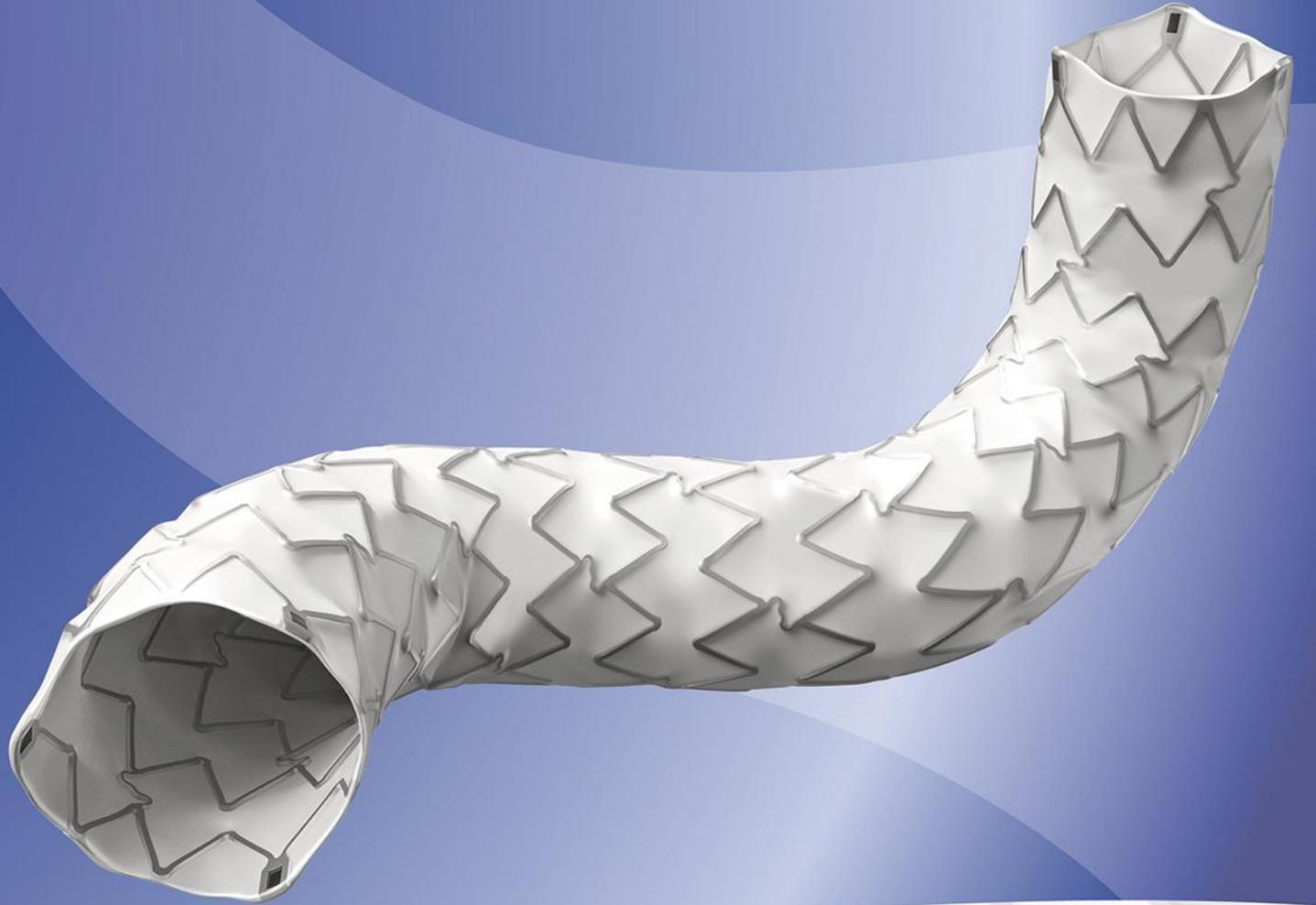


iCover

BX ePTFE covered stent

**Designed to
cover all needs**



www.ivascular.global

iVascular[®]
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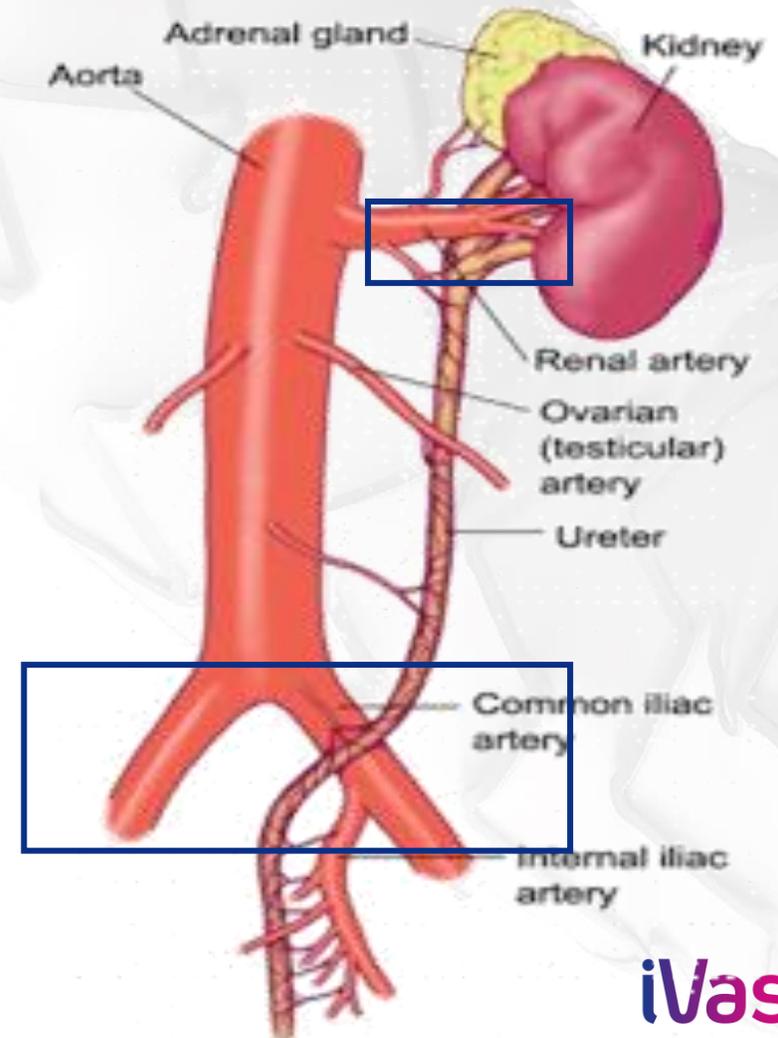
iCover indications

Indication of use

- Patients presenting peripheral vascular disease pathology

Intended use

- Restoring atherosclerotic lesions of the common and external iliac arteries and the renal arteries.
- Treatment of aneurysms and perforations, ruptures and acute fistulas

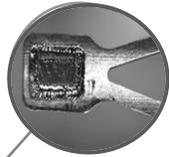


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Technical features: stent



Unique visibility

- **UNIQUE STENT WITH RADIOPAQUE MARKERS**

Enhanced **visibility** through 3 tantalum radiopaque markers at each end.

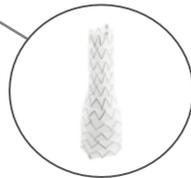
- **Material: CoCr L605**

It offers **higher radiopacity**.



High flexibility

Maximized **flexibility** by alternate links, open cell design and nested peaks to avoid strut-to-strut contact on bends.



Best in class post-expansion capacity

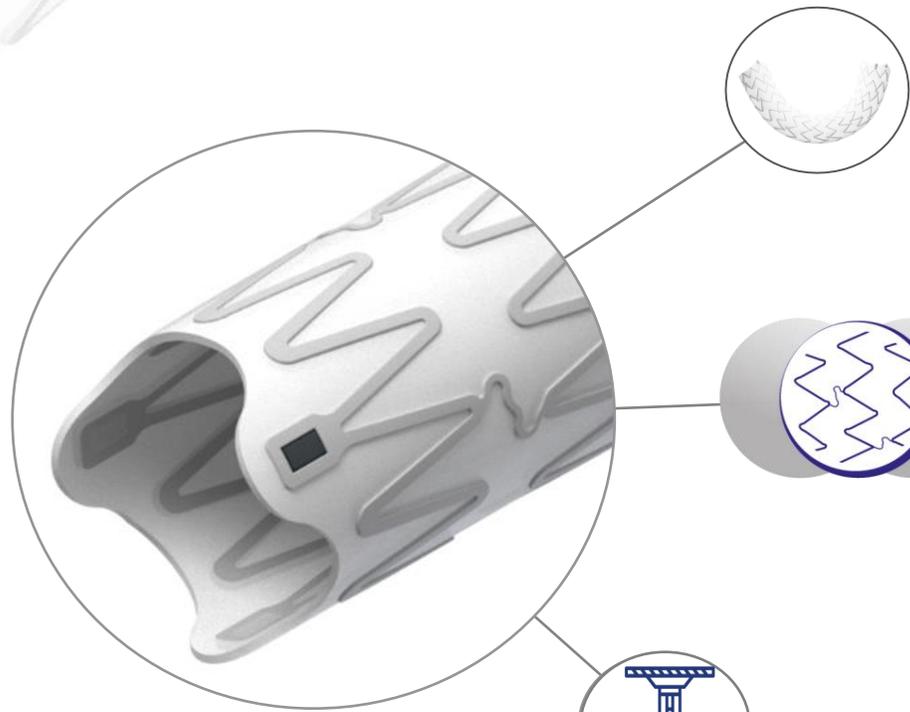
- **Stent design:** The number of crowns and cell length to allow the stent to reach **post-expanded diameters** to perfectly conform the arteries.
- **CoCr L605:** alloy with greater capacity to overexpand

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Technical features: ePTFE encapsulation



High flexibility and post-expansion capacity
Low density ePTFE to ensure a good flexibility



CoverTech
iVascular proprietary encapsulation technology



Specific ePTFE laser cutting technology
Laser cut of both ends to perfectly seal the edges
and remove extra material.

