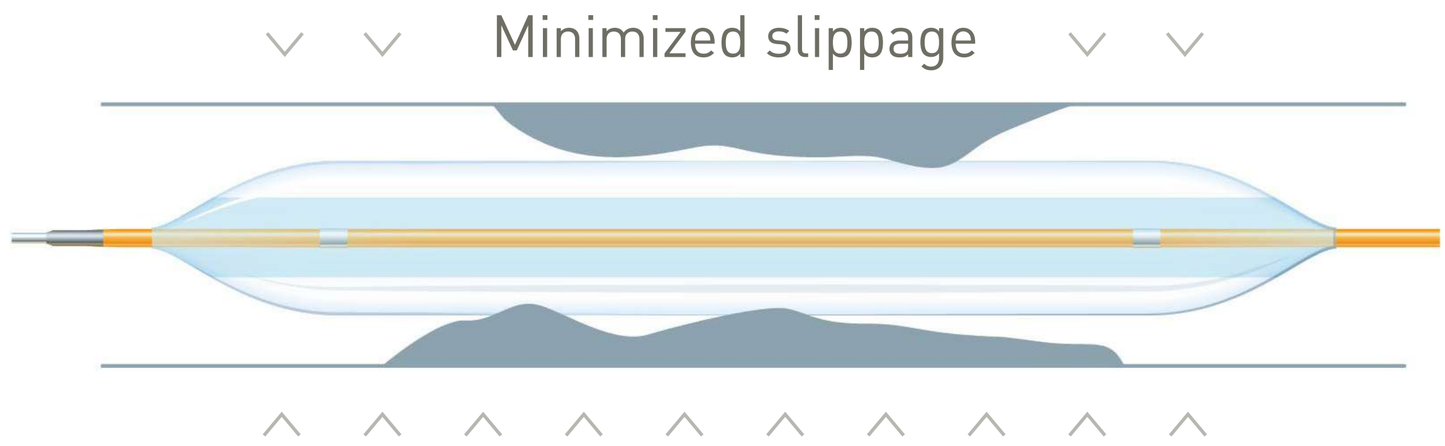
Enhanced crossability and accurate placement

Patchwork coating

The tri-fold balloon is fully coated when folded but only partially coated when inflated. The resulting patchwork coating enables enhanced crossability while minimizing slippage during dilatation.

Folded balloon

Inflated balloon



● Hydrophobic coating ○ Uncoated

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**
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

5F

1. When compared to main competitors, compliance curves 3.0 mm balloons, BIOTRONIK Data on file; 2. BIOTRONIK Data on file.

Trek and NC Trek are registered trademarks of Abbott; Emerge is a registered trademark of Boston Scientific; Euphora is a registered trademark of Medtronic.

*Indication as per IFU.

369835/F/Jan_2018_DV

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BIOTRONIK
excellence for life

Clinically proven solution for in-stent restenosis and de novo lesions

Lux coating technology for rapid drug absorption

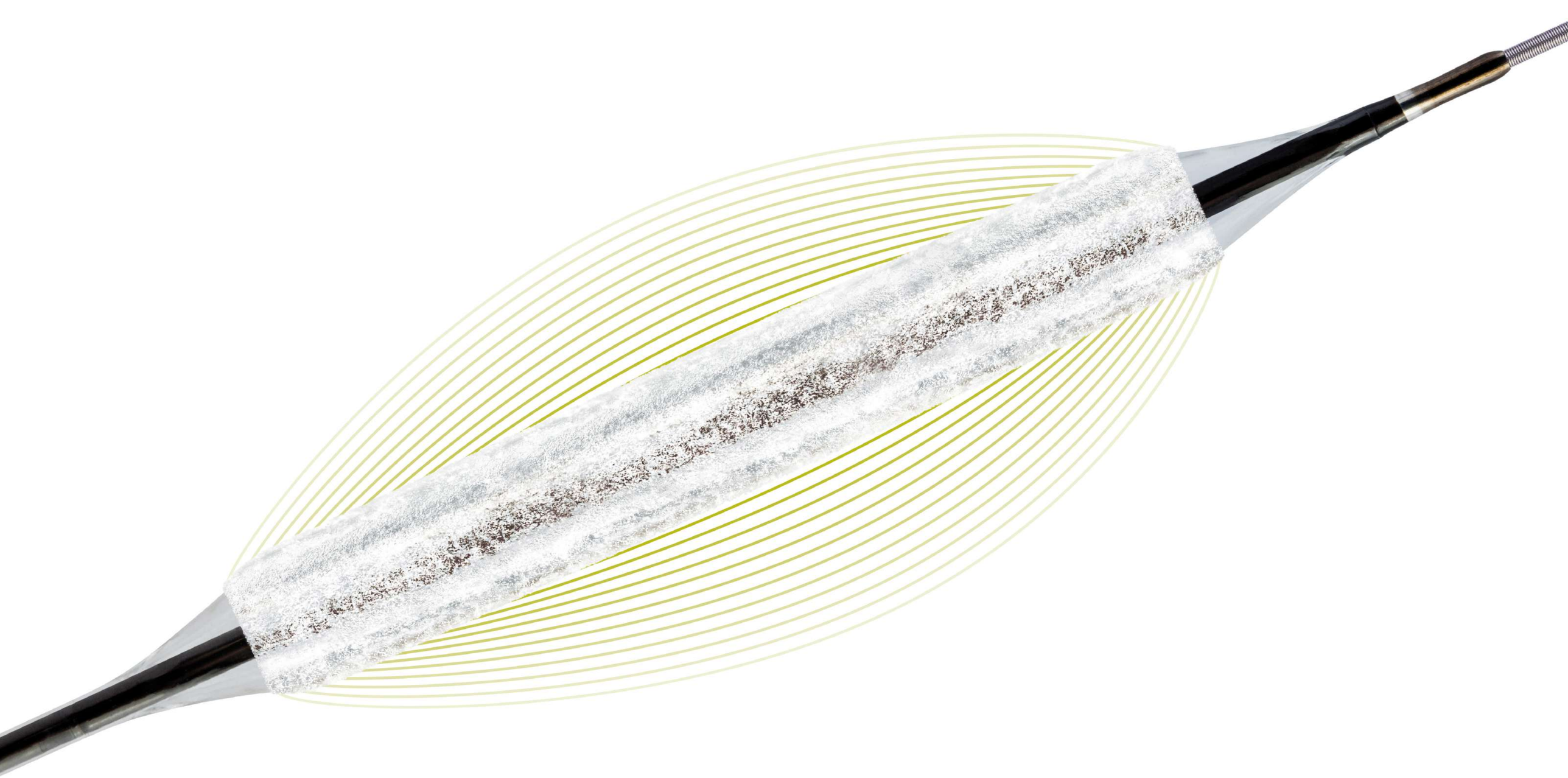
Advanced trackability

Technical data / ordering info

Vascular Intervention // Coronary
Drug-Coated Balloon Catheter

BIOTRONIK
excellence for life

Pantera Lux



Clinically proven solution for in-stent restenosis and de novo lesions

Clinical outcomes from multiple studies[1-8] including randomized controlled trials like BIOLUX RCT, ISAR-DESIRE 4 and PEBSI show high efficacy and safety for both in-stent restenosis and de novo lesions.

Lux coating technology for rapid drug absorption

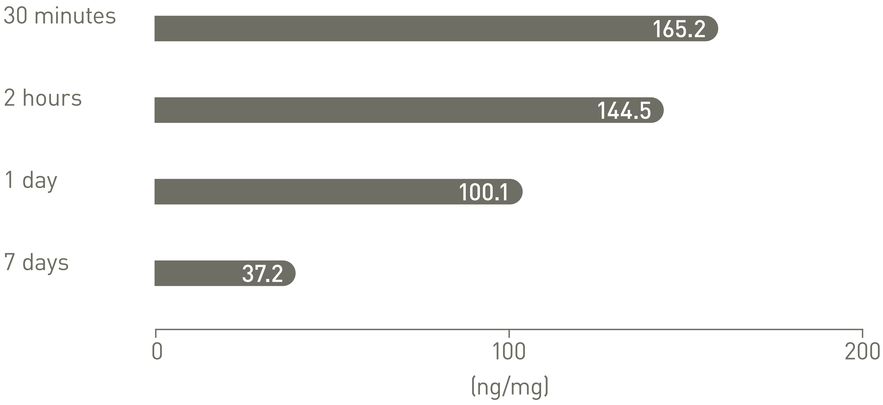
Drug Paclitaxel
- 3.0 µg Paclitaxel / mm^2 balloon surface
- Anti-proliferative

Excipient Butyryl-tri-hexyl citrate (BTHC)
- Degrades to citric acid and alcohol, rapidly metabolized
- Keeps Paclitaxel in microcrystalline structure

Lux coating technology
- For rapid drug absorption into the vessel wall[9]
- Improving bioavailability at the target site[9]

Prolonged tissue retention at the target site[9, 10]

