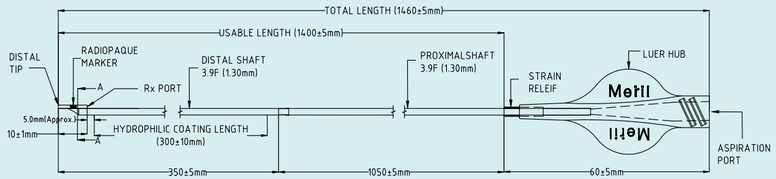
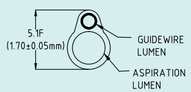
ASPIRON™ TECHNICAL SPECIFICATIONS

Distal Tip Profile	:	1.7 F / 0.022”
Lumen for Thrombus Aspiration	:	2.85 F / 0.037”
Rapid Exchange Port Length	:	10 mm
Outer Shaft Diameter - Distal & Proximal	:	3.9 F / 1.30 mm
Usable Catheter Length	:	140 cm
Guide Catheter Minimum ID Compatibility	:	6 F (Min. I.D. 0.070”/ 1.78 mm)
Guidewire Compatibility	:	0.014” (0.36 mm)
Maximum Outer Diameter	:	5.1F / 1.70 mm





ASPIRON ORDERING INFORMAITON

ASP6F

Aspiron™ is not approved by USFDA and is not available for sale in USA.
Aspiron™ is a registered trademark of Meril Life Sciences Pvt. Ltd.

Meril

Meril Life Sciences Pvt. Ltd.
Muktanand Marg, Chala,
Vapi 396 191. Gujarat. India.
T +91 260 305 2100
F +91 260 305 2125

Meril, Inc.
116, Village Boulevard, Suite 200,
Princeton, NJ 08540, USA.
T +1 609 951 2287
F +1 609 951 1702

Meril South America.
Doc Med LTDA.
Al. dos Tupiniquins,
1079 – Cep: 04077-003 – Moema.
Sao Paulo. Brazil.
T +55 11 3624 5935
F +55 11 3624 5936

Meril GmbH.
Bornheimer Strasse 135-137,
D-53119 Bonn. Germany.
T +49 228 7100 4000
F +49 228 7100 4001

Meril Tibbi Cihazlar Imalat Ve Ticaret A. S.
6, Mimar sinan Mah.,
Çavusbasi Cad. Özde Sok.
Aydin Eksi Is Merkezi Kat:1
Cekmekoy/Istanbul, Turkey.
T +90 53 2272 5172

E askinfo@merillife.com
W www.merillife.com

ASP/BROCHURE/001/20150319/IND

Aspiron™

Aspiration Catheter

Aspiron™ Use Pictorial Guideline

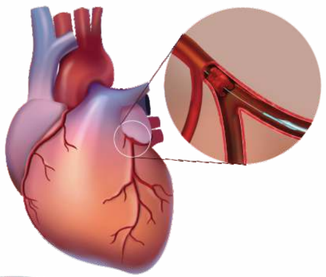
Aspiron™

Aspiration Catheter

Aspirate for reflow.

Aspiron™ is specifically designed to aspirate thrombus rapidly to restore reflow

- Distal hydrophilic coating ensures smooth passage through guide catheter to the vessel with optimal trackability
- Deliverability enhanced by innovative tip design & short and easy to use rapid exchange lumen port
- Short and soft tip design facilitates increased safety during aspiration procedure
- Distal radiopaque marker enables precise positioning
- Proximal transparent hub – Ergonomic handling with kink resistance support



Rapid Thrombus Management

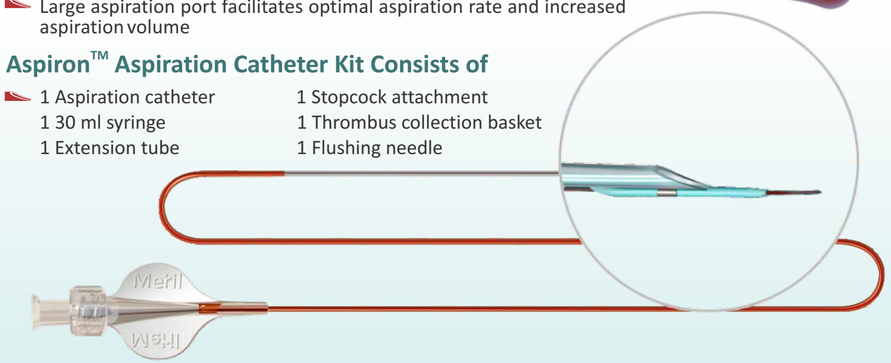
- Short rapid exchange guide wire lumen allows rapid catheter exchange, clot engagement and aspiration of thrombus

Aspiration Volume

- Large aspiration port facilitates optimal aspiration rate and increased aspiration volume

Aspiron™ Aspiration Catheter Kit Consists of

- 1 Aspiration catheter
  1 30 ml syringe
  1 Extension tube
  1 Stopcock attachment
  1 Thrombus collection basket
  1 Flushing needle



Step 1

With the help of syringe flush the entire system - Aspiron™ catheter, extension tube, guide wire lumen with 5 to 10 cc Heparinised saline.

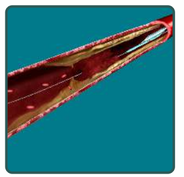
Step 2

Close the stopcock. Retract the syringe plunger and rotate it until it locks fully extended.

Step 3

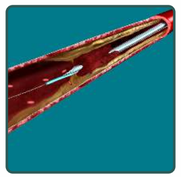
Load 0.014" guide wire through guide wire lumen.

