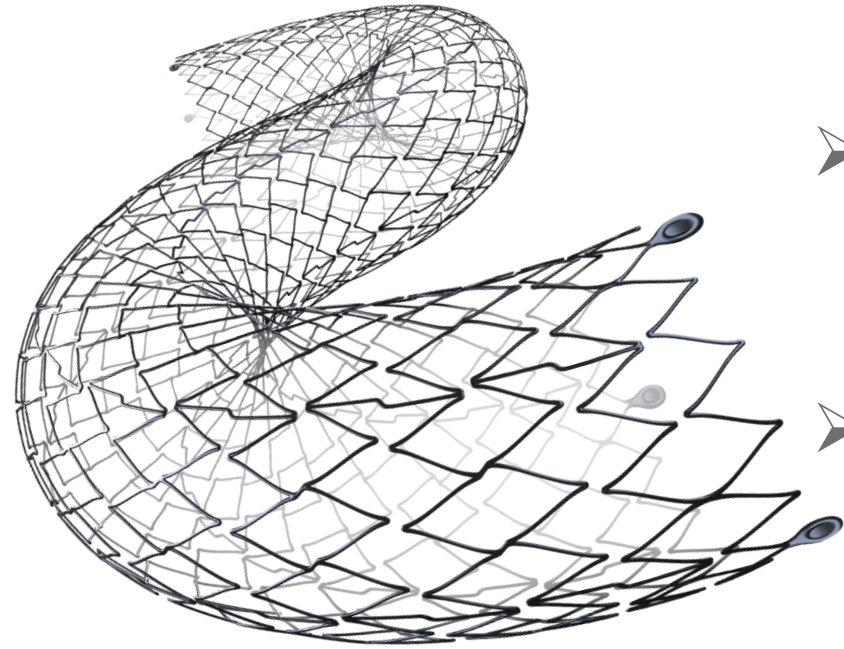


# Easy Flype & Easy HiFlype

*Peripheral Self-Expanding Stent System*

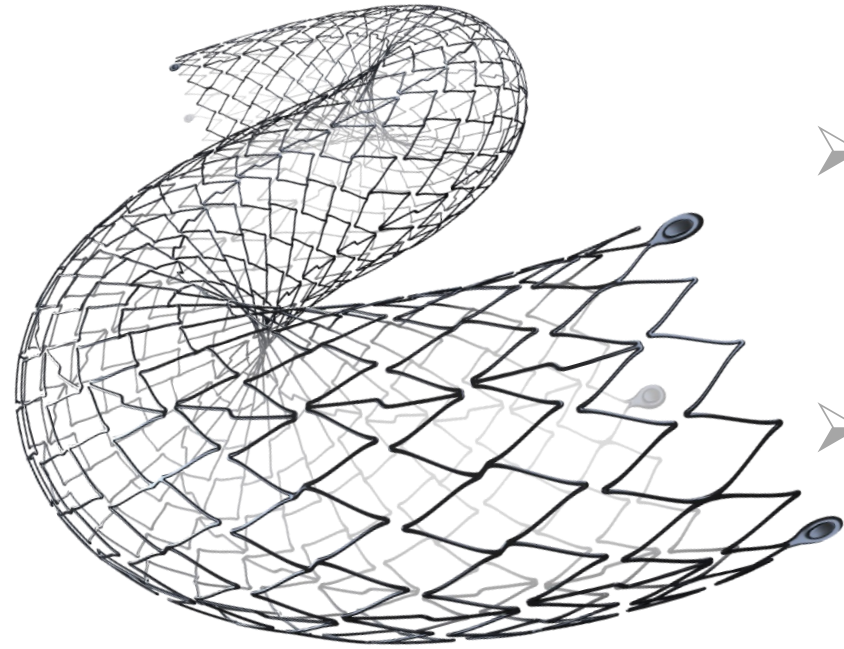
20/07/2018

# Easy Flype & Easy HiFlype



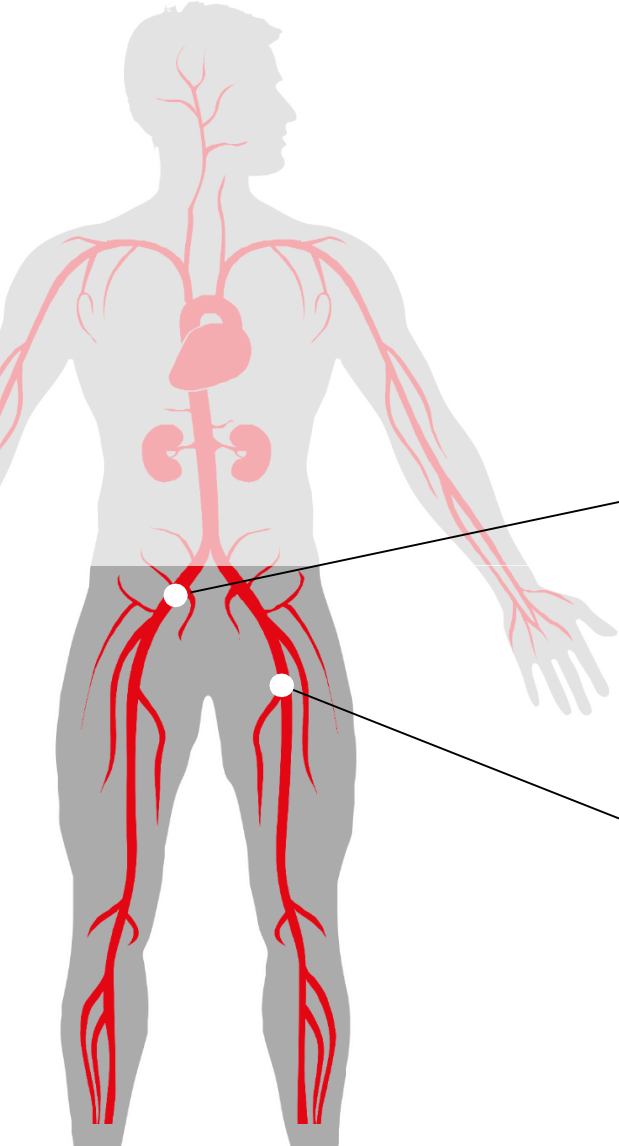
- **Dedicated specific platforms** in order to match perfectly the different needs of the Iliac and SFA artery stentings.
- Proven biocompatibility enabled by the **Bio Inducer Surface coating** accelerating the rate of endothelialization and strut coverage, reducing the thrombogenicity.
- **Tantalum markers with zero stent foreshortening** provide complete visualization during the positioning and placement accuracy.