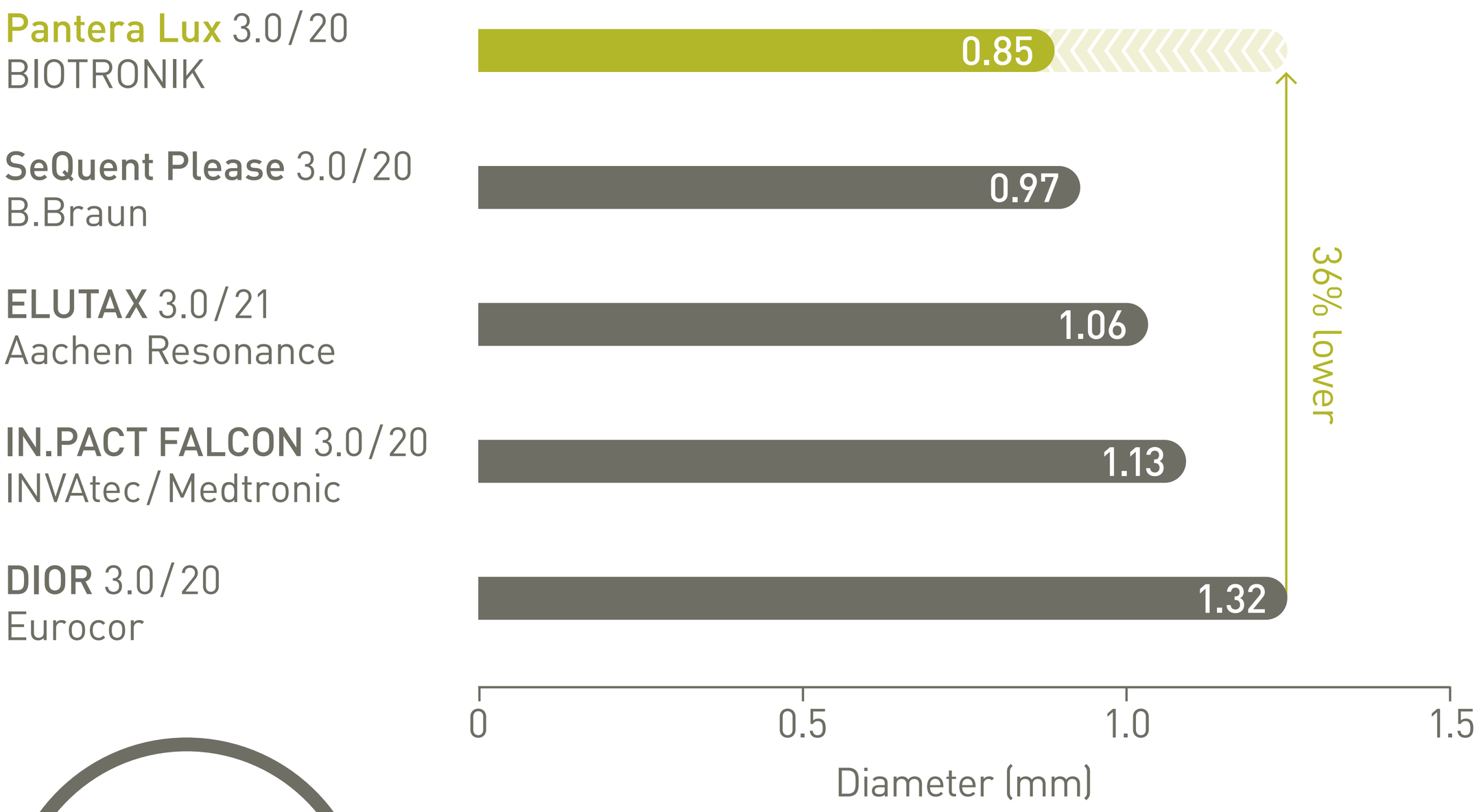
Pig coronary artery Paclitaxel tissue concentrations



Advanced trackability

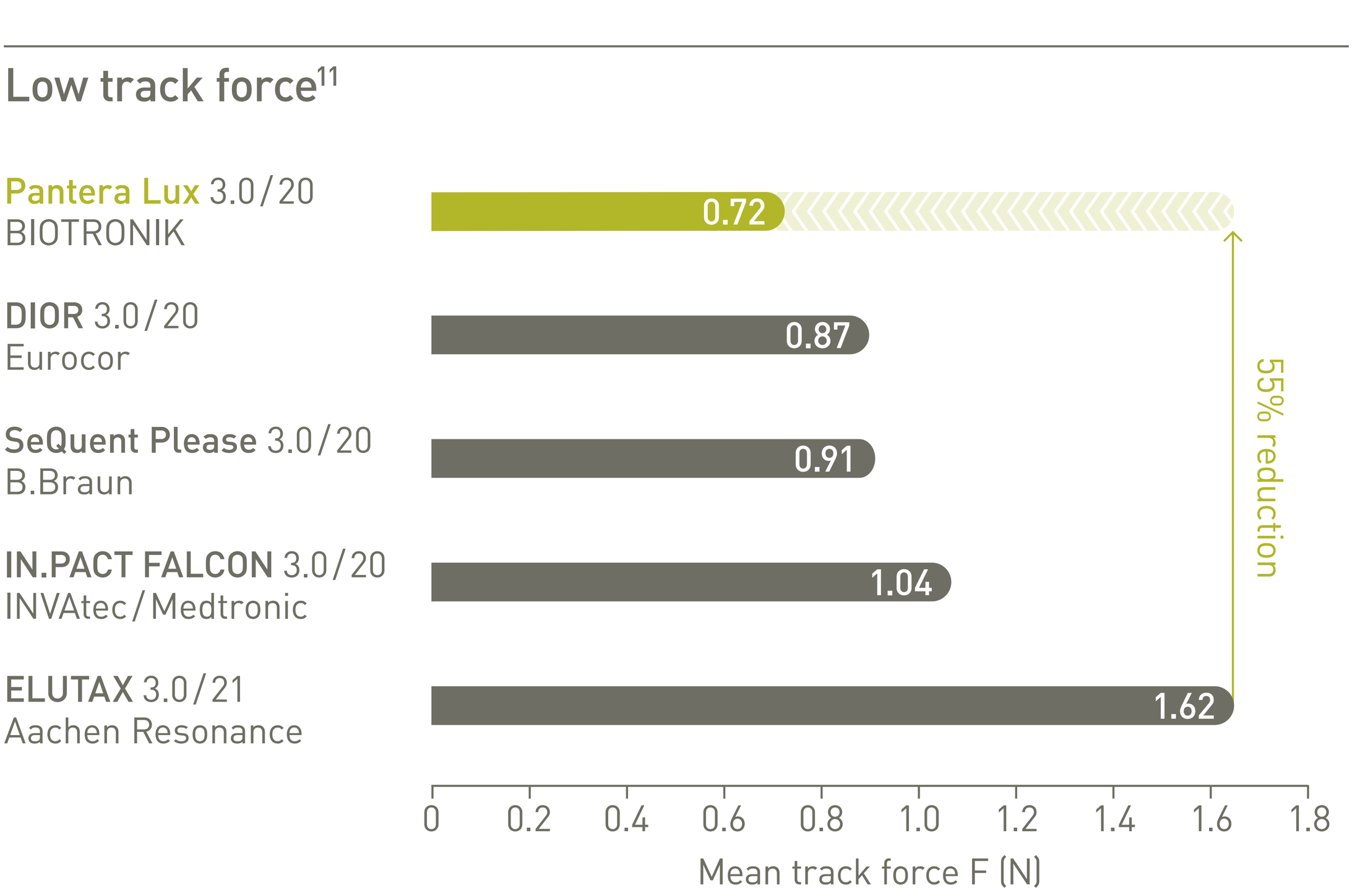
Pantera Lux, with its low crossing profile, provides advanced trackability to successfully reach and treat most cases in daily practice.

Low crossing profile[11]



36%
lower crossing profile[11]

Low track force[11]



Pantera Lux

Vascular
Intervention
Coronary

Indicated for balloon dilatation for in-stent restenosis, de-novo lesions, acute or impending vascular occlusion and treatment of small vessel disease.*

Technical Data

Drug-coated balloon catheter	
Catheter type	Fast-exchange PTCA balloon catheter
Recommended guide catheter	5F (min. I.D. 0.056”)
Lesion entry profile	0.017”
Guide wire diameter	0.014”
Usable catheter length	140 cm
Balloon folding	3-fold
Balloon markers	Two embedded platinum-iridium markers
Brachial shaft marker	92 cm from tip
Femoral shaft marker	102 cm from tip
Proximal shaft diameter	2.0F
Distal shaft diameter	2.5F (ø 2.0 - 3.5 mm), 2.6F (ø 4.0 mm)
Nominal Pressure (NP)	7 atm
Rated Burst Pressure (RBP)	13 atm (ø 2.0 - 3.5 mm); 12 atm (ø 4.0 mm)

Coating

Drug	Paclitaxel
Drug dose	3.0 µg / mm^2
Delivery matrix	Paclitaxel and Butyryl-tri-hexyl citrate (BTHC)
Coated area	Cylindrical section of the balloon, exceeding the proximal and distal markers

Compliance Chart

Balloon diameter x length (mm)		ø 2.0 x 10-30	ø 2.5 x 10-30	ø 3.0 x 10-30	ø 3.5 x 10-30	ø 4.0 x 10-30
Nominal Pressure (NP)	atm**	7	7	7	7	7
	ø (mm)	2.00	2.50	3.00	3.50	4.00
Rated Burst Pressure (RBP)	atm**	13	13	13	13	12
	ø (mm)	2.26	2.82	3.48	4.11	4.59

**1 atm = 1.013 bar

Ordering Information

Balloon ø (mm)	Catheter length 140cm Balloon length (mm)				
	10	15	20	25	30
2.0	365110	365111	365112	365113	365114
2.5	365120	365121	365122	365123	365124
3.0	365125	365126	365127	365128	365129
3.5	365130	365131	365132	365133	365134
4.0	365135	365136	365137	365138	365139

1. Hehrlein C. et al. Cardiovasc. Revasc. Med. 2012 Sep; 13(5): 260-4; 2. Toelg R. et al. EuroIntervention 2014 Sep; 10(5): 591-9; 3. Naber C.K. EuroPCR 2016. oral presentation. BIOLUX RCT Clinical performance of the Pantera Lux Paclitaxel coated balloon vs. drug-eluting Orsiro hybrid stent system in patients with in-stent restenosis: a randomized controlled trial; 4. Kufner et al. J Am Coll Cardiol Intv 2017;10: 1332 -40, Clinical trials.gov, NCT01632371; 5. Garcia-Touchard et al. EuroIntervention. 2017 Jan 20;12(13):1587-1594. NCT01839890; 6. Vos N. S. et al. EuroIntervention 2014;10:584-590; 7. Jim M. H. AsiaPCR 2014, oral presentation, Six-month Angiographic Restudy of Paclitaxel-Eluting balloon kissing in Dealing with side branch Ostial Narrowing (SARPEDON); 8. Worthley S. et al. Cardiovasc. Revasc. Med. 2015; 16: 413-417; 9. Radke P. et al. EuroIntervention. 2011 Oct; 7(6): 730-7; 10. BIOTRONIK data on file; 11. BIOTRONIK data on file, compared to main competitors.

