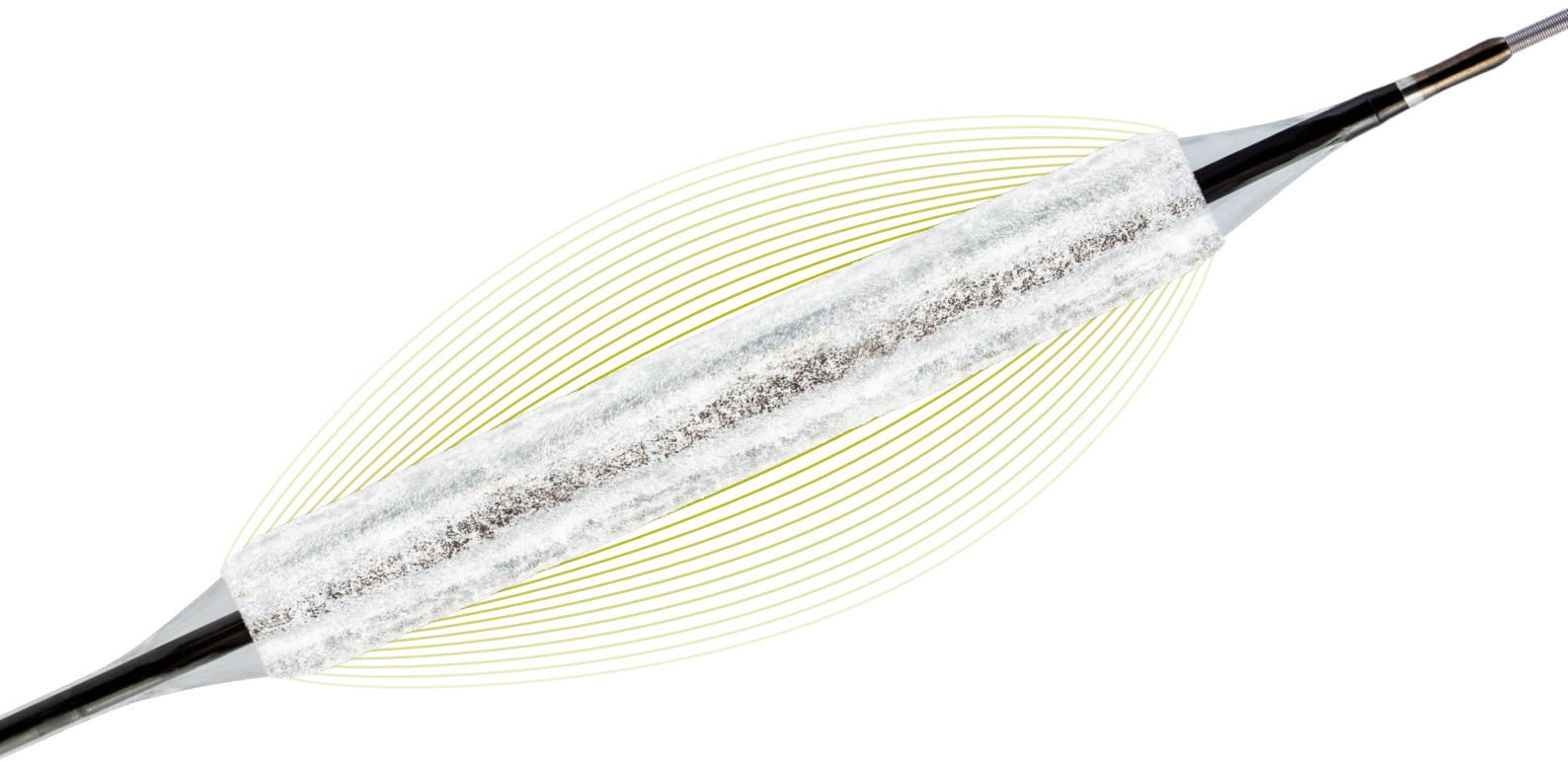
Vascular Intervention // Coronary
Drug-Coated Balloon Catheter

Pantera® Lux® DCB

Clinically proven. Best in class crossability.



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

BIOTRONIK
excellence for life

Pantera® Lux® DCB

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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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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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

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