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Location: Moldova

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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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. 11-02-01 Issue: 18

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

Product Category:	Drug-eluting stents for vascular intervention
Product Name:	Orsiro Sirolimus Eluting Coronary Stent System
Class:	III, according to Council Directive 93/42/EEC, Annex IX, rule 8 and 13
Conformity Assessment Route:	Council Directive 93/42/EEC, Annex II, Section 3 and 4
Scope:	54 different variants. See list on next pages

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.

For these products the following EC-Design Examination Certificate has been issued:

Certificate Number:	CE 608284
Notified Body:	BSI Group The Netherlands B.V.
EEC No:	2797
Expiry date:	26.May.2024

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:	25.FEB.2011
Place, Date of issue:	Bülach, 21.MAY.2021

Signature:

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

A11 REG 151631 EN 07

Scope of DoC No. 11-02-01

Pos.	Designation	Catalogue number (REF)	Stent diameter [mm]	Stent length [mm]	Nominal Total Drug Load TDL [µg]
1	Orsiro 2.25/9	364469	2.25	9	55
2	Orsiro 2.5/9	364470	2.5	9	55
3	Orsiro 2.75/9	364471	2.75	9	55
4	Orsiro 3.0/9	364472	3.0	9	55
5	Orsiro 3.5/9	364473	3.5	9	70
6	Orsiro 4.0/9	364474	4.0	9	70
7	Orsiro 2.25/13	364475	2.25	13	80
8	Orsiro 2.5/13	364476	2.5	13	80
9	Orsiro 2.75/13	364477	2.75	13	80
10	Orsiro 3.0/13	364478	3.0	13	80
11	Orsiro 3.5/13	364479	3.5	13	95
12	Orsiro 4.0/13	364480	4.0	13	95
13	Orsiro 2.25/15	364481	2.25	15	93
14	Orsiro 2.5/15	364482	2.5	15	93
15	Orsiro 2.75/15	364483	2.75	15	93
16	Orsiro 3.0/15	364484	3.0	15	93
17	Orsiro 3.5/15	364485	3.5	15	113
18	Orsiro 4.0/15	364486	4.0	15	113
19	Orsiro 2.25/18	364487	2.25	18	109
20	Orsiro 2.5/18	364488	2.5	18	109
21	Orsiro 2.75/18	364489	2.75	18	109
22	Orsiro 3.0/18	364490	3.0	18	109
23	Orsiro 3.5/18	364491	3.5	18	131
24	Orsiro 4.0/18	364492	4.0	18	131
25	Orsiro 2.25/22	364499	2.25	22	134
26	Orsiro 2.5/22	364500	2.5	22	134
27	Orsiro 2.75/22	364501	2.75	22	134
28	Orsiro 3.0/22	364502	3.0	22	134
29	Orsiro 3.5/22	364503	3.5	22	162
30	Orsiro 4.0/22	364504	4.0	22	162
31	Orsiro 2.25/26	364505	2.25	26	159
32	Orsiro 2.5/26	364506	2.5	26	159
33	Orsiro 2.75/26	364507	2.75	26	159
34	Orsiro 3.0/26	364508	3.0	26	159
35	Orsiro 3.5/26	364509	3.5	26	193
36	Orsiro 4.0/26	364510	4.0	26	193
37	Orsiro 2.25/30	364511	2.25	30	184
38	Orsiro 2.5/30	364512	2.5	30	184
39	Orsiro 2.75/30	364513	2.75	30	184
40	Orsiro 3.0/30	364514	3.0	30	184
41	Orsiro 3.5/30	364515	3.5	30	224
42	Orsiro 4.0/30	364516	4.0	30	224
43	Orsiro 2.25/35	391234	2.25	35	213

44	Orsiro 2.5/35	391235	2.5	35	213
45	Orsiro 2.75/35	391236	2.75	35	213
46	Orsiro 3.0/35	391237	3.0	35	213
47	Orsiro 3.5/35	391018	3.5	35	261
48	Orsiro 4.0/35	391019	4.0	35	261
49	Orsiro 2.25/40	391238	2.25	40	247
50	Orsiro 2.5/40	391239	2.5	40	247
51	Orsiro 2.75/40	391240	2.75	40	247
52	Orsiro 3.0/40	391241	3.0	40	247
53	Orsiro 3.5/40	391020	3.5	40	298
54	Orsiro 4.0/40	391021	4.0	40	298

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 from previous template to new template TMP 111387. New issue due to transfer of Notified Body to BSI Group The Netherlands B.V.
02	New issue due to sterilizer addition
03	Revised for the introduction of the electronic IFU in compliance with regulation 207/2012.
04	Declaration of Conformity updated with the new expiry date of the EC Full Quality Assurance System Certificate
05	Implementation of the recertification
06	New issue due to changes affecting Sirolimus at supplier Biocon Limited (heavy metals in specification; test methods for particle size and residual solvent; and re-test period).
07	Designation of Authorised (EU) Representative. Addition of name and address.

EC-Declaration of Conformity

BIOTRONIK
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DOC No. 13-06-02 Issue: 11

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

Product Category:	Coronary stent system
Product Name:	PK Papyrus Covered Coronary Stent System
Class:	III, according to Council Directive 93/42/EEC, Annex IX, rule 8
Conformity Assessment Route:	Council Directive 93/42/EEC, Annex II, Section 3 and 4
Scope:	17 different variants. See list on next page

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.

