

iVascular[®]

therapies for living

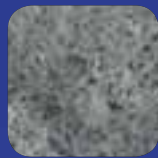
luminor 14m

Paclitaxel eluting PTA balloon dilatation catheter

Safe and precise
delivery of Paclitaxel

LUMINOR Registry
207 patients

Nanotechnology
dosage system.
Ultra-thin coating



Assured coating
stability during
navigation



Proprietary coating
technology **TransferTech**



Homogeneous
& **anti-cracking** coating



www.ivascular.global

luminor 14m features

- > **Over-the-wire catheter (OTW)**
- > Usable catheter length: **100 cm** and **150 cm**
- > Recommended guidewire: **0.014"**
- > Tip profile: **0.017"**
- > Crossing profile: **from 0.026" up to 0.042"**
- > Nominal pressure: **7 atm**
- > RBP: **16 atm**
- > ABP: **22 atm**

Product with CE mark, certified by Notified Body 0318

Usable catheter length	Balloon Ø (mm)	Balloon Length (mm)					
		40	60	80	120	150	200
100 cm	1.5	BP DPC14M 100 150 040	BP DPC14M 100 150 060	BP DPC14M 100 150 080	-	-	-
	2.0	BP DPC14M 100 200 040	BP DPC14M 100 200 060	BP DPC14M 100 200 080	BP DPC14M 100 200 120	BP DPC14M 100 200 150	BP DPC14M 100 200 200
	2.5	BP DPC14M 100 250 040	BP DPC14M 100 250 060	BP DPC14M 100 250 080	BP DPC14M 100 250 120	BP DPC14M 100 250 150	BP DPC14M 100 250 200
	3.0	BP DPC14M 100 300 040	BP DPC14M 100 300 060	BP DPC14M 100 300 080	BP DPC14M 100 300 120	BP DPC14M 100 300 150	BP DPC14M 100 300 200
	3.5	BP DPC14M 100 350 040	BP DPC14M 100 350 060	BP DPC14M 100 350 080	BP DPC14M 100 350 120	BP DPC14M 100 350 150	BP DPC14M 100 350 200
	4.0	BP DPC14M 100 400 040	BP DPC14M 100 400 060	BP DPC14M 100 400 080	BP DPC14M 100 400 120	-	-
150 cm	1.5	BP DPC14M 150 150 040	BP DPC14M 150 150 060	BP DPC14M 150 150 080	-	-	-
	2.0	BP DPC14M 150 200 040	BP DPC14M 150 200 060	BP DPC14M 150 200 080	BP DPC14M 150 200 120	BP DPC14M 150 200 150	BP DPC14M 150 200 200
	2.5	BP DPC14M 150 250 040	BP DPC14M 150 250 060	BP DPC14M 150 250 080	BP DPC14M 150 250 120	BP DPC14M 150 250 150	BP DPC14M 150 250 200
	3.0	BP DPC14M 150 300 040	BP DPC14M 150 300 060	BP DPC14M 150 300 080	BP DPC14M 150 300 120	BP DPC14M 150 300 150	BP DPC14M 150 300 200
	3.5	BP DPC14M 150 350 040	BP DPC14M 150 350 060	BP DPC14M 150 350 080	BP DPC14M 150 350 120	BP DPC14M 150 350 150	BP DPC14M 150 350 200
	4.0	BP DPC14M 150 400 040	BP DPC14M 150 400 060	BP DPC14M 150 400 080	BP DPC14M 150 400 120	-	-

The availability of each reference for the sale is linked to the authorization of commercialization in the country of destination

● Introducer compatibility: **4F**

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Manufactured by:

Life Vascular Devices Biotech, S.L.
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info@ivascular.global



