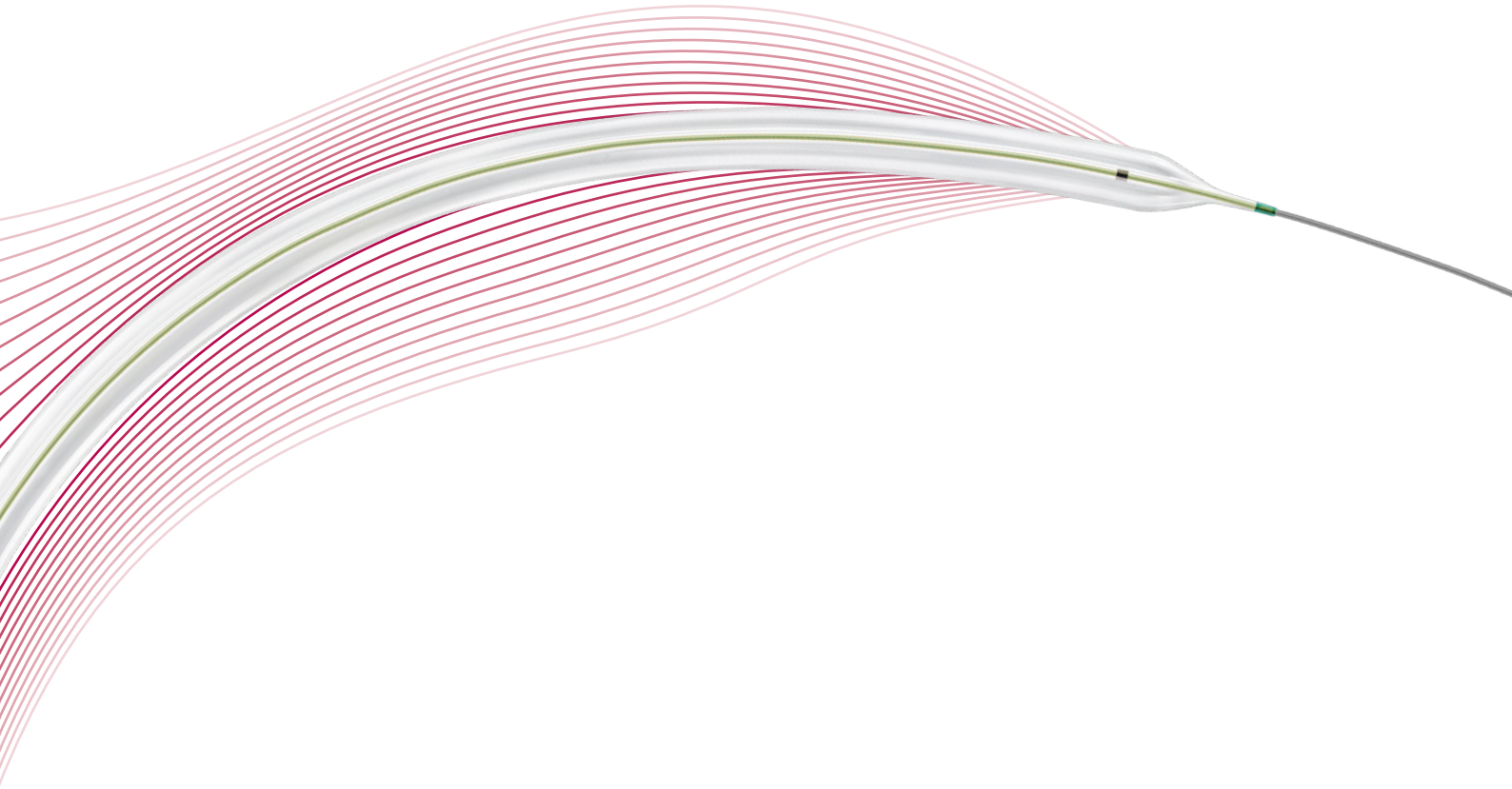
Vascular Intervention // Peripheral
PTA Balloon Catheter / 0.018" / OTW

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

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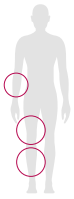
Passeo®-18

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.*

Vascular Intervention Peripheral



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

Antegrade approach

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

Retrograde approach

Catheter Length (cm)	Balloon ø (mm)	Balloon Length (mm) 20	40	60	80	120	150	170	200
150	2.0	366115	366118	366119	366123	366126	366129	366137	376296
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]

[a]8 weeks pre-order only

*Indication as per IFU.