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Technical features: ePTFE

Polytetrafluoroethylene (PTFE)

Is a synthetic fluoropolymer of tetrafluoroethylene that has numerous applications. Is also known as Teflon

ePTFE: expanded PTFE

- Expanded PTFE (ePTFE) emerged on the market in 1976 to lower the thrombogenicity and permeability of vascular grafts.
- ePTFE offers a great radial expansion due to its stretched microstructure characterized by fibres that connect to nodes.

Technical features: ePTFE

iCover ePTFE:

- Keeps the non permeability of the prosthesis to prevent leaks



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Technical features: post-expansion

With catheter length of 80 and 140cm

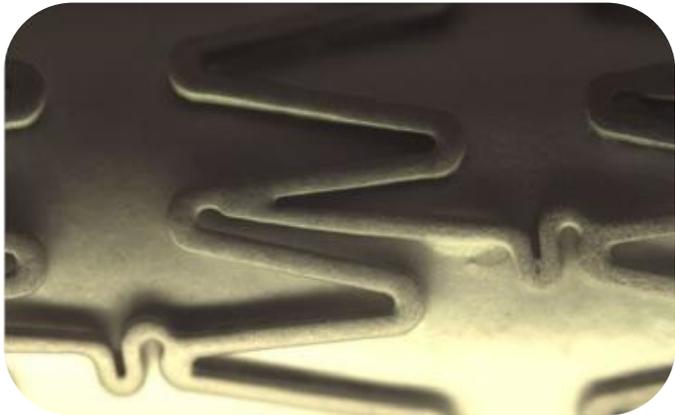
STENT DIMENSIONS		STENT DIAMETERS (mm)					
		5	6	7	8	9	10
STENT LENGTH (mm)	17	X	X	X	X		
	27	X	X	X	X	X	X
	37	X	X	X	X	X	X
	57	X	X	X	X	X	X

Up to 10mm

Up to 12mm

Technical features: CoverTech

iCover is a stent completely encapsulated with 2 ePTFE layers



- Proprietary spray technology to encapsulate the stent into an inner and outer ePTFE layers
- Ensures a complete encapsulation avoiding delamination

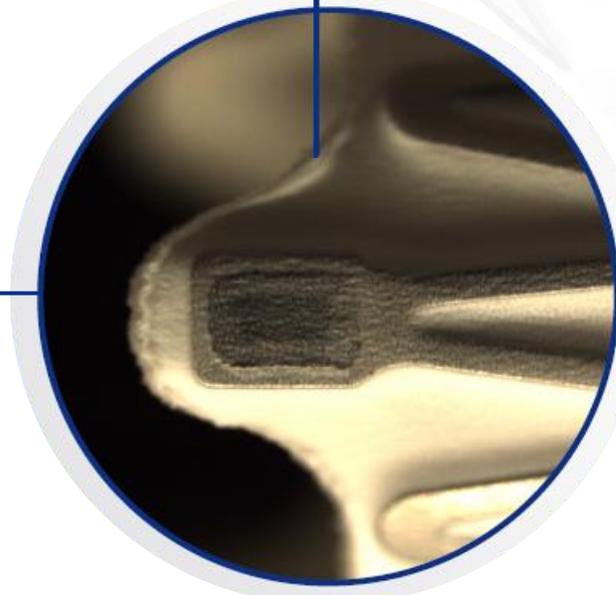
Technical features: ePTFE laser cut



Specific ePTFE laser cutting technology

Perfect sealing

**The laser follows the
stent outline while
cutting the contour**



Technical features: PTA balloon crimping



1

Oceanus 35 PTA balloon
With excellent navigability and deflation times

2

Crimping technology
Complete encapsulated stent with the smallest profiles

Technical features: profiles

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

Competitors: Introduction

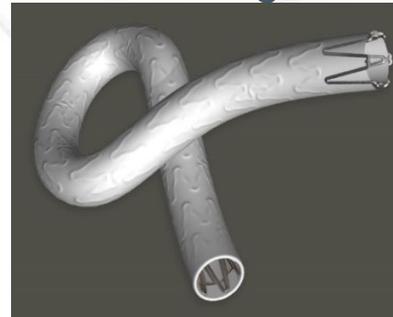
Advanta V12
(Getinge)



LifeStream
(Bard)



BeGraft
(Bentley)



Viabahn VBX
(Gore)



iCover
(iVascular)



iCover

BX ePTFE covered stent

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Competitors: Indications

INDICATIONS OF USE (as in the IFUs)

Advanta V12 (Getinge)

The Advanta V12 balloon expandable covered stent is indicated for restoring and improving the patency of **iliac and renal arteries**. Renal approval includes for **5 mm, 6 mm and 7 mm** Advanta V12 sizes.

LifeStream (BD-BARD)

The LifeStream Balloon Expandable Vascular Covered Stent is indicated for the treatment of atherosclerotic lesions in **common and external iliac arteries**.

BeGraft (Bentley)

The BeGraft Peripheral Stent Graft System is indicated for intraluminal chronic placement in **iliac and renal arteries** for restoring and improving the patency. Treating **aneurysms, acute perforations, acute ruptures and fistulas**.

Viabahn VBX (Gore)

The Viabahn VBX Balloon Expandable Endoprosthesis is indicated for the treatment of de novo or restenotic lesions found in **iliac arteries** with reference vessel diameters ranging from 5 mm - 13 mm and lesion lengths up to 110 mm, including lesions at the aortic bifurcation.

iCover (iVascular)

The iCover covered peripheral stent system is indicated for: restoring atherosclerotic lesions of the **common and external iliac arteries** and the **renal arteries**. Treatment of **aneurysms and perforations, ruptures and acute fistulas**.

iCover

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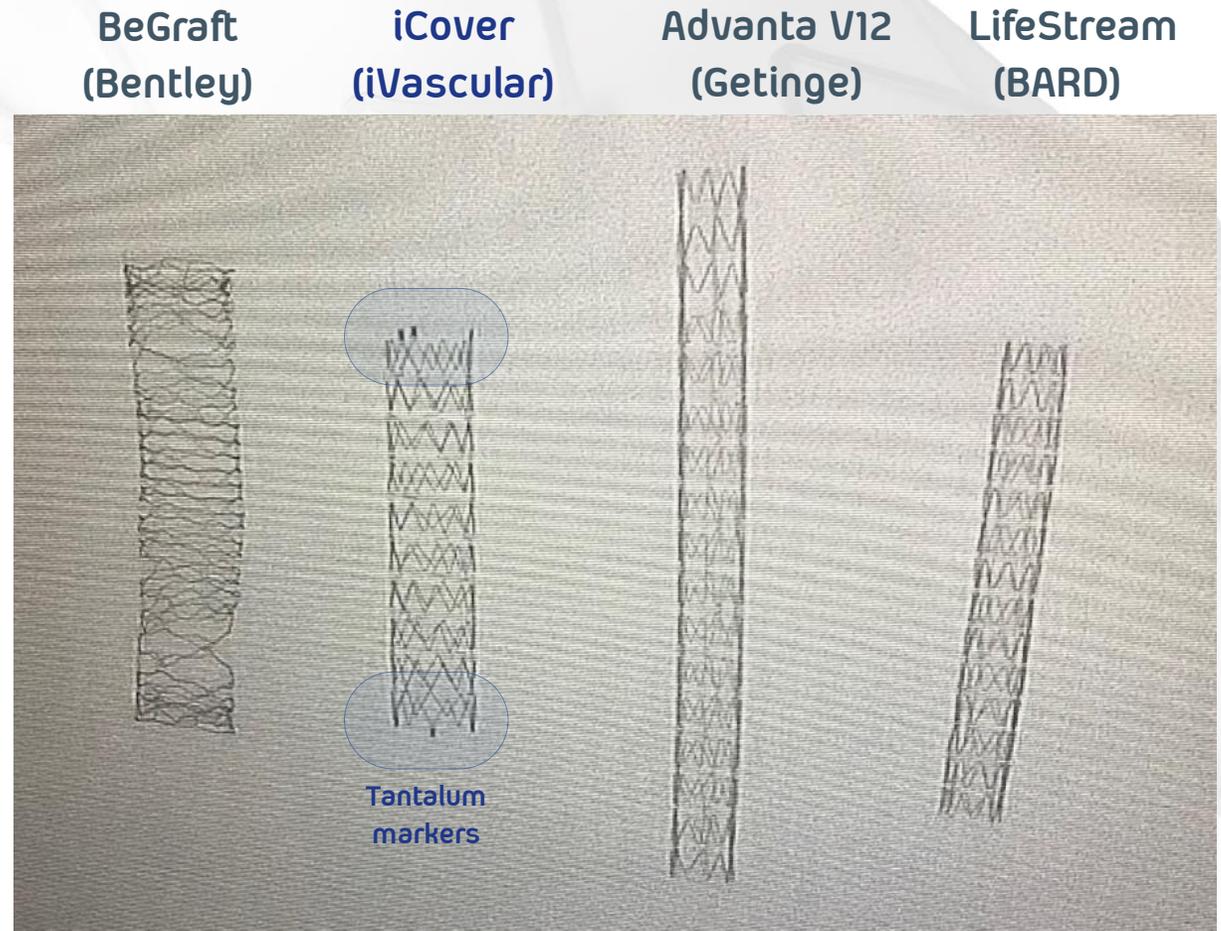
Competitors: Materials

