Digitally signed by Captari Alexandru
Date: 2019.01.21 14:04:53 EET
Reason: MoldSign Signature
Location: Moldova

REPUBLICA MOLDOVA

CERTIFICAT DE ÎNREGISTRARE

Societatea cu Răspundere Limitată "CAVATEH M"
ESTE ÎNREGISTRATĂ LA CAMERA ÎNREGISTRĂRII DE STAT

Numărul de identificare de stat - codul fiscal
1012600031918

Data înregistrării **16.10.2012**

Data eliberării **16.10.2012**

Bobeica Ion, registrator
Funcția, numele, prenumele persoanei care a eliberat certificatul

semnătura

MINISTERUL JUSTIȚIEI AL REPUBLICII MOLDOVA
CAMERA ÎNREGISTRĂRII DE STAT I.S.
1004600077771

MD 019178

Digitally signed by Captari Alexandru
Date: 2021.07.07 11:59:36 EEST
Reason: MoldSign Signature
Location: Moldova

S.R.L. CAVATEH M.

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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BSI Group America Inc. is an MDSAP authorized auditing organization

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
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**

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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 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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EC-Declaration of Conformity

BIOTRONIK
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DOC No. **12-05-01** Issue: 7

Manufacturer:	Biotronik AG Ackerstrasse 6 8180 Bülach Switzerland	Authorised Representative:	BIOTRONIK SE & Co. KG Woermannkehre 1 12359 Berlin Germany

Product Category:	PTA Balloon Catheter
Product Name:	Passeo-14 Peripheral Dilatation Catheter
Class:	IIa, according to Council Directive 93/42/EEC, Annex IX, rule 6
Conformity Assessment Route:	Council Directive 93/42/EEC, Annex II, Section 3
Scope:	68 different variants. *See list on next page 2*

We hereby declare that the above-mentioned products meet the provisions of Council Directive 93/42/EEC for medical devices. All supporting documentation is retained under the premises of the manufacturer.

To these products our approved Full Quality Assurance System according to Annex II of the Directive 93/42/EEC is applied. For this Quality Assurance System the following certificate has been issued:

Certificate Number:	CE 608280
Notified Body:	BSI Group The Netherlands B.V.
EEC No:	2797
Expiry date:	26.MAY.2024

Date of first CE-marking: 16.MAY.2012

Place, Date of issue: Bülach, 21.MAY.2021

Signature:

Marcel Schäfer, Ph.D.
Senior Director Regulatory Affairs & Post Market Surveillance

A11 REG 151644 EN 04

Scope of DoC No. 12-05-01

Pos.	Designation	Catalogue number (REF)	Balloon diameter [mm]	Balloon length [mm]	Usable length [cm]
1	Passeo-14 1.5/20/120	380271	1.5	20	120
2	Passeo-14 2/20/120	380272	2.0	20	120
3	Passeo-14 2.5/20/90	380273	2.5	20	90
4	Passeo-14 3/20/90	380274	3.0	20	90
5	Passeo-14 3.5/20/90	380275	3.5	20	90
6	Passeo-14 4/20/90	380276	4.0	20	90
7	Passeo-14 1.5/40/120	380277	1.5	40	120
8	Passeo-14 2/40/120	380278	2.0	40	120
9	Passeo-14 2.5/40/90	380279	2.5	40	90
10	Passeo-14 3/40/90	380280	3.0	40	90
11	Passeo-14 3.5/40/90	380281	3.5	40	90
12	Passeo-14 4/40/90	380282	4.0	40	90
13	Passeo-14 1.5/70/120	380283	1.5	70	120
14	Passeo-14 2/70/120	380284	2.0	70	120
15	Passeo-14 2.5/70/90	380285	2.5	70	90
16	Passeo-14 3/70/90	380286	3.0	70	90
17	Passeo-14 3.5/70/90	380287	3.5	70	90
18	Passeo-14 4/70/90	380288	4.0	70	90
19	Passeo-14 2/100/120	380290	2.0	100	120
20	Passeo-14 2.5/100/90	380291	2.5	100	90
21	Passeo-14 3/100/90	380292	3.0	100	90
22	Passeo-14 3.5/100/90	380293	3.5	100	90
23	Passeo-14 4/100/90	380294	4.0	100	90
24	Passeo-14 2/140/120	380296	2.0	140	120
25	Passeo-14 2.5/140/90	380297	2.5	140	90
26	Passeo-14 3/140/90	380298	3.0	140	90
27	Passeo-14 3.5/140/90	380299	3.5	140	90
28	Passeo-14 4/140/90	380300	4.0	140	90
29	Passeo-14 2/180/120	380302	2.0	180	120
30	Passeo-14 2.5/180/90	380303	2.5	180	90
31	Passeo-14 3/180/90	380304	3.0	180	90
32	Passeo-14 2/220/120	380308	2.0	220	120
33	Passeo-14 2.5/220/90	380309	2.5	220	90
34	Passeo-14 3/220/90	380310	3.0	220	90
35	Passeo-14 1.5/20/150	380313	1.5	20	150
36	Passeo-14 2/20/150	380314	2.0	20	150
37	Passeo-14 2.5/20/150	380315	2.5	20	150
38	Passeo-14 3/20/150	380316	3.0	20	150
39	Passeo-14 3.5/20/150	380317	3.5	20	150
40	Passeo-14 4/20/150	380318	4.0	20	150
41	Passeo-14 1.5/40/150	380319	1.5	40	150
42	Passeo-14 2/40/150	380320	2.0	40	150
43	Passeo-14 2.5/40/150	380321	2.5	40	150
44	Passeo-14 3/40/150	380322	3.0	40	150

