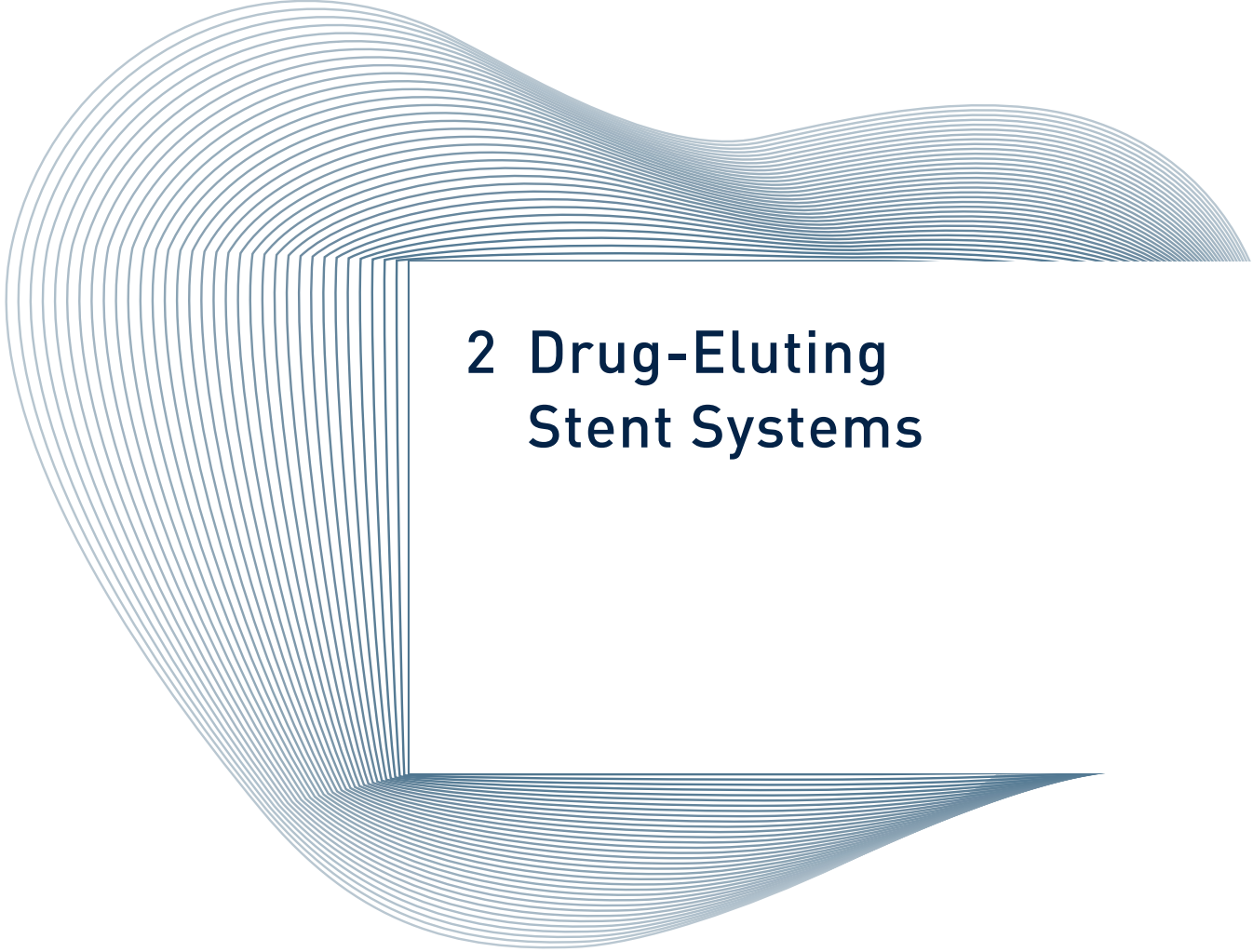




VI Product Catalogue

May 2024

- Coronary Products
- Peripheral Products
- Accessory Products



2 Drug-Eluting Stent Systems

Synsiro[®] Pro_{DES}

The Next Level of Deliverability.
Proven Clinical Performance.^Δ



The next level of deliverability¹



Ultrathin struts²



Outstanding patient outcomes³

Synsiro[®] Pro DES

Vascular
Intervention
Coronary



The Synsiro Pro Sirolimus-Eluting Coronary Stent System is a drug-eluting balloon-expandable stent pre-mounted on a rapid-exchange PTCA catheter delivery system.