Step 4



Advance the Aspiron™ catheter to the target site by sliding it parallel to the guide wire & guide catheter to avoid kinking.

Step 5

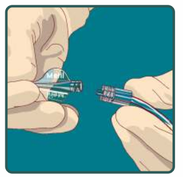


Position the catheter at distal section of the thrombus.

Step 6

Disconnect the extension tube from the stylet connector and remove the stylet from the catheter.

Step 7



Reconnect the extension tube to the Aspiron™ catheter hub.

Step 8

Open the stopcock valve to begin aspiration manually.

Step 9

Manually aspire thrombus.

Step 10

After completing the extraction process, close the stopcock and remove the catheter slowly.

Step 11

Pass all the extracted material through filter basket to check the content.

If you are required to repeat the procedure, it is necessary to re-introduce the wire stylet and commence from the beginning of the procedure guideline.

Covered single stent design

58% greater flexibility

Low crossing profile

Technical data / ordering info

Vascular Intervention // Coronary
Covered Coronary Stent System

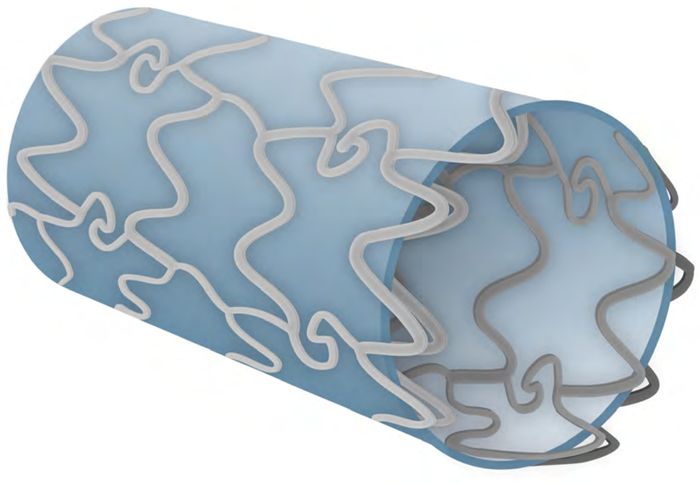
BIOTRONIK
excellence for life

PK Papyrus

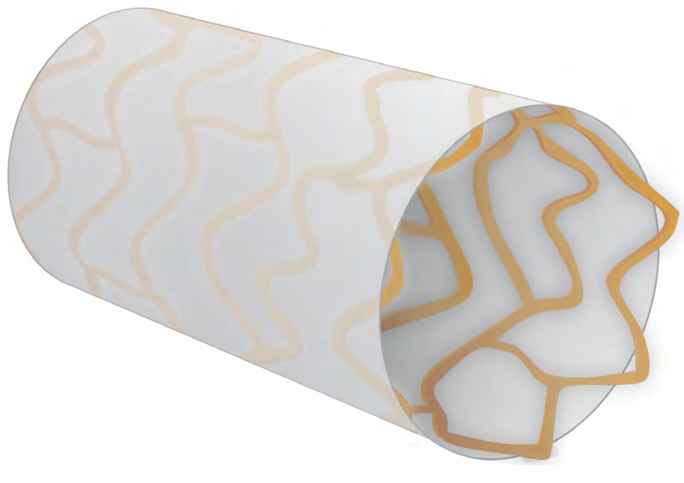
SOS

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[1], allowing you to seal perforations with confidence.