	STENT MATERIAL	COVER MATERIAL
Advanta V12 (Getinge)	316 L Stainless Steel	ePTFE
LifeStream (BD-BARD)	316 L Stainless Steel	ePTFE
BeGraft (Bentley)	CoCr (L605)	ePTFE
Viabahn VBX (Gore)	316 L Stainless Steel	ePTFE
iCover (iVascular)	CoCr (L605)	ePTFE

- ✓ CoCr L605 is an alloy with higher radiopacity
- ✓ CoCr L605 can have higher elongation, which means greater capacity to expand before ruptures occur

Competitors: Visibility

iCover is the only BX covered stent with radiopaque markers on the stent



Visibility under fluoroscopy (Phillips AlluraClarity FD20) of iCover vs. Competitors

Competitors: Encapsulation technique

ENCAPSULATION DESIGN	
Advanta V12 (Getinge)	Full encapsulation (1 tube)
LifeStream (BD-BARD)	Full encapsulation (2 tubes)
BeGraft (Bentley)	External cover (1 tube)
Viabahn VBX (Gore)	Full encapsulation (2 tubes)
iCover (iVascular)	Full encapsulation (2 tubes)

One-layer encapsulation presents certain benefits such as less material on the stent that can be translated to lower entrance profiles and higher flexibility. Nonetheless, there are significant drawbacks related to one-layer encapsulation. The probability of ePTFE rupture increases

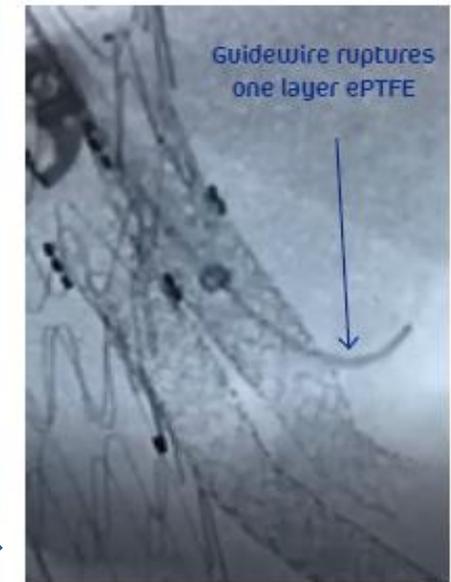


Figure 15. ePTFE rupture of BeGraft by a guidewire

Competitors: References

	CATHETER LENGTH (cm)	STENT LENGTH (mm)	STENT DIAMETER (mm)
Advanta V12 (Getinge)	80, 120	16, 22, 32, 38, 59	5, 6, 7, 8, 9, 10, 12
LifeStream (BD-BARD)	80, 135	16, 26, 37, 58	5, 6, 7, 8, 9, 10, 12
BeGraft (Bentley)	75, 120	18, 22-23, 27-28, 37-38, 57-58	5, 6, 7, 8, 9, 10
Viabahn VBX (Gore)	80, 135	15, 19, 29, 39, 59, 79	5, 6, 7, 8, 9, 10, 11
iCover (iVascular)	80, 140	17, 27, 37, 57	5, 6, 7, 8, 9, 10 (available in longer length)

iCover

BX ePTFE covered stent

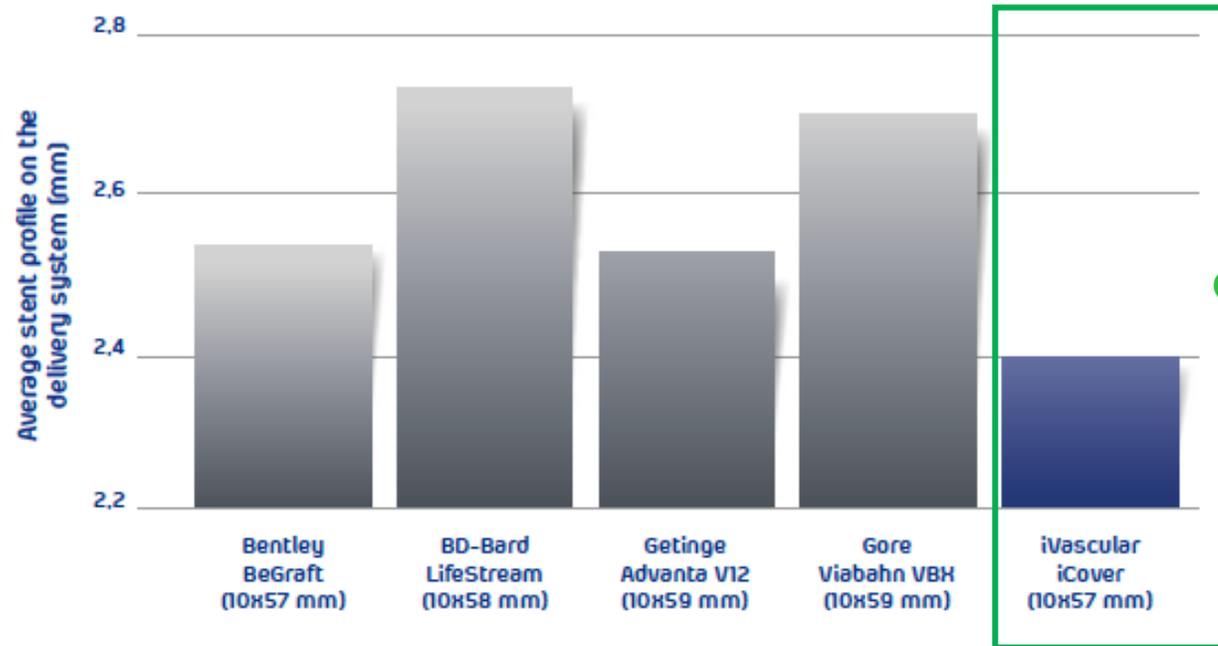
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Competitors: Compatibilities

Diameter (mm)	Advanta V12	LifeStream	BeGraft	Viabahn VBX	iCover
5	6F (OTW long, 16-22 mm) 7F (OTW long, 38-59 mm)	6F	6F	7F	6F
6	6F (OTW long, 16-22 mm) 7F (OTW long, 38-59 mm)	6F	6F	7F	6F
7	7F (OTW)	6F / 7F (L: 58 mm)	6F	7F	6F
8	7F	7F	6F	7F/8F	6F (L: 17 mm) / 7F
9	7F	7F	7F	8F	7 F
10	7F	8F	7F	8F	7 F
11	-	-	-	8F	-
12	9F	8F			



Competitors: Crimped stent profiles



“the lower the better”

Competitors: Post-expansion

POST-EXPANSION (as in the IFUs)	
Advanta V12 (Getinge)	ø5-7 mm; L 16-22 mm: up to 7.3 mm ø5-10 mm; L 38-59 mm: up to 10,6 mm
LifeStream (BD-BARD)	ø5-8 mm: up to 10 mm ø9-12 mm: up to 12 mm
BeGraft (Bentley)	Not specified in IFUs
Viabahn VBX (Gore)	Ø5-6 mm: up to 8 mm Ø7-8 mm: up to 11 mm Ø9-10 mm: up to 13 mm Ø11 mm: up to 13 mm
iCover (iVascular)	Ø5 -8 mm: up to 10 mm Ø9-10 mm: up to 12 mm