TECHNICAL DATA SHEET

luminor 14 m

DESCRIPTION	
<p>Paclitaxel eluting balloon with coaxial design (OTW), intended for dilatation of lesions located at the femoral, popliteal and infrapopliteal arteries.</p> <p>The catheter features two coaxial tubes throughout its length; it has a dual lumen from the proximal connection to the balloon. The inner lumen is for guide wire insertion and leading to the lesion; while the outer lumen allows contrast liquid passage for balloon in-deflation and this it comprises the in-deflation channel.</p> <p>The balloon is coated with the drug Paclitaxel; which is included in a physiologically innocuous matrix.</p> <p>On the proximal part of the catheter, there is a hub comprising two ports; one for balloon in-deflation and another one for guidewire passage.</p> <p>The balloon is supplied in different lengths (from 40 to 200 mm) and diameters (from 1.5 to 4 mm).</p> <p>The catheter is coated for minimize friction.</p>	
MATERIAL	
Nylon/Pebax. The product does not contain latex components.	
BALLOON COATING	
Paclitaxel eluting formulation, 3 $\mu\text{g}/\text{mm}^2$	
BALLOON	
Semi-compliant (10-15% of compliance from nominal pressure to RBP)	
NOMINAL PRESSURE	7 atm
RATED BURST PRESSURE (RBP)	16 atm
AVERAGE BURST PRESSURE (ABP)	22 atm



TECHNICAL DATA SHEET

luminor 14 m

BALLOON PROFILE (crossing profile at maximum balloon length)

Diameter (mm)	INCHES =mm=FRENCH
1.5	0.026= 0.67= 2.0F
2	0.029= 0.75= 2.2F
2.5	0.032= 0.83= 2.5F
3	0.035= 0.91= 2.7F
3.5	0.038= 0.99= 3.0F
4	0.042= 1.08= 3.2F

RADIOPAQUE MARKERS

2 metallic markers of Platinum / Iridium

DIMENSIONS

Catheter shaft 3.9F Proximal
2.9F Distal

Entry profile 0.017 inches

Recommended guidewire 0.014 inches

INTRODUCER COMPATIBILITY

4F for all diameters

DEFLATION TIMES

Maximum 10 s

AVAILABLE DIAMETERS 1.5 to 4 mm

AVAILABLE LENGTHS 40 to 200 mm

STORAGE CONDITIONS

Store in a cool and dry place, away from direct sunlight

Storage temperature: between **15°C and 30°C**

iVascular[®]

therapies for living

luminor 35

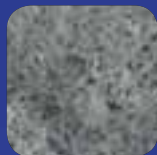
Paclitaxel eluting PTA balloon dilatation catheter

EFFPAC trial
171 patients



Homogeneous
& **anti-cracking**
coating

Safe and precise
delivery of Paclitaxel



Assured coating
stability during
navigation

Nanotechnology
dosage system.
Ultra-thin coating



Proprietary coating
technology **TransferTech**



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luminor 35 features

- > **Over-the-wire catheter (OTW)**
- > Usable catheter length: **80 cm** or **140 cm**
- > Recommended guidewire: **0.035"**
- > Tip profile: **0.036"**
- > Crossing profile: **from 0.065" up to 0.077"**
- > Nominal pressure: **6/7 atm**
- > RBP: **16 atm**
- > ABP: **23 atm**

Product with CE mark, certified by Notified Body 0318

Usable catheter length	Balloon Ø (mm)	Balloon Length (mm)					
		20	40	60	80	120	150
80 cm	5.0	BP DPC35 080 500 020	BP DPC35 080 500 040	BP DPC35 080 500 060	BP DPC35 080 500 080	BP DPC35 080 500 120	BP DPC35 080 500 150
	6.0	BP DPC35 080 600 020	BP DPC35 080 600 040	BP DPC35 080 600 060	BP DPC35 080 600 080	BP DPC35 080 600 120	BP DPC35 080 600 150
	7.0	BP DPC35 080 700 020	BP DPC35 080 700 040	BP DPC35 080 700 060	BP DPC35 080 700 080	BP DPC35 080 700 120	-
140 cm	5.0	BP DPC35 140 500 020	BP DPC35 140 500 040	BP DPC35 140 500 060	BP DPC35 140 500 080	BP DPC35 140 500 120	BP DPC35 140 500 150
	6.0	BP DPC35 140 600 020	BP DPC35 140 600 040	BP DPC35 140 600 060	BP DPC35 140 600 080	BP DPC35 140 600 120	BP DPC35 140 600 150
	7.0	BP DPC35 140 700 020	BP DPC35 140 700 040	BP DPC35 140 700 060	BP DPC35 140 700 080	BP DPC35 140 700 120	-