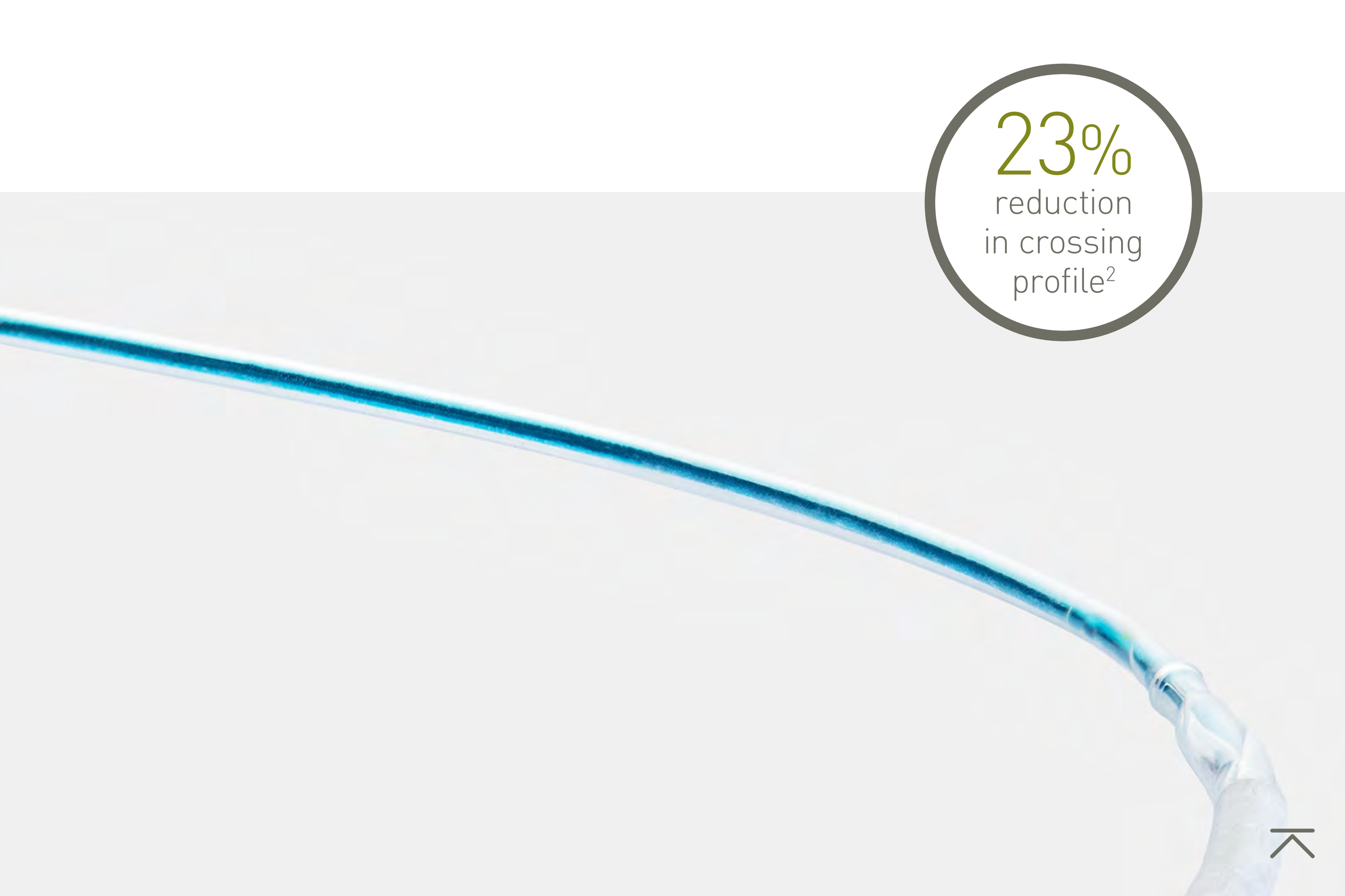


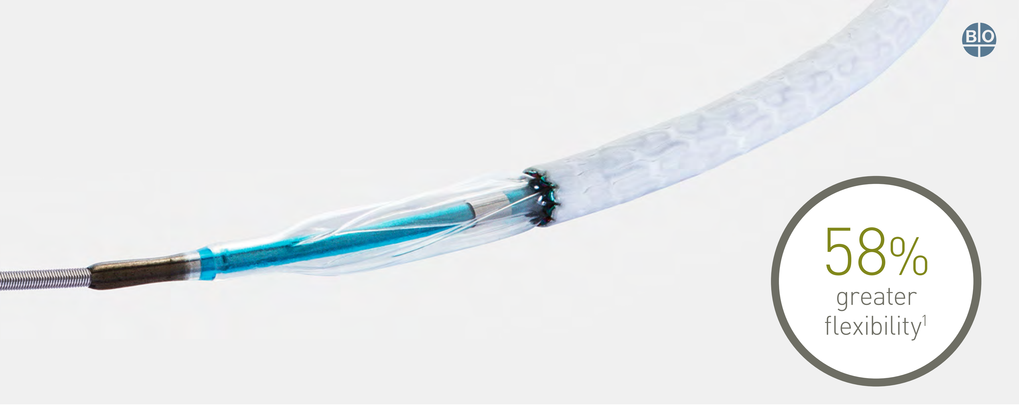
Traditional sandwich design stent[1]



PK Papyrus
Covered single stent design

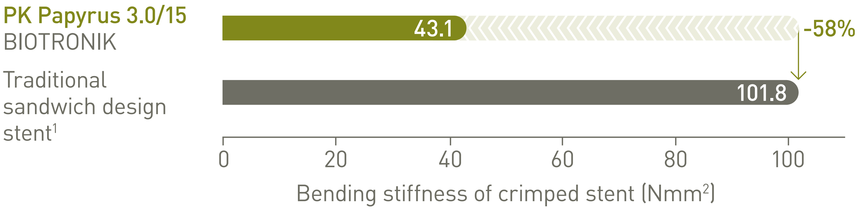
23%
reduction in crossing profile[2]

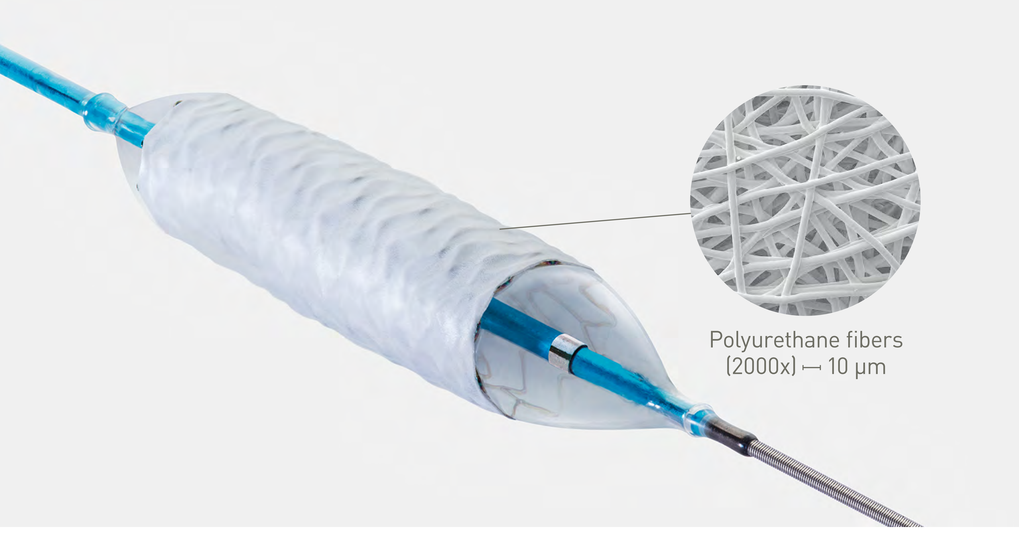




58%
greater
flexibility[1]