For these products the following EC-Design Examination Certificate has been issued:

Certificate Number:	CE 608286
Notified Body:	BSI Group The Netherlands B.V.
EEC No:	2797
Expiry date:	10.Jun.2023

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: 12.Jun.2013

Place, Date of issue: Bülach, 21.MAY.201

Signature:

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

A11 REG 146249 EN 06

Scope of DoC No. 13-06-02

Pos.	Designation	Catalogue number (REF)	Stent diameter [mm]	Stent length [mm]
1	PK Papyrus 2.5/15	369380	2.5	15
2	PK Papyrus 3.0/15	369381	3.0	15
3	PK Papyrus 3.5/15	369382	3.5	15
4	PK Papyrus 4.0/15	369383	4.0	15
5	PK Papyrus 4.5/15	369384	4.5	15
6	PK Papyrus 5.0/15	369385	5.0	15
7	PK Papyrus 2.5/20	369386	2.5	20
8	PK Papyrus 3.0/20	369387	3.0	20
9	PK Papyrus 3.5/20	369388	3.5	20
10	PK Papyrus 4.0/20	369389	4.0	20
11	PK Papyrus 4.5/20	369390	4.5	20
12	PK Papyrus 5.0/20	369391	5.0	20
13	PK Papyrus 3.0/26	381789	3.0	26
14	PK Papyrus 3.5/26	381790	3.5	26
15	PK Papyrus 4.0/26	381791	4.0	26
16	PK Papyrus 4.5/26	369392	4.5	26
17	PK Papyrus 5.0/26	369393	5.0	26

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	New Document using current template. Replaces "PK Papyrus 130602 Issue 5".
02	Declaration of Conformity updated with the new expiry date of the EC Design Examination Certificate.
03	New issue due to transfer of Notified Body to BSI Group The Netherlands B.V.
04	New issue due to sterilizer addition.
05	Declaration of Conformity updated with the new expiry date of the EC Full Quality Assurance System Certificate.
06	Designation of Authorised (EU) Representative. Addition of name and address.

Covered single stent design

Low crossing profile

Exceptional deliverability

Technical data / ordering info

Vascular Intervention // Coronary
Covered Coronary Stent System

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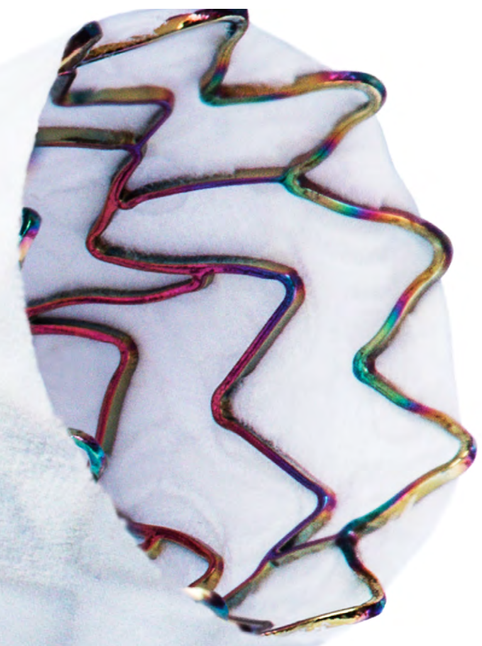
PK Papyrus®

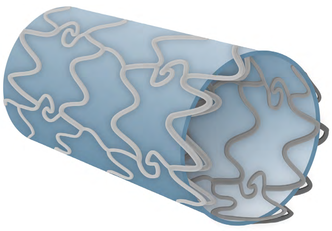


PK Papyrus

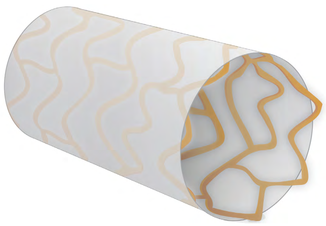
Designed to save lives when seconds count.

Covered single stent design

With its covered single stent design, PK Papyrus achieves greater bending flexibility and a smaller crossing profile compared to the traditional sandwich design stent, allowing you to seal perforations with confidence.

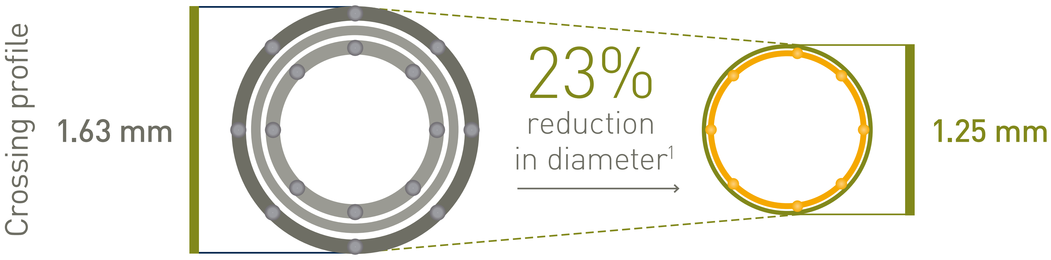


Traditional sandwich design stent



PK Papyrus
Covered single stent design

Low crossing profile[1]