The availability of each reference for the sale is linked to the authorization of commercialization in the country of destination

- Introducer compatibility: **5F**
- Introducer compatibility: **6F (ID 2.20 mm)**

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TECHNICAL DATA SHEET

luminor 35

DESCRIPTION	
<p>Paclitaxel eluting balloon catheter with dual lumen design (OTW), intended for dilatation of lesions located at the iliac, femoral, iliofemoral, popliteal, infrapopliteal and renal arteries.</p> <p>The catheter features a dual lumen tube from the proximal connection to the balloon. One lumen is for guide wire insertion and catheter leading to the lesion; while the other one allows contrast liquid passage for balloon in-deflation and this it comprises the in-deflation channel.</p> <p>The balloon is coated with the drug Paclitaxel; which is included in a physiologically innocuous matrix.</p> <p>At the proximal end, there is a hub comprising two ports; one for balloon in-deflation and another one for guidewire passage.</p> <p>The balloon is supplied in different lengths (from 20 to 150 mm) and diameters (from 5 to 7 mm).</p> <p>The catheter is coated for minimize friction.</p>	
MATERIAL	
Nylon/Pebax. The product does not contain latex components.	
BALLOON COATING	
Paclitaxel eluting formulation, 3 $\mu\text{g}/\text{mm}^2$	
BALLOON	
Semi-compliant (10% of compliance from nominal pressure to RBP)	
NOMINAL PRESSURE	6/7 atm
RATED BURST PRESSURE (RBP)	16 atm
AVERAGE BURST PRESSURE (ABP)	23 atm



TECHNICAL DATA SHEET

luminor 35

BALLOON PROFILE (crossing profile)	
Diameter	INCHES =MM=FRENCH
5.0	0.065" = 1.65mm = 4.9F
6.0	0.071" = 1.81mm = 5.4F
7.0	0.077" = 1.97mm = 5.9F
RADIOPAQUE MARKERS	
2 Platinum/Iridium markers embedded on the guiding lumen	
DIMENSIONS	
Catheter shaft	5F
Entry profile	0.036 inches
Recommended guidewire	0.035 inches
INTRODUCER COMPATIBILITY	
∅ [mm]: 5.0	5F
∅ [mm]: 6.0 - 7.0	6F (2,20 mm)
DEFLATION TIMES	
∅ [mm]: 5 to 7	8 s maximum
AVAILABLE DIAMETERS	5mm to 7mm
AVAILABLE LENGHTS	20mm to 150mm

STORAGE CONDITIONS

Store in a cool and dry place, away from direct sunlight

Storage temperature: between **15°C and 30°C**

iCover

Peripheral balloon expandable
PTFE covered stent system

Designed to
cover all needs



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iVascular[®]
therapies for living