*Indication as per IFU (may differ in countries not accepting CE mark).

371257/E/Jan_2018_DV

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Superior patient outcomes

Ultrathin struts

Excellent deliverability

Technical data / ordering info

Vascular Intervention // Coronary
Drug-Eluting Stent System

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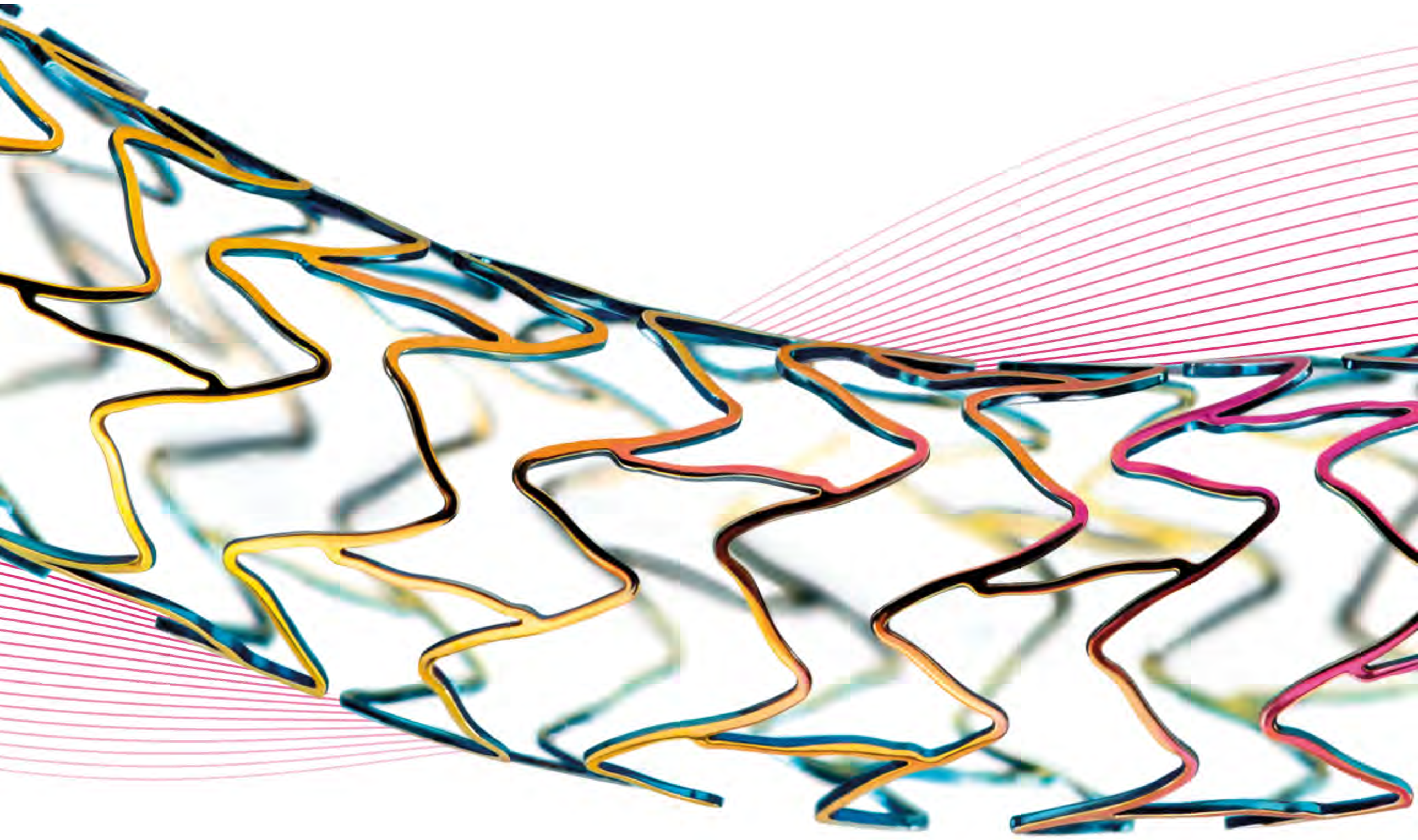
Orsiro®

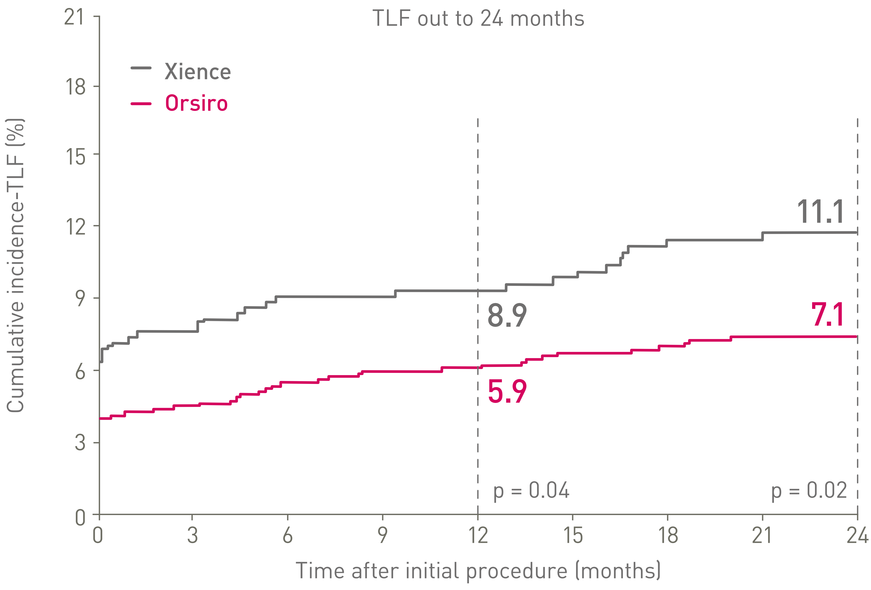
Ultrathin struts. Superior patient outcomes.



Superior patient outcomes

In the FDA pivotal trial BIOFLOW-V (n = 1,334)

Orsiro shows statistically significant lower Target Lesion Failure (TLF) rates at 12 and 24 months in a more-comers population with >50% ACS in both study arms.[1,2]



Orsiro outperforms Xience* at two-year clinical follow-up[1]

37%
lower
TLF rate
(p = 0.02)

47%
Lower
Ischemia-driven
TLR rate
(p = 0.04)

44%
reduction in
TV-MI rate
(p = 0.01)

"Results from this trial establish a new standard for safety and efficacy among contemporary drug-eluting stents."

Dr. David Kandzari
BIOFLOW-V US Principal Investigator

TLR – Target Lesion Revascularization; TV-MI - Target Vessel Myocardial Infarction

Ultrathin Struts - thinnest available in the US[3]

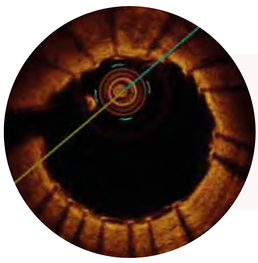
Thinner struts, faster endothelialization[4]

Improved outcomes start in the acute phase

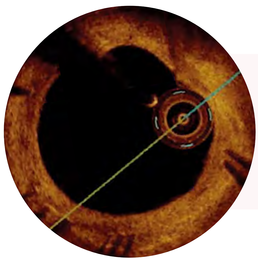
43%
lower in-hospital MI rate‡ vs. Xience[2]

48 hours
Thinner struts mean less vessel injury[4]

Vascular Healing



30 days
80.4% strut coverage[5]



90 days
98.7% strut coverage[5]

Ultrathin, Ultraeffective

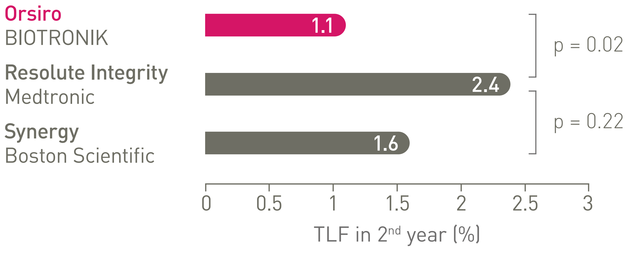
Ultrathin vs. thin strut DES in a large scale meta-analysis including more than 11,000 patients[6]

16%
reduction in TLF rate at 12m
(RR=0.84; 95% CI 0.72-0.99)

‡ Driven by peri-procedural MI events (<48 hours). In-hospital rate may include events > 48 hours.