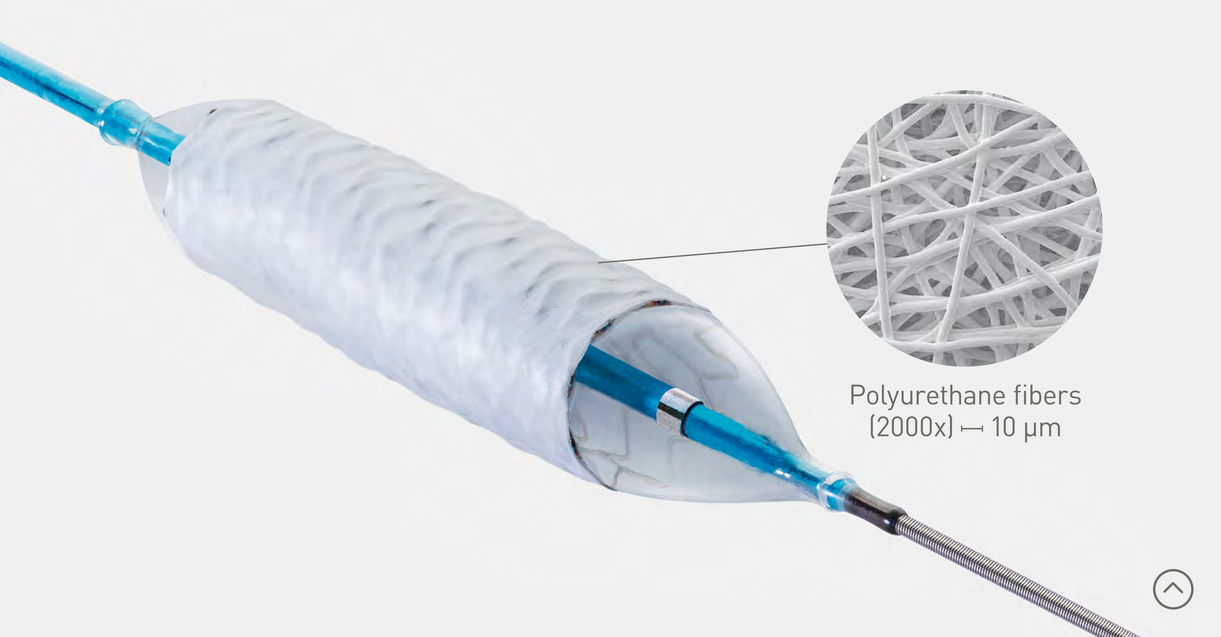
Traditional sandwich design stent

PK Papyrus
3.0 / 15

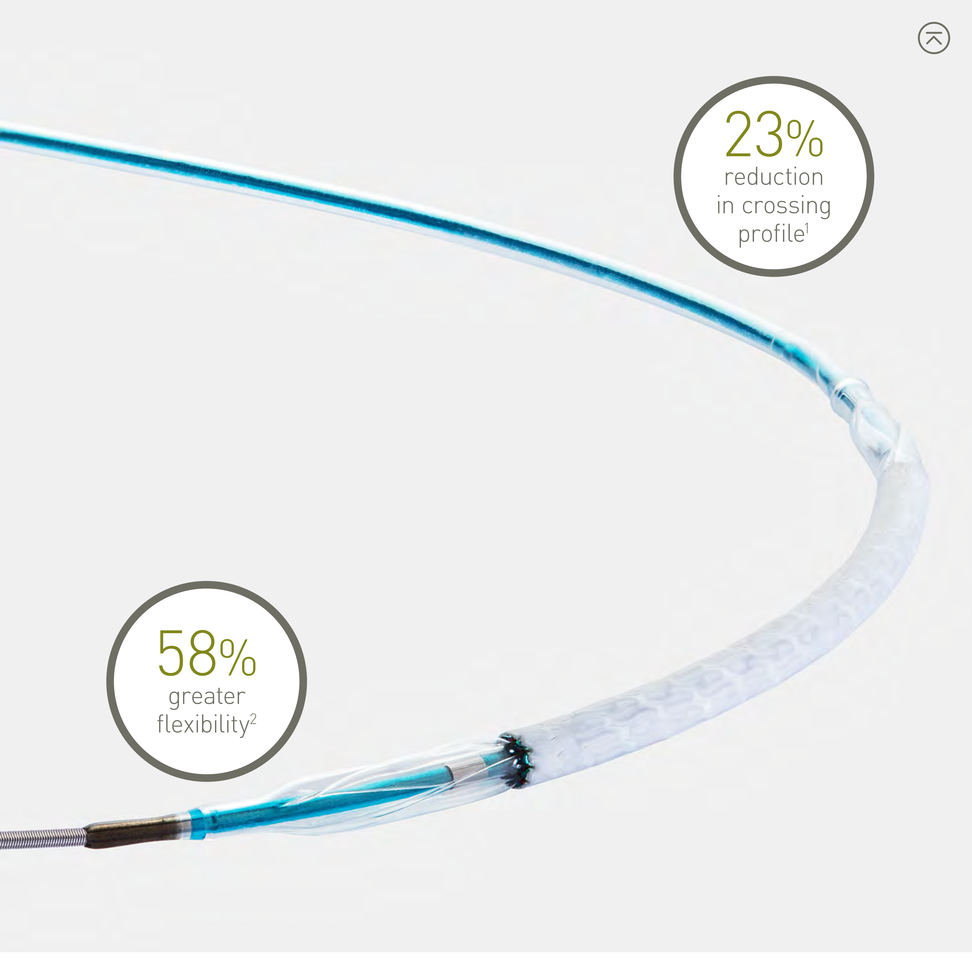
Illustration depicts crimped devices prior to inflation

Innovative polyurethane membrane

Electrostatic forces spin polyurethane fibers onto the stent surface, creating a thin and highly elastic membrane.