Indication

Synsiro Pro DES is indicated for improving coronary luminal diameter in patients with symptomatic ischemic heart disease due to discrete de-novo stenotic lesions and in-stent restenotic lesions (length \leq 40 mm) in the native coronary arteries with a reference vessel diameter of 2.25 mm to 4.0 mm including the following patient and lesion subsets:

Acute Coronary Syndrome (ACS)	Long Lesions (LL) (e.g. \geq 20 mm)
ST-Elevation Myocardial Infarction (STEMI)	Small Vessels (SV) (e.g. \leq 2.75 mm)
Diabetes Mellitus (DM)	Multi-Vessel Disease (MVD)
Complex Lesions (B2/C)	Male/Female
High Bleeding Risk (HBR)	Old Patients (e.g. $>$ 65 y)

Technical Data

Stent

Stent material	Cobalt chromium, L-605
Strut thickness	\varnothing 2.25 – 3.0 mm: 60 μ m (0.0024"); \varnothing 3.50 – 4.0 mm: 80 μ m (0.0031")
Passive coating	proBIO (Amorphous Silicon Carbide)
Active coating	BIOLute bioabsorbable Poly-L-Lactide (PLLA) eluting a limus drug
Drug dose	1.4 μ g/mm ²

Delivery System

Catheter type	Rapid exchange
Recommended guide catheter	5F (min. I.D. 0.056")
Guide wire diameter	0.014"
Usable catheter length	140 cm
Balloon material	Semi crystalline polymer
Coating (Distal shaft)	Hydrophilic
Coating (Proximal shaft)	Hydrophobic
Marker bands	Two swaged platinum-iridium markers
Lesion entry profile	0.017"
Distal shaft diameter	2.7F: \varnothing 2.25 – 3.0 mm; 2.9F: \varnothing 3.5 – 4.0 mm
Proximal shaft diameter	2.0F
Nominal pressure (NP)	10 atm
Rated burst pressure (RBP)	16 atm

Storage

Use Before Date (UBD)	24 months
Temperature	Between 15°C (59°F) and 25°C (77°F), short term excursions between 10°C (50°F) and 40°C (104°F) are allowed

Ordering Information	Stent \varnothing (mm)	Stent Length (mm)								
		9	13	15	18	22	26	30	35	40
	2.25	419155	419161	419167	419173	419179	419185	419191	419197	419203
	2.5	419156	419162	419168	419174	419180	419186	419192	419198	419204
	2.75	419157	419163	419169	419175	419181	419187	419193	419199	419205
	3.0	419158	419164	419170	419176	419182	419188	419194	419200	419206
	3.5	419159	419165	419171	419177	419183	419189	419195	419201	419207
	4.0	419160	419166	419172	419178	419184	419190	419196	419202	419208

1. In comparison to Xience Sierra, Resolute Onyx and Synergy for bench tests on pushability, trackability and crossability, BIOTRONIK data on file; 2. As characterized with respect to strut thickness in Bangalore et al. Meta-analysis; 3. Based on investigator's interpretation of BIOFLOW-V primary endpoint result.

Synsiro, proBIO and BIOLute are trademarks or registered trademarks of the BIOTRONIK Group of Companies.

Δ Clinical data collected with Orsiro and Orsiro Mission bench performance testing can be used to illustrate Synsiro Pro clinical safety and performance.