Statistically lower clinical event rates between 1-2 years compared to Resolute Integrity*[7]

BIO-RESORT (n = 3,514) is a large, randomized, investigator-initiated, all-comers trial, including a large subset of complex patients with high-bleeding risk[7]



Lower revascularization rates in the 2nd year

BIO-RESORT[7]

60%
lower TLR rate vs Resolute Integrity*

(p = 0.04)

BIOFLOW-V[2]

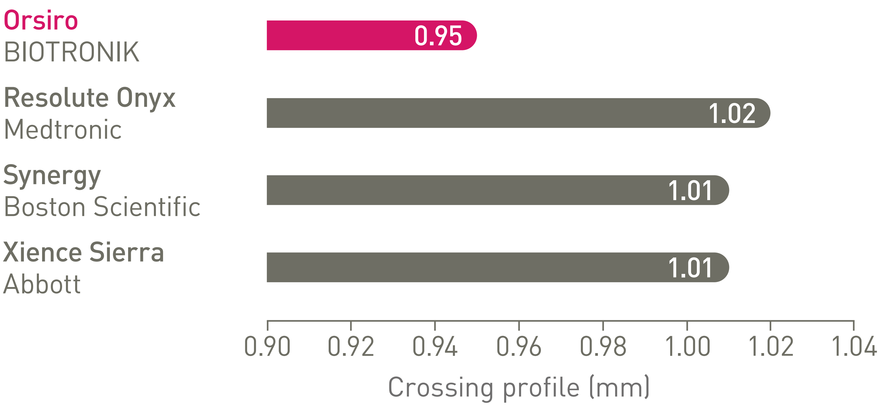
73%
lower TLR rate vs Xience*

(p = 0.01)

Excellent deliverability

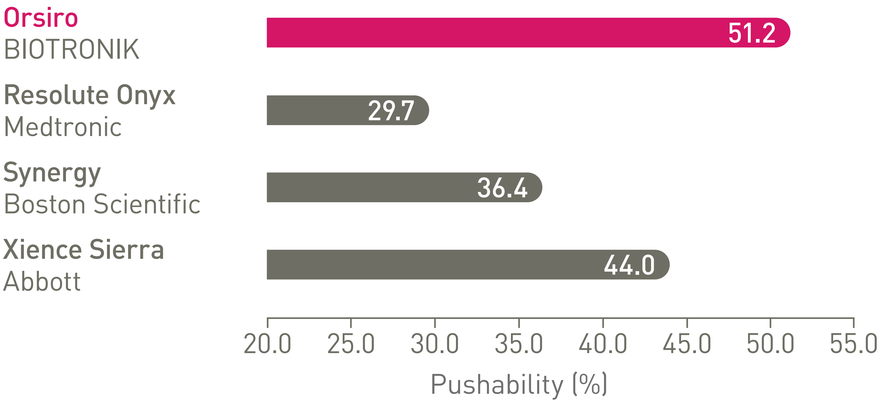
Lowest crossing profile[8]

Designed for challenging cases



Better push

Transmits up to 72% more force from hub to tip[8]



"Low profile and great deliverability coupled with superb clinical outcomes is a game-changer. In the current era of coronary stents, thinner struts are better and thinnest might be best."

Dr. Dean Kereiakes

BIOFLOW-V Site Principal Investigator

Orsiro®

Sirolimus-Eluting Coronary Stent System

Vascular
Intervention
Coronary

Indication

Orsiro is indicated for improving coronary luminal diameter in patients, including those with diabetes mellitus, with symptomatic heart disease, stable angina, unstable angina, non-ST-elevation myocardial infarction or documented silent ischemia due to atherosclerotic lesions in the native coronary arteries with a reference vessel diameter of 2.25 mm to 4.0 mm and a lesion length of ⩽ 36 mm.

Technical Data

Stent	
Stent material	Cobalt chromium, L-605
Passive coating	proBIO™ amorphous silicon carbide
Active coating	BIOlute™ bioabsorbable drug matrix consisting of sirolimus and polymer poly-l-lactide (PLLA)
Nominal drug content	1.4 µg/mm²

Delivery system	
Catheter type	Fast-exchange
Recommended guide catheter	5F (min. I.D.$^{\Delta}$ ⩾ 0.056“)
Guide wire diameter	0.014” (0.36 mm)
Usable catheter length	140 cm
Balloon material	Polymer
Coating (distal shaft)	Hydrophilic coating
Marker bands	Two platinum-iridium markers
Proximal shaft diameter	2.0F
Distal shaft diameter	ø 2.25-3.5 mm: 2.7F ø 4.0 mm: 3.0F
Nominal pressure (NP)	ø 2.25-2.75, 3.5-4.0 mm: 7 atm ø 3.0 mm: 8 atm
Rated burst pressure (RBP)	16 atm

$^{\Delta}$I.D. = Inner Diameter

Compliance Chart

Balloon diameter x length (mm)		ø 2.25 x 9-30	ø 2.50 × 9-40	ø 2.75 × 9-40	ø 3.00 × 9-40	ø 3.50 × 9-40	ø 4.00 × 9-40
Nominal Pressure (NP)	atm**	7	7	7	8	7	7
	ø (mm)	2.26	2.52	2.75	3.07	3.54	4.00
Rated Burst Pressure (RBP)	atm**	16	16	16	16	16	16
	ø (mm)	2.57	2.92	3.14	3.42	3.95	4.48
Maximum diameter for post-dilation	ø (mm)	3.5	3.5	3.5	3.5	4.5	4.5

**1 atm = 1.013 bar

Ordering Information

Stent ø (mm)	Stent length (mm)								
	9	13	15	18	22	26	30	35	40
2.25	401729	401735	401741	401747	401753	401759	401765		
2.50	401730	401736	401742	401748	401754	401760	401766	404667	404673
2.75	401731	401737	401743	401749	401755	401761	401767	404668	404674
3.00	401732	401738	401744	401750	401756	401762	401768	404669	404675
3.50	401733	401739	401745	401751	401757	401763	401769	404670	404676
4.00	401734	401740	401746	401752	401758	401764	401770	404671	404677

1. Kandzari D et al. Journal of the American College of Cardiology. 2018 Sep 23:25565; 2. Kandzari D et al. The Lancet. 2017 Oct 21;390(10105):1843-52; 3. When compared to FDA approved Drug Eluting Stents. BIOTRONIK data on file; 4. Foin N et al. International journal of cardiology. 2014 Dec 20;177(3):800-8; 5. Secco G. Cardiovasc Revasc Med. 2016 Jan-Feb;17(1):38-43; 6. Bangalore S et al. Circulation. 2018 Jun 26:CIRCULATIONAHA-118; 7. Kok M et al. EuroIntervention 2018; published online May 23. DOI: 10.4244. EIJ-D-18-00336; 8. BIOTRONIK data on file; IIB(P)24/2018.

℞ ONLY

BR388 2/6/19_DV

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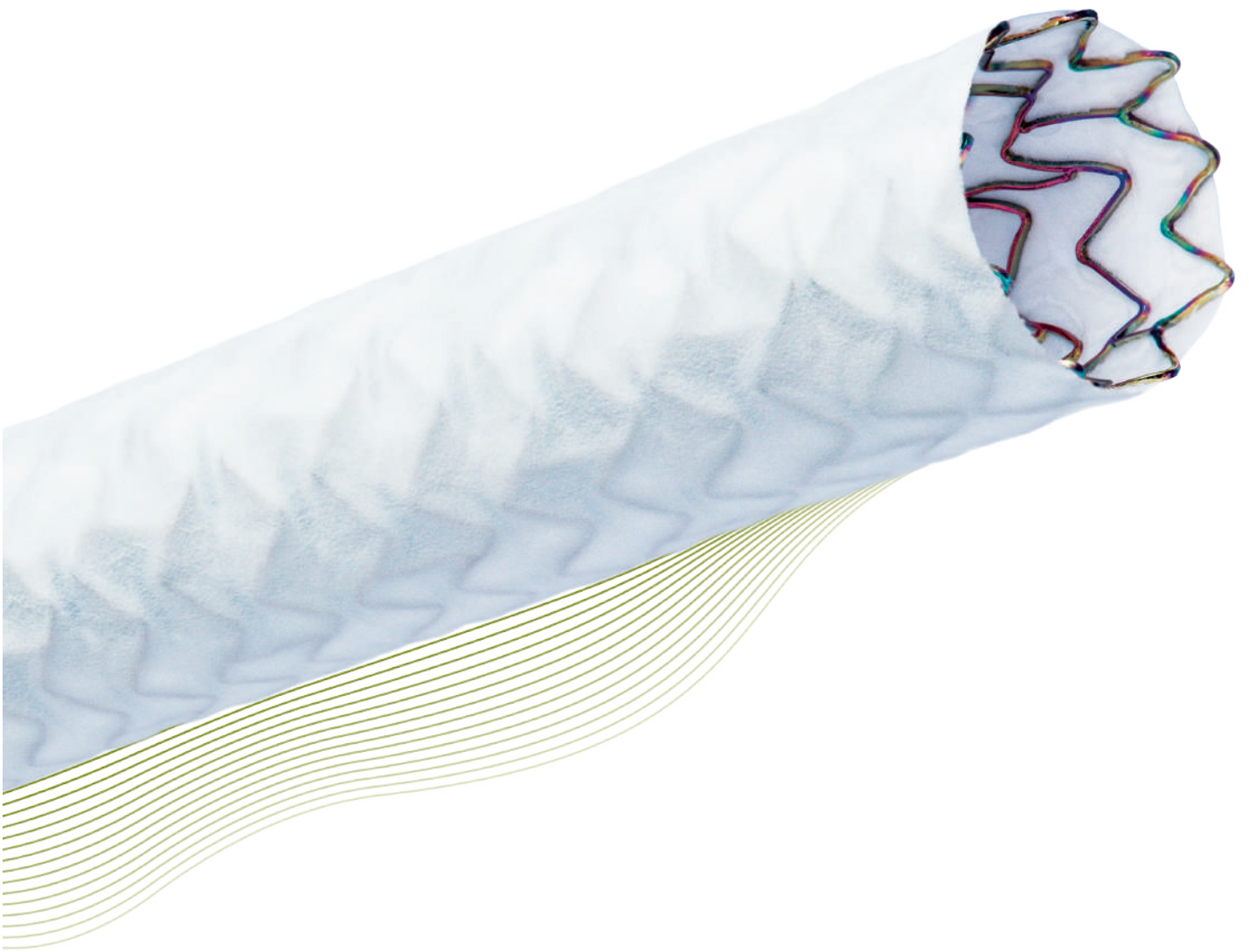
BIOTRONIK
excellence for life