Able to treat the most tortuous arteries

iCover

Designed to cover all needs

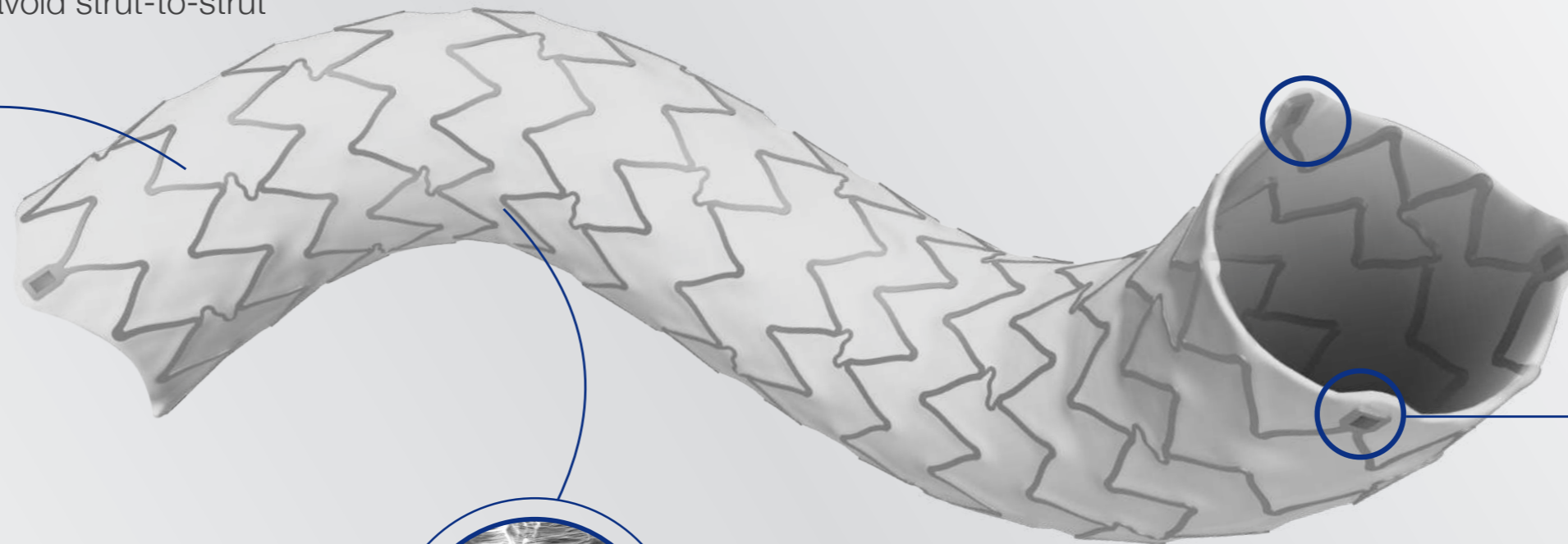
Enhanced visibility

Unique stent with radiopaque markers to facilitate the implantation and the post-dilation

ePTFE covered stent with high flexibility

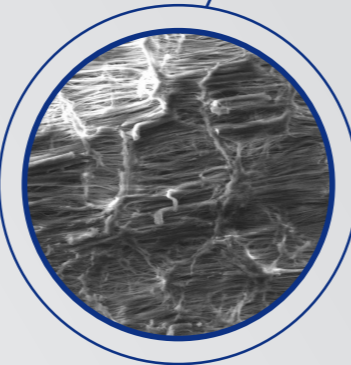
Due to:

- Open cell design and alternated links
- Nested peaks to avoid strut-to-strut contact



Best in class post-expansion capacity ($\geq 2\text{mm}$)