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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

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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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 722508 R000

Manufacturer: Biotronik AG

Address:
Ackerstrasse 6
Bülach
8180
Switzerland

Single Registration Number: CH-MF-000010176

EU Authorised Representative: BIOTRONIK SE & Co. KG

Address:
Woermannkehre 1
12359 Berlin
Germany

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

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

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2021-06-21**

Current Issue Date: **2024-02-09**

Starting Validity Date: **2024-02-09**

Expiry Date: **2026-06-20**

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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 722508 R000

Device Schedule: Class III and Class IIb devices

Class III, Implantable	Intended purpose
Orsiro Mission Sirolimus Eluting Coronary Stent System	See MDR 760568
Synsiro Pro Sirolimus Eluting Coronary Stent System	See MDR 760570
Freesolve Sirolimus Eluting Coronary Resorbable Magnesium Scaffold System	See MDR 764462
PK Papyrus Covered Coronary Stent System	See MDR 767742

Class III	Intended purpose
Pantera LEO Fast-Exchange PTCA Catheter	See MDR 722974
Pantera Pro Coronary Dilatation Catheter	See MDR 739591
Pantera Lux Paclitaxel Releasing PTCA Balloon Catheter	See MDR 767740
Passeo-18 Lux Paclitaxel releasing PTA Balloon Catheter	See MDR 767744

Class IIb, Implantable	Intended purpose
Pulsar-18 T3 Peripheral Self-Expanding Nitinol Stent System	See MDR 739593
Dynamic Renal Stent System	See MDR 784097
Dynetic-35 Peripheral Balloon-Expandable Stent System	See MDR 784098
Astron Peripheral Self-Expanding Nitinol Stent System	See MDR 784100

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Peripheral Balloon Catheters	Class IIa

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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 722508 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2021-06-21	3119775	Issued.
2021-12-16	3566636	Amended – Addition of Manufacturer Single Registration Number CH-MF-000010176. Addition of a manufacturing site for Pantera LEO sub-components and delivery systems.
2022-04-15	3656773	Supplemented – Addition of Peripheral Balloon Catheters to the Device Schedule
2022-06-01	3679069	Supplemented — Addition of Pulsar-18 T3 device to the Device Schedule Amended — Addition of Pulsar-18 T3 specific subcontractor
2022-12-01	3772802	Supplemented – Addition of Pantera Pro device to the Device Schedule Amended - Administrative update to the history. Removal of subcontractor pages
2023-06-20	3909515	Supplemented – Addition of devices: PK Papyrus Covered Coronary Stent System and Passeo-18 Lux Paclitaxel releasing PTA Balloon Catheter
2023-10-30	30001603	Supplemented – Addition of Pantera Lux Paclitaxel Releasing PTCA Balloon Catheter and Astron Peripheral Self-Expanding Nitinol Stent System devices to the Device Schedule
2023-12-18	30034841	Supplemented – Addition of Orsiro Mission Sirolimus Eluting Coronary Stent System and Synsiro Pro Sirolimus Eluting Coronary Stent System devices to the Device Schedule
Current	30036514	Supplemented – Addition of Freesolve Sirolimus Eluting Coronary Resorbable Magnesium Scaffold (RMS) System, Dynamic Renal Stent System, and Dynetic-35 Peripheral Balloon-Expandable Stent System devices to the Device Schedule

First Issue Date: **2021-06-21**

Current Issue Date: **2024-02-09**

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