Pos.	Designation	Catalogue number (REF)	Balloon diameter [mm]	Balloon length [mm]	Usable length [cm]
45	Passeo-14 3.5/40/150	380323	3.5	40	150
46	Passeo-14 4/40/150	380324	4.0	40	150
47	Passeo-14 1.5/70/150	380325	1.5	70	150
48	Passeo-14 2/70/150	380326	2.0	70	150
49	Passeo-14 2.5/70/150	380327	2.5	70	150
50	Passeo-14 3/70/150	380328	3.0	70	150
51	Passeo-14 3.5/70/150	380329	3.5	70	150
52	Passeo-14 4/70/150	380330	4.0	70	150
53	Passeo-14 2/100/150	380332	2.0	100	150
54	Passeo-14 2.5/100/150	380333	2.5	100	150
55	Passeo-14 3/100/150	380334	3.0	100	150
56	Passeo-14 3.5/100/150	380335	3.5	100	150
57	Passeo-14 4/100/150	380336	4.0	100	150
58	Passeo-14 2/140/150	380338	2.0	140	150
59	Passeo-14 2.5/140/150	380339	2.5	140	150
60	Passeo-14 3/140/150	380340	3.0	140	150
61	Passeo-14 3.5/140/150	380341	3.5	140	150
62	Passeo-14 4/140/150	380342	4.0	140	150
63	Passeo-14 2/180/150	380344	2.0	180	150
64	Passeo-14 2.5/180/150	380345	2.5	180	150
65	Passeo-14 3/180/150	380346	3.0	180	150
66	Passeo-14 2/220/150	380350	2.0	220	150
67	Passeo-14 2.5/220/150	380351	2.5	220	150
68	Passeo-14 3/220/150	380352	3.0	220	150

Change History

Check version index is up to date prior to use.

Version of SAP Document	Main changes from previous release to current release
01	Transfer to new template TMP111387. Replaces "Passeo-14_DOC_120501_issue3". New issue due to transfer of Notified Body to BSI Group The Netherlands B.V.
02	Corrected to TMP 110093 due to corrected CE 608280 expiry date to 2019-AUG-3, and addition of a new sterilizer (Sterimed).
03	New issue initiated by an update of the EC Full Quality Assurance System Certificate, having a new expiry date.
04	Designation of Authorised (EU) Representative. Addition of name and address.