High ePTFE porosity to ensure covered stent post-expansion capacity



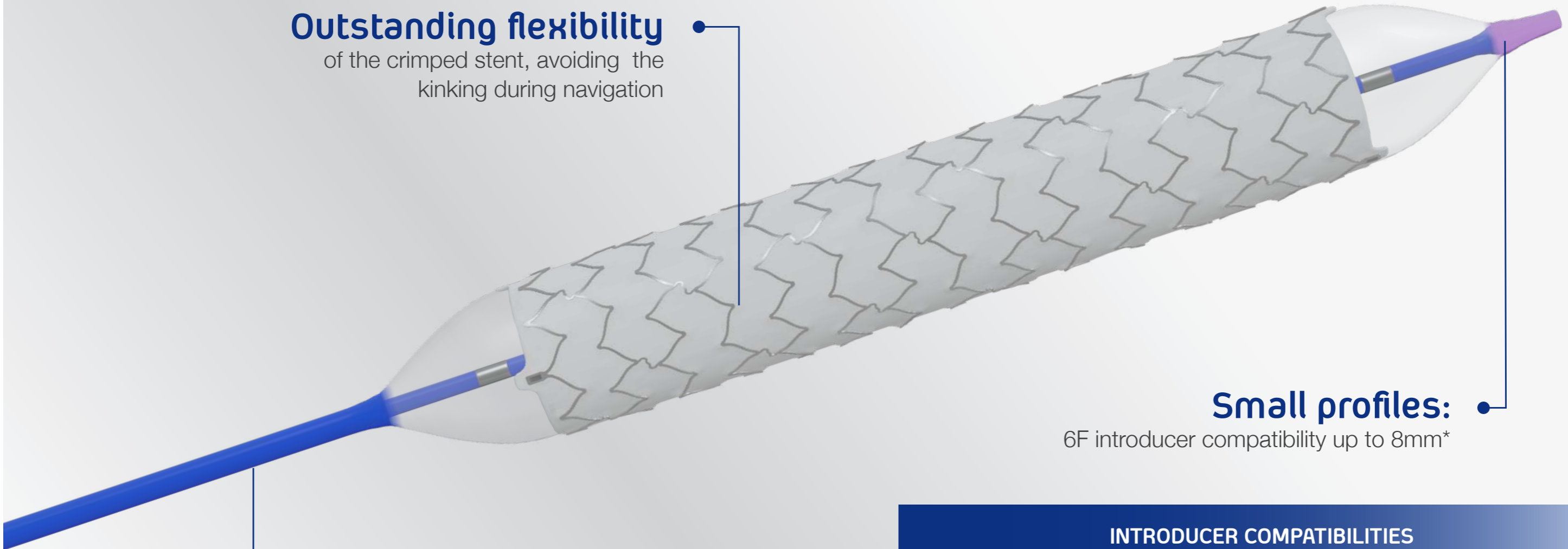
STENT DIMENSIONS		MAXIMUM POST-EXPANSION DIAMETERS						
		STENT DIAMETERS (mm)						
		5	6	7	8	9	10	
STENT LENGTH (mm)	17	$\leq 10\text{mm}$					$\leq 12\text{mm}$	
	27							
	37							
	57							

Excellent navigability and easy to implant

iCover
Designed to cover all needs

Outstanding flexibility

of the crimped stent, avoiding the kinking during navigation



Small profiles:

6F introducer compatibility up to 8mm*

Crimped on an Oceanus 35 PTA balloon, offering:

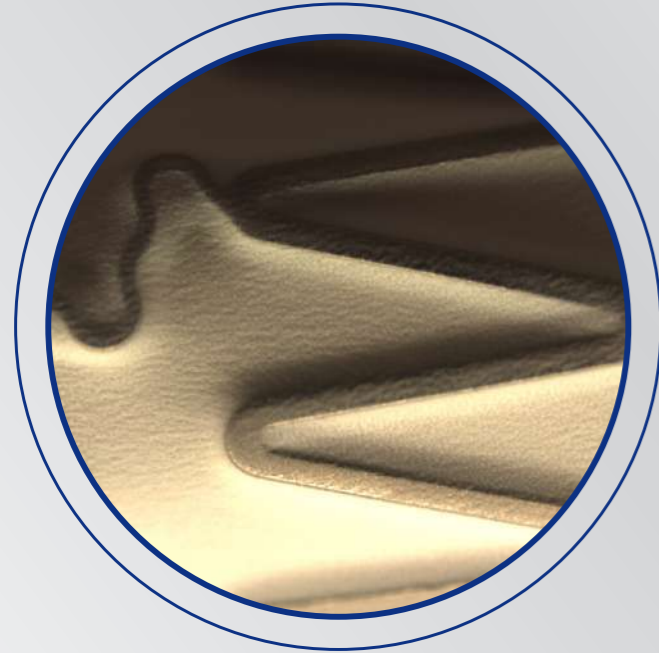
- Short deflation times
- Good pushability and trackability

		INTRODUCER COMPATIBILITIES					
STENT DIMENSIONS		STENT DIAMETERS (mm)					
		5	6	7	8	9	10
STENT LENGTH (mm)	17	6F				7F	
	27						
	37						
	57						

* 6F up to 8x17 mm and 7F from 8x27mm up to 10 mm.