58% greater flexibility[1]

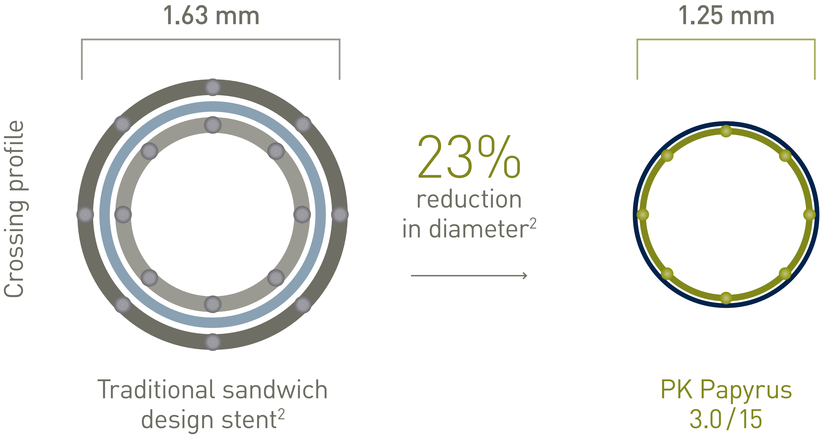




Innovative polyurethane membrane

Enabled by an electrospinning process, creating a polyurethane membrane only 90 µm thin.

Low crossing profile



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 Jostent Graftmaster 3.0/16 (BIOTRONIK data on file); 2. Compared to Graftmaster 2.8/16 (BIOTRONIK data on file)

Jostent and Graftmaster are registered trademarks of Abbott.

*Indication as per IFU.

394771/E/Jan_2018_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

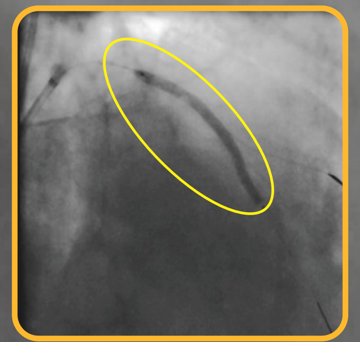
BioMime 48 mm long, also available!

Master LIVE Case demonstrated by **Dr. Farrel Hellig,**
Sunninghill and Sunward Hospital, South Africa during **EuroPCR 2013**

Pre

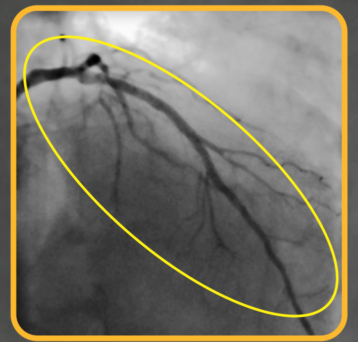
LCA shows a long lesion of LAD and diffused disease in LCx

Peri



Excellent trackability and conformability of BioMime 2.75 x 48 mm

Post



Post dilated proximally to achieve excellent final result

Angiographic images reproduced with approval from Dr. Farrel Hellig

Available in 75 sizes-
Diameters (mm) : 2.00, 2.25, 2.50, 2.75, 3.00, 3.50, 4.00, 4.50
Lengths (mm) : 8, 13, 16, 19, 24, 29, 32, 37, 40, 44, 48

BIOMIME™ TECHNICAL SPECIFICATIONS

STENT

Stent Material	:	Cobalt Chromium L605
Strut Thickness	:	65 µm (0.065 mm or 0.0026”)
Stent Diameters (mm)	:	2.00, 2.25, 2.50, 2.75, 3.00, 3.50, 4.00, 4.50
Stent Lengths (mm)	:	8, 13, 16, 19, 24, 29, 32, 37, 40, 44, 48
Mean Recoil	:	3%
Mean Foreshortening	:	0.29%

DRUG / POLYMER

Drug	:	Sirolimus
Equivalent Drug Dose	:	1.25 µg / mm^2
Polymer	:	Biodegradable and Biocompatible

DELIVERY SYSTEM

Delivery System	:	Rapid Exchange
Stent Diameter	:	Crossing Profile
mm		mm / inches
2.00		0.83 mm / 0.033”
2.25		0.85 mm / 0.033”
2.50		0.91 mm / 0.036”
2.75		0.98 mm / 0.039”
3.00		0.99 mm / 0.039”
3.50		1.06 mm / 0.042”
4.00		1.16 mm / 0.046”
4.50		1.19 mm / 0.047”
Nominal Pressure	:	9 atm
Rated Burst Pressure	:	14 / 16 atm depending upon size and length of stent (Refer IFU for more details)
Balloon Overhang	:	< 0.5 mm
Shaft Outer Diameter	:	Proximal 1.95-1.98 F (2.13 F for stent length 44 mm, 48 mm) Distal 2.7 F (2.4 F for diameter 2.00 mm)
Radiopaque Markers	:	2 – Platinum / Iridium
Usable Catheter Length	:	140-142 cm
Guide Catheter Compatibility	:	5 F (Min. I. D. 0.056” / 1.42 mm)
Max. Guide Wire	:	0.014” (0.36 mm)