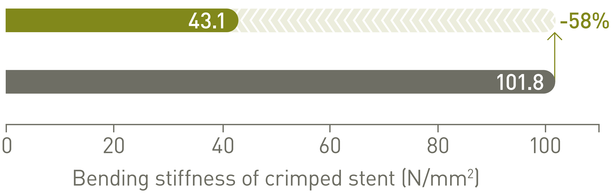


Polyurethane fibers
(2000x) ⟼ 10 µm



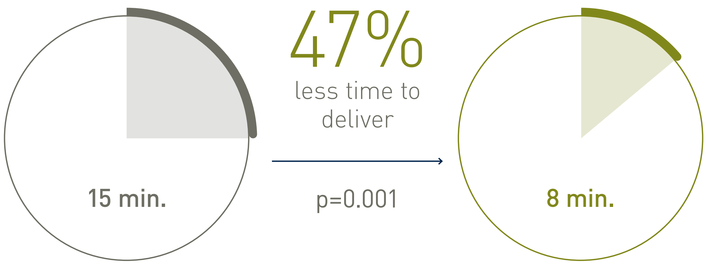
Exceptional deliverability

58% greater flexibility[2]



Shorter median time to deliver

Single center, retrospective investigation of 61 patients treated with covered coronary stents.[3,4]



Jostent Graftmaster
n = 39

PK Papyrus
n = 22

"In rare cases of a coronary perforation, time is the enemy."

Dr. Dean Kereiakes, Interventional Cardiologist and Medical Director of The Christ Hospital and Vascular Center, Cincinnati, Ohio, USA.

5F Compatibility

5F

For main sizes - no need for guide catheter upgrade (ø 2.5-4.0 mm).

PK Papyrus

Indicated for acute coronary artery perforations.*

Vascular
Intervention
Coronary

Technical Data

Stent	
Stent cover material	Non-woven, electrospun polyurethane
Stent cover thickness	90 µm
Stent strut thickness	ø 2.5 - 3.0 mm: 60 µm (0.0024”); ø 3.5 - 4.0 mm: 80 µm (0.0031”); ø 4.5 - 5.0 mm: 120 µm (0.0047”)
Stent material	Cobalt chromium (L-605) with **proBIO** (Amorphous Silicon Carbide) coating
Maximum stent expansion diameter	ø 2.5 - 3.0 mm: 3.50 mm; ø 3.5 - 4.0 mm: 4.65 mm; ø 4.5 - 5.0 mm: 5.63 mm

Delivery system	
Guide wire diameter	0.014”
Usable catheter length	140 cm
Recommended guide catheter	ø 2.5 - 4.0 mm: 5F (min. I.D.** 0.056”); ø 4.5 - 5.0 mm: 6F (min. I.D.** 0.070”)
Nominal pressure (NP)	ø 2.5 - 3.5 mm: 8 atm; ø 4.0 - 5.0 mm: 7 atm
Rated burst pressure (RBP)	ø 2.5 - 4.0 mm: 16 atm; ø 4.5 - 5.0 mm: 14 atm

**I.D. = Inner Diameter

Ordering Information

Stent		Catheter length 140 cm		
	ø (mm)	Stent length (mm)		
		15	20	26
5F	2.5	369380	369386	-
	3.0	369381	369387	381789
	3.5	369382	369388	381790
	4.0	369383	369389	381791
6F	4.5	369384	369390	369392
	5.0	369385	369391	369393

1. Compared to Graftmaster 2.8/16 (BIOTRONIK data on file); 2. Compared to Jostent Graftmaster 3.0/16 (BIOTRONIK data on file); 3. Hernández-Enríquez M, Lairez O, Campelo-Parada F, et al. Outcomes after use of covered stents to treat coronary artery perforations. Comparison of old and new-generation covered stents. J Interv Cardiol. 2018;1–7. doi: 10.1111/joic.12525; 4. Population is representative of real world interventional practice and was not a randomized prospective clinical trial.

*Indication as per IFU.