- **Dedicated single hand delivery system** with dual release - micrometric and fast.

# Easy Flype & Easy HiFlype



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# Easy Flype & Easy HiFlype



## Dedicated Nitinol platforms:

Easy Flype and Easy HiFlype are self expanding stents with dedicated hybrid cell designs for iliac and femoral lesions.

### Easy HiFlype

Uniform and high radial force with excellent scaffolding for the Iliac lesions also in presence of tight calcified segment

### Easy Flype

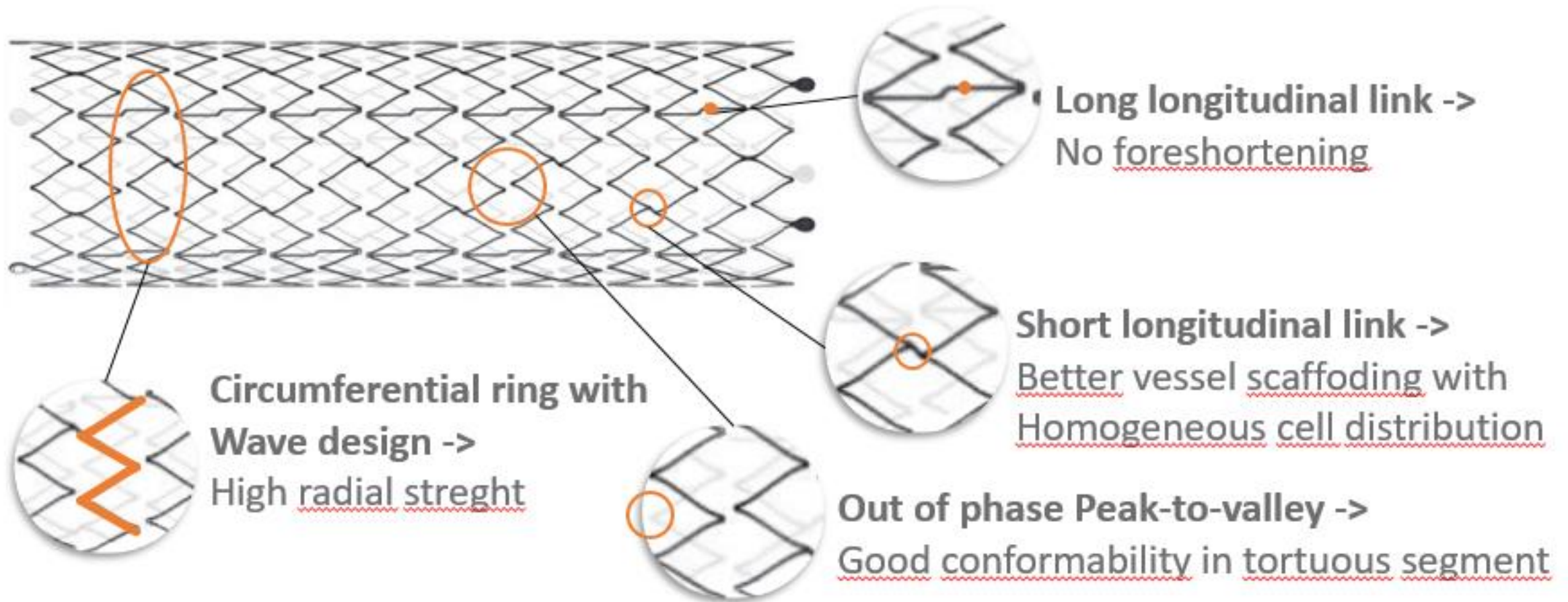
Optimal flexibility, conformability and durability for the femoro-popliteal lesions also in tortuous SFA anatomies