Also available in Ø2.00 & 2.25 & ℓ 44 & 48mm

BIOMIME™ STENT ORDERING INFORMATION

Dia / Length	8 mm	13 mm	16 mm	19 mm	24 mm	29 mm
2.00 mm	-	BIO20013	BIO20016	BIO20019	BIO20024	-
2.25 mm	BIO22508	BIO22513	BIO22516	BIO22519	BIO22524	BIO22529
2.50 mm	BIO25008	BIO25013	BIO25016	BIO25019	BIO25024	BIO25029
2.75 mm	BIO27508	BIO27513	BIO27516	BIO27519	BIO27524	BIO27529
3.00 mm	BIO30008	BIO30013	BIO30016	BIO30019	BIO30024	BIO30029
3.50 mm	BIO35008	BIO35013	BIO35016	BIO35019	BIO35024	BIO35029
4.00 mm	BIO40008	BIO40013	BIO40016	BIO40019	BIO40024	BIO40029
4.50 mm	BIO45008	BIO45013	BIO45016	BIO45019	BIO45024	BIO45029

Dia / Length	32 mm	37 mm	40 mm	44 mm	48 mm
2.00 mm	-	-	-	-	-
2.25 mm	BIO22532	BIO22537	BIO22540	-	-
2.50 mm	BIO25032	BIO25037	BIO25040	BIO25044	BIO25048
2.75 mm	BIO27532	BIO27537	BIO27540	BIO27544	BIO27548
3.00 mm	BIO30032	BIO30037	BIO30040	BIO30044	BIO30048
3.50 mm	BIO35032	BIO35037	BIO35040	BIO35044	BIO35048
4.00 mm	BIO40032	BIO40037	BIO40040	-	-
4.50 mm	BIO45032	BIO45037	BIO45040	-	-

Meril

Meril Life Sciences Pvt. Ltd.
Survey No. 135/139, Bilakhia House,
Muktanand Marg, Chala,
Vapi 396 191.
Gujarat. India.
T +91 260 305 2100
F +91 260 305 2125

Meril, Inc.
116, Village Boulevard, Suite 200,
Princeton, NJ 08540. USA.
T +1 609 951 2287
F +1 609 520 1702

Meril South America
Doc Med LTDA
Al. dos Tupiniquins,
1079 - Cep: 04077-003 - Moema.
Sao Paulo. Brazil.
T +55 11 3624 5935
F +55 11 3624 5936

Meril GmbH.
Bornheimer Strasse 135-137,
D-53119 Bonn.
Germany.
T +49 228 7100 4000
F +49 228 7100 4001

Meril Tibbi Cihazlar
Imalat Ve Ticaret A. S.
6, Mimar sinan Mah.,
Çavusbasi Cad. Özde Sok.
Aydin Eksi Is Merkezi Kat:1
Cekmekoy/Istanbul, Turkey.
T +90 53 2272 5172

E askinfo@merillife.com
W www.merillife.com

EU Representative.
Obelis S. A.
Bd, General Wahis 53,
1030, Brussels, Belgium.
T +32 2 732 5954
F +32 2 732 6003
E mail@obelis.net

CE 1023

BIO/BROCHURE/008/MLS/20140802/IND

biomime™

Sirolimus Eluting Coronary Stent System

biomime™

Sirolimus Eluting Coronary Stent System

Mimes so well, you can't tell.

Also available in Ø 2.00 & 2.25 & L 44 & 48 mm

In BioMime™, the polarized triad of DES design is taken care of!

STENT ARCHITECTURE

POLYMER DRUG

Taken Care!

The resultant stent blends the Safety of a BMS with efficiency of DES

MeriT-II[1] Complex, Real World Study

N = 250, Prospective, Non-Randomized, Multi-Centre Study
Stent diameters - 2.50, 2.75, 3.00, 3.50 mm
Stent lengths - 13, 16, 19, 24, 29, 32, 37, 40 mm

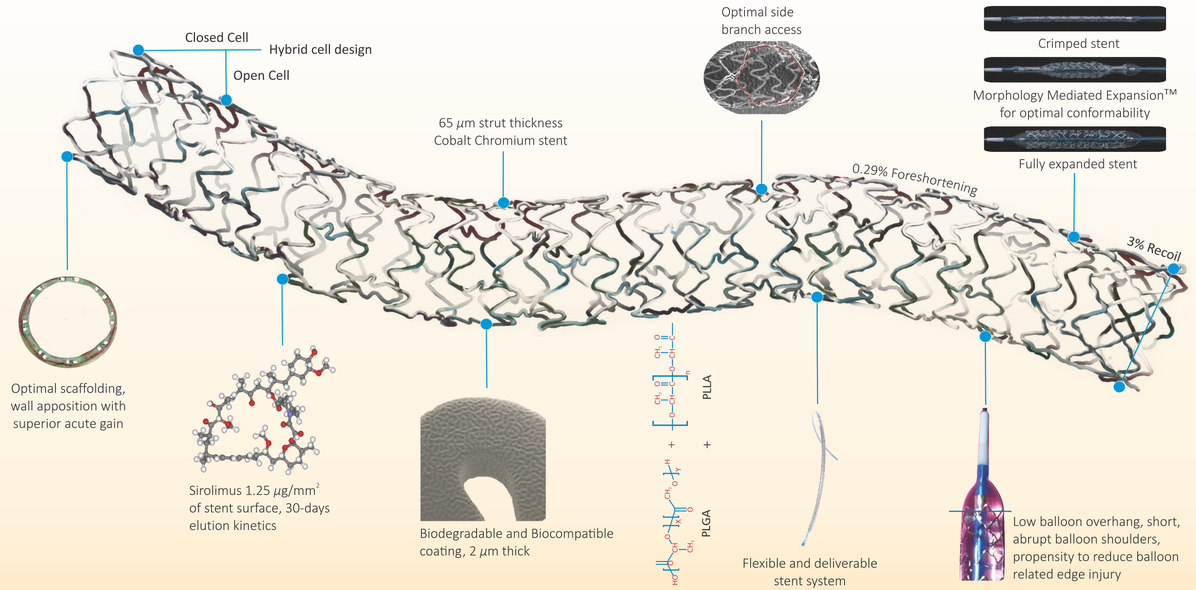
Primary Demographics – Treatment Influencing Factors