Up to 3.8 x faster deflation times

Enhanced crossability

High pushability and flexibility

Technical data / ordering info

Vascular Intervention // Peripheral
PTA Balloon Catheter/0.014”/OTW

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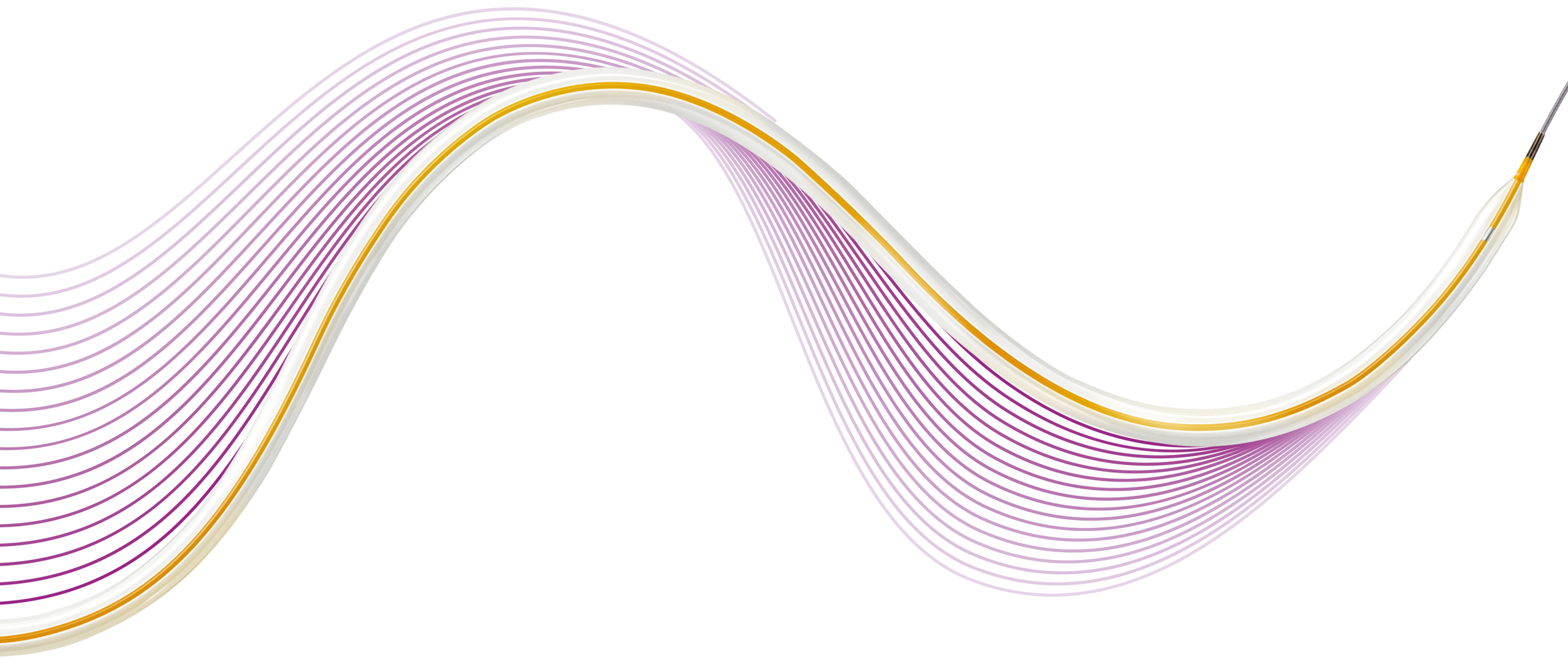
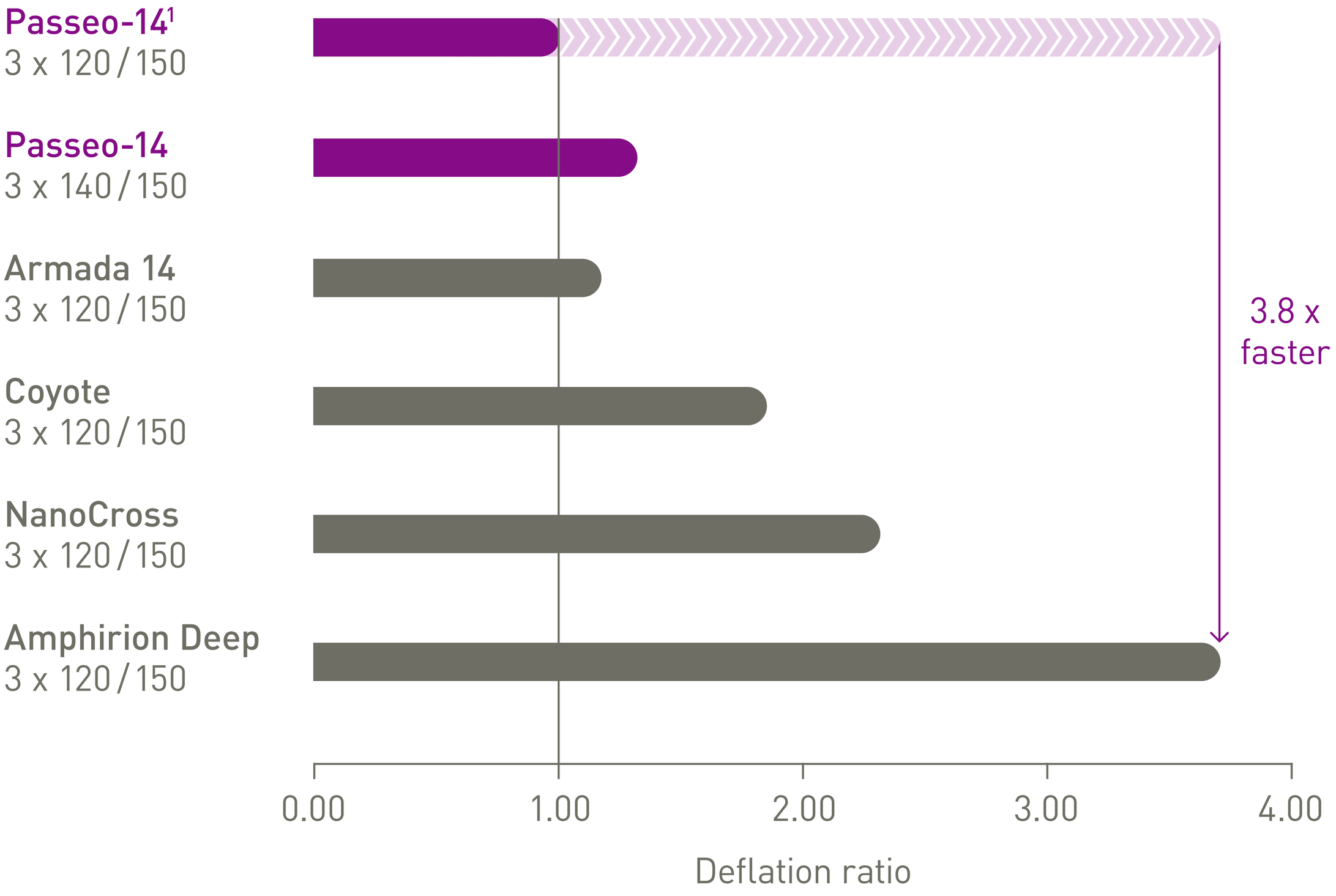
Passeo-14