# Easy Flype & Easy HiFlype

Dedicated Nitinol platforms – common design elements:

The Easy Flype and Easy HiFlype stent family is characterized by the follow elements



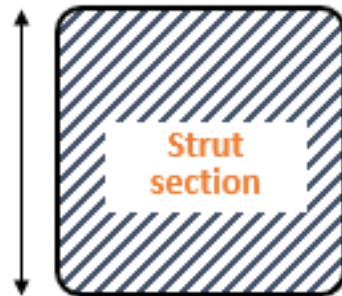
# Easy Flype & Easy HiFlype

Dedicated Nitinol platforms:

## Easy Flype

SFA dedicated design ( $6\text{mm} \leq \phi \leq 8\text{mm}$ )

Strut thickness  
190 micron



Optimized thickness for an adequate support in femoral lesion

Standard circumferential distribution of short longitudinal links for better flexibility and conformability

Short rings with standard wave design for better scaffolding in tortuous anatomies

## Easy HiFlype

Iliac dedicated design ( $9\text{mm} \leq \phi \leq 12\text{mm}$ )

Strut thickness  
220 micron



Bigger strut thickness (+16%) for homogenous and enhanced radial strength in iliac calcified lesion

Increased circumferential number of short longitudinal links for homogeneous mesh distribution in large vessel

Long rings with longer wave design for increased radial force

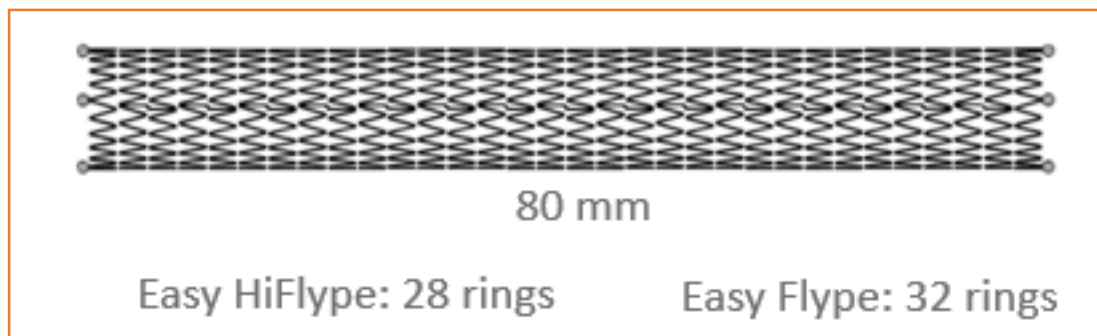


# Easy Flype & Easy HiFlype

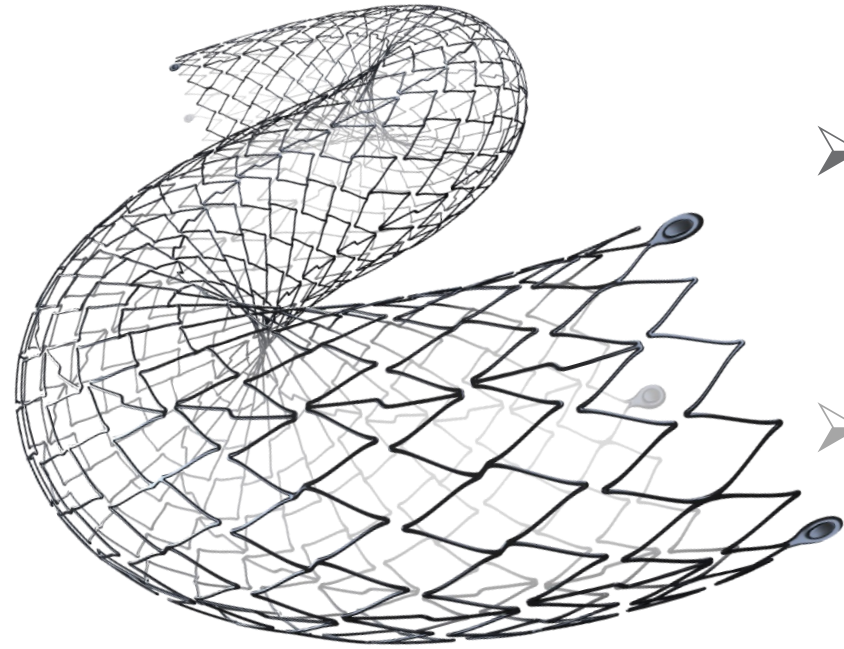
## Dedicated Nitinol platforms:

Easy Flype and Easy HiFlype are available in 2 stent designs to offer an optimal performance in iliac and SFA stenting

	Nominal Diameter [mm]	Strut thickness [micron]	N. of Short longitudinal links	N. of Rings [with Stent length: 20, 40, 60, 80, 100mm]
Easy Flype	6 – 8	190	Standard	8, 16, 24, 32, 40
Easy HiFlype	9 – 12	220 (+16%)	Increased	8, 14, 22, 28, 36



# Easy Flype & Easy HiFlype



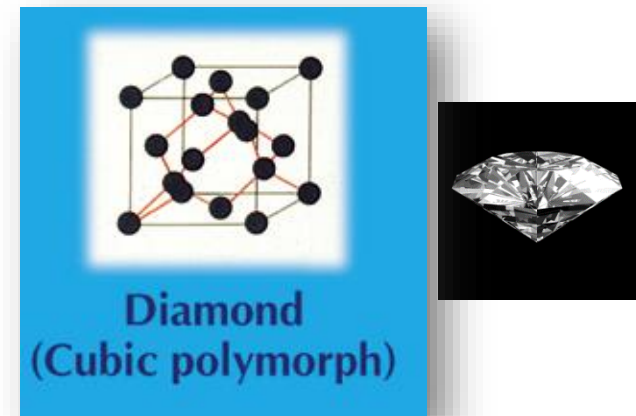
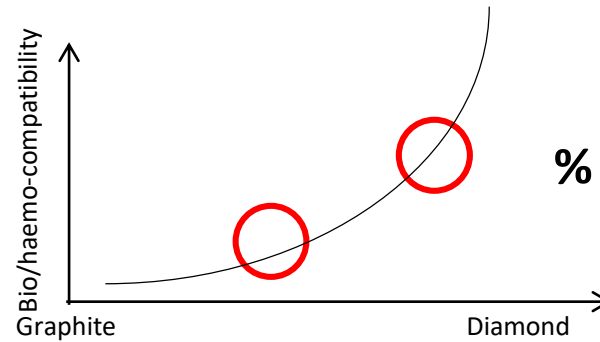
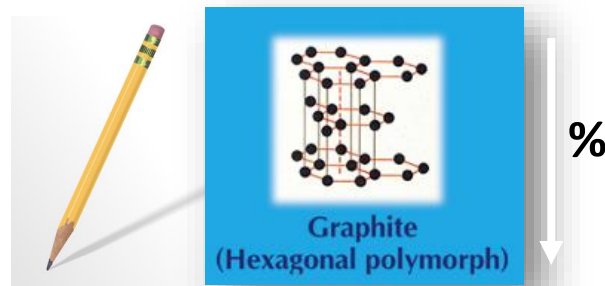
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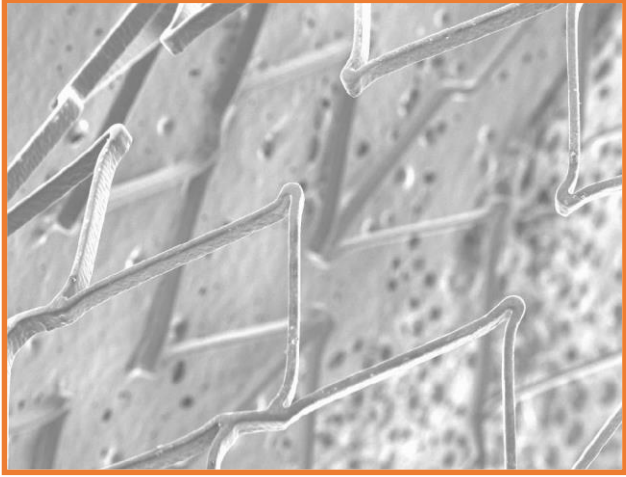
# The Bio Inducer Surface (BIS)