Diabetics 36%; Hypertensive 49%; Smokers 28%

Results at 1 year

High Safety	High Efficacy
• A low MACE at 6.0%	• 0.12 mm in-stent late lumen loss
• 0.8% Stent Thrombosis	• 6.2% binary restenosis at 8 months QCA

1. Data Presented by Dr. Ashok Seth during EuroPCR 2013



Armada 35

PTA Catheter

A Step Ahead

Balloon Dilatation Catheters

0.035"

Designed to streamline your procedure from start to finish

Armada 35 is designed to optimize PTA performance at each stage of your procedure. The combination of finesse and power reduces the need for specialty balloons and keeps you **a step ahead** in your cases.

Engineered to treat the broadest range of lesions

A comprehensive portfolio* with each size range engineered for specific clinical situations.

Workhorse and Pre-Dilatation	• Small lesion entry profile • Strong pushability • High RBP (up to 28 bar)
Large Diameter	• Diameters up to 14 mm • Low sheath size compatibility (6F sheath compatible up to 12 mm) • Fast deflation times

6F sheath

compatible up to 12 mm

* Source: AV Market Intelligence among top competitive devices.

Armada 35

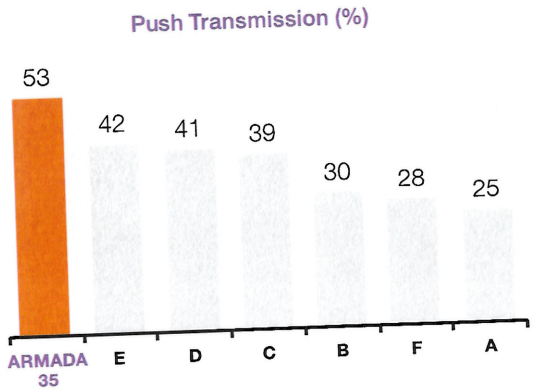
PTA Catheter

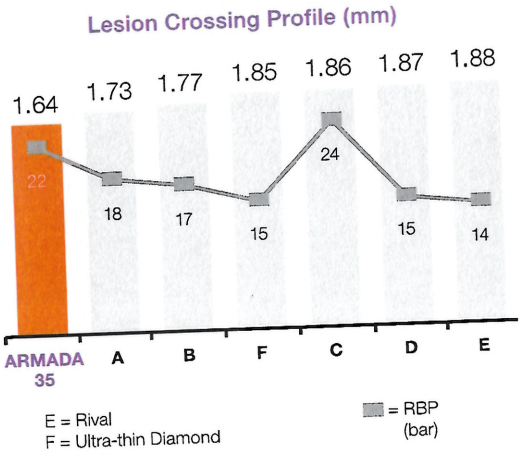
A Step Ahead

0.035"

Frontline performance even in high pressure situations

Unmatched pushability with the lowest tip and balloon crossing profiles* to enter and cross lesions without compromising RBP.





* Based on tip and balloon crossing profile measurements and pushability performance bench tests among competitors tested. (Powerflex P3, Ultra-thin Diamond, Admiral Xtreme, Dorado, Rival, EverCross)

Armada 35

PTA Catheter

A Step Ahead

0.035"

Ordering Information (1/3)

80 cm Catheter Length Ref. No.	135 cm Catheter Length Ref. No.	Balloon Diameter [mm]	Balloon Length [mm]	Min Sheath Size [F]	Nominal Pressure [atm]	RBP [atm]
B1030-020	B2030-020	3.0	20	5	8	28
B1030-040	B2030-040	3.0	40	5	8	28
B1040-020	B2040-020	4.0	20	5	8	25
B1040-040	B2040-040	4.0	40	5	8	25
B1040-060	B2040-060	4.0	60	5	8	25
B1040-080	B2040-080	4.0	80	5	8	20
B1040-100	B2040-100	4.0	100	5	8	20
B1040-120	B2040-120	4.0	120	5	8	20
B1050-020	B2050-020	5.0	20	5	8	22
B1050-040	B2050-040	5.0	40	5	8	22
B1050-060	B2050-060	5.0	60	5	8	20
B1050-080	B2050-080	5.0	80	5	8	18
B1050-100	B2050-100	5.0	100	5	8	18
B1050-120	B2050-120	5.0	120	5	8	18
B1060-020	B2060-020	6.0	20	5	6	20
B1060-040	B2060-040	6.0	40	5	6	20
B1060-060	B2060-060	6.0	60	5	6	18
B1060-080	B2060-080	6.0	80	5	6	16
B1060-100	B2060-100	6.0	100	5	6	16
B1060-120	B2060-120	6.0	120	5	6	16

Armada 35

PTA Catheter

A Step Ahead

0.035"

Ordering Information (2/3)