Up to 3.8 x faster deflation times[1]

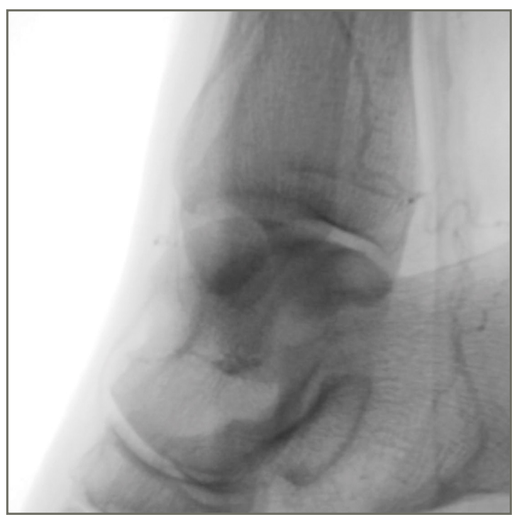
Due to the coaxial catheter shaft design that creates a large balloon lumen facilitating rapid inflation and deflation, Passeo-14 deflates:

3.8 x faster than Amphirion Deep
2.0 x faster than Coyote
2.4 x faster than NanoCross

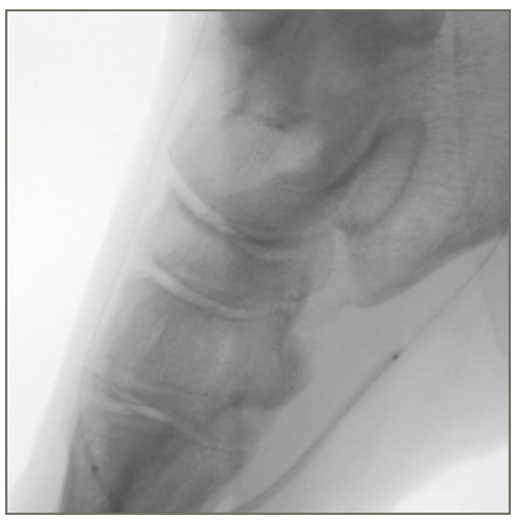


The solution for dedicated below the ankle sizes

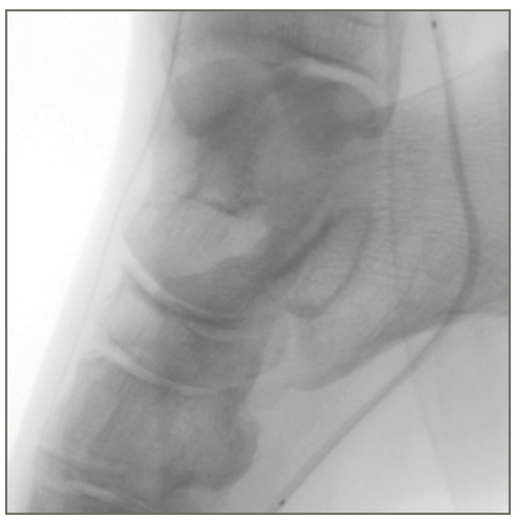
- ø 1.5 - 2.0 mm
- 150 mm flexible distal shaft
- Tailored stiffening wire



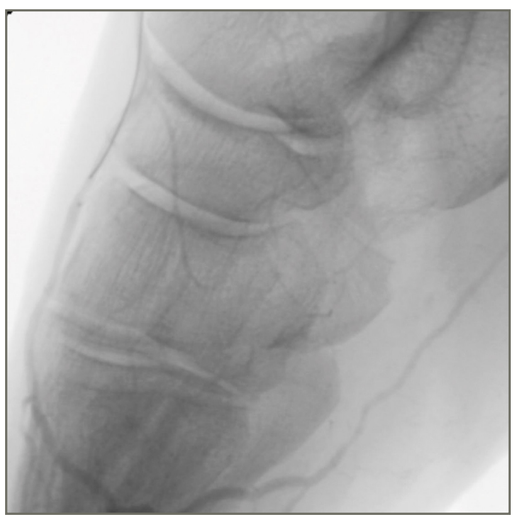
Pre-treatment



Dilatation
pedal arch



Dilatation
plantar arch



Post dilatation

Courtesy of Dr. L. Steffanon, Vicenza, Italy

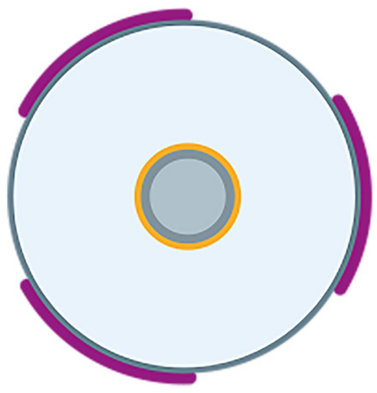
Enhanced crossability

The tri-fold balloon, which is fully coated when folded and only partly coated when inflated, enables an enhanced crossability while minimizing slippage during inflation.

