bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

BIOTRONIK AG
Ackerstrasse 6
8180 Bülach
Switzerland

Digitally signed by Captari Alexandru
Date: 2023.04.08 11:01:54 EEST
Reason: MoldSign Signature
Location: Moldova

Facility ID Number: F000099

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; 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, and distribution of the following sterile devices: 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:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2018-10-11 Effective Date: 2021-10-11 Expiry Date: 2024-10-10

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

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By Royal Charter

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
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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**

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EC Certificate - Full Quality Assurance System

Supplementary Information to CE 608280

Issued To:

BIOTRONIK AG
Ackerstrasse 6
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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**

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BIOTRONIK // Vascular Intervention

VI Product Catalogue

Oct 2021

- Coronary Products
- Peripheral Products
- Accessory Products

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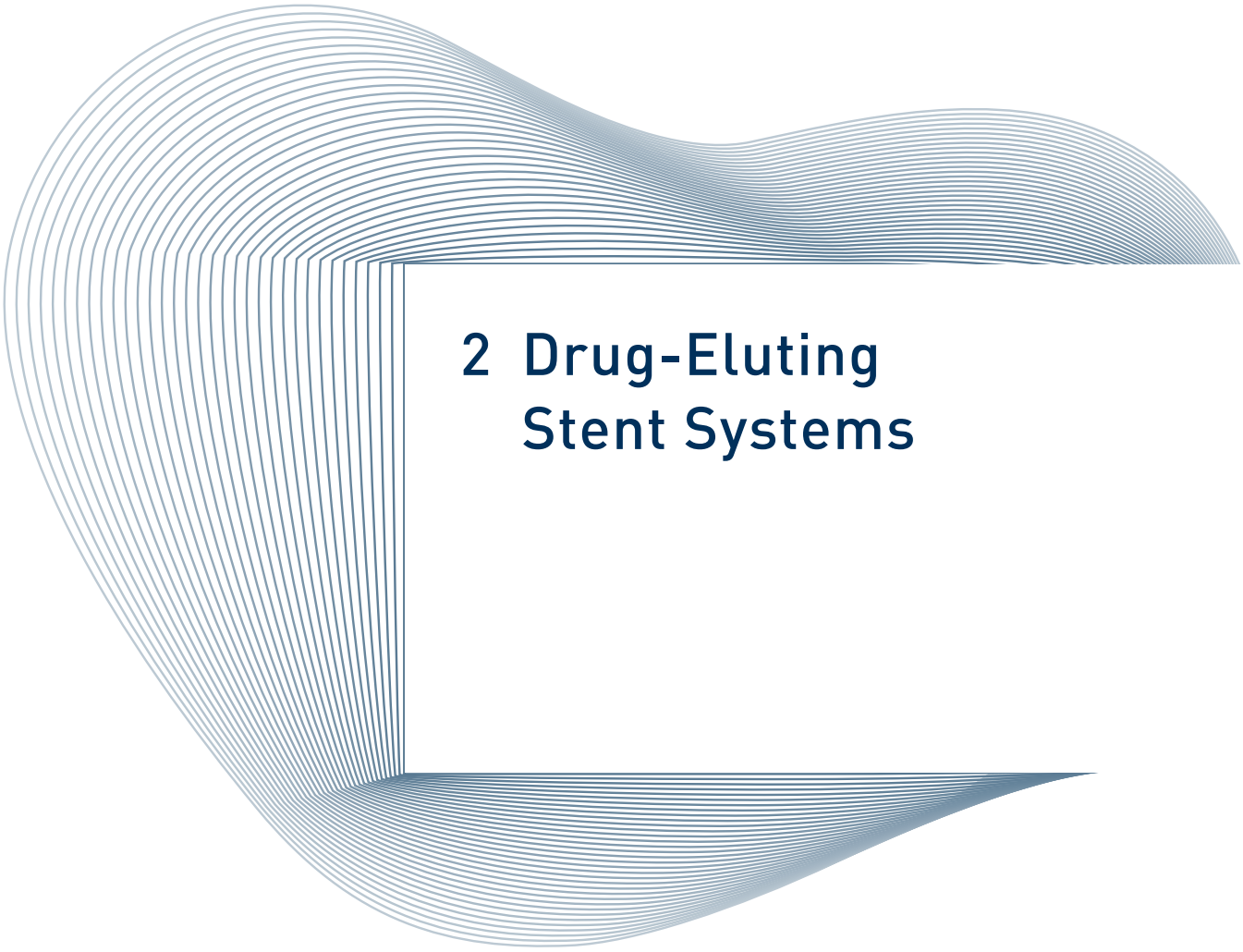

2 Drug-Eluting Stent Systems

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4 Drug-Coated Balloon Catheters