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

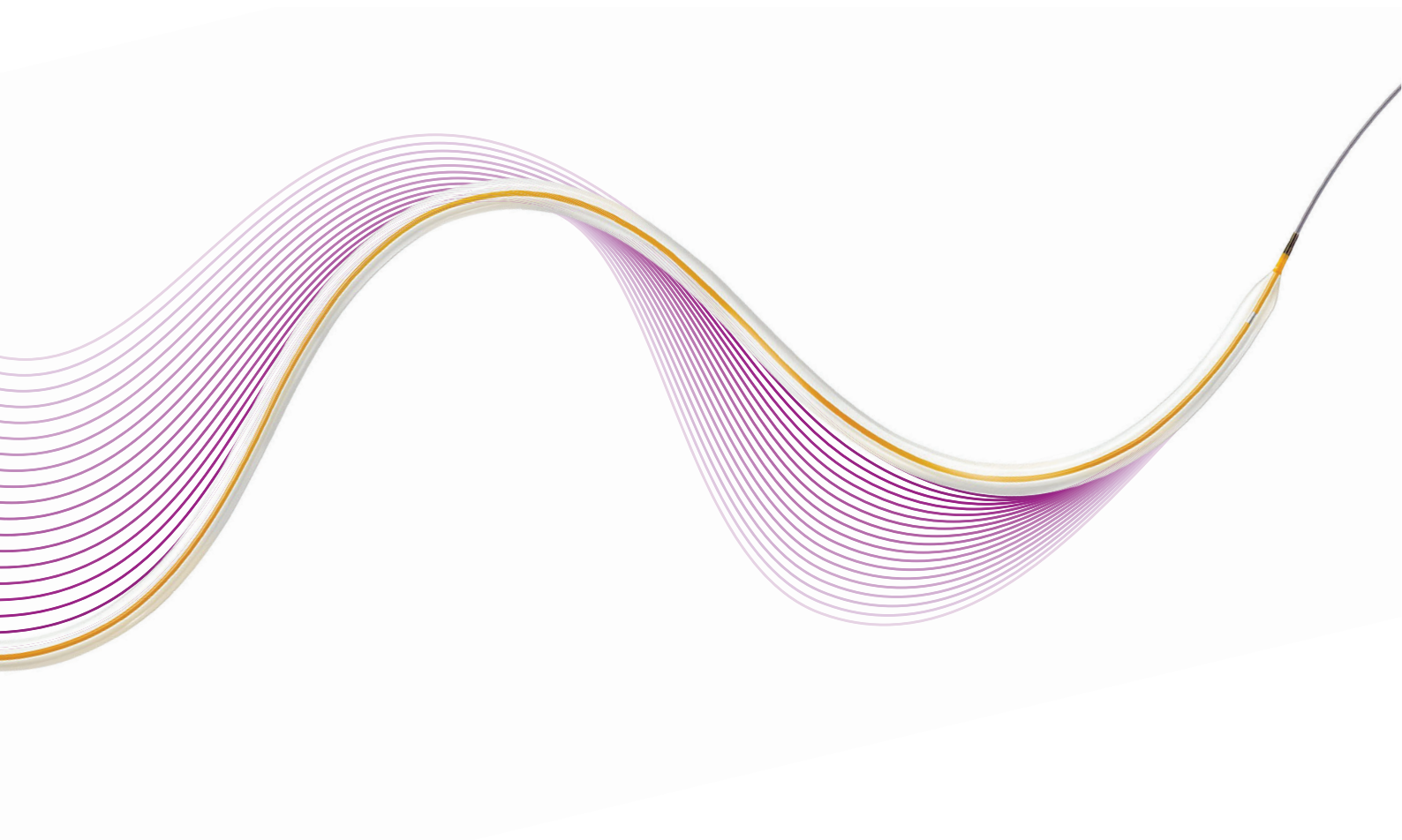
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2 Peripheral Balloon Catheters

Passeo[®]-14



Up to 3.8 x faster deflation times



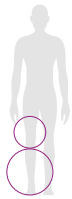
Enhanced crossability



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	-	-
		150	4.0	-	-	-	-	-	-	-
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	-	-	-	-	-	-	-

^a8 weeks pre-order only

*Indication as per IFU.