Folded balloon

Enhanced crossability

Minimized slippage

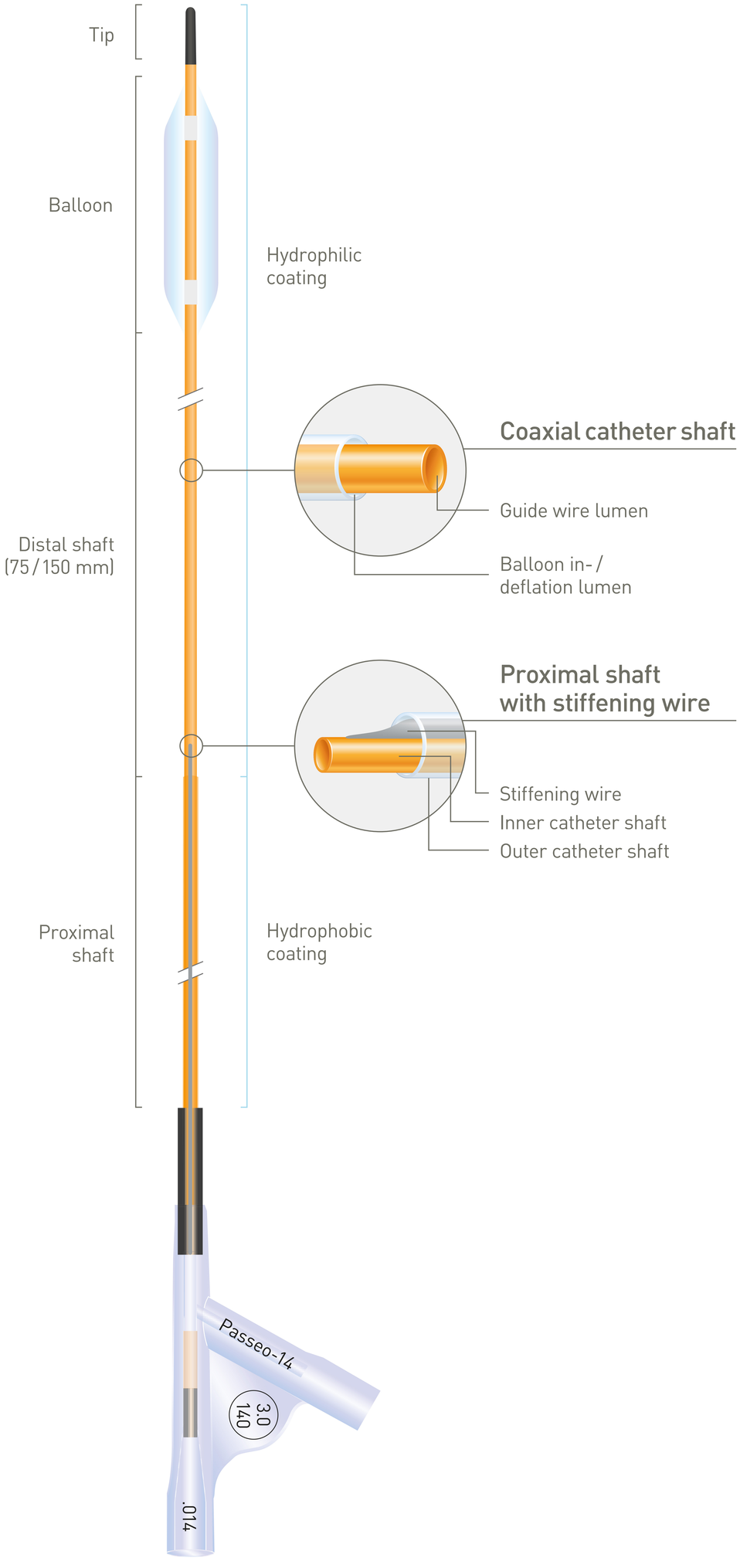


Inflated balloon

● Hydrophilic coating ○ Uncoated

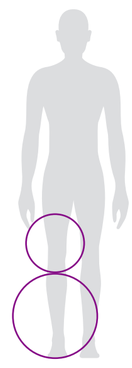
High pushability and flexibility[2]

Impressive pushability due to catheter shaft design featuring a unique stiffening wire in the proximal shaft of the catheter, while enabling high flexibility due to a lower profile distal shaft in small, tortuous vessels.



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	-	-
		90	4.0	-	380282	380288	380294	380300	-	-

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

[a]8 weeks pre-order only

1. BIOTRONIK data on file. Volume adjustment: A 3mm x 120mm balloon contains 17% less contrast media volume than a 3mm x 140mm balloon. The measured deflation time of a 3mm x 140mm balloon was adjusted by 17 % to make a direct competitive comparison; 2. BIOTRONIK Data on file.

398937/D/Jan_2018_DV

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