Vascular Intervention // Coronary
Covered Coronary Stent System

PK Papyrus



- Exceptional deliverability[1,2]
- Covered single stent design
- Designed to save lives when seconds count[3]

Humanitarian Device. Authorized by Federal law for use in the treatment of acute perforations of native coronary arteries and coronary bypass grafts in vessels 2.5 to 5.0 mm in diameter. The effectiveness of this device for this use has not been demonstrated.

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PK Papyrus

Designed to deliver more like a conventional stent[1, 2]

Superior design for exceptional deliverability[1,2]

Lowest crossing profile[1]

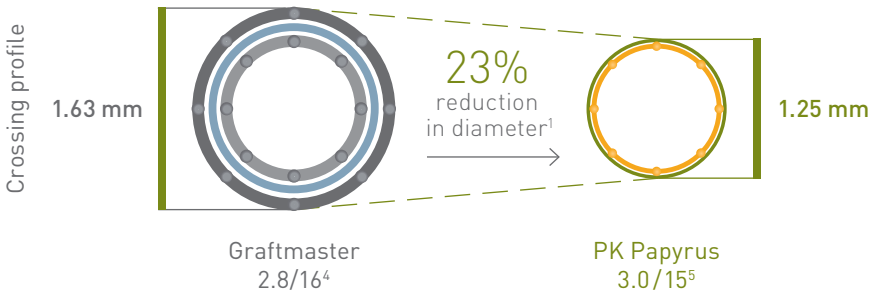
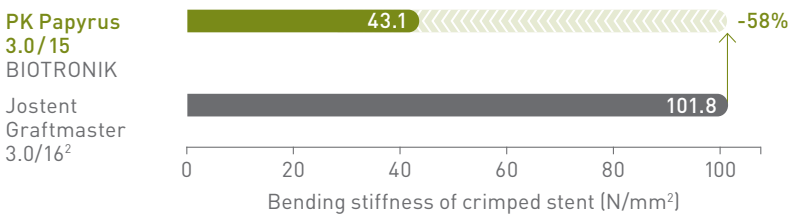


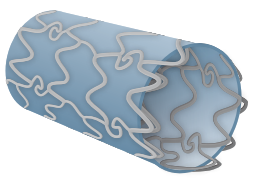
Illustration depicts crimped devices prior to inflation

Superior flexibility[2]

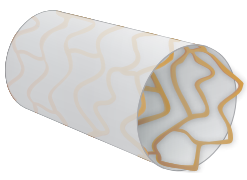


Covered single stent design

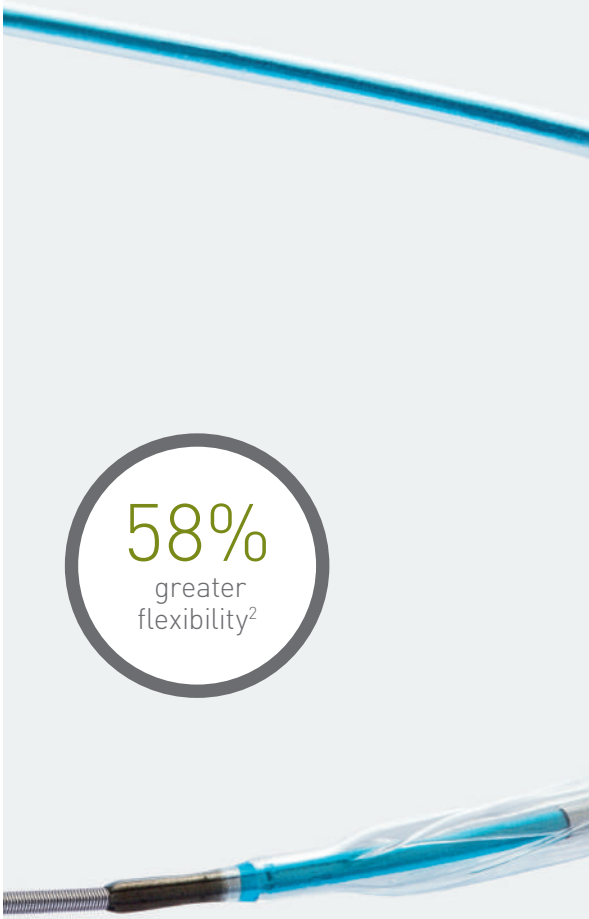
- BIOTRONIK's ultrathin strut stent platform (Cobalt Chromium).
- Highly elastic membrane capable of sealing coronary artery perforations.[6]

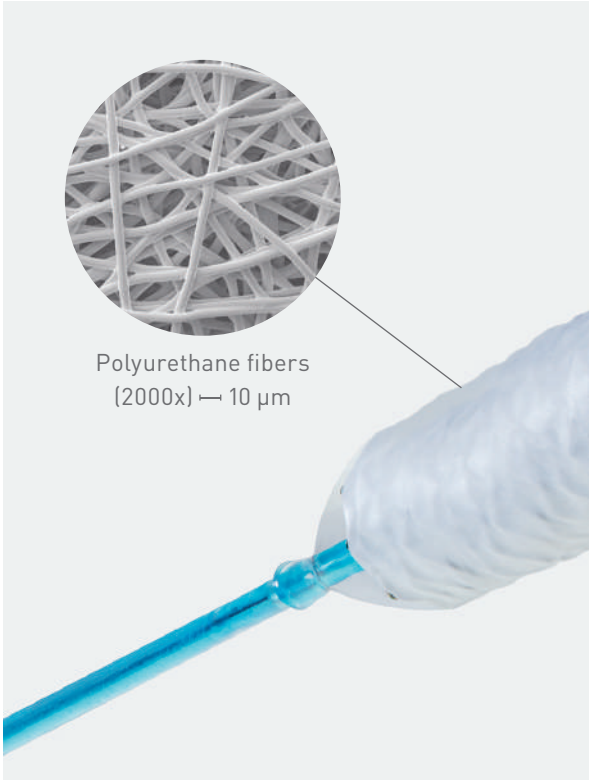


Jostent Graftmaster
Traditional sandwich stent design



PK Papyrus
Covered single stent design





The only
5F
compatibility*

47%
less time to deliver[6]

Time to expand your options with **PK Papyrus**

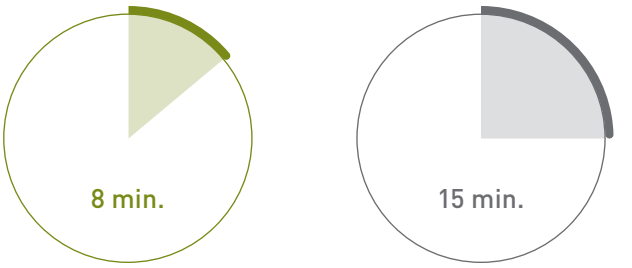
Broadest range of sizes on the US market[7]

- The only 5F compatible* covered coronary stent with the broadest range of sizes.[7] For main sizes – no need for guide catheter upgrade.*
- First FDA approved 2.5 mm diameter.

Designed to save lives when seconds count[3]

Shorter time to deliver[6]

Single center, retrospective investigation of 61 patients treated with covered coronary stents.[8]



PK Papyrus
n = 22

Jostent Graftmaster
n = 39

Median time to deliver (p=0.001)

*5F compatible for ø 2.5-4.0 mm; 6F compatible for ø 4.5-5.0 mm

PK Papyrus

Vascular Intervention Coronary

Indicated for the treatment of acute perforations of native coronary arteries and coronary bypass grafts in vessels 2.5 to 5.0 mm in diameter*

Technical Data

Stent	
Stent cover material	Non-woven, electrospun polyurethane
Stent cover thickness	90 µm
Stent material	Cobalt chromium (L-605) with proBIO (amorphous silicon carbide) coating
Maximum stent expansion diameter	ø 2.5 - 3.0 mm: 3.50 mm; ø 3.5 - 4.0 mm: 4.65 mm; ø 4.5 - 5.0 mm: 5.63 mm

Delivery system	
Guide wire diameter	0.014"
Usable catheter length	140 cm
Recommended guide catheter	ø 2.5 - 4.0 mm: 5F (min. I.D.** 0.056"); ø 4.5 - 5.0 mm: 6F (min. I.D.** 0.070")
Nominal pressure (NP)	ø 2.5 - 3.5 mm: 8 atm; ø 4.0 - 5.0 mm: 7 atm
Rated burst pressure (RBP)	ø 2.5 - 4.0 mm: 16 atm; ø 4.5 - 5.0 mm: 14 atm