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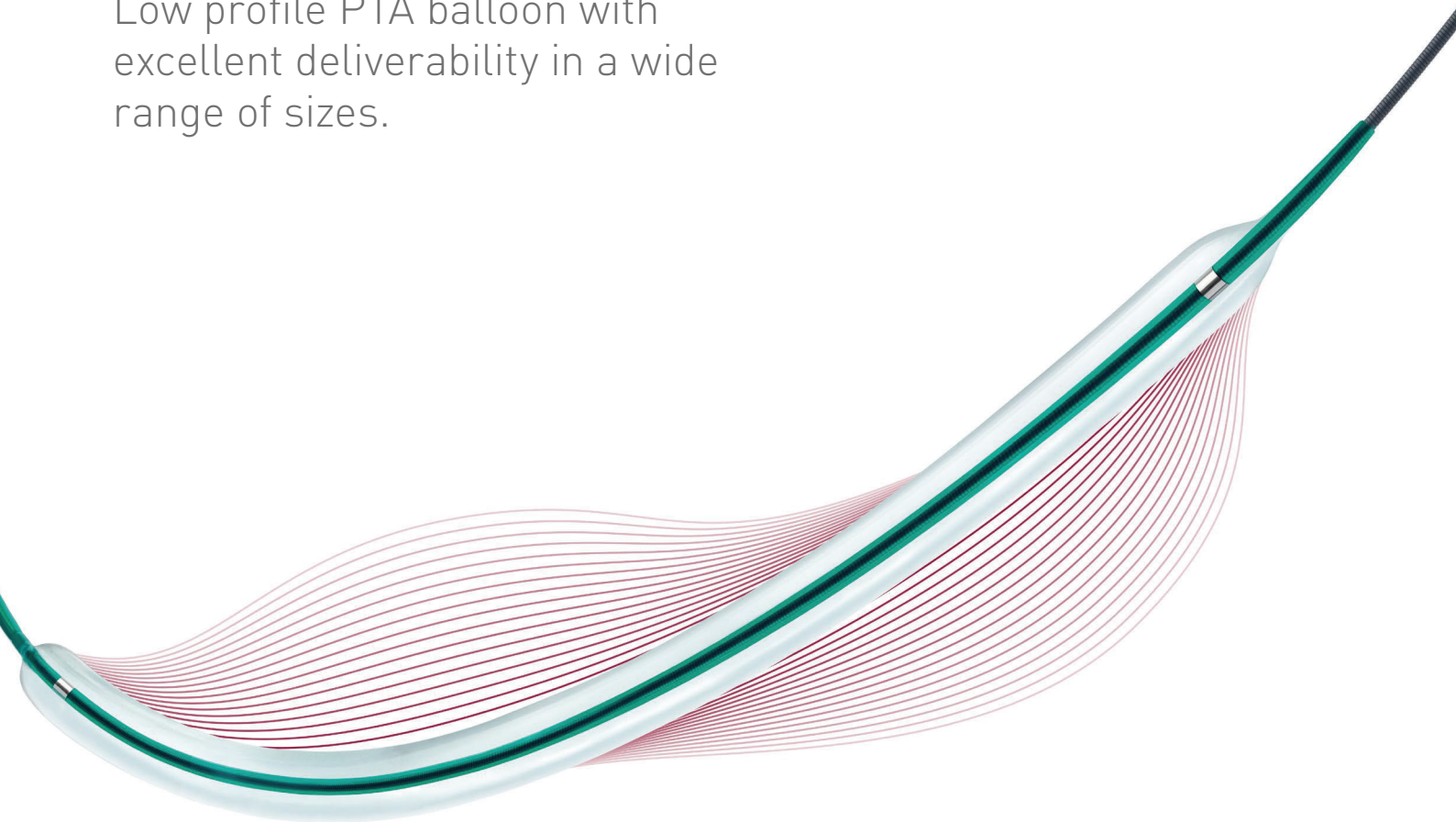
BIOTRONIK AG
Ackerstrasse 6
8180 Bülach, Switzerland
Tel +41 (0) 44 8645111
Fax +41 (0) 44 8645005
info.vi@biotronik.com
www.biotronik.com

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Passeo[®]-35 Xeo

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



Improved crossability



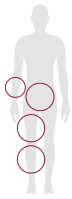
Excellent deliverability



Low profile, wide range of sizes

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	3.0	9	21	428777	428786	428795	428804	-	-	-	-	-	-
	4.0	9	20	428778	428787	428796	428805	428814	428823	-	-	-	-
	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	-	-	-	-	-
6F	8.0	9	14	428782	428791	428800	428809	428818	-	-	-	-	-
	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 ^a	RBP ^a	Catheter length 130 cm									
				Balloon length (mm)									
				20	40	60	80	100	120	150	170	200	250
5F	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
	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
6F	8.0	9	14	428856	428865	428874	428883	428892	428901	-	-	-	-
	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 ^a	RBP ^a	Catheter length 170 cm									
				Balloon length (mm)									
				20	40	60	80	100	120	150	170	200	250
5F	4.0	9	20	-	428935 ^b	428944 ^b	428953 ^b	-	428971 ^b	428980 ^b	-	428990 ^b	428995 ^b
	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	-	-	-	-	-	-