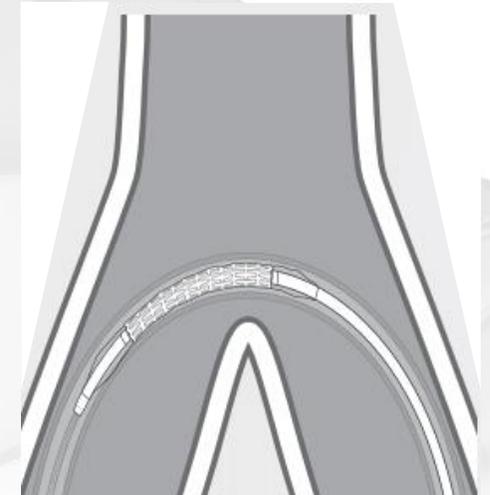
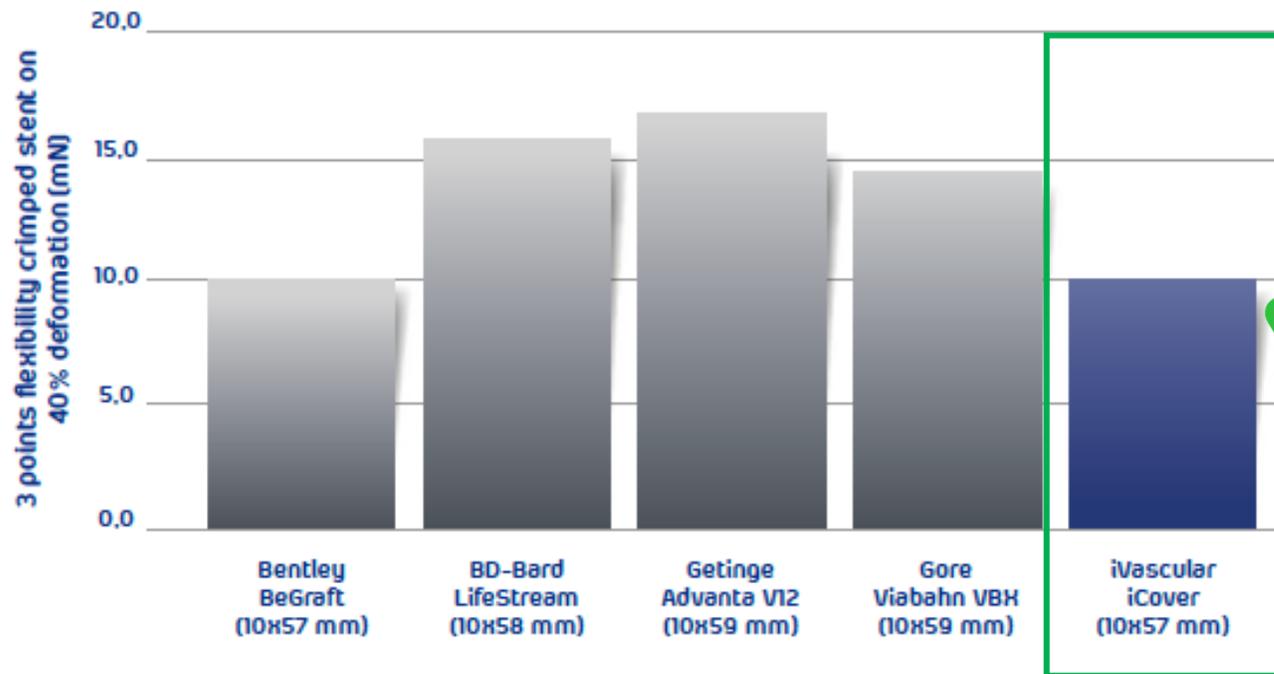


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Competitors: Flexibility (stent crimped)



“the lower the better”

Competitors: Flexibility (stent)

Kinking radius is at the diameter that the stent kinks

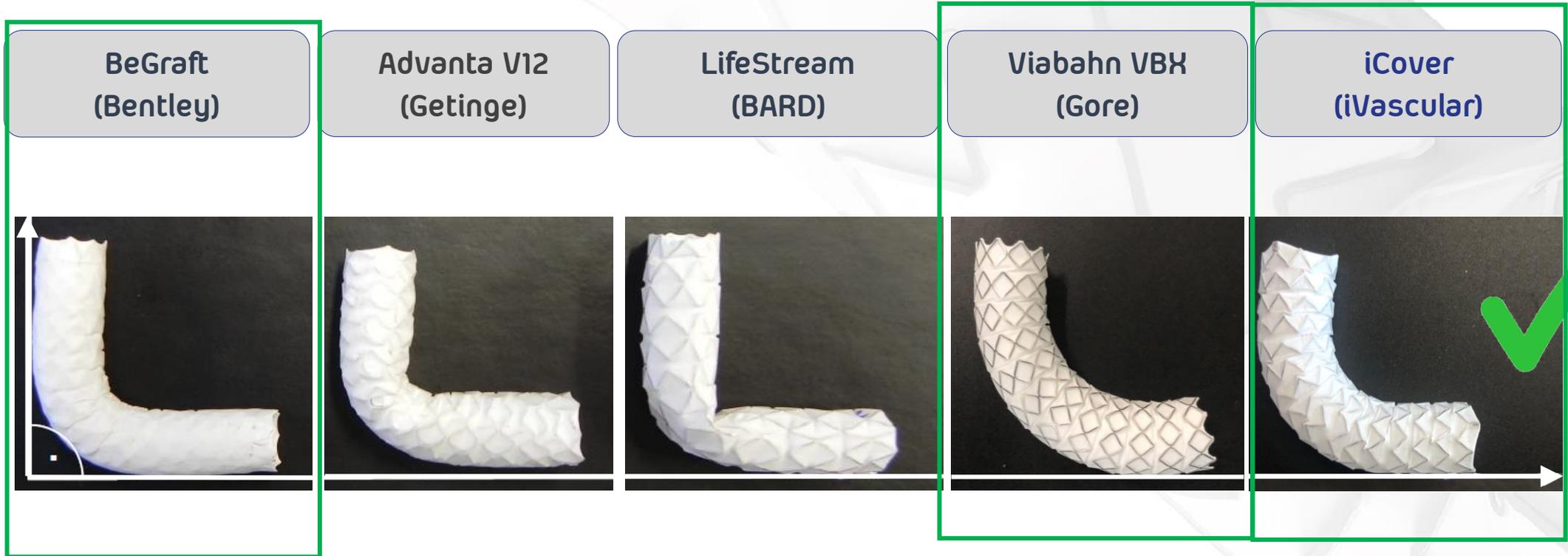


	BeGraft (Bentley)	Advanta V12 (Getinge)	LifeStream (BARD)	Viabahn VBX (Gore)	iCover (iVascular)
Kinking radius	4,5 mm	8 mm	8 mm	5 mm	5 mm

Considering iCover has a double ePTFE layer

Outstanding
flexibility

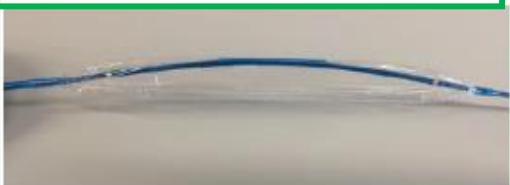
Competitors: Flexibility (stent)



Considering iCover has a double ePTFE layer

Outstanding
flexibility

Competitors: Deflation times

	Deflation time at RBP (s)	Deflated balloon
Advanta V12 10x59 mm (Getinge)	32.33 (at RBP 12 atm)	
LifeStream 10x58 mm (BD-Bard)	8.20 (at RBP 12 atm)	
BeGraft 10x57 mm (Bentley)	15.15 (at RBP 12 atm)	
Viabahn 10x59 mm VBH (Gore)	20.97 (at RBP 13 atm)	
iCover 10x57 mm (iVascular)	7.16 (at RBP 13 atm)	





First clinical experiences

First evaluations summary

- 20 clinical cases done by 17 physicians from 6 countries
- Uses tested: iliac stenosis, iliac total occlusion, renal stenosis, renal aneurism, kissing stents, CERAB technique and FEVAR
- Feedback:
 - Unique visibility
 - Small profiles
 - Good navigation
 - Stent high flexibility adapting to the most angulated arteries
 - Good radial force

“I can not say anything wrong about iCover”
Dr Deloose

“In a so difficult to arrive artery, no other covered stent would have been able to arrive”
Dr Manzoni

1st clinical experience

Renal artery in-stent restenosis (Spain)

- Done by Prof Riambau 24/03/2021
- Feedback: Good navigability and great stent performance. He pushed the stent from the balloon, with no dislodgement.