**I.D. = Inner Diameter

Compliance Chart

	Inflation pressure	Stent inner diameter (mm)					
	atm	2.5	3.0	3.5	4.0	4.5	5.0
Nominal pressure (NP)	7	-	-	-	4.01	4.55	4.93
Nominal pressure (NP)	8	2.52	2.99	3.53	4.14	4.69	5.09
	9	2.59	3.07	3.63	4.26	4.82	5.23
	10	2.65	3.15	3.71	4.35	4.91	5.34
	11	2.70	3.21	3.77	4.43	4.99	5.43
	12	2.74	3.26	3.82	4.49	5.06	5.50
	13	2.77	3.30	3.86	4.54	5.11	5.56
Rated burst pressure (RBP)	14	2.80	3.34	3.90	4.59	5.16	5.61
	15	2.83	3.37	3.93	4.63	-	-
Rated burst pressure (RBP)	16	2.86	3.40	3.96	4.67	-	-

Ordering Information

	Stent ø (mm)	Catheter length 140 cm Stent length (mm)		
		15	20	26
5F	2.5	434887	434893	-
5F	3.0	434888	434894	434899
5F	3.5	434889	434895	434900
5F	4.0	434890	434896	434901
6F	4.5	434891	434897	434902
6F	5.0	434892	434898	434903

1. Compared to Graftmaster 2.8 /16 (BIOTRONIK data on file); 2. Compared to Jostent Graftmaster 3.0/16 (BIOTRONIK data on file); 3. Broad range of sizes available on the US market; 4. Data obtained from Graftmaster Coronary Stent Graft System Brochure 11/13/12; 5. PK Papyrus 3.0/15 (BIOTRONIK data on file); 6. Hernandez-Enriquez M, et al. Outcomes after use of covered stents to treat coronary artery perforations. Comparison of old and new-generation covered stents. J Interv Cardiol. 2018; 1-7; 7. Compared to Graftmaster based on the broader range of sizes available on the US market; 8. Population is representative of real world interventional practice and was not a randomized prospective clinical trial.

*Indication as per IFU.

Information on devices manufactured at companies other than BIOTRONIK was gathered from multiple sources. However, it has not been verified by the vendors and we cannot guarantee its accuracy.

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442278/A/US/Nov_2018

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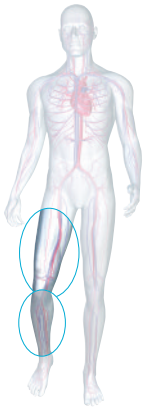
Passeo-14

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 times[1]
- Offering dedicated pedal sizes
- Patchwork coating designed to facilitate crossing
- High pushability and flexibility

4F Solutions

BIOTRONIK
excellence for life

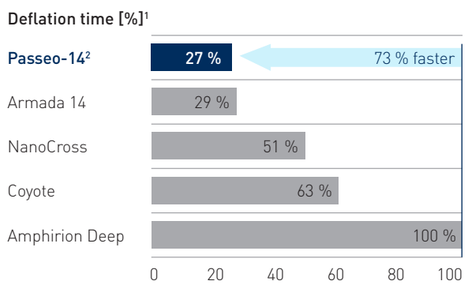
Passeo-14
PTA Balloon/0.014"/OTW

Up to 73 % faster deflation times[1] due to the catheter shaft design featuring a large balloon inflation lumen to facilitate rapid inflation and deflation.

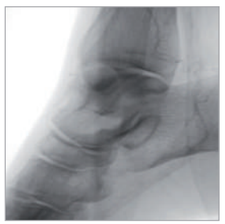
"Impressive deflation time!"
(Dr. M. A. De Gregorio Ariza, Saragossa, Spain, during initial product testing)

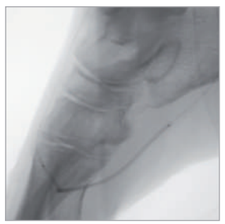
Fast deflation times

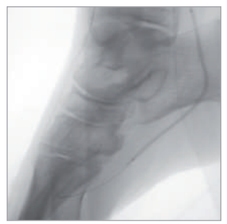
Passeo-14[2] deflates:
- 73 % faster than Amphirion Deep
- 36 % faster than Coyote
- 24 % faster than NanoCross

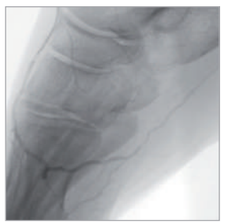


Providing dedicated pedal design:
- ø 1.5 - 2.0 mm
- 150 mm flexible distal shaft
- tailored stiffening wire


Pre-treatment


Dilatation pedal arch


Dilatation plantar arch


Post-treatment

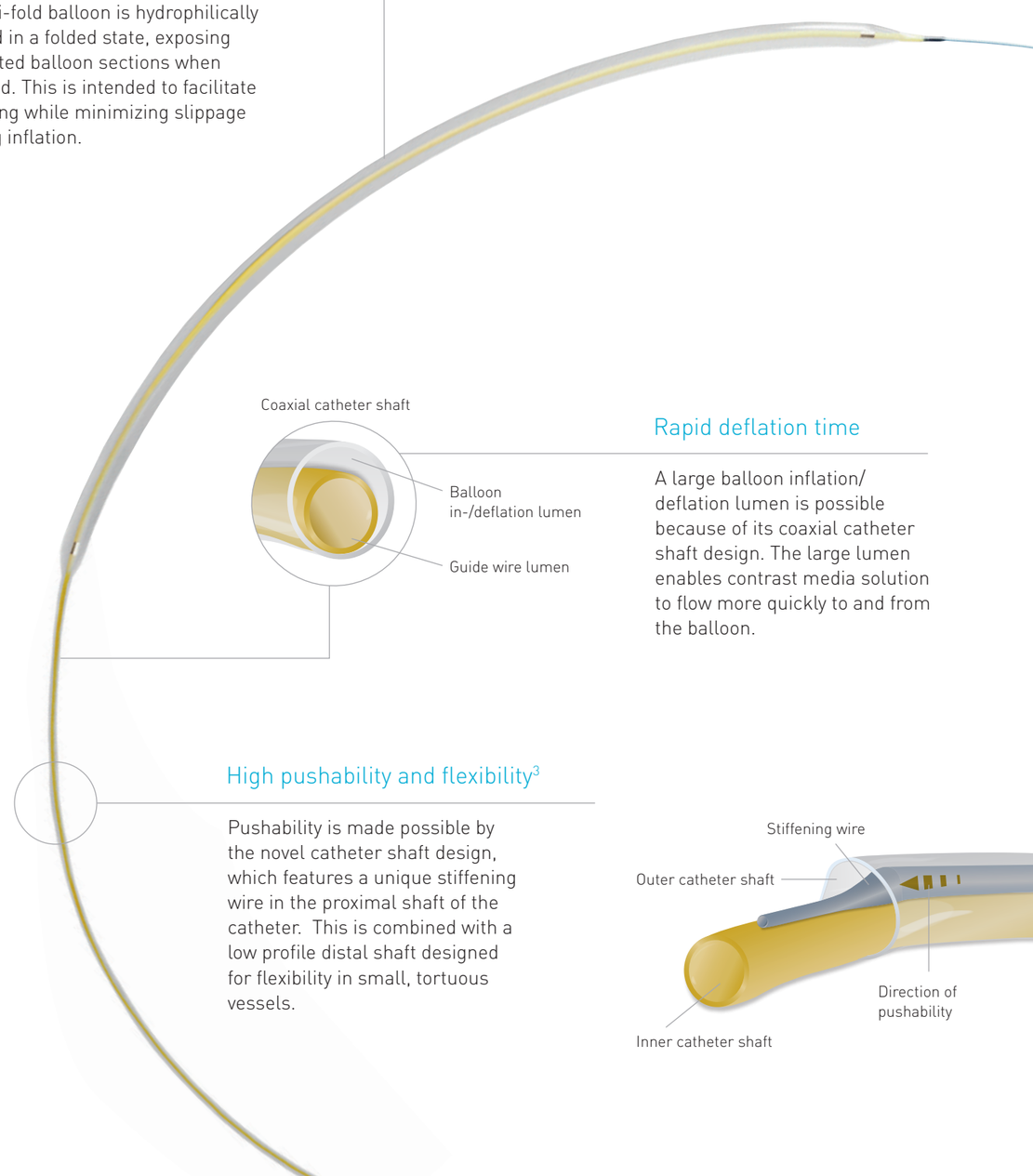
Courtesy of Dr. L. Steffanon, Vicenza, Italy

[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 flexibility[3]

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	atm*	7	7	7	7	7	7
(NP)	ø (mm)	1.5	2.0	2.5	3.0	3.5	4.0
Rated Burst Pressure	atm*	14	14	14	14	14	14
(RBP)	ø (mm)	1.57	2.08	2.61	3.18	3.63	4.16

* 1 atm = 1.013 bar

Ordering Information

Antegrade approach

Catheter Length (cm)	Balloon ø (mm)	Balloon Length (mm) 20	40	70	100	140	180	220
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]	-	-

Crossover approach

Catheter Length (cm)	Balloon ø (mm)	Balloon Length (mm) 20	40	70	100	140	180	220
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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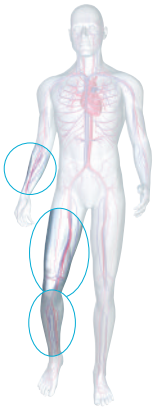
417921/A/603/US

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: ø 2 - 7 mm and 20 - 200 mm balloon lengths
- Patchwork coating designed to facilitate crossing

4F Solutions

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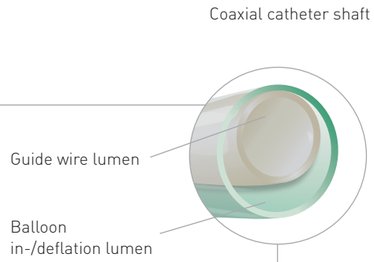
Passeo-18

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.