80 cm Catheter Length Ref. No.	135 cm Catheter Length Ref. No.	Balloon Diameter [mm]	Balloon Length [mm]	Min Sheath Size [F]	Nominal Pressure [atm]	RBP [atm]
B1070-020	B2070-020	7.0	20	5	6	15
B1070-040	B2070-040	7.0	40	5	6	15
B1070-060	B2070-060	7.0	60	5	6	15
B1070-080	B2070-080	7.0	80	5	6	14
B1070-100	B2070-100	7.0	100	6	6	14
B1070-120	B2070-120	7.0	120	6	6	14
B1080-020	B2080-020	8.0	20	6	6	15
B1080-040	B2080-040	8.0	40	6	6	15
B1080-060	B2080-060	8.0	60	6	6	14
B1080-080	B2080-080	8.0	80	6	6	13
B1090-020	B2090-020	9.0	20	6	6	14
B1090-040	B2090-040	9.0	40	6	6	13
B1090-060	B2090-060	9.0	60	6	6	12
B1090-080	B2090-080	9.0	80	6	6	12

Armada 35

PTA Catheter

A Step Ahead

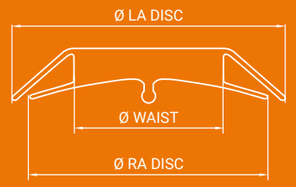
0.035"

Ordering Information (3/3)

80 cm Catheter Length Ref. No.	135 cm Catheter Length Ref. No.	Balloon Diameter [mm]	Balloon Length [mm]	Min Sheath Size [F]	Nominal Pressure [atm]	RBP [atm]
B1100-020	B2100-020	10.0	20	6	6	13
B1100-040	B2100-040	10.0	40	6	6	12
B1100-060	B2100-060	10.0	60	6	6	11
B1100-080	B2100-080	10.0	80	6	6	10
B1120-020	B2120-020	12.0	20	6	4	10
B1120-040	B2120-040	12.0	40	6	4	10
B1120-060	B2120-060	12.0	60	6	4	9
B1120-080	B2120-080	12.0	80	6	4	9
B1140-020	B2140-020	14.0	20	7	4	8
B1140-040	B2140-040	14.0	40	7	4	8
B1140-060	B2140-060	14.0	60	7	4	7
B1140-080	B2140-080	14.0	80	7	4	7

Occlutech ASD Occluder
Product specifications

ASD



Article No.	Defect Size [mm]	Ø Waist [mm]	Ø LA Disc [mm]	Ø RA Disc [mm]	Sheath Size* [F]	Pusher Article No. (color)** Pistol Pusher	Flex Pusher II
29ASD04	D≤4	4	11	9	7	55PP090	51FP060
29ASD05	4<D≤5	5	14	11	7	55PP090	51FP060
29ASD06	5<D≤6	6	16.5	12.5	7	55PP125	51FP100
29ASD07	6<D≤7.5	7.5	18	14	7	55PP125	51FP100
29ASD09	7.5<D≤9	9	20.5	16.5	7	55PP125	51FP100
29ASD10	9<D≤10.5	10.5	22	18	7	55PP125	51FP100
29ASD12	10.5<D≤12	12	27	23	9	55PP165	51FP120
29ASD13	12<D≤13.5	13.5	28.5	24.5	9	55PP165	51FP120
29ASD15	12<D≤15	15	30	26	9	55PP165	51FP120
29ASD16	15<D≤16.5	16.5	31.5	27.5	9	55PP165	51FP120
29ASD18	15<D≤18	18	33	29	9	55PP165	51FP120
29ASD19	16.5<D≤19.5	19.5	34.5	30.5	10	55PP165	51FP120
29ASD21	18<D≤21	21	36	32	11	55PP185	51FP150
29ASD24	21<D≤24	24	39	35	11	55PP185	51FP150
29ASD27	24<D≤27	27	42	38	12	55PP210	51FP160
29ASD30	27<D≤30	30	45	41	12	55PP210	51FP160
29ASD33	30<D≤33	33	48	43	12	55PP210	51FP160
29ASD36	33<D≤36	36	52	46	12	55PP210	51FP160
29ASD39	36<D≤39	39	54	49	12	55PP210	51FP160
29ASD40	39<D≤40	40	55	50	12	55PP210	51FP160

Availability subject to regulatory approval. Product data may be subject to change. Contact your Occlutech representative for information.

* Occlutech Delivery Set (ODS).

** Color defines Pusher color.

Quality made in Europe

Occlutech adheres to the highest quality standards. We never compromise on quality. Our dedication to patients and the medical community is the main driver of our vision. We want to be at the forefront of developing technologies and products that matter, that make a difference and that help our customers to be at the leading edge of better treatment for structural heart disease.

Content references:

1. *Optimal septum alignment of the Figulla Flex occluder to the atrial septum in patients with secundum atrial septal defects.*
2. *Castleman LS et. al. Biocompatibility of Nitinol Alloy as an Implant Material. Journal of Biomedical Materials Research | 97 6;10:695.*
3. *Electrochemical Characterization of Nitinol Occluder, Natural and Medical Sciences Institute at the University of Tübingen, mNI<0,014 µg/(cm*d).*
4. *Early single clinical experience with the new Figulla ASD Occluder for transcatheter closure of atrial septal defect in adults.*
5. *Haas NA et.al. Closure of Secundum Atrial Septal Defects by Using the Occlutech Occluder Devices in More Than 1300 Patients: The IRFACODE Project: A Retrospective Case Series.*
6. *Comparison of the Occlutech ® Figulla ® septal occluder and Amplatzer ® septal occluder for atrial septal defect device closure.*

Occlutech International AB
Landskronavägen 2, SE-252 32 Helsingborg, Sweden
order@occlutech.com, **www.occlutech.com**