This 2<sup>nd</sup> generation pure carbon coating ( $\leq 0.3 \mu\text{m}$ ) brings the crystalline structure closer to the diamond structure with a further improvement of its bio/haemo compatibility

The Bio-Inducer Surface is made of pure carbon atoms

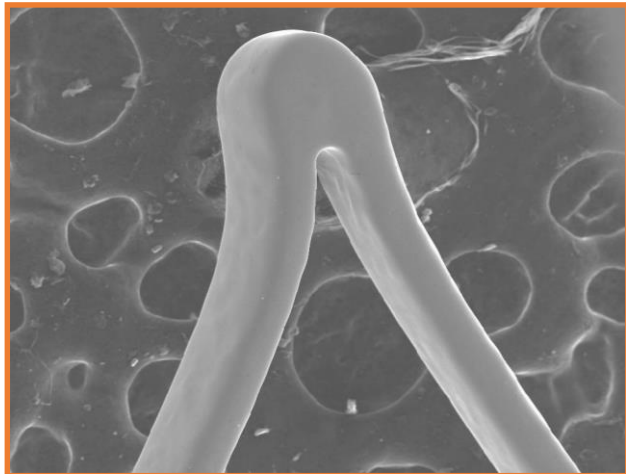


# The Bio Inducer Surface (BIS)



The Bio Inducer Surface (*iCarbofilm*) clinical benefits demonstrate:

- accelerating rate of endothelization and struts coverage
- reducing the thrombogenicity
- sealing against the release of heavy metal ions like nickel from nitinol alloy.



**Bio Inducer Surface** with its exceptional bio&haemo compatibility, **seals** the bulk Nitinol material (Nickel-Titanium alloy) avoiding any release of heavy metal ions.

This is extremely important in case of long self-expandable stents because nitinol contains ~50% of nickel, a very high allergenic metal component.

# The Bio Inducer Surface (BIS)

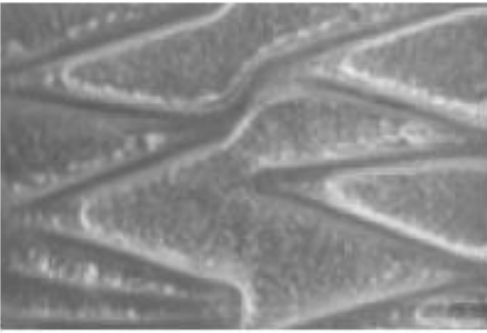
## Self Expanding Stents

### Stent endothelization

### Vessel biological reaction to stent implant

#### Bio Inducer Surface coated Nitinol peripheral stent

Bio Inducer Surface coated Nitinol peripheral stent at 7 days from implant. Continuous and homogeneous endothelial cell carpet.

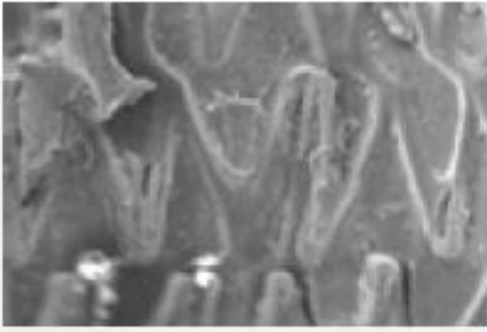


Bio Inducer Surface coated Nitinol peripheral stent at 30 days from implant. A continuous and homogeneous endothelial cell carpet covers a thin layer of neointima. No signs of inflammation or blood deposits are present.