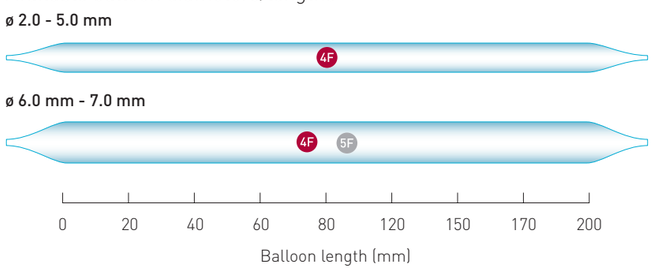
Highly pushable coaxial shaft design

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



Low profile and wide array of sizes

Available balloon diameters/lengths



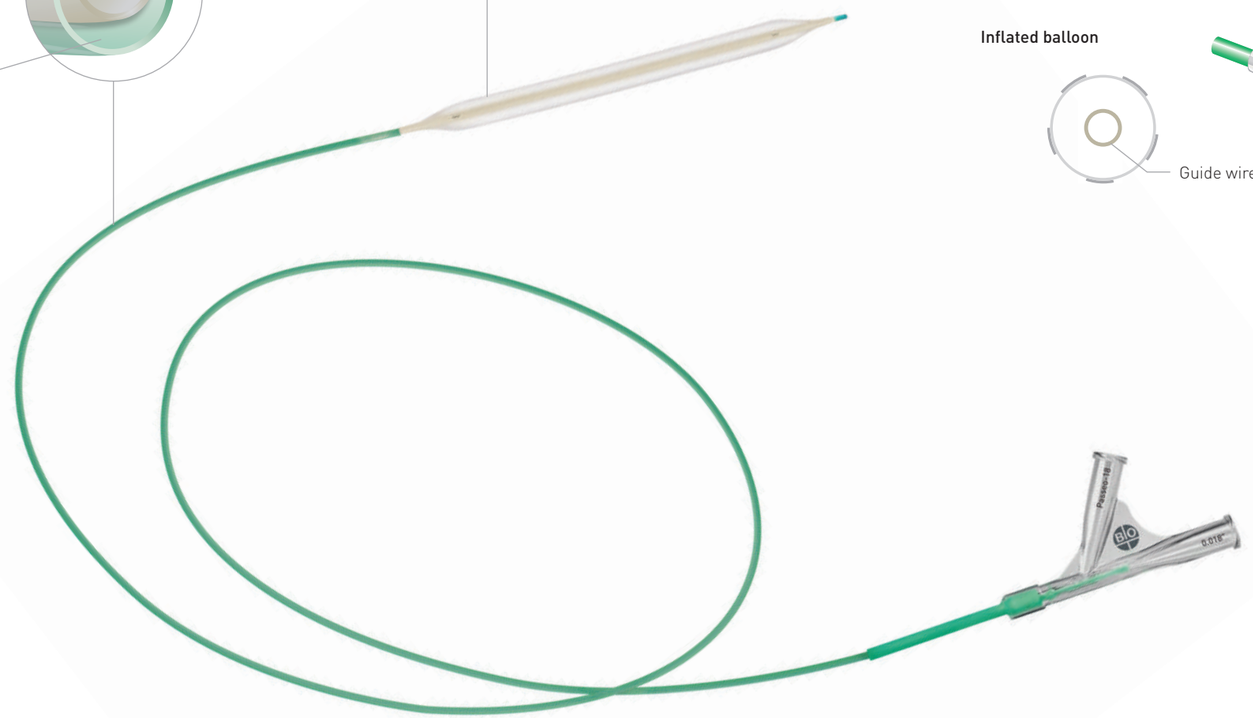
Tip

Smooth tapered tip entry profile promotes lesion crossing.

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

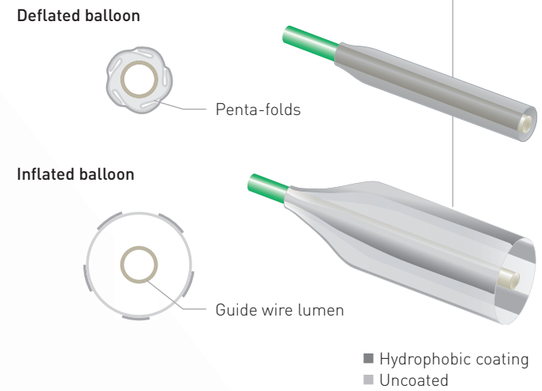
Controlled compliance

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.



[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

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	atm[2]	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6
(NP)	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	atm[2]	15	14	15	14	15	14	15	14	15	13	15	12	13	12	12
(RBP)	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

Antegrade approach

Catheter Length (cm)	Balloon ø (mm)	Balloon Length (mm) 20	40	60	80	120	150	170	200
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]
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

Catheter Length (cm)	Balloon ø (mm)	Balloon Length (mm) 20	40	60	80	120	150	170	200
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
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**

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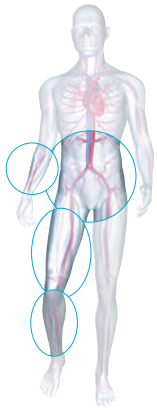
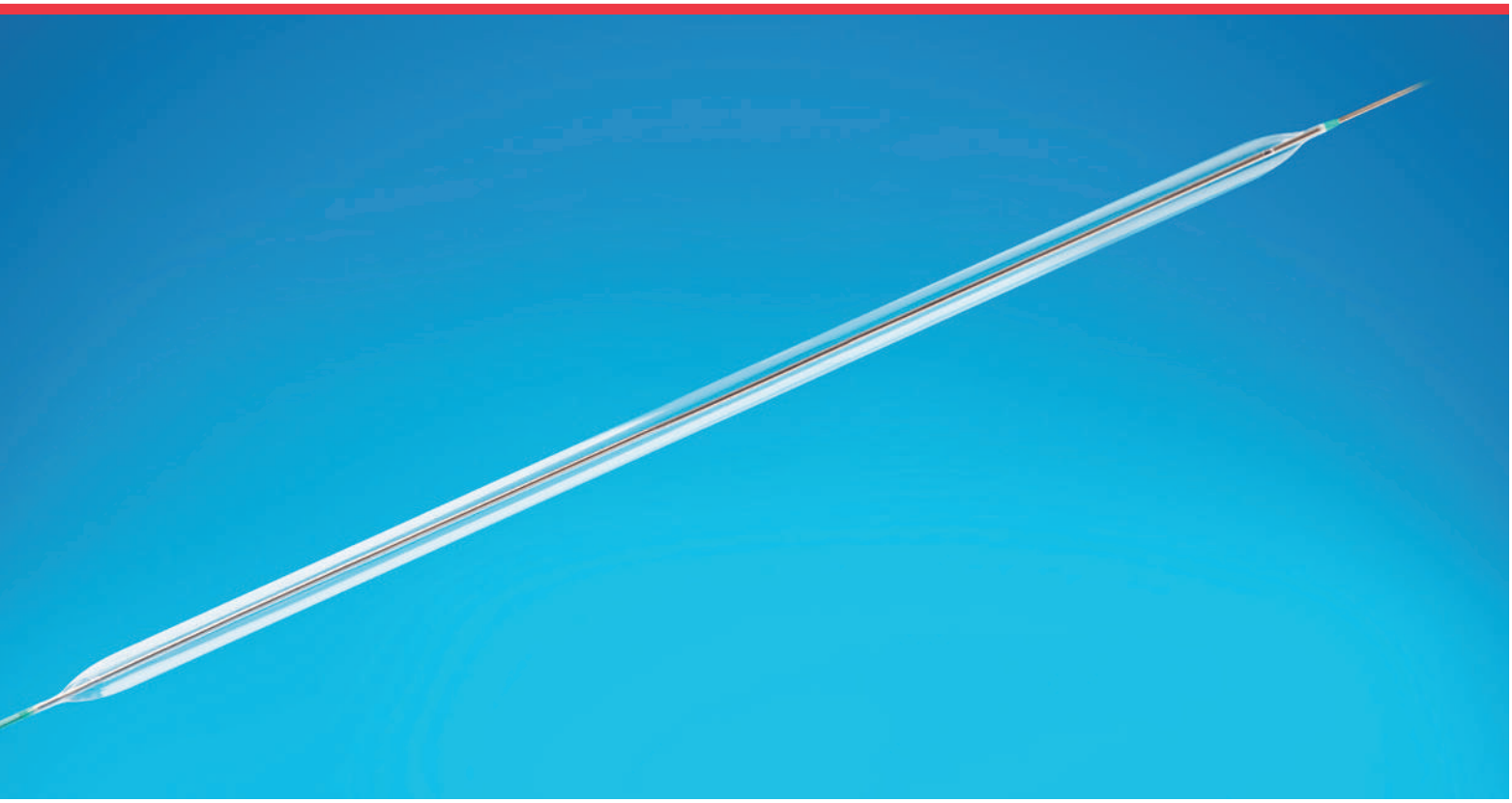
Passeo-35

PTA Balloon/0.035"/OTW

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





- Low profile, wide size range: ø 3-10 mm and up to 200 mm balloon length
- Semi-crystalline polymer (SCP) designed for puncture resistance
- Patchwork coating designed to facilitate crossing

6F Solutions

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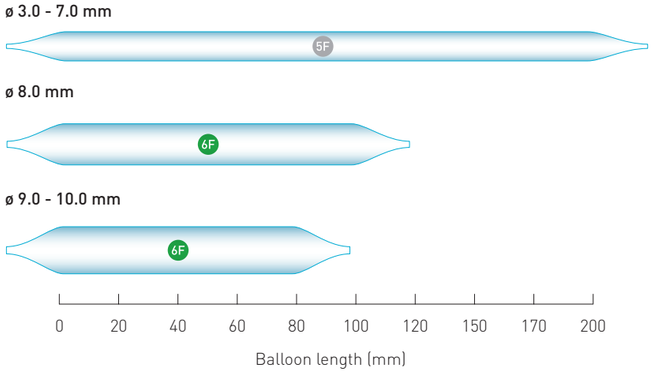
Passeo-35
Engineered excellence

Passeo-35 features a low profile design for 5F and 6F sheath compatibility, a wide range of balloon diameters (3-10 mm) and lengths up to 200 mm.