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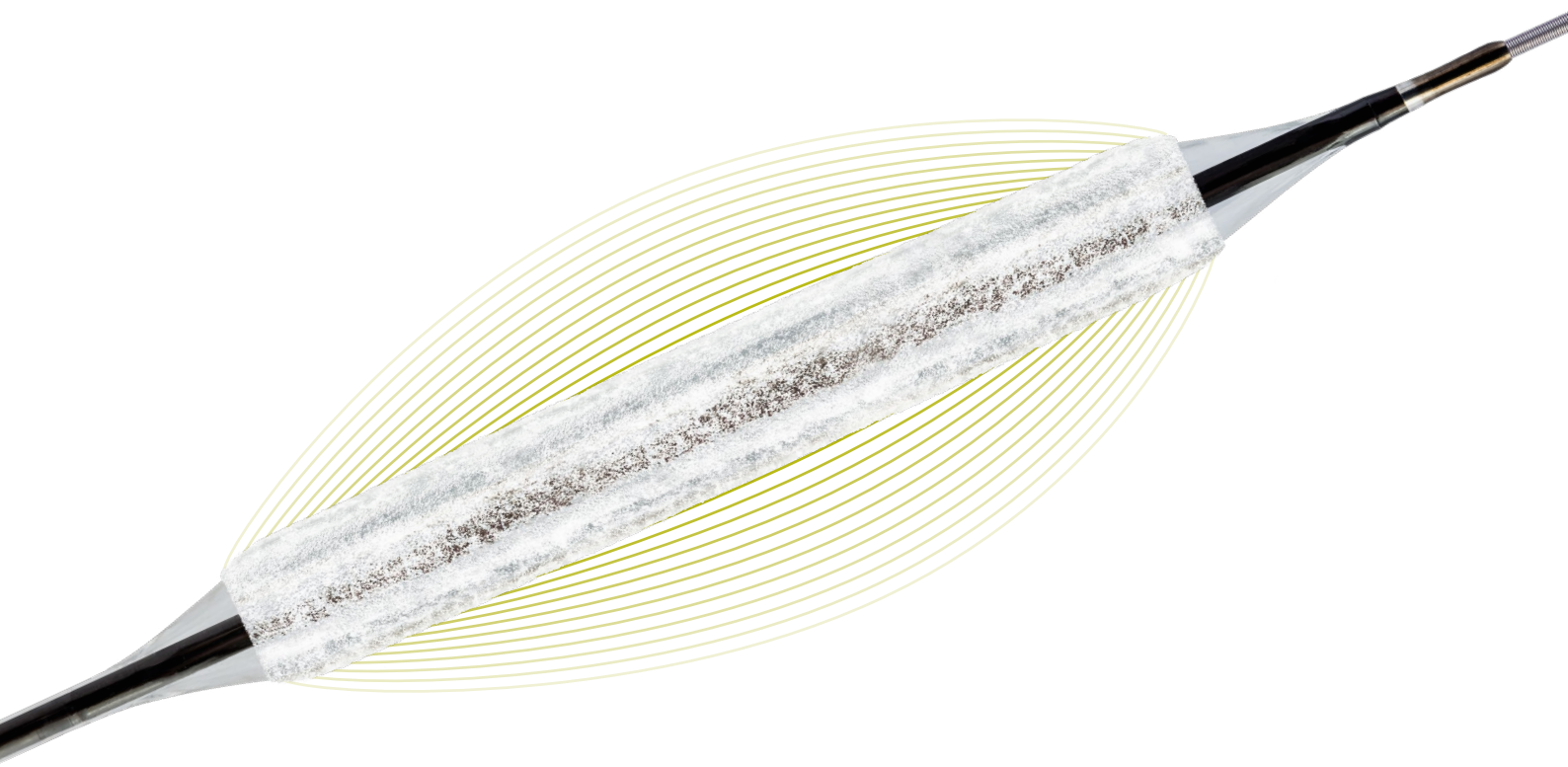
Pantera® Lux®



- Clinically proven solution for in-stent-restenosis and further indications
- Lux® coating technology for rapid drug absorption
- Excellent deliverability

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excellence for life

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/mm²
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