iVascular proprietary encapsulation technology

iCover
Designed to cover all needs



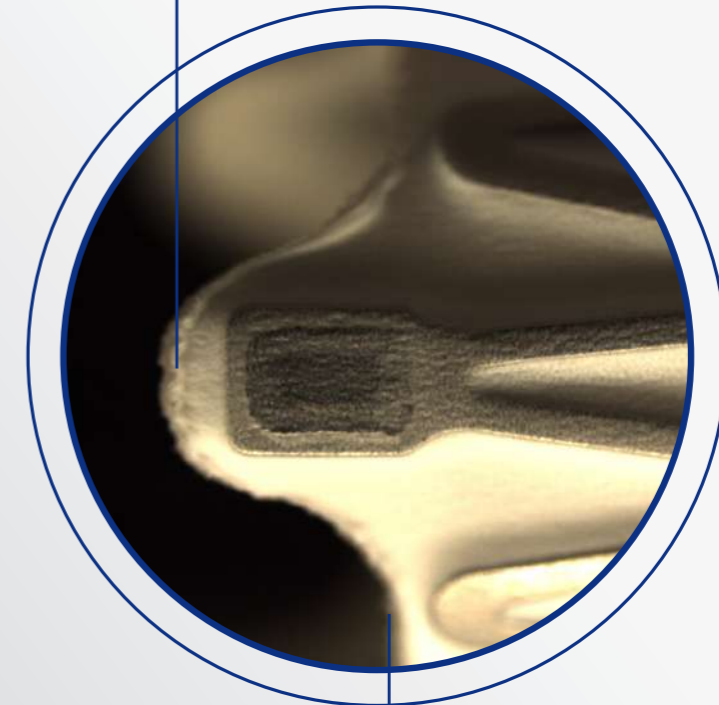
Encapsulation technology

iCover is a stent completely encapsulated with 2 ePTFE layers



Specific ePTFE laser cutting technology

• Perfect sealing



The laser follows the stent outline while cutting the contour



Proprietary technology to encapsulate the stent into an inner and outer ePTFE layer

Ensures complete encapsulation avoiding delamination

iCover features

- > Over the wire catheter (OTW)
- > Guidewire compatibility: **0.035"**
- > Catheter length: **80** and **140** cm
- > NP: 9 atm
- > RBP:
 - Ø 5-7mm: 15 atm
 - Ø 8mm: 14 atm
 - Ø 9-10mm: 13 atm
- > Maximum post-expansion:
 - Ø 5-8mm: ≤10mm
 - Ø 9-10mm: ≤ 12mm
- > CoverTech encapsulation technology
- > Introducer compatibility
6F (up to Ø8mm, L 17mm), **7F** (≥8mmØ, L27mm)
- > **3 radiopaque markers** at each stent end
- > Stent material: CoCr L605
- > Graft material: ePTFE
- > Recoil: ≤ 10 %
- > Shortening:
 - Length 17mm: ≤ 12 %
 - Length 57mm: ≤ 8 %

Product with CE mark, certified by Notified Body 0318

Effective catheter length (cm)	Stent diameter (mm)	Stent length (mm)			
		17	27	37	57
80	5	SPCBCC35080050017	SPCBCC35080050027	SPCBCC35080050037	SPCBCC35080050057
	6	SPCBCC35080060017	SPCBCC35080060027	SPCBCC35080060037	SPCBCC35080060057
	7	SPCBCC35080070017	SPCBCC35080070027	SPCBCC35080070037	SPCBCC35080070057
	8	SPCBCC35080080017	SPCBCC35080080027	SPCBCC35080080037	SPCBCC35080080057
	9		SPCBCC35080090027	SPCBCC35080090037	SPCBCC35080090057
	10		SPCBCC35080100027	SPCBCC35080100037	SPCBCC35080100057
140	5	SPCBCC35140050017	SPCBCC35140050027	SPCBCC35140050037	SPCBCC35140050057
	6	SPCBCC35140060017	SPCBCC35140060027	SPCBCC35140060037	SPCBCC35140060057
	7	SPCBCC35140070017	SPCBCC35140070027	SPCBCC35140070037	SPCBCC35140070057
	8	SPCBCC35140080017	SPCBCC35140080027	SPCBCC35140080037	SPCBCC35140080057
	9		SPCBCC35140090027	SPCBCC35140090037	SPCBCC35140090057
	10		SPCBCC35140100027	SPCBCC35140100037	SPCBCC35140100057

- Introducer compatibility: **6F**
- Introducer compatibility: **7F**

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