394771/F/Jul_2019_DV

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

BIOTRONIK
excellence for life

Outstanding patient outcomes

Highly deliverable

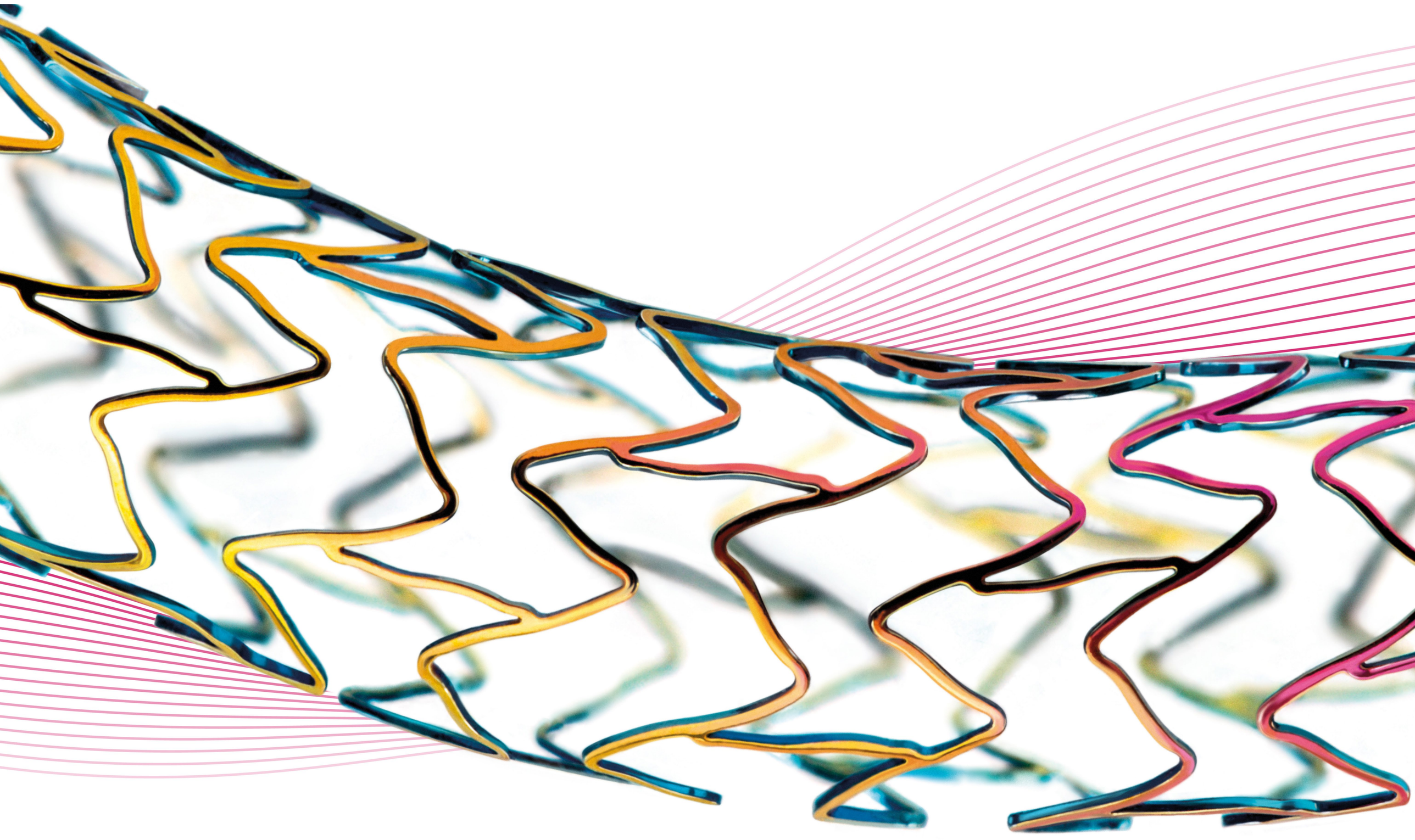
Ultrathin 60* µm struts

Technical data / ordering info

Vascular Intervention // Coronary
Drug-Eluting Stent System

BIOTRONIK
excellence for life

Orsiro®



*ø 2.25 – 3.0 mm

Orsiro
Ultrathin struts§. Outstanding patient outcomes◊.

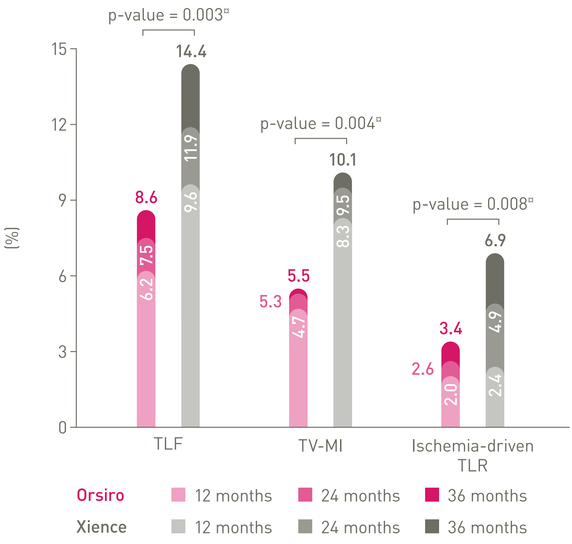
Outstanding patient outcomes

Improving patient outcomes, year after year*

BIOFLOW-V (n = 1,334) the FDA pivotal trial

Significant differences in TLF observed at year 1 and 2 were maintained and further increased at year 3 (8.6% vs. 14.4%, p = 0.003), driven by significant differences in TV-MI (5.5% vs. 10.1%, p = 0.004) and Ischemia-driven TLR (3.4% vs. 6.9%, p = 0.008) that favor Orsiro over Xience.[1,2,3]

TLF and components at 12, 24 and 36 Months



40% lower TLF rate[3 ϕ] (p=0.003)

46% lower TV-MI rate[3 ϕ] (p=0.004)

52% lower Ischemia-driven TLR rate[3 ϕ] (p= 0.008)

TLF – Target Lesion Failure; TV-MI – Target Vessel Myocardial Infarction; TLR – Target Lesion Revascularization.