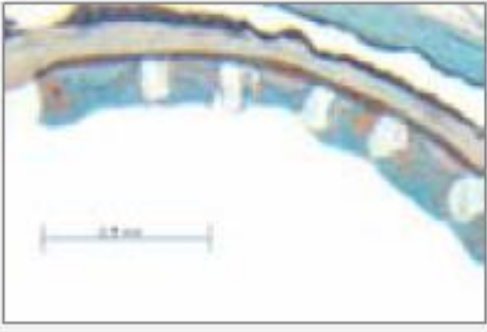


#### Non coated Nitinol peripheral stent

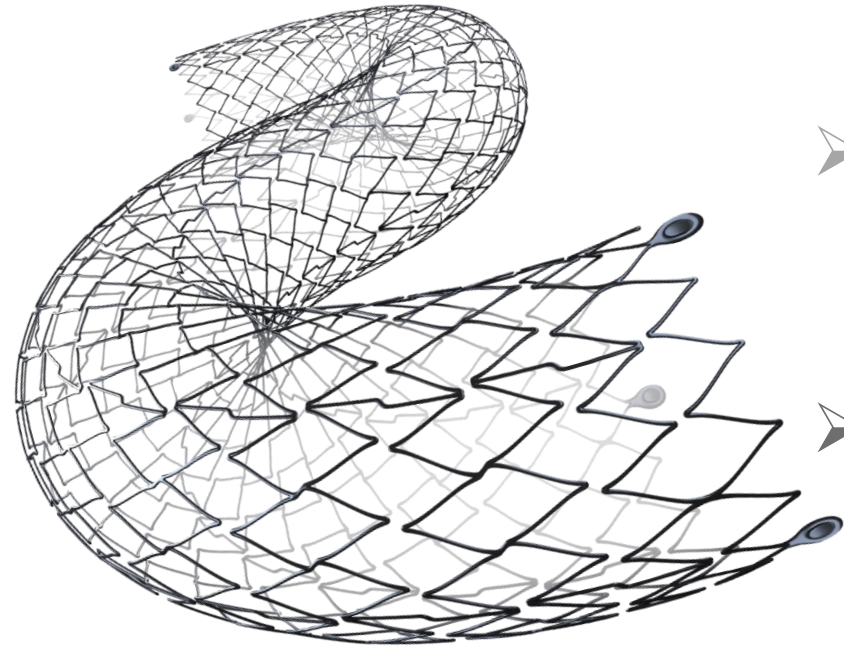
Nitinol peripheral stent at 7 days from implant. Endothelization is irregular and not confluent. Several struts were uncovered.



Nitinol peripheral stent at 30 days from implant. Endothelization is almost complete but blood clots and fibrin deposits are still detectable around struts.