Low profile, wide size range:
ø 3-10 mm and up to 200 mm balloon length

A comprehensive choice of 5F and 6F configurations.

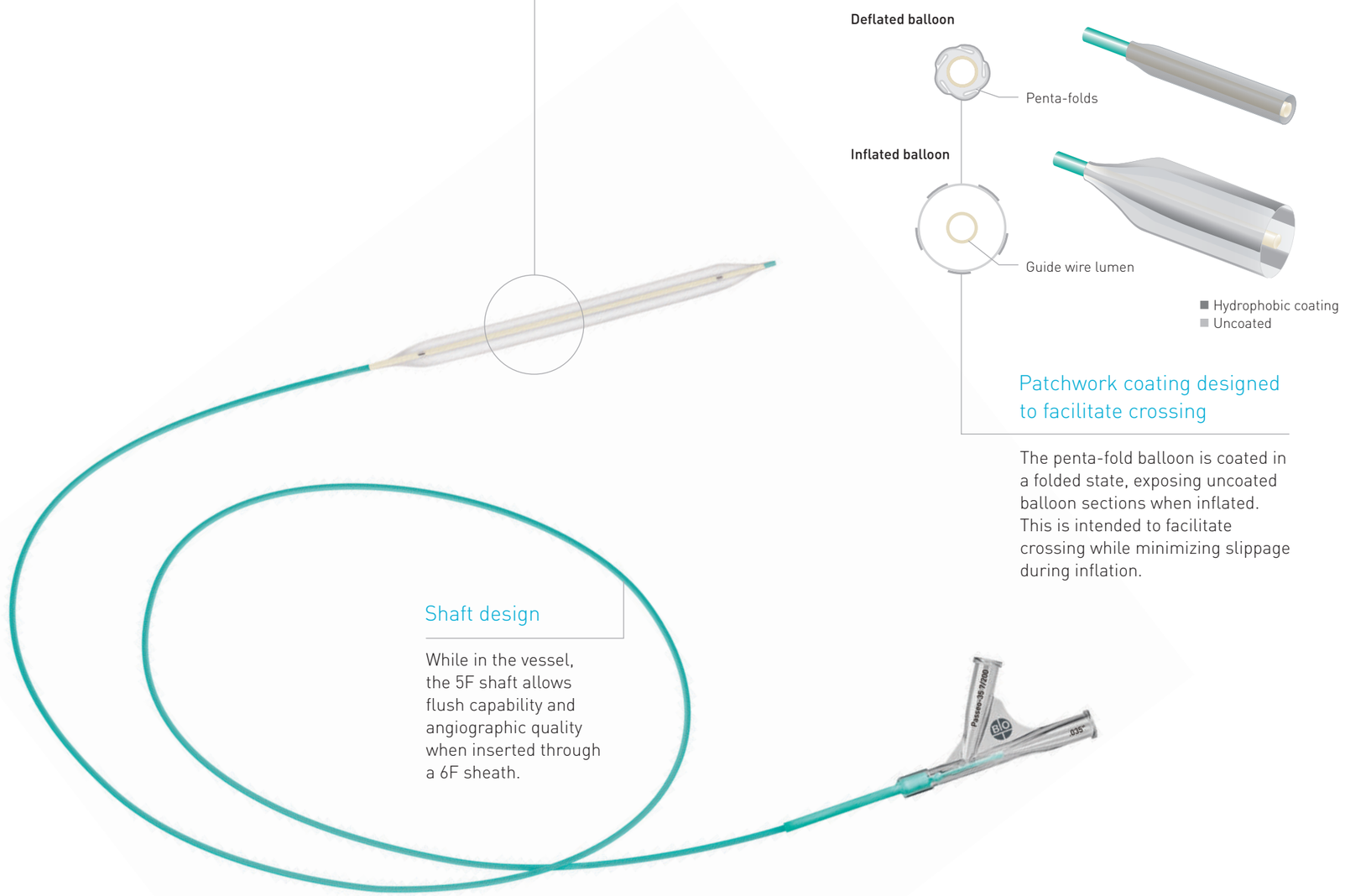
Catheter 80, 90 and 130 cm



A unique PTA Balloon to dilate lesions in complex anatomy

Semi-crystalline polymer (SCP) designed for puncture resistance

A robustly engineered balloon that provides effective dilation.



Patchwork coating designed to facilitate crossing

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.

Shaft design

While in the vessel, the 5F shaft allows flush capability and angiographic quality when inserted through a 6F sheath.

Passeo-35 – PTA Balloon/0.035"/OTW

Technical Data

Balloon catheter	
Catheter type	OTW
Recommended guide wire	0.035"
Tip	Soft, short, tapered, colored
Balloon material	SCP (Semi-Crystalline Polymer), controlled compliance
Balloon folding	5-fold
Balloon coating	Hydrophobic patchwork coating
Balloon markers	2 swaged markers
Sizes	ø 3.0 - 10.0 mm; L: 20 - 200 mm
Shaft	5F, hydrophobic coating, dual-lumen
Usable length	80, 90 and 130 cm
Guide wire lumen	Hydrophobic coating

Compliance Chart

		Balloon diameter x length (mm)													
		ø 3.0 x 20-40	ø 3.0 x 60-200	ø 4.0 x 20-40	ø 4.0 x 60-200	ø 5.0 x 20-100	ø 5.0 x 120-200	ø 6.0 x 20-100	ø 6.0 x 120-200	ø 7.0 x 20-100	ø 7.0 x 120-200	ø 8.0 x 20-100	ø 9.0 x 20-80	ø 10.0 x 20-40[2]	ø 10.0 x 20-80
Nominal Pressure	atm[1]	7	7	7	7	7	7	7	7	7	7	7	7	7	7
(NP)	ø (mm)	3.0	3.00	4.0	4.00	5.0	5.0	6.0	6.0	7.0	7.0	8.0	9.0	10.0	10.0
Rated Burst Pressure	atm[1]	20	20	20	18	16	16	16	16	14	14	14	12	12	11
(RBP)	ø (mm)	3.5	3.20	4.5	4.32	5.7	5.3	6.7	6.4	7.7	7.3	8.7	9.4	10.5	10.3

[1] 1 atm = 1.013 bar; [2] Usable length: 80 cm

Ordering Information

	Balloon ø (mm)	Catheter length 80 cm, Balloon length (mm)					Catheter length 90 cm, Balloon length (mm)						
		20	40	60	80	100	60	80	100	120	150	170	200
	3.0	359545[3]	359547	-	-	-	383231[3]	383235[3]	383239[3]	383243[3]	389775[3]	389776[3]	387162[3]
	4.0	359546[3]	359548	-	-	-	383232[3]	383236[3]	383240[3]	383244[3]	383248[3]	383252[3]	383256[3]
5F	5.0	357282	357288	357294	357298	357302	-	-	-	383245[3]	383249[3]	383253[3]	383257[3]
	6.0	357283	357289	357295	357299	357303	-	-	-	383246[3]	383250[3]	383254[3]	383258[3]
	7.0	357284	357290	357296	357300	357304[3]	-	-	-	383247[3]	383251[3]	383255[3]	383259[3]
	8.0	357285	357291	357297	357301[3]	357305[3]	-	-	-	-	-	-	-
6F	9.0	357286[3]	357292	-	-	-	383233[3]	383237[3]	-	-	-	-	-
	10.0	357287[3]	357293	-	-	-	383234[3]	383238[3]	-	-	-	-	-

	Balloon ø (mm)	Catheter length 130 cm, Balloon length (mm)								
		20	40	60	80	100	120	150	170	200
	3.0	359549[3]	359551	383264[3]	383268[3]	383272[3]	383276[3]	389777[3]	389778[3]	387163[3]
	4.0	359550[3]	359552	383265[3]	383269[3]	383273[3]	383277[3]	383281[3]	383285[3]	383289[3]
5F	5.0	357306	357310	357314	357318	357322	383278[3]	383282[3]	383286[3]	383290[3]
	6.0	357307[3]	357311	357315	357319	357323	383279[3]	383283[3]	383287[3]	383291[3]
	7.0	357308[3]	357312	357316	357320	357324[3]	383280[3]	383284[3]	383288[3]	383292[3]
	8.0	357309[3]	357313	357317	357321	357325[3]	-	-	-	-
6F	9.0	383260[3]	383262[3]	383266[3]	383270[3]	-	-	-	-	-
	10.0	383261[3]	383263[3]	383267[3]	383271[3]	-	-	-	-	-

[3] Size available upon special request

Passeo-35 is part of the BIOTRONIK 6F Solutions portfolio, including:
■ Introducer Sheath: **Fortress** ■ Balloons: **Passeo-35 HP** ■ Stents: **Astron**

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