§As characterized with respect to strut thickness in Bangalore et al. Meta-analysis.
◊Based on investigator's interpretation of BIOFLOW-V primary endpoint results.
*Compared to Xience, based on three consecutive years.
¤p-values for 36-m frequentist analysis.
ϕvs. Xience, based on 36-m frequentist analysis.

Superiority in STEMI[4]

BIOSTEMI (n=1,300) is the first RCT demonstrating superiority between two contemporary DES

Orsiro is superior to Xience in STEMI patients undergoing primary PCI with respect to Target Lesion Failure (TLF) rate at 12 months.

4% Orsiro

6% Xience

41% Lower risk* of TLF with Orsiro in STEMI

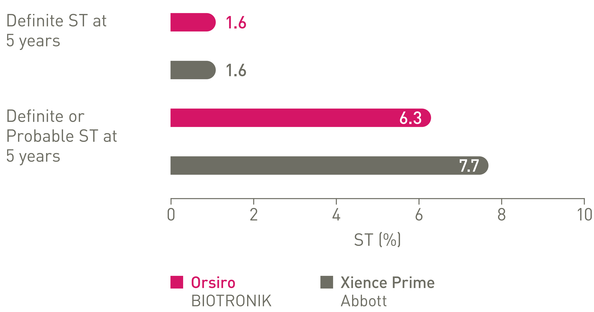
Rate Ratio (95% BCI**): 0.59, (0.37-0.94),
Posterior Probability of Superiority: 98.6%

Bayesian ITT Population¤

Long-term safety

In the randomized, all-comers BIOSCIENCE trial (n= 2,119)[5]

Orsiro shows numerically equal or lower Stent Thrombosis (ST) in complex patients in comparison to Xience.

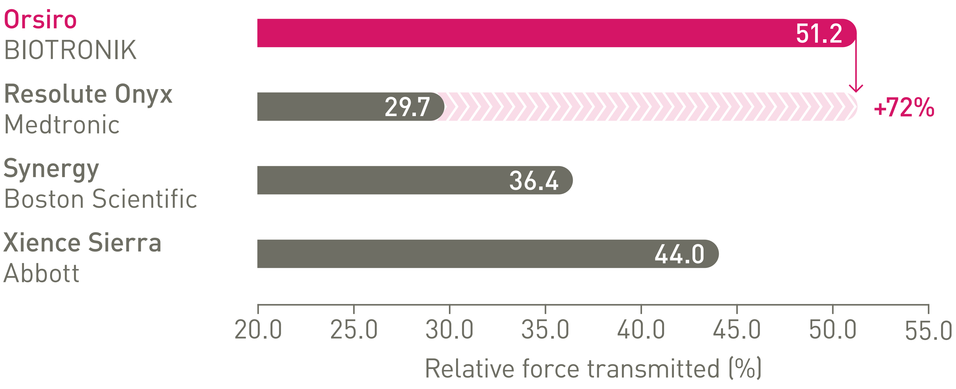


*Compared to Xience, BIOTRONIK data on file based on the Rate Ratio of 0.59.
**BCI: Bayesian Credibility Interval.
¤n= 1,300 newly enrolled STEMI patients including 407 patients from the BIOSCIENCE STEMI subgroup used as prior information.

Highly deliverable

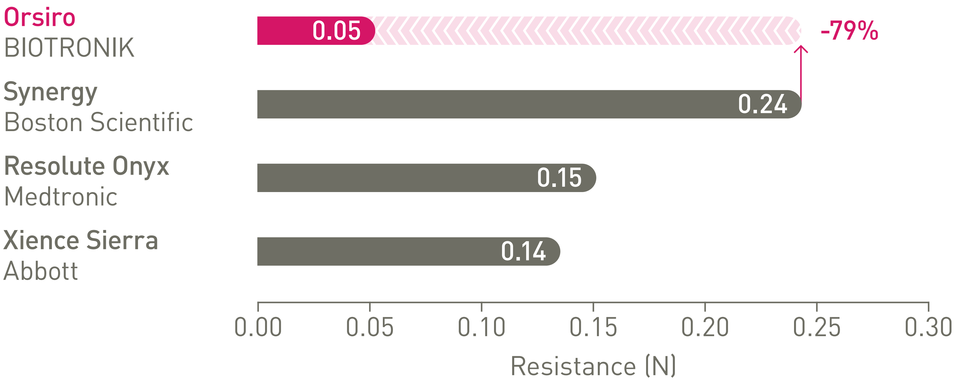
Better push

Transmits up to 72% more force from hub to tip.[13]