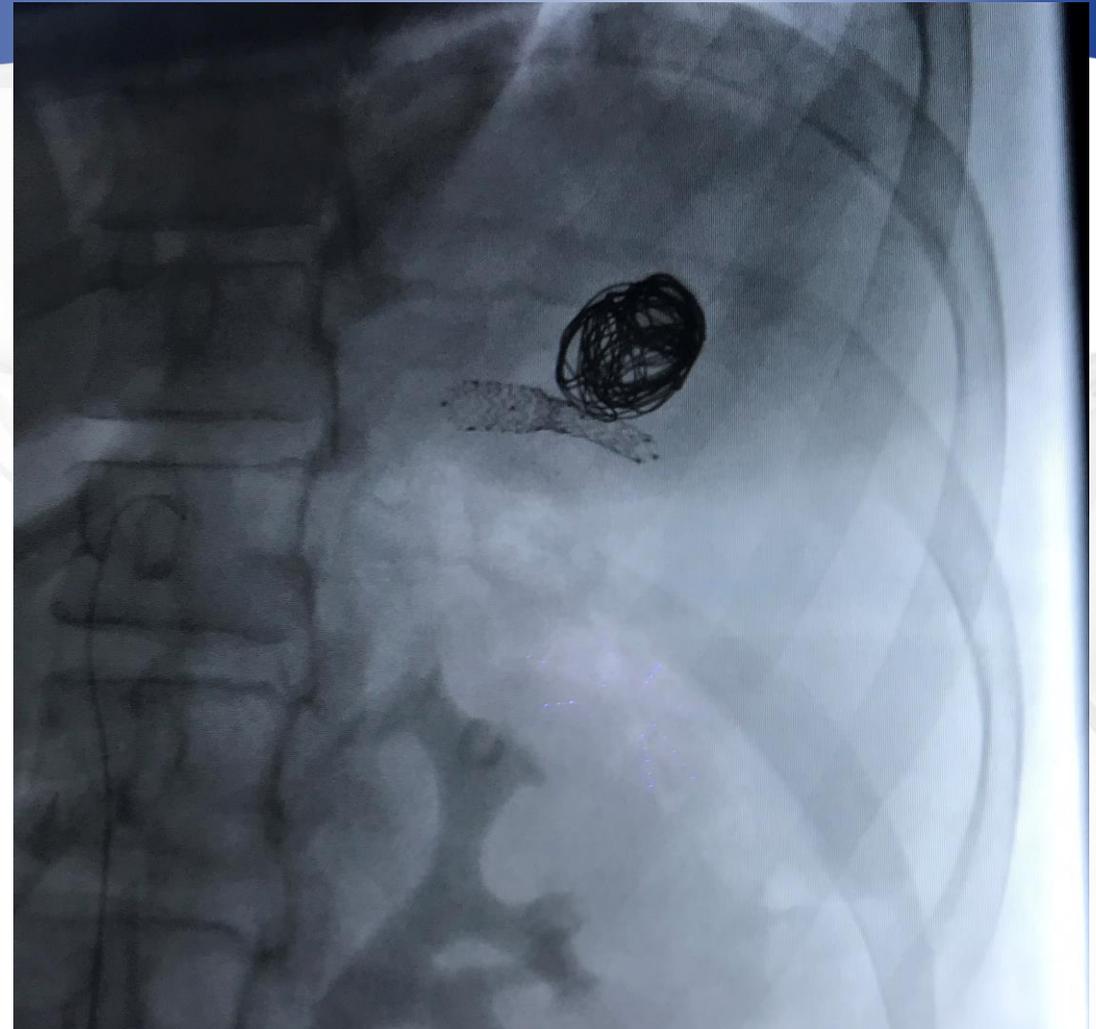


2nd clinical experience

Renal artery aneurism (Luxembourg)

Sergeant + 2 iCover + Oceanus 35

- Done by Dr Manzoni and Dr Schutz 20/04/2021
- Feedback:
 - Good flexibility to reach the most tortuous
 - Unique visibility, which has allowed them to visualize at all times where each of the stents was. No other competitor offers this feature
 - The stent is very well crimped on the balloon
 - Other competitors wouldn't have performed so well



iCover

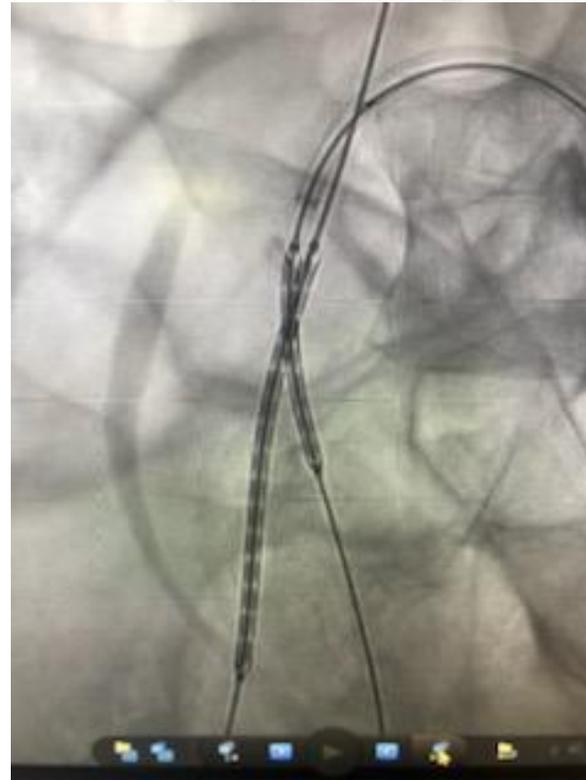
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4th clinical experience

Kissing stent in iliac and hypogastric artery (France)

- Done by Dr Brunet 22/04/2021

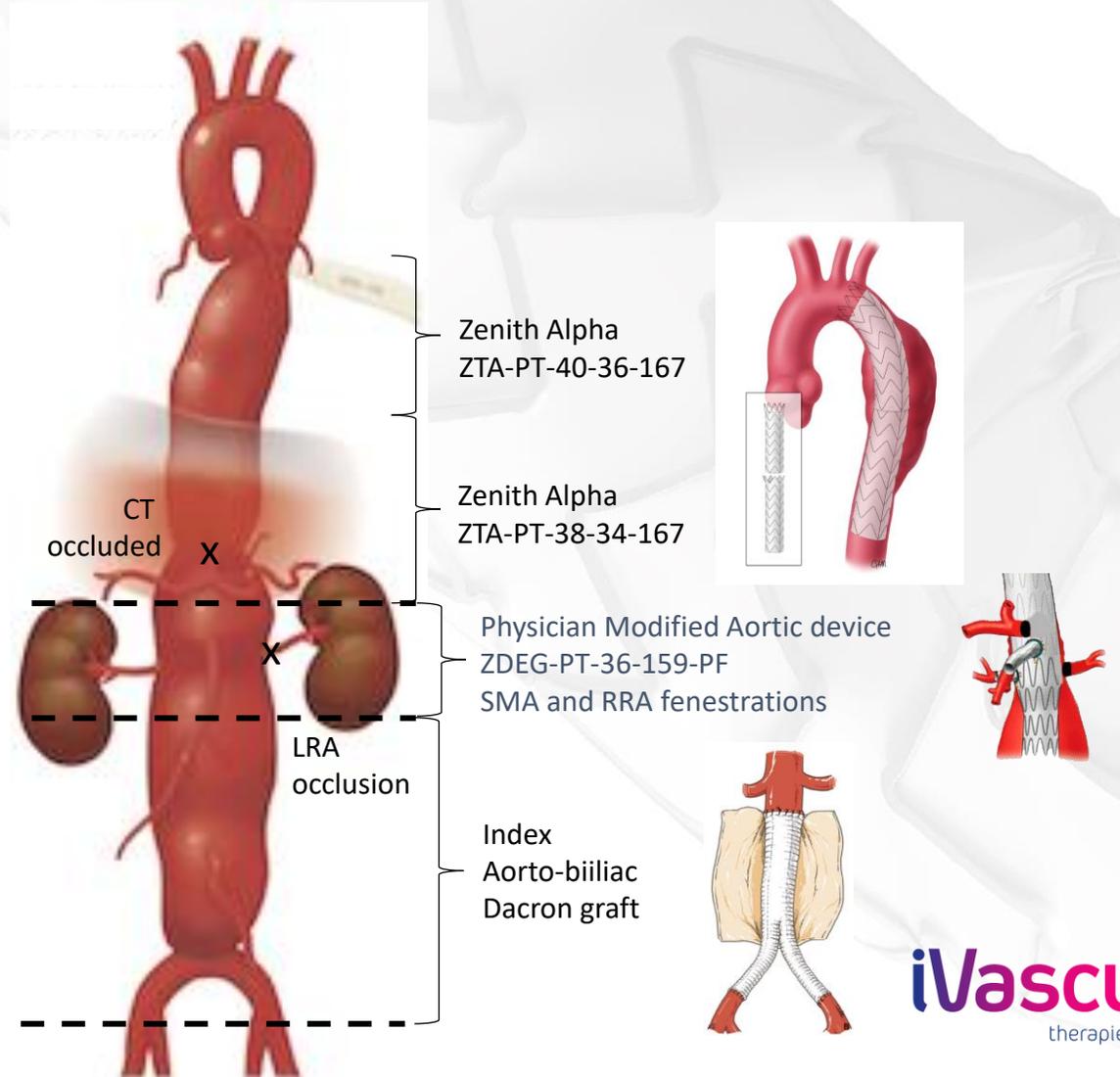


6th clinical experience

FEVAR (France)