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

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5 Balloon Catheters

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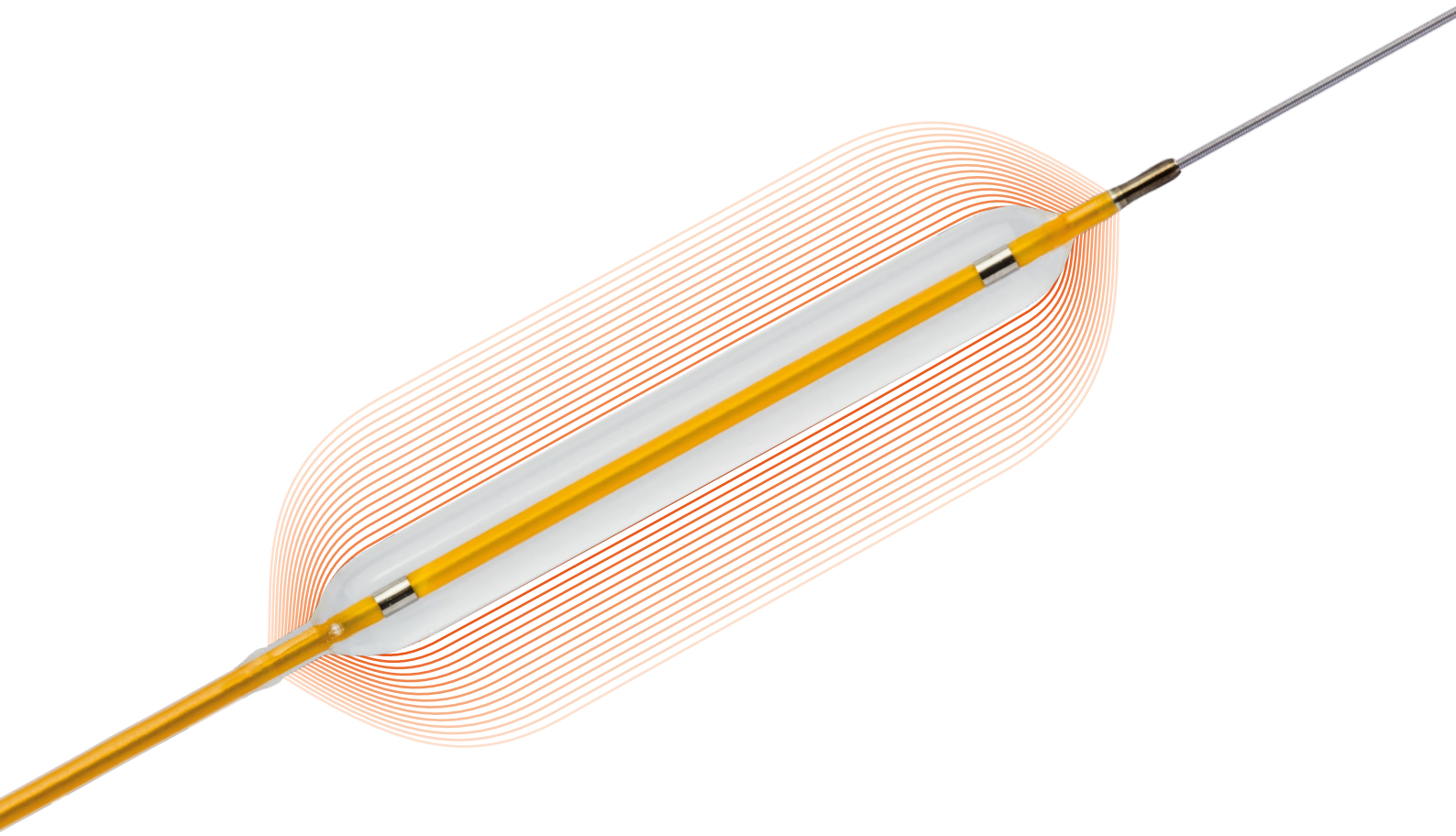
Pantera® LEO



- Lowest compliance in class avoiding dog-bone effect
- Precise dilatation
- Enhanced crossability and accurate placement

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Pantera® LEO

Indicated for stent post-dilatation and dilatation of a 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
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

*Indication as per IFU.