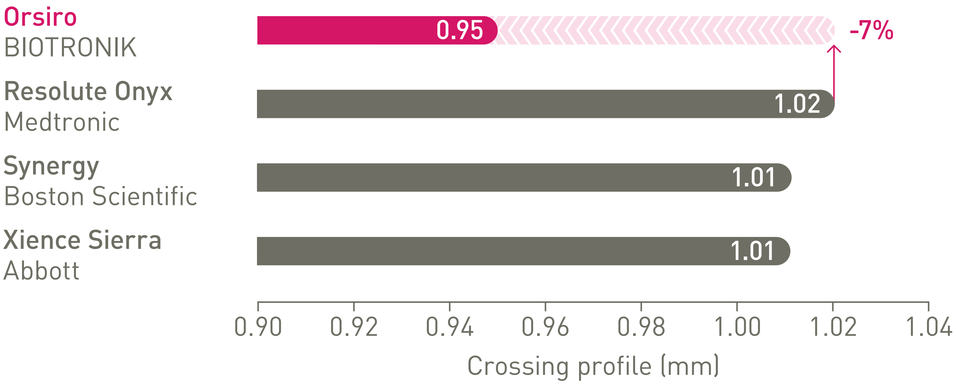
Easier cross

Up to 79% less force needed to successfully cross demanding anatomies.[13]



Lower crossing profile

Improved acute performance – up to 7% lower crossing profile.[13]

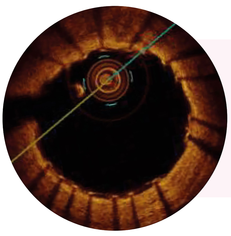


Ultrathin 60 µm struts

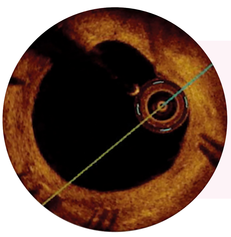
Improved outcomes start in the early phase

43%
lower in-hospital MI rate‡ vs. Xience[1]

48 hours
Thinner struts mean less vessel injury[6]



30 daysΔ
80.4% strut coverage[7]



90 daysΔ
98.7% strut coverage[7]

Thinner struts make the difference

Ultrathin vs. second generation DES in a large scale meta-analysis including more than 11,000 patients[8, 9]

16%

Relative risk reduction in TLF at 12 months
RR (95% CI) 0.84 (0.72, 0.99)

‡ Driven by peri-procedural MI events (<48 hours). In-hospital rate may include events > 48 hours.
Δ Images: Secco G et al. Time-related changes in neointimal tissue coverage following a new generation SES implantation: an OCT observational study. Presented at: euro PCR, May 20, 2014; Paris, France.

Strut thickness in perspective[10]

Orsiro
BIOTRONIK
CoCr-SES
60 µm*

Synergy
Boston Scientific
PtCr-EES
74 µm

Ultimaster
Terumo
CoCr-SES
80 µm

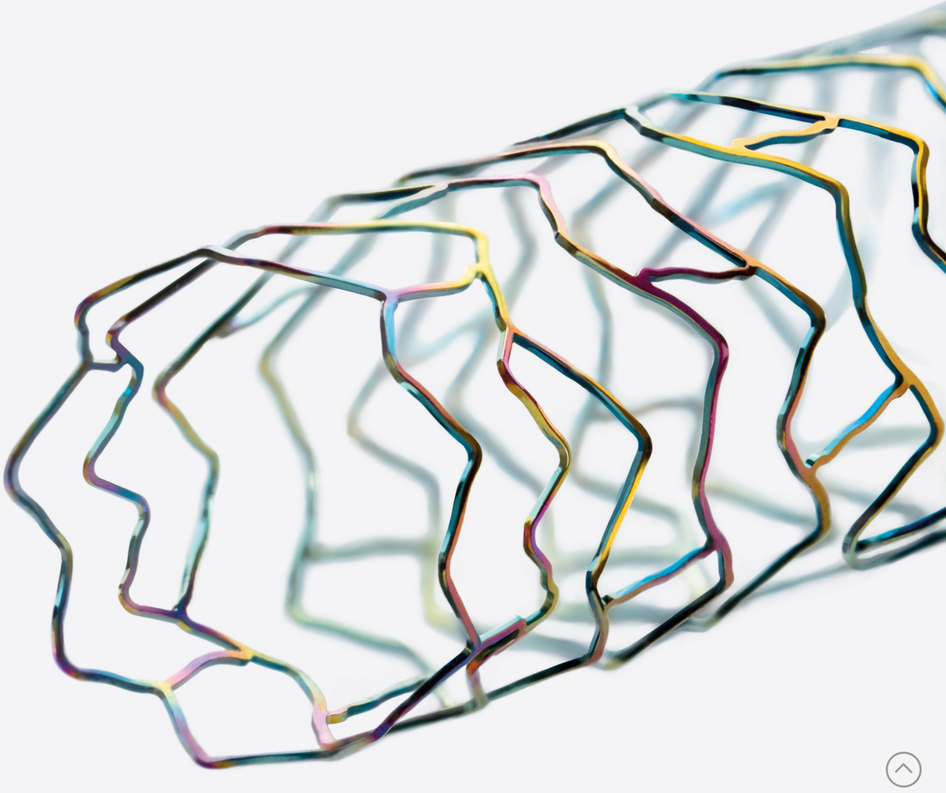
Resolute Onyx[11,12]
Medtronic
CoNi-ZES
81 µm