^aNP = Nominal Pressure and RBP = Rated Burst Pressure in atm (1 atm = 1.013 bar)
^b8 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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BIOTRONIK AG
Ackerstrasse 6
8180 Bülach, Switzerland
Tel +41 (0) 44 8645111
Fax +41 (0) 44 8645005
info.vi@biotronik.com
www.biotronik.com

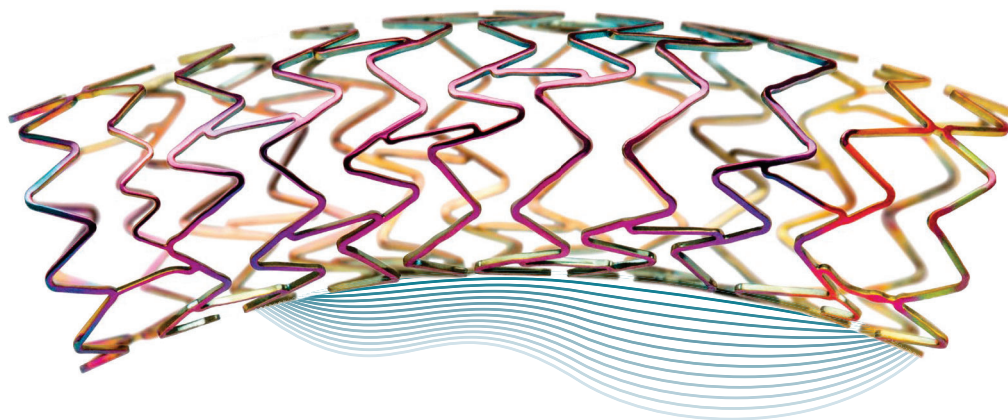
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4 Peripheral Stent Systems

Dynamic Renal



Proximal gold marker for superior visibility to support accurate stent placement



Cobalt chromium alloy combining a lower profile with high radial force

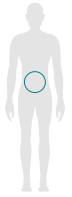


Double helix stent design for high flexibility

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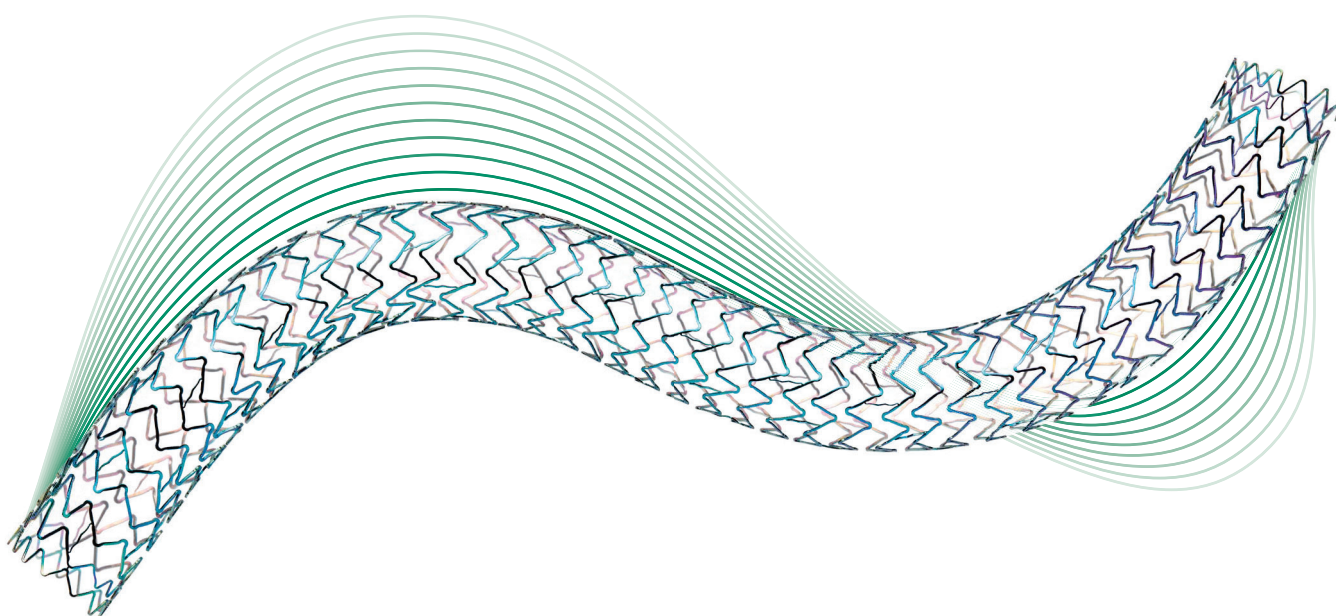
BIOTRONIK AG
Ackerstrasse 6
8180 Bülach, Switzerland
Tel +41 (0) 44 8645111
Fax +41 (0) 44 8645005
info.vi@biotronik.com
www.biotronik.com