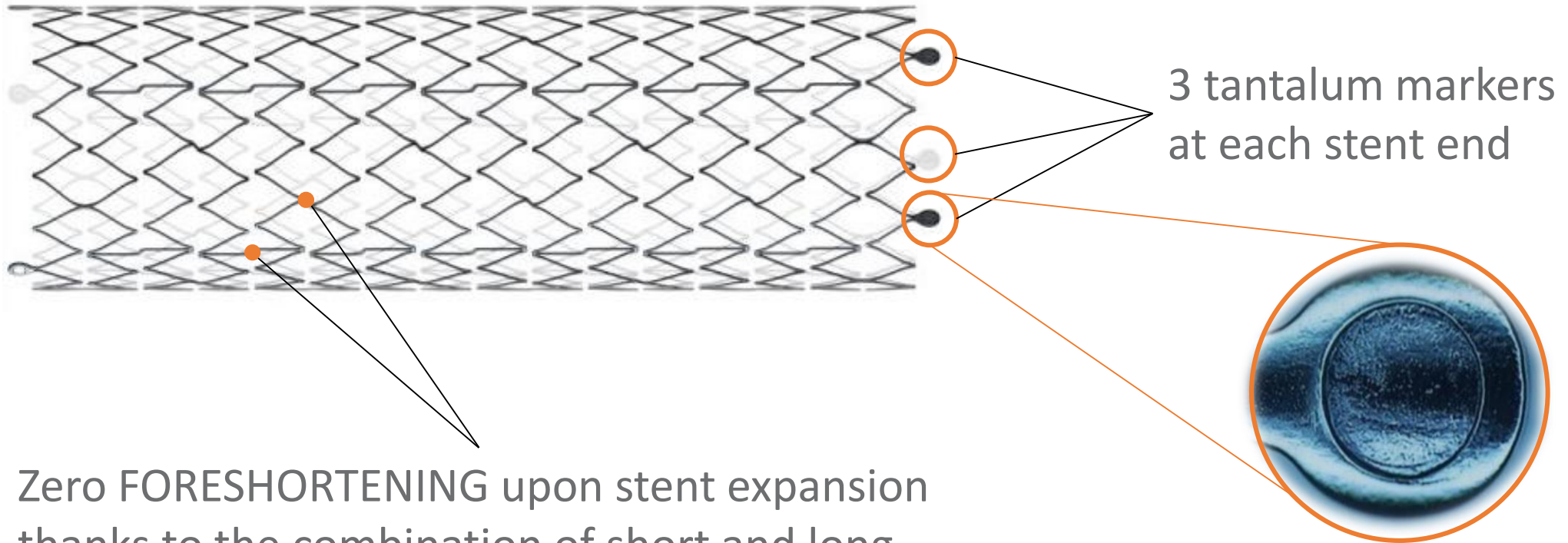
# Easy Flype & Easy HiFlype



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# Easy Flype & Easy HiFlype

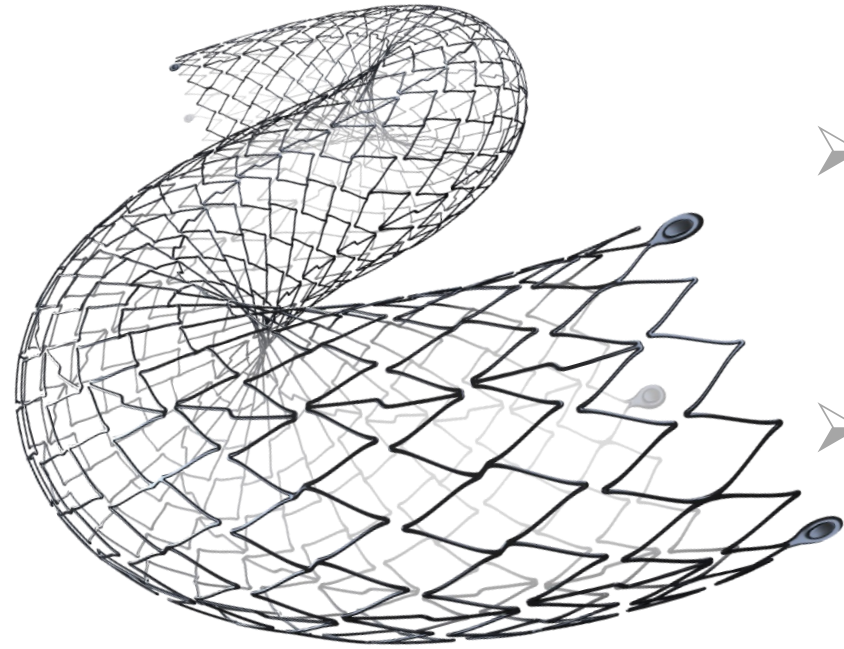
Radiopaque markers & Zero foreshortening:



Zero FORESHORTENING upon stent expansion thanks to the combination of short and long longitudinal connectors



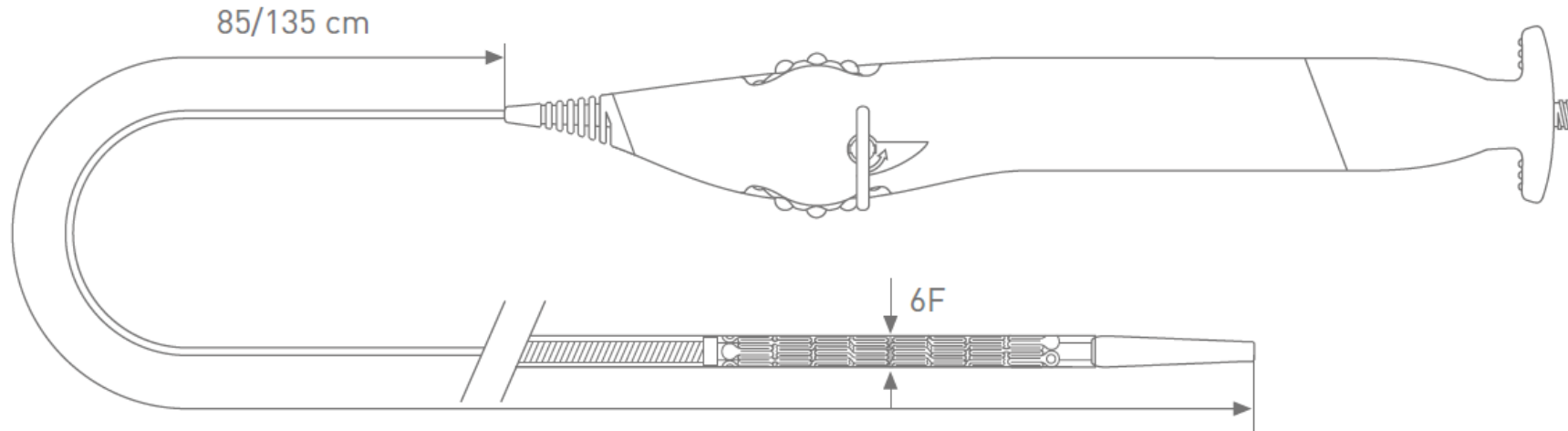
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# Easy Flype & Easy HiFlype