Occlutech

Perfecting Performance

Occlutech

Occlutech ASD Occluder

ASD

Occlutech ASD Occluder

Designed for safety and excellence

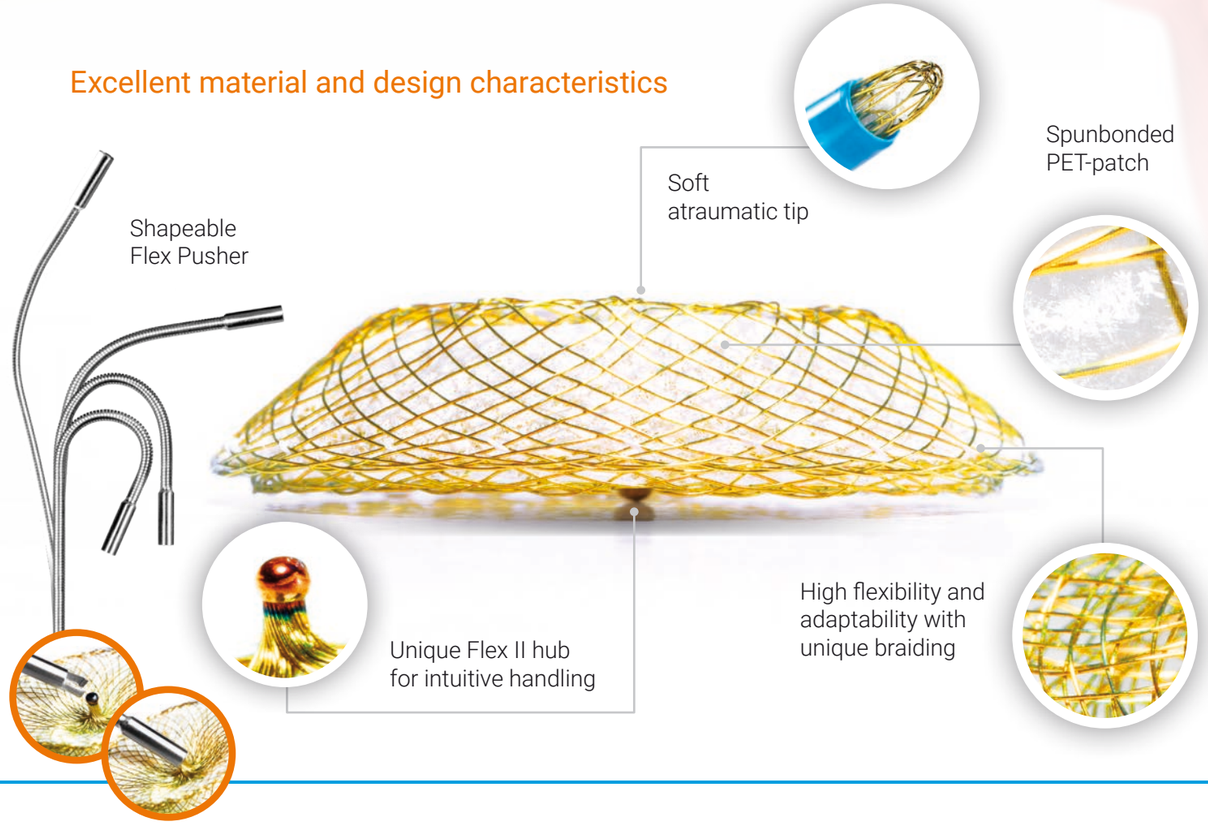
ASD

PRODUCT FEATURES

The design of the Flex II ASD Occluder results in an ideal septum alignment which increases its feasibility and patient safety during implantation.[1]

- Optimized braiding pattern and less material at left atrial disc.
- Titanium oxide-covered Nitinol shows the best values of biocompatibility[2] and minimum Nickel release.[3]
- Spunbonded PET-patch allows for fast endothelialization.
- The unique ball-connection between pusher and Occluder safely locks it, while it freely follows the anatomy. Once in place it is easy and fast to deliver.

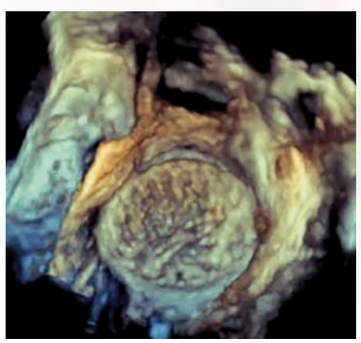
Excellent material and design characteristics



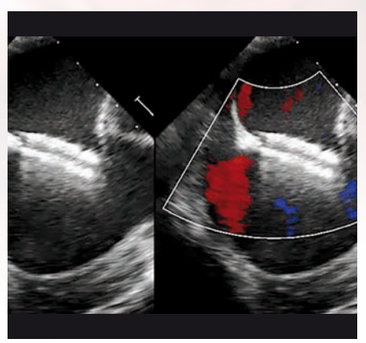
CLINICAL BENEFITS

Recent studies found that transcatheter closure of isolated secundum atrial septal defects using the novel design of the Occlutech ASD Occluder was safe, effective and had an excellent outcome during the 6 months follow-up period.[4,5]

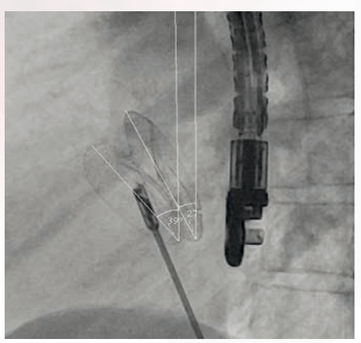
- Lower pull in forces and improved delivery sheath compatibility.
- Reduced material exposure.
- Significantly reduced mean procedure and fluoroscopic time compared to other devices (34%).[6]



3D TEE image of an implanted Occlutech ASD Occluder.



Perfect alignment of the Occluder to the Septum.



50° angulation of Flex Pusher vs Occluder hub.