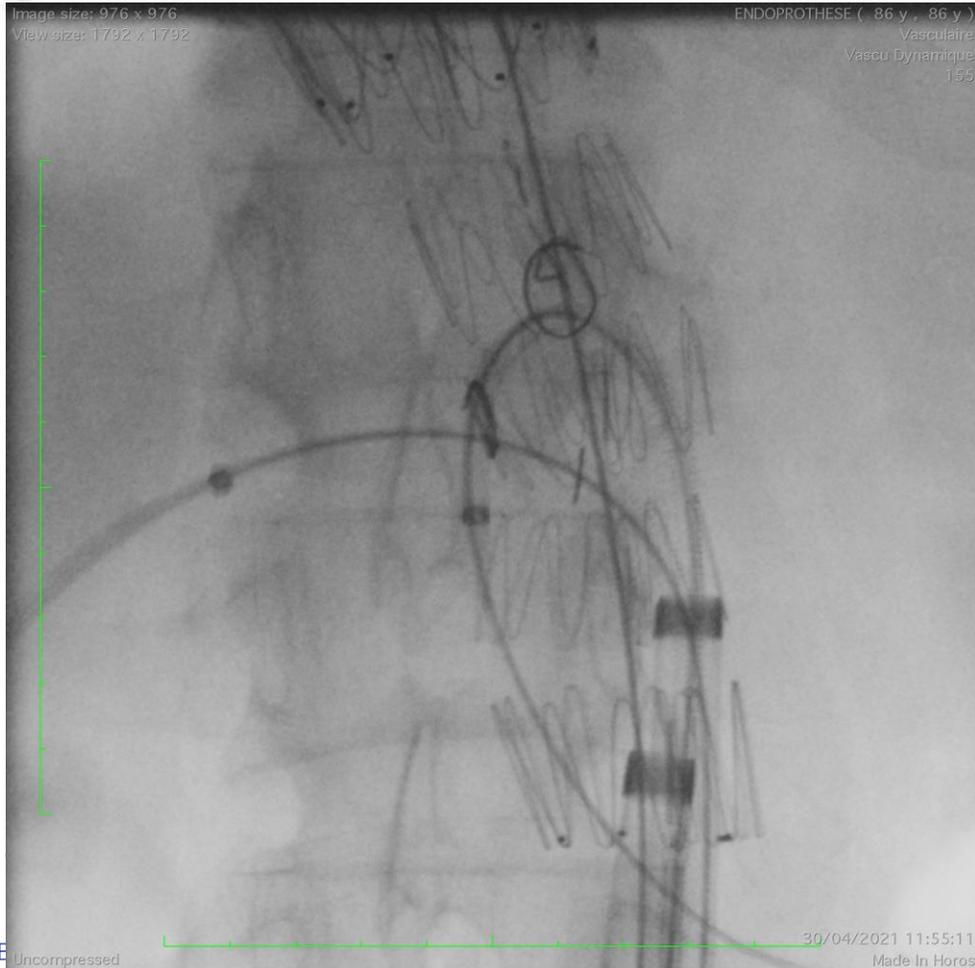
- Dr Ducasse 30/04/2021
- Feedback
 - Visibility
 - Profiles

Plan:

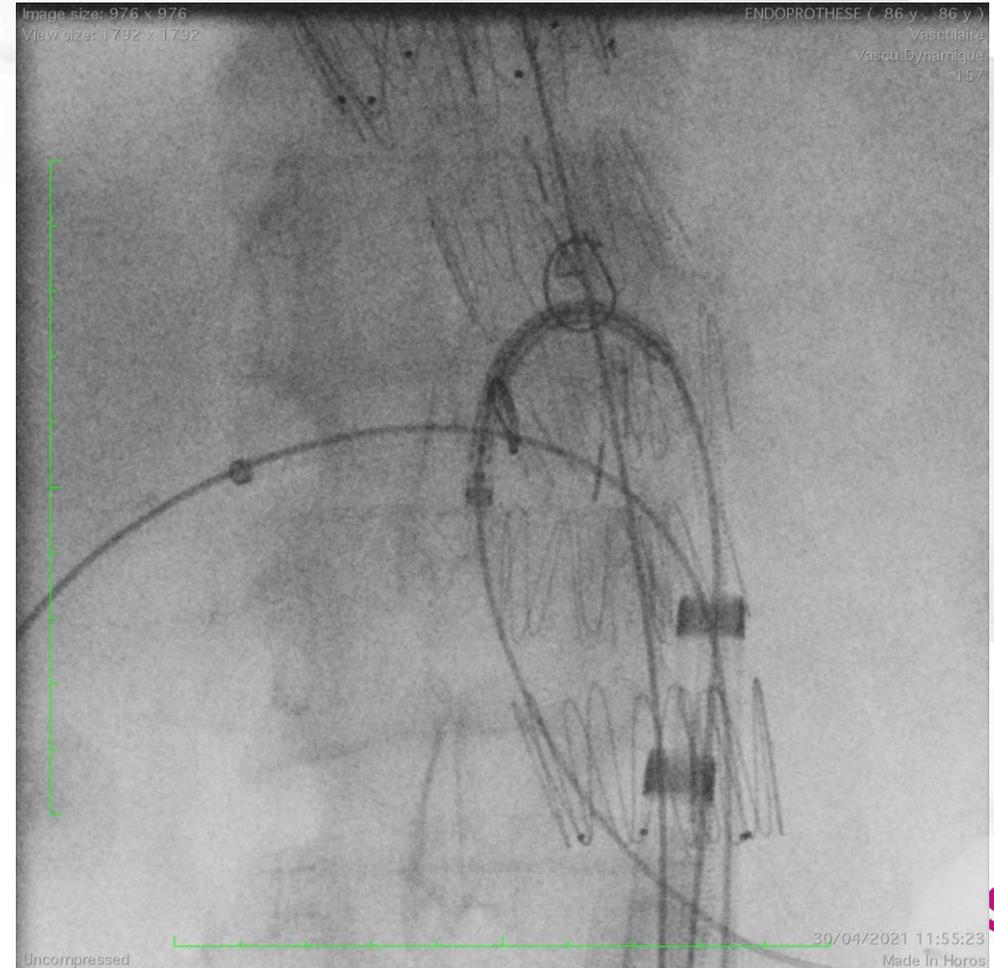


6th clinical experience

SMA iCover stent (8x37mm) inserted in 7-F Sheath



7-F Sheath pushed back to the aorta
No problem with crimping

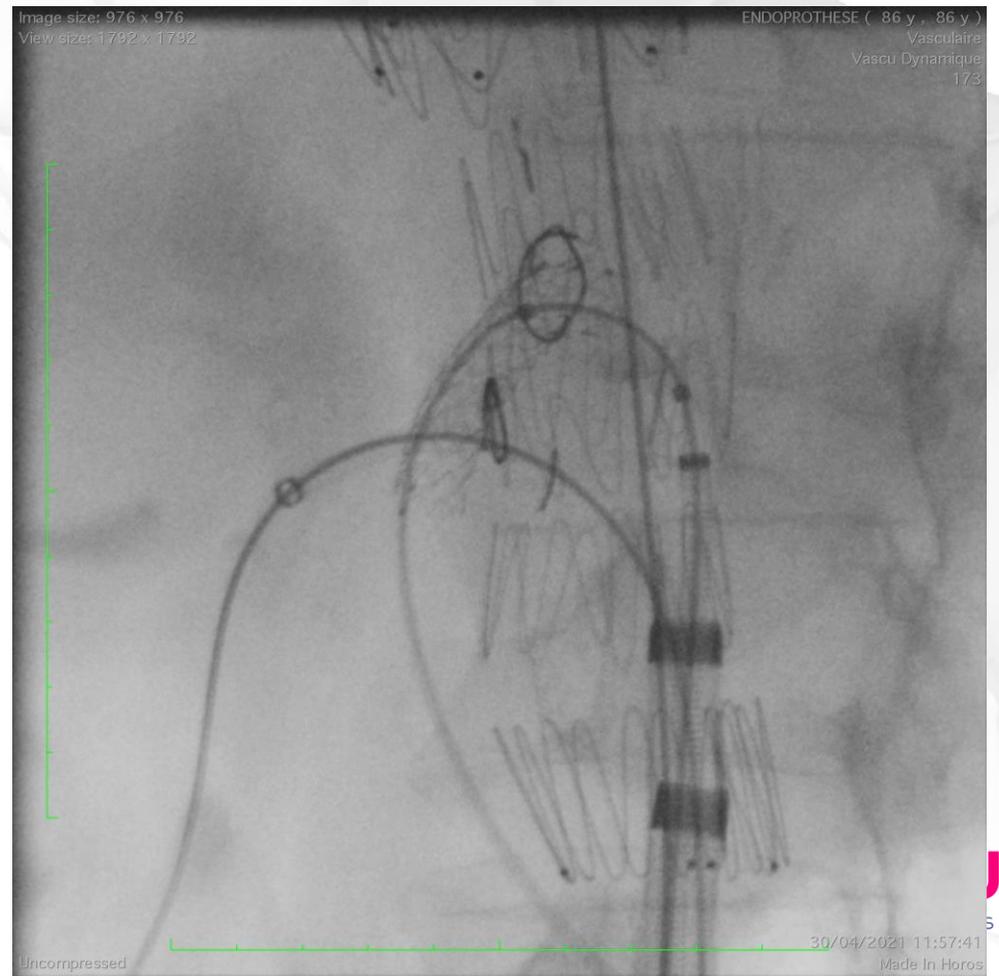
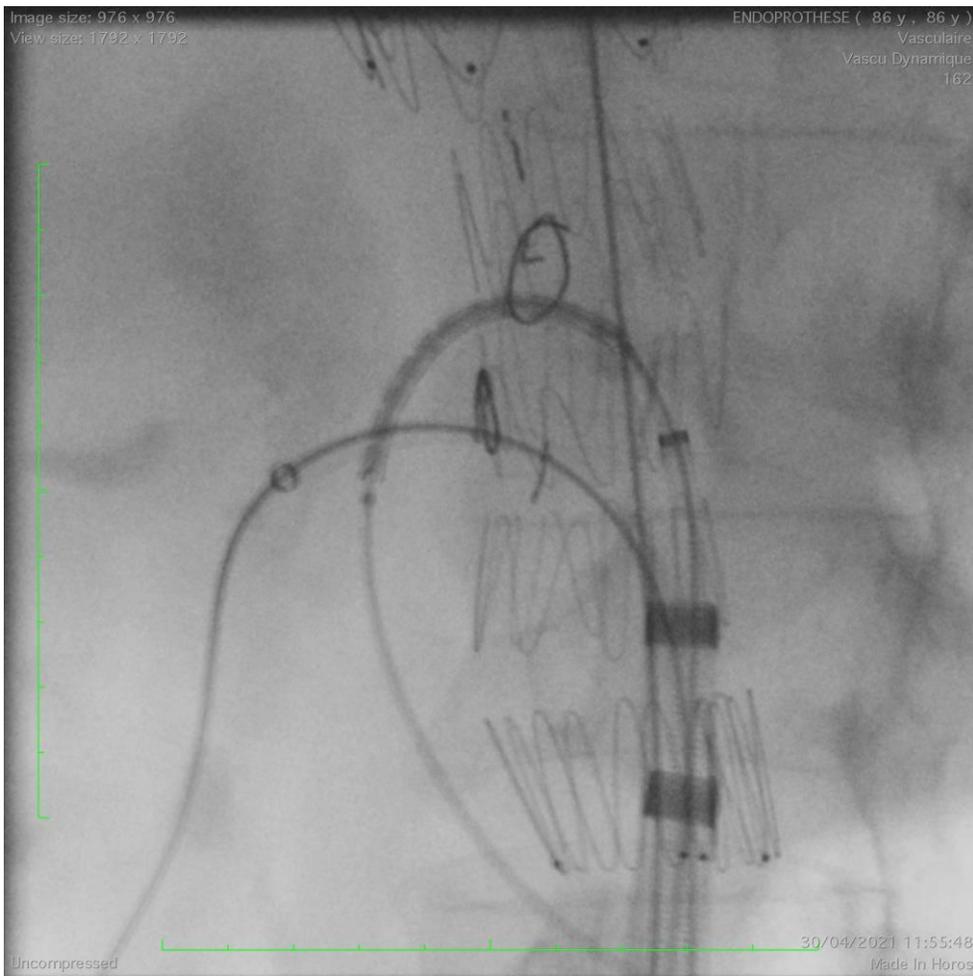