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Dynetic[®]-35

The next generation iliac stent with excellent radial strength and superb flexibility.



High radial strength



Largest size range



Deliverability in 6F compatibility

Dynetic®-35

Vascular
Intervention
Peripheral



Indicated for the treatment of de novo or restenotic atherosclerotic lesions in iliac arteries. *

Technical Data		Stent
Stent		Balloon-Expandable
Stent material		Cobalt Chromium
Strut thickness		110 µm (ø 5.0 - 7.0 mm), 140 µm (ø 8.0 - 10.0 mm)
Shortening		Negligible
Stent coating		proBIO® (Amorphous Silicon Carbide)
Sizes		ø 5.0 - 10.0 mm; L: 18 - 28 - 38 - 58 - 78 mm
		Delivery system
Catheter type		OTW
Recommended guide wire		0.035"
Tip		Low entry profile, colored
Balloon markers		2 swaged markers
Shaft		5.1 - 5.4F, hydrophobic coating, dual-lumen
Usable length		90 cm, 130 cm and 170 cm
Markers		2 swaged markers
Guide wire lumen		Hydrophobic coating
Nominal Pressure (NP)		10 atm
Rated Burst Pressure (RBP)		14 atm (ø 5.0 - 8.0 mm), 12 atm (ø 9.0 - 10.0 mm)

Ordering Information	Stent ø (mm)	Catheter length 90 cm Stent length (mm)				
		18	28	38	58	78
6F	5.0	428690	428694	428700	428706	-
	6.0	428691	428695	428701	428707	-
	7.0	428692	428696	428702	428708	428712
	8.0	448939	448942	448945	448948	448951
	9.0	-	448943	448946	448949	448952
	10.0	-	448944	448947	448950	448953

Ordering Information	Stent ø (mm)	Catheter length 130 cm Stent length (mm)				
		18	28	38	58	78
6F	5.0	428716	428720	428726	428732	-
	6.0	428717	428721	428727	428733	-
	7.0	428718	428722	428728	428734	428738
	8.0	448954	448957	448960	448963	448966
	9.0	-	448958	448961	448964	448967
	10.0	-	448959	448962	448965	448968

Ordering Information	Stent ø (mm)	Catheter length 170 cm Stent length (mm)				
		18	28	38	58	78
6F	5.0	-	-	428752 ^a	-	-
	6.0	-	428747	428753	428759	-
	7.0	-	428748	428754	428760	428764 ^a
	8.0	-	448972	448975	448978	448981 ^a
	9.0	-	448973	448976	448979	-
	10.0	-	-	448977 ^a	-	-

^a8 weeks pre-order

*Indication as per IFU. Note: The Dynetic-35 does not have TGA (Therapeutic Goods Administration – Australia) approval for use within the common iliac artery.