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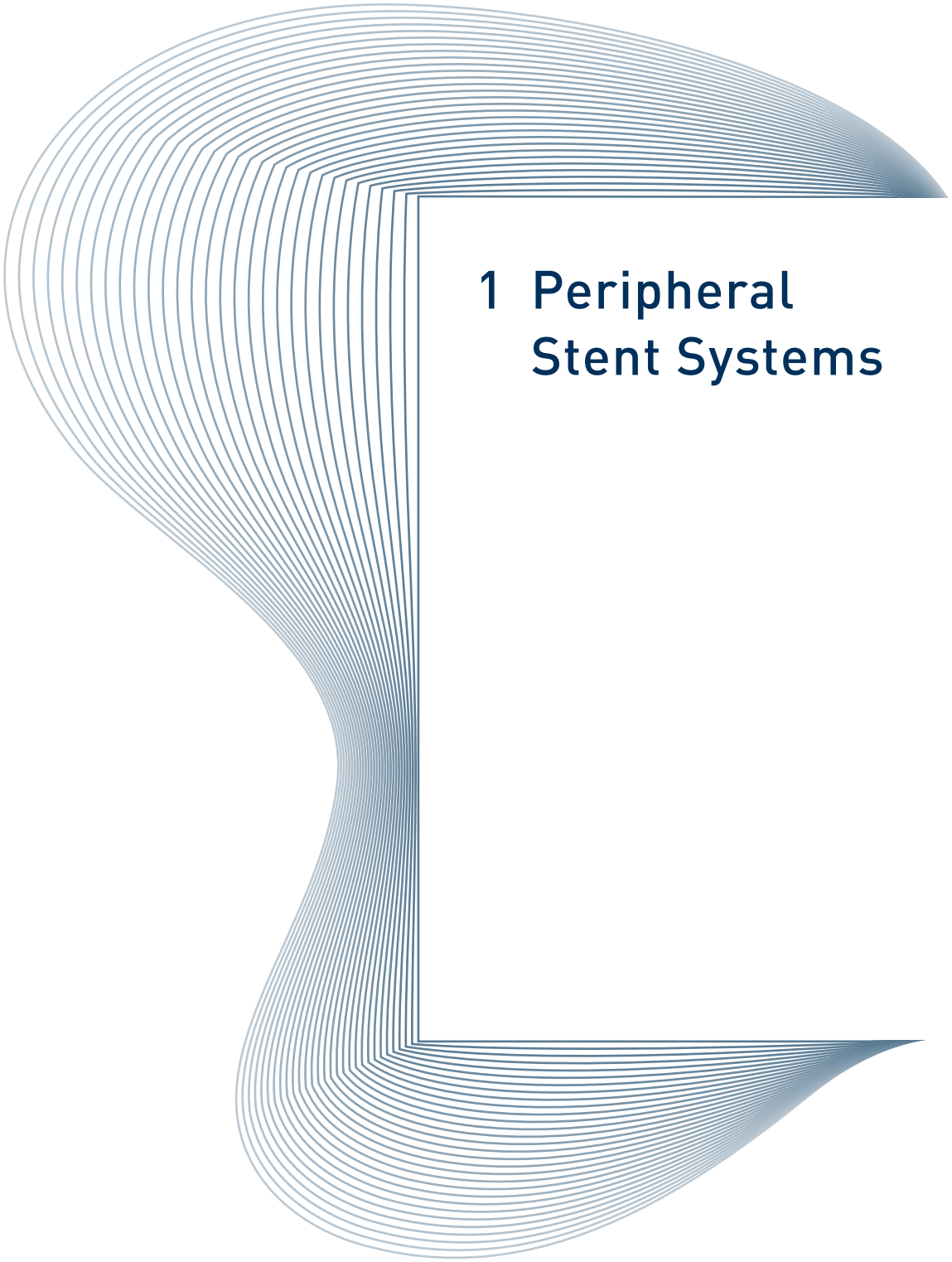

1 Peripheral Stent Systems

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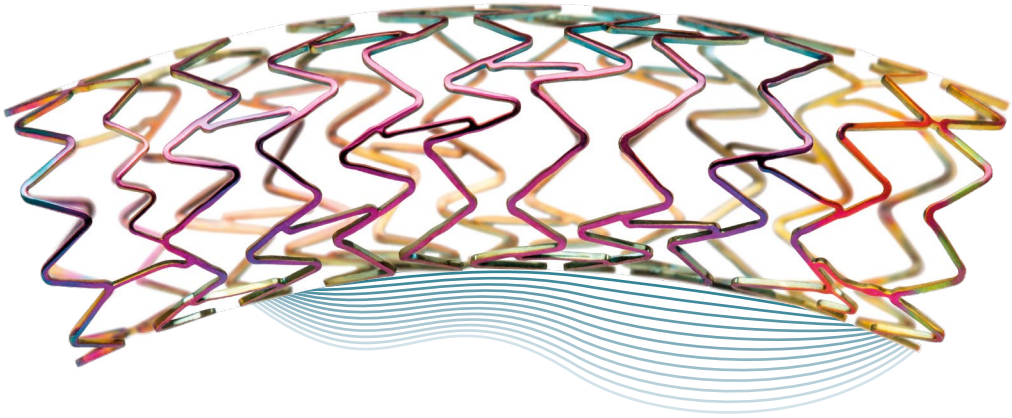
Dynamic Renal



- Proximal gold marker for superior visibility to support accurate stent placement
- Cobalt chromium alloy combining a lower profile with high radial force
- Double helix stent design for high flexibility

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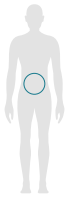
Dynamic Renal