6th clinical experience

Stent inflated at NP : 9 Atm / Rapid expansion

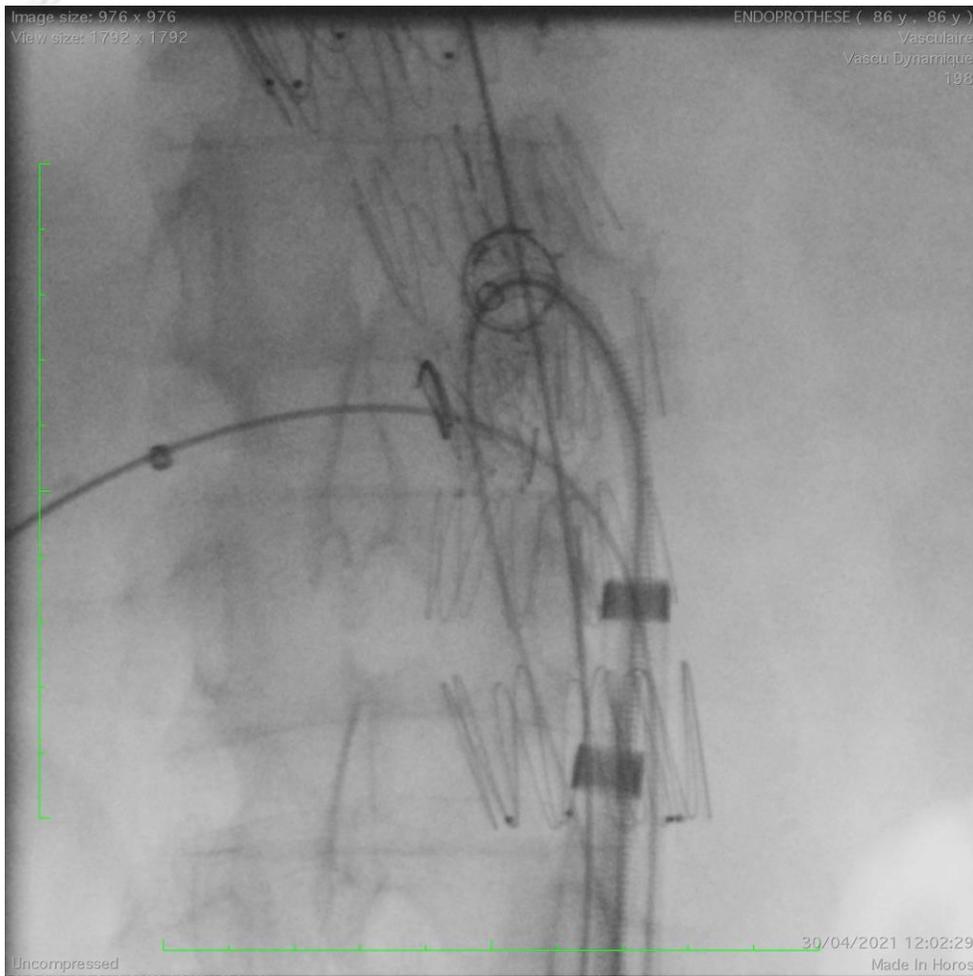
No difficulty reintegrating the sheath into the stent over the balloon

Stent flared at 10mm



6th clinical experience

RRA iCover stent (5x37mm) inserted in 6-F Sheath



Stent inflated at NP : 9 Atm / Rapid expansion
No difficulty reintegrating the sheath into the stent over the balloon