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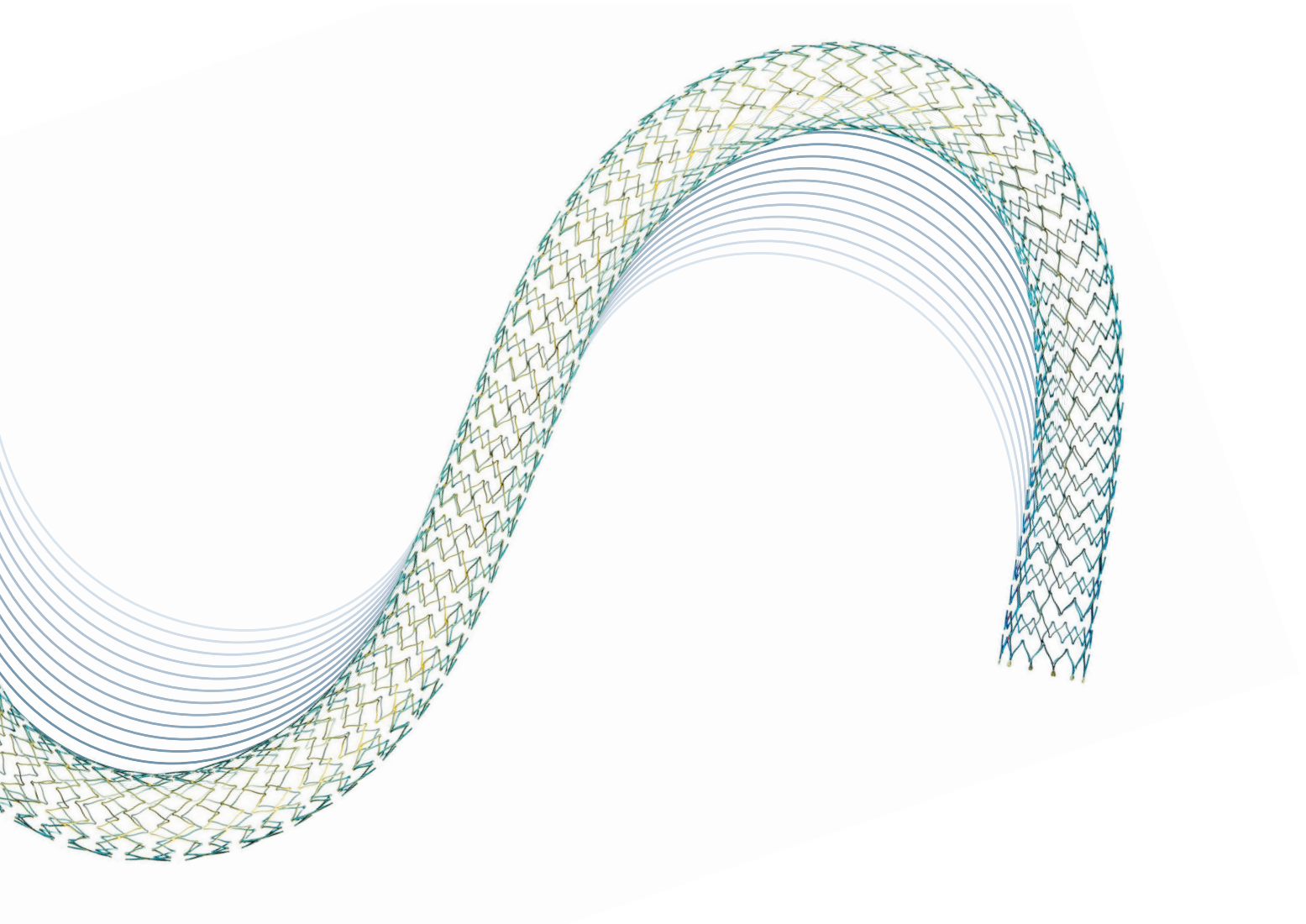
BIOTRONIK AG
Ackerstrasse 6
8180 Bülach, Switzerland
Tel +41 (0) 44 8645111
Fax +41 (0) 44 8645005
info.vi@biotronik.com
www.biotronik.com

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Vascular Intervention // Peripheral
Self-Expanding Stent System / 0.035" / OTW

Pulsar[®]-35



140 µm thin struts



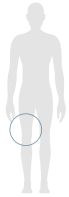
Clinically proven



Tri-axial delivery system

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
6F	5.0	379878	379879	379880	379881	379917	379918	379919	379920	379921
	6.0	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
6F	5.0	379898	379899	379900	379901	379937	379938	379939	379940	379941
	6.0	379903	379904	379905	379906	379942	379943	379944	379945	379946
	7.0	379908	379909	379910	379911	379947	379948	379949	379950	379951

*Indication as per IFU.

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