Indicated for improving arterial luminal diameter in patients with clinical symptoms attributable to atherosclerotic stenosis of the renal arteries.*

Vascular Intervention Peripheral



Technical Data

Stent

Stent	Balloon-expandable
Stent material	Cobalt Chromium (L605)
Strut thickness	120 µm (ø 4.5 - 5.0 mm) 140 µm (ø 6.0 - 7.0 mm)
Stent coating	proBIO® (Amorphous Silicon Carbide)
Stent marker	Proximal gold marker
Sizes	ø 4.5 - 7.0 mm; L: 12 - 19 mm

Delivery system

Catheter type	Rapid exchange (Rx)
Recommended guide wire	0.014"
Tip	Soft, short and tapered
Balloon markers	2 swaged markers
Shaft (proximal)	Hydrophobic coating
Usable length	140cm
Nominal Pressure (NP)	10 atm
Rated Burst Pressure (RBP)	15 atm (ø 4.5 - 6.0 mm) 13 atm (ø 7.0 mm)

Compliance Chart

Balloon diameter x length (mm)

		ø 4.5	ø 5.0	ø 6.0	ø 7.0
Nominal Pressure (NP)	atm*	10	10	10	10
	ø (mm)	4.5	5.0	6.0	7.0
Rated Burst Pressure (RBP)	atm*	15	15	15	13
	ø (mm)	4.7	5.3	6.2	7.2

*1 atm = 1.013 bar

Ordering Information

	Stent ø (mm)	Catheter length 140 cm Stent length (mm)		
		12	15	19
4F	4.5	358582	368711	358586
	5.0	358583	368712	358587
5F	6.0	358584	368713	358588
	7.0	358585	368714	358589

*Indication as per IFU.

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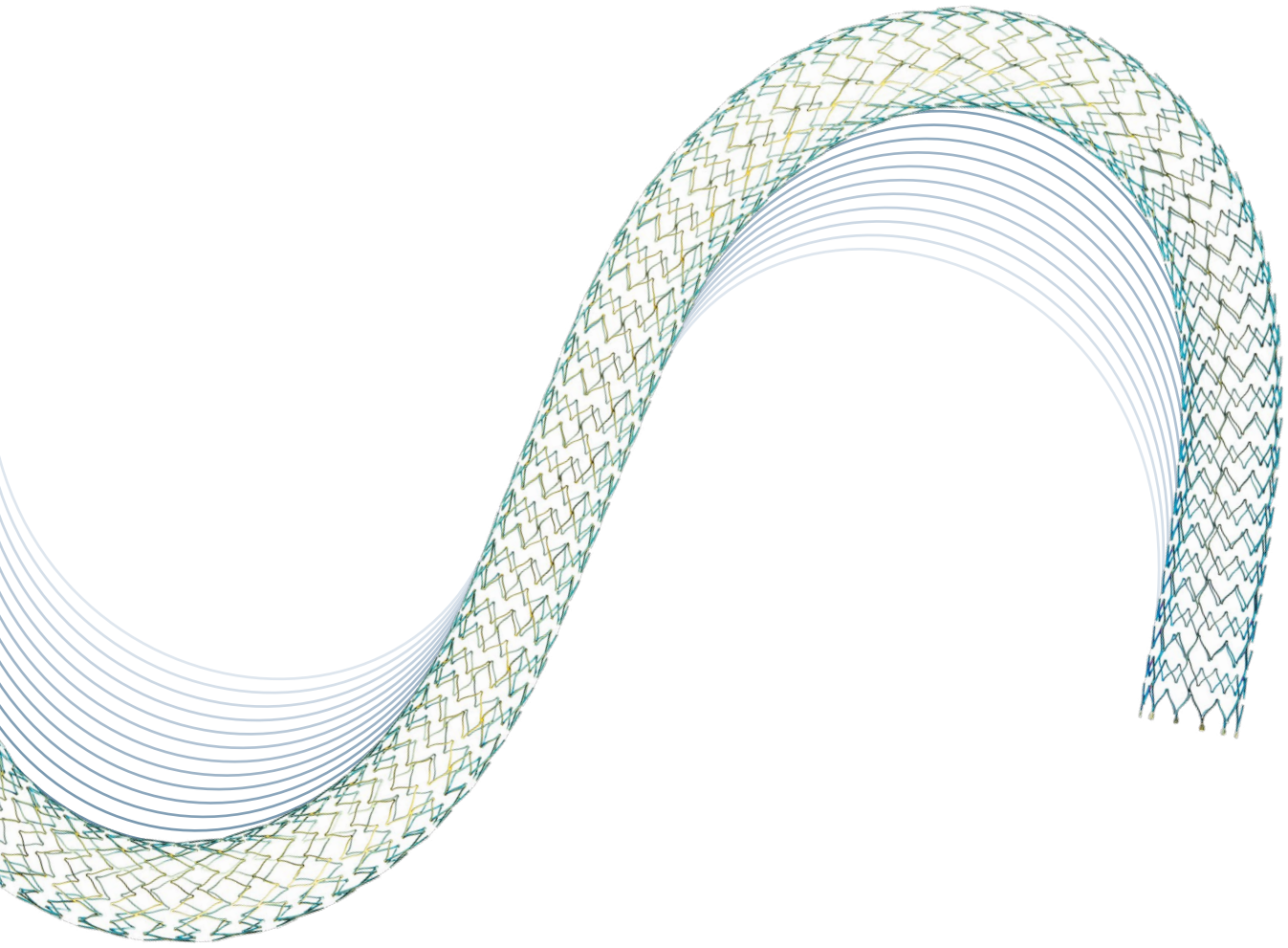
Pulsar®-35