6th clinical experience

Stent flared at 8 than 9mm

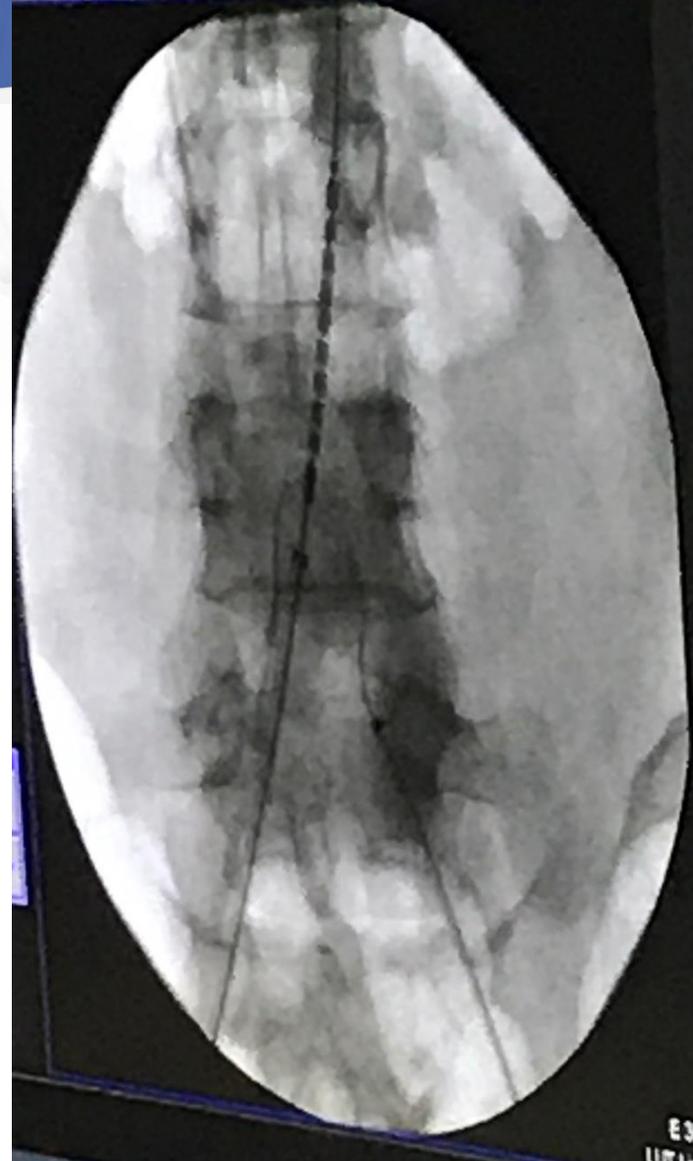


9th clinical experience

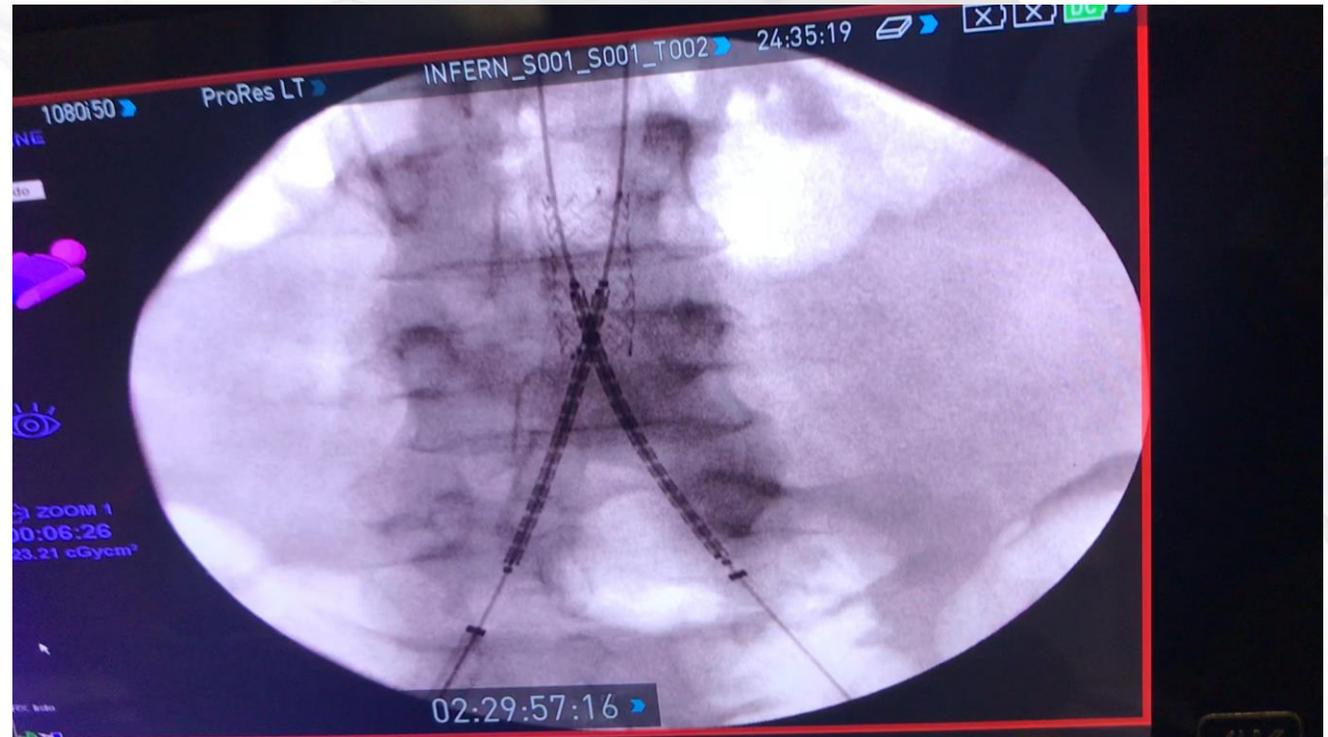
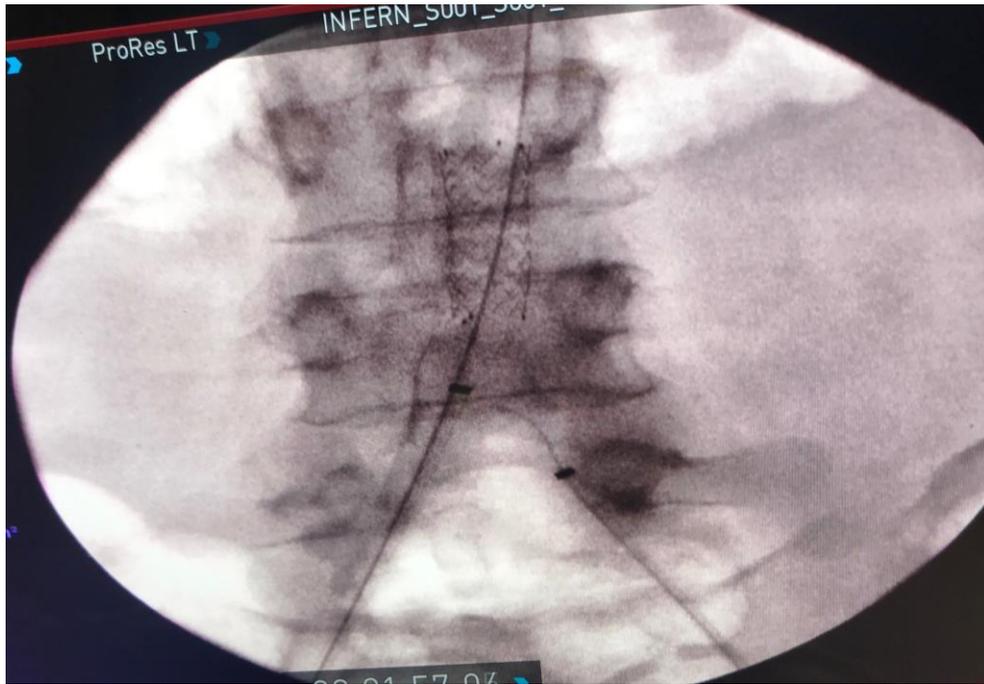
CERAB (Spain)

4 iCover: 7x57 (2), 10x37, 6x27

- Dr Riambau 04/05/2021
- Feedback
 - Visibility
 - Post-expansion capacity
 - No shortening



9th clinical experience

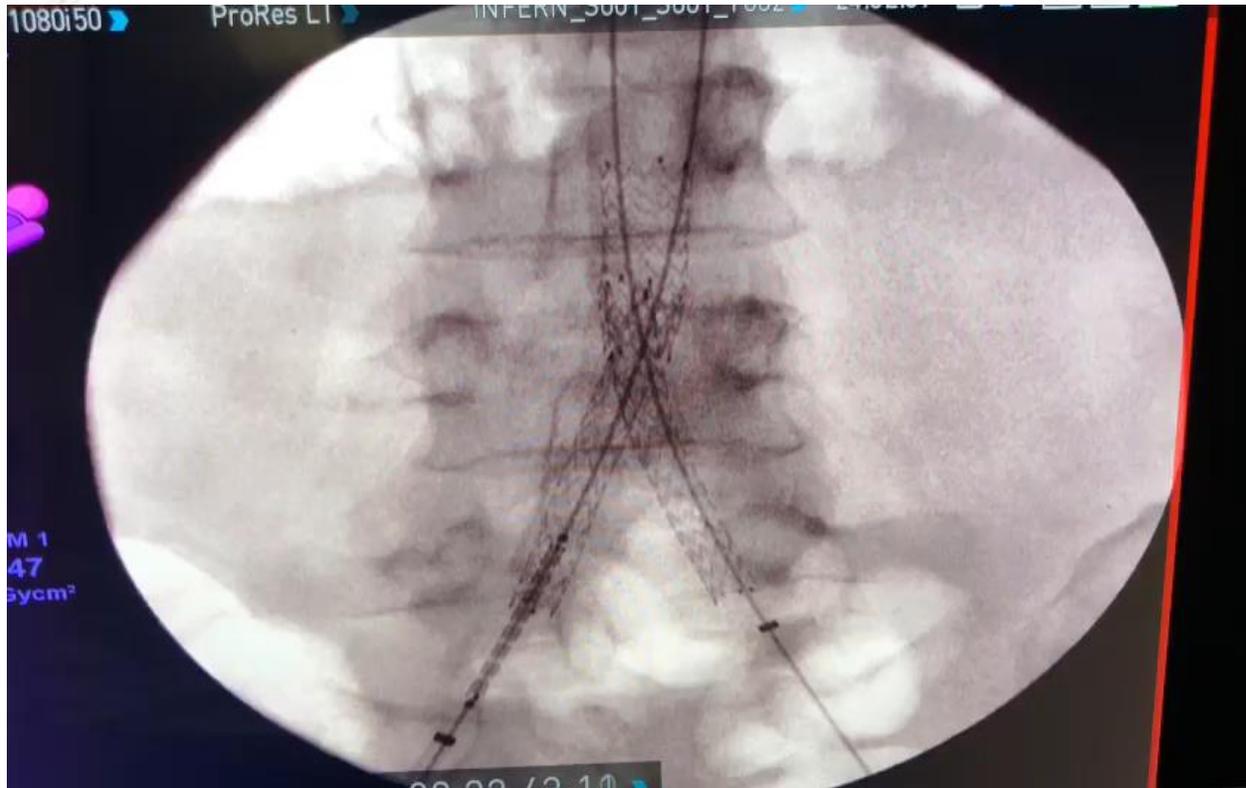


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9th clinical experience



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iCover main messages

iCover

Designed to cover all needs

1

Excellent navigability

- **Great flexibility** of the stent crimped, avoiding the kinking during navigation.
- **Small profiles** even with a full encapsulated stent. 6F until 8mm diameter

2

Easy to implant

- **Visibility:** unique stent with 3 radiopaque markers at each end
- **Best deflation times (7s)**

3

Able to treat the most tortuous arteries

- **Flexible covered stents** to treat tortuous and angulated parts of the artery
- **High post expansion capacity** ($\geq 2\text{mm}$)

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Thank You