## Delivery system

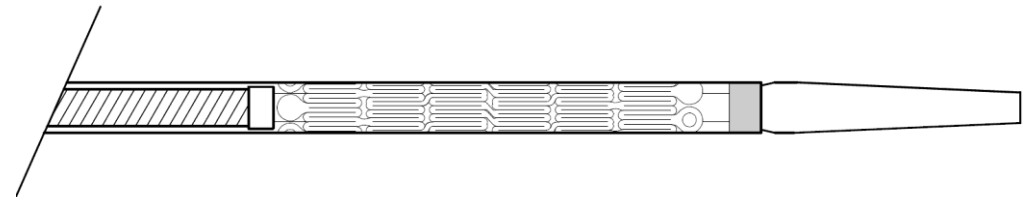


### Over the wire (OTW) catheter

Catheter Length: 85/135 cm

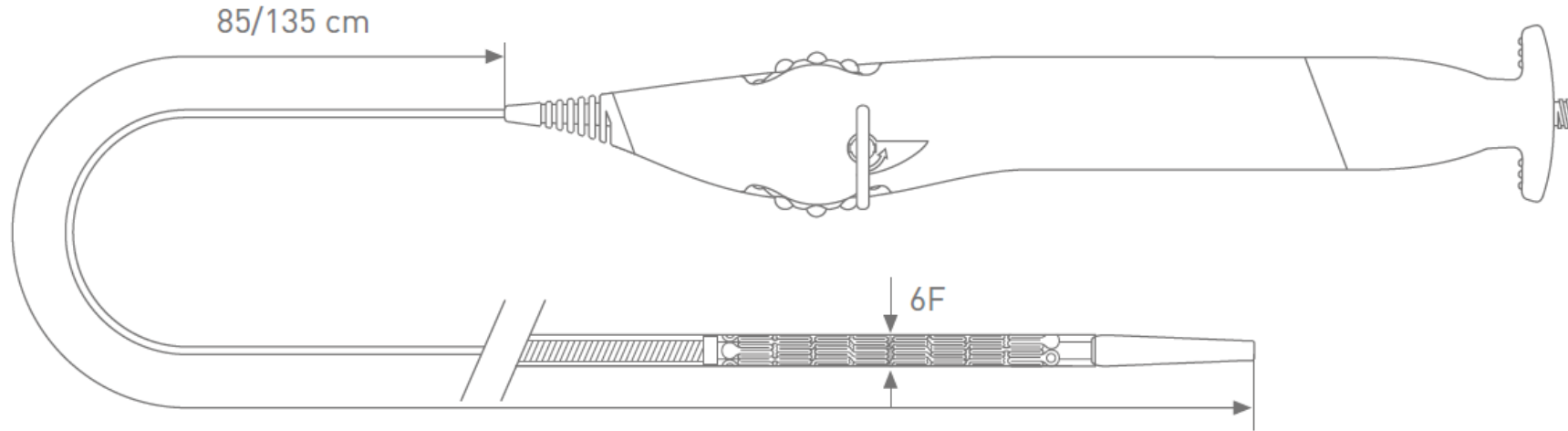
Outer Diameter: 2,00 mm (6 French)

Compatibility: Guidewire 0.035"  
Introducer sheath 6F



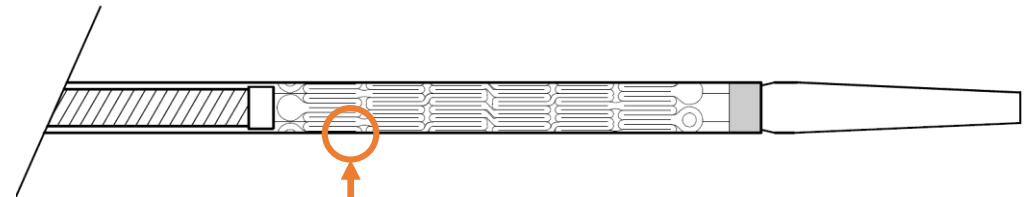
# Easy Flype & Easy HiFlype

## Delivery system – outer sheath



## Over the wire (OTW) catheter

Outer retractile sheath - Material:  
Braided Polyamide



# Easy Flype & Easy HiFlype

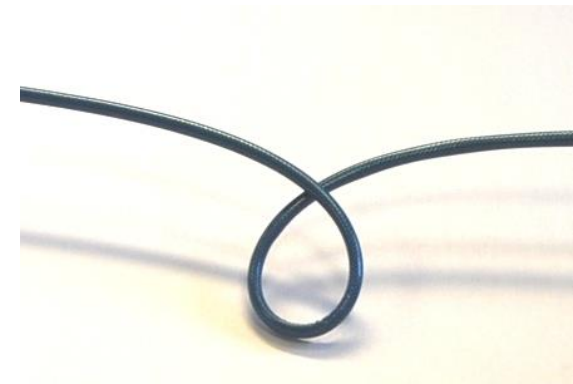
Delivery system – outer braided polyamide sheath



Proximal segment:  
Blue cover