Xience Family
Abbott
CoCr-EES
81 µm

Promus
Boston Scientific
PtCr-EES
81 µm

BioMatrix
Biosensors
316L-BES
120 µm

* ø 2.25 – 3.0 mm



Orsiro®

Indicated for discrete de novo stenotic lesions and in-stent restenotic lesions.*

Vascular
Intervention
Coronary

Technical Data

Stent	
Stent material	Cobalt chromium, L-605
Passive coating	proBIO (Amorphous Silicon Carbide)
Active coating	BIOlute bioabsorbable Poly-L-Lactide (PLLA) eluting a limus drug
Drug dose	1.4 µg / mm²
Strut thickness	ø 2.25 - 3.0 mm: 60 µm (0.0024"); ø 3.50 - 4.0 mm: 80 µm (0.0031")
Delivery system	
Catheter type	Rapid exchange
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 material	Semi crystalline polymer material
Coating (distal shaft)	Hydrophilic coating
Marker bands	Two swaged platinum-iridium markers
Proximal shaft diameter	2.0F
Distal shaft diameter	2.6F: ø 2.25 - 3.5 mm; 2.8F: ø 4.0 mm
Nominal pressure (NP)	8 atm
Rated burst pressure (RBP)	16 atm

Compliance Chart

		Balloon diameter x length (mm)					
		ø 2.25 x 9-40	ø 2.50 × 9-40	ø 2.75 × 9-40	ø 3.00 × 9-40	ø 3.50 × 9-40	ø 4.00 × 9-40
Nominal Pressure (NP)	atm**	8	8	8	8	8	8
	ø (mm)	2.25	2.50	2.75	3.00	3.50	4.00
Rated Burst Pressure (RBP)	atm**	16	16	16	16	16	16
	ø (mm)	2.50	2.77	3.05	3.33	3.88	4.44

**1 atm = 1.013 bar

Ordering Information

Stent ø (mm)	Catheter length 140 cm Stent length (mm)								
	9	13	15	18	22	26	30	35	40
2.25	364469	364475	364481	364487	364499	364505	364511	391234	391238
2.50	364470	364476	364482	364488	364500	364506	364512	391235	391239
2.75	364471	364477	364483	364489	364501	364507	364513	391236	391240
3.00	364472	364478	364484	364490	364502	364508	364514	391237	391241
3.50	364473	364479	364485	364491	364503	364509	364515	391018	391020
4.00	364474	364480	364486	364492	364504	364510	364516	391019	391021

1. Kandzari D et al. Ultrathin, bioresorbable polymer sirolimus-eluting stents versus thin, durable polymer everolimus-eluting stents in patients undergoing coronary revascularisation (BIOFLOW V): a randomised trial. Lancet. 2017 Oct 21; 390(10105):1843-1852; 2. Kandzari D et al. Ultrathin bioresorbable polymer sirolimus-eluting stents versus thin durable polymer everolimus-eluting stents. Journal of the American College of Cardiology. 2018 Dec 17;72(25):3287-97; 3. Kandzari D et al. J Am Coll Cardiol. Cardiovasc Interven. 2020, doi: 10.1016/j.jcin.2020.02.019. 4. Iglesias JF et al. Biodegradable polymer sirolimus-eluting stents versus durable polymer everolimus-eluting stents in patients with ST-segment elevation myocardial infarction (BIOSTEMI): a single-blind, prospective, randomised superiority trial; Lancet, September, 2019; 5. Pilgrim T et al. 5-year outcomes of the BIOSCIENCE randomised trial. Supplementary appendix; Lancet 2018; published online Aug 28. http://dx.doi.org/10.1016/S0140-6736(18)31715-X; 6. Foin et al. Impact of stent strut design in metallic stents and biodegradable scaffolds. Int J Cardiol.2014 Dec 20;177(3):800-8; 7. Secco G et al. Time-related changes in neointimal tissue coverage of a novel Sirolimus eluting stent: Serial observations with optical coherence tomography. Cardiovascular Revascularization Medicine 17.1 (2016): 38-43; 8. Bangalore S et al. Newer-generation ultrathin strut drug-eluting stents versus older second-generation thicker strut drug-eluting stents for coronary artery disease: meta-analysis of randomized trials. Circulation. 2018 Nov 13;138(20):2216-26; 9. Bangalore S, et al. Newer-generation ultrathin strut drug-eluting stents versus older second-generation thicker strut drug-eluting stents for coronary artery disease: meta-analysis of randomized trials. Circulation. 2018 Jul. 24: 2216-2226; 10. Stefanini GG et al. Coronary stents: novel developments. Heart. 2014 Jul 1;100(13):1051-61; 11. Low AF. Stent platform for procedural success: Introducing the Continuous Sinusoidal & Core Wire Technologies. Presented at: AsiaPCR; 22-24 January, 2015; Singapore, Singapore; 12. Tolentino A. Evolving DES Strategy: Biodegradable Polymer vs. Bioabsorbable Scaffold. Presented at: Cardiovascular Nurse/TechnologistSymposium; June 17, 2016; New York, USA; 13. BIOTRONIK data on file.

Target Lesion Failure (TLF), Target Lesion Revascularization (TLR), Target Vessel Myocardial Infarction (TV-MI), Stent Thrombosis (ST).

*Indication as per IFU.

380085/J/Mar_2020

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

BIOTRONIK
excellence for life