- 140 µm thin struts
- Clinically proven
- Tri-axial delivery system

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Pulsar®-35

Vascular Intervention Peripheral

Indicated for use in patients with atherosclerotic disease of the femoral and proximal popliteal arteries, in particular for the treatment of insufficient results after percutaneous transluminal angioplasty (PTA).*

Technical Data

Stent	
Catheter type	OTW
Recommended guide wire	0.035"
Stent material	Nitinol
Strut thickness	140 µm
Strut width	85 µm
Stent coating	proBIO® (Amorphous Silicon Carbide)
Stent markers	6 gold markers each end
Sizes	ø 5.0 - 7.0 mm; L: 30 - 170 mm
Proximal shaft	6F, hydrophobic coating
Usable length	90 and 135 cm

Ordering Information

Stent ø (mm)	Catheter length 90 cm (Stent length mm)								
	30	40	60	80	100	120	150	170	200
5.0	379878	379879	379880	379881	379917	379918	379919	379920	379921
6.0 (6F)	379883	379884	379885	379886	379922	379923	379924	379925	379926
7.0	379888	379889	379890	379891	379927	379928	379929	379930	379931

Stent ø (mm)	Catheter length 135 cm (Stent length mm)								
	30	40	60	80	100	120	150	170	200
5.0	379898	379899	379900	379901	379937	379938	379939	379940	379941
6.0 (6F)	379903	379904	379905	379906	379942	379943	379944	379945	379946
7.0	379908	379909	379910	379911	379947	379948	379949	379950	379951

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3 Peripheral Balloon Catheters

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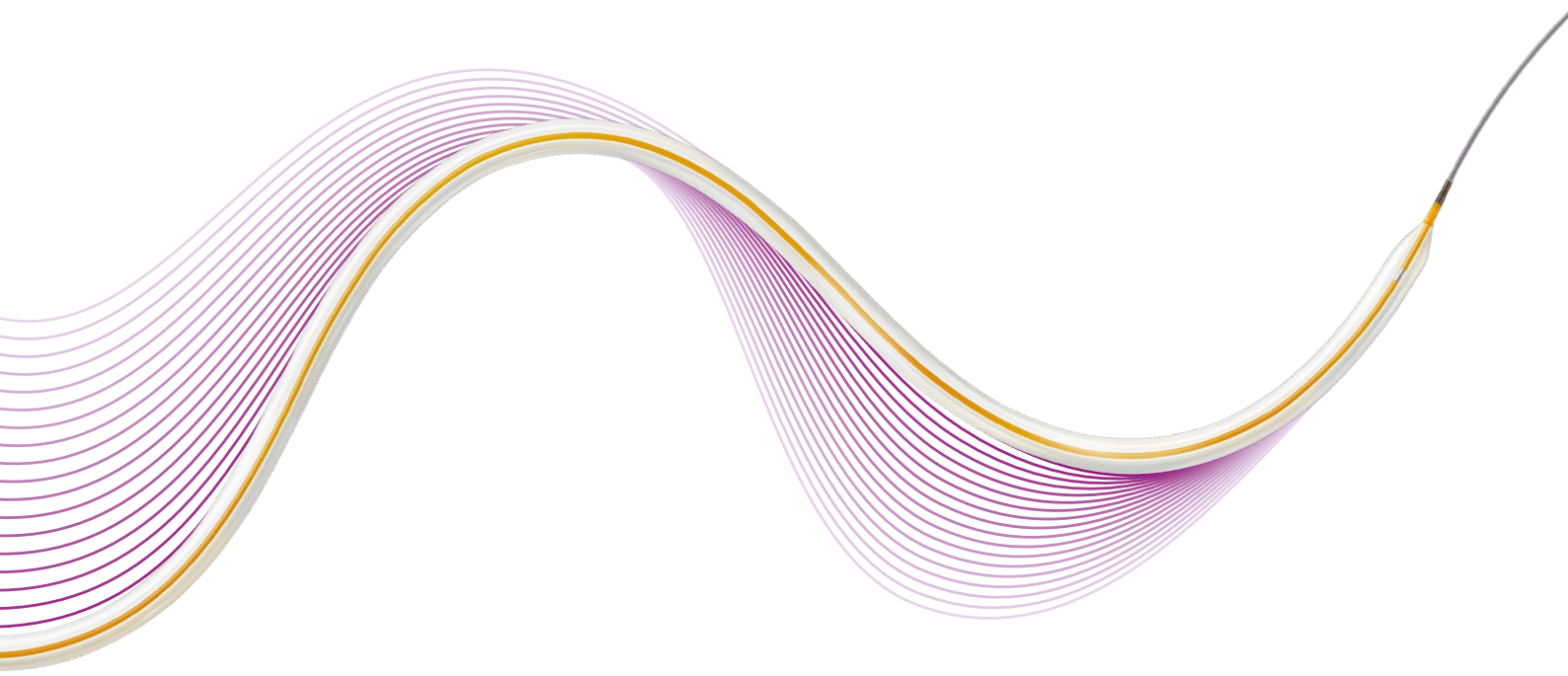
Passeo®-14



- Up to 3.8 x faster deflation times
- Enhanced crossability
- High pushability and flexibility

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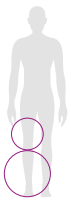
Passeo®-14

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

Vascular Intervention Peripheral



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

Antegrade approach

4F	Catheter Length (cm)	Balloon ø (mm)	Balloon Length (mm) 20	40	70	100	140	180	220
	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	-	-

Crossover approach

4F	Catheter Length (cm)	Balloon ø (mm)	Balloon Length (mm) 20	40	70	100	140	180	220
	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	-	-

[a]8 weeks pre-order only

*Indication as per IFU.

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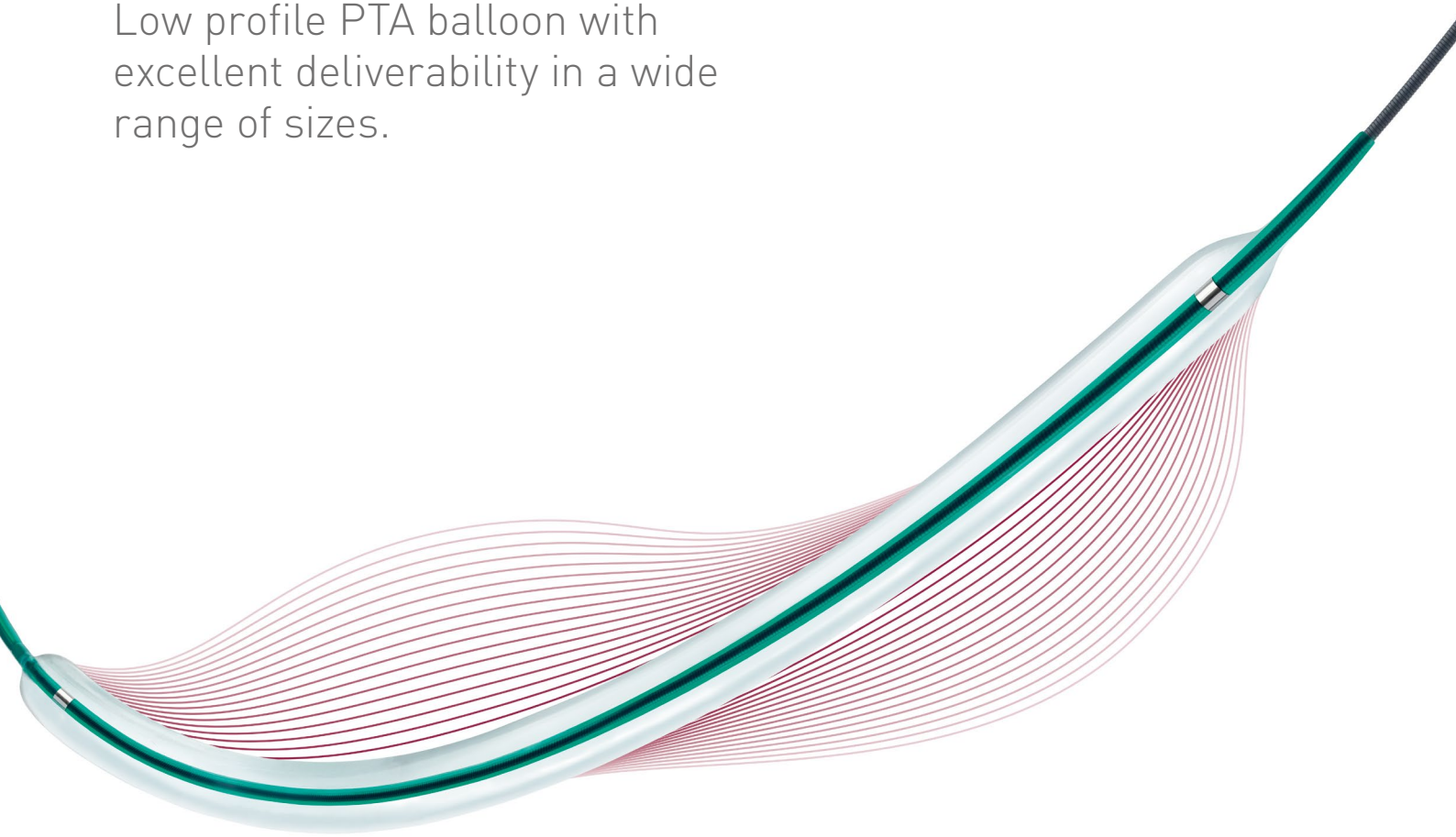
Passeo®-35 Xeo

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



- Improved crossability
- Excellent deliverability
- Low profile, wide range of sizes

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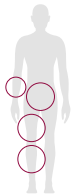
Passeo®-35 Xeo

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¤	RBP¤	Catheter length 90 cm Balloon length (mm)									
				20	40	60	80	100	120	150	170	200	250
	3.0	9	21	428777	428786	428795	428804	-	-	-	-	-	-
	4.0	9	20	428778	428787	428796	428805	428814	428823	-	-	-	-
5F	5.0	9	19	428779	428788	428797	428806	428815	428824	428833	-	428843	428848
	6.0	9	16	428780	428789	428798	428807	428816	428825	428834	-	428844	428849
	7.0	9	15	428781	428790	428799	428808	428817	-	-	-	-	-
	8.0	9	14	428782	428791	428800	428809	428818	-	-	-	-	-
6F	9.0	9	12	428783	428792	428801	428810	428819	-	-	-	-	-
	10.0	8	11	428784	428793	428802	428811	428820	-	-	-	-	-
7F	12.0	8	10	-	428794	428803	428812	428821	-	-	-	-	-

	Balloon ø (mm)	NP¤	RBP¤	Catheter length 130 cm Balloon length (mm)									
				20	40	60	80	100	120	150	170	200	250
	3.0	9	21	428851	428860	428869	428878	428887	428896	428905	428910	428915	428920
	4.0	9	20	428852	428861	428870	428879	428888	428897	428906	428911	428916	428921
5F	5.0	9	19	428853	428862	428871	428880	428889	428898	428907	428912	428917	428922
	6.0	9	16	428854	428863	428872	428881	428890	428899	428908	428913	428918	428923
	7.0	9	15	428855	428864	428873	428882	428891	428900	428909	428914	428919	428924
	8.0	9	14	428856	428865	428874	428883	428892	428901	-	-	-	-
6F	9.0	9	12	428857	428866	428875	428884	428893	428902[b]	-	-	-	-
	10.0	8	11	428858	428867	428876	428885	428894	428903[b]	-	-	-	-
7F	12.0	8	10	-	428868	428877	428886	428895	428904[b]	-	-	-	-

	Balloon ø (mm)	NP¤	RBP¤	Catheter length 170 cm Balloon length (mm)									
				20	40	60	80	100	120	150	170	200	250
	4.0	9	20	-	428935[b]	428944[b]	428953[b]	-	428971[b]	428980[b]	-	428990[b]	428995[b]
5F	5.0	9	19	428927[b]	428936[b]	428945[b]	428954[b]	-	428972[b]	428981[b]	-	428991[b]	428996[b]
	6.0	9	16	428928[b]	428937[b]	428946[b]	428955[b]	-	428973[b]	428982[b]	-	428992[b]	428997[b]
	7.0	9	15	428929[b]	428938[b]	428947[b]	428956[b]	-	-	-	-	-	-
	8.0	9	14	428930[b]	428939[b]	428948[b]	428957[b]	-	-	-	-	-	-
6F	9.0	9	12	-	428940[b]	428949[b]	428958[b]	-	-	-	-	-	-
	10.0	8	11	-	428941[b]	428950[b]	428959[b]	-	-	-	-	-	-

¤NP = Nominal Pressure and RBP = Rated Burst Pressure in atm (1 atm = 1.013 bar)
[b]8 weeks pre-order only

*Note for Australia: Passeo-35 Xeo not approved by Therapeutic Goods Administration for use in the common iliac arteries. **Indication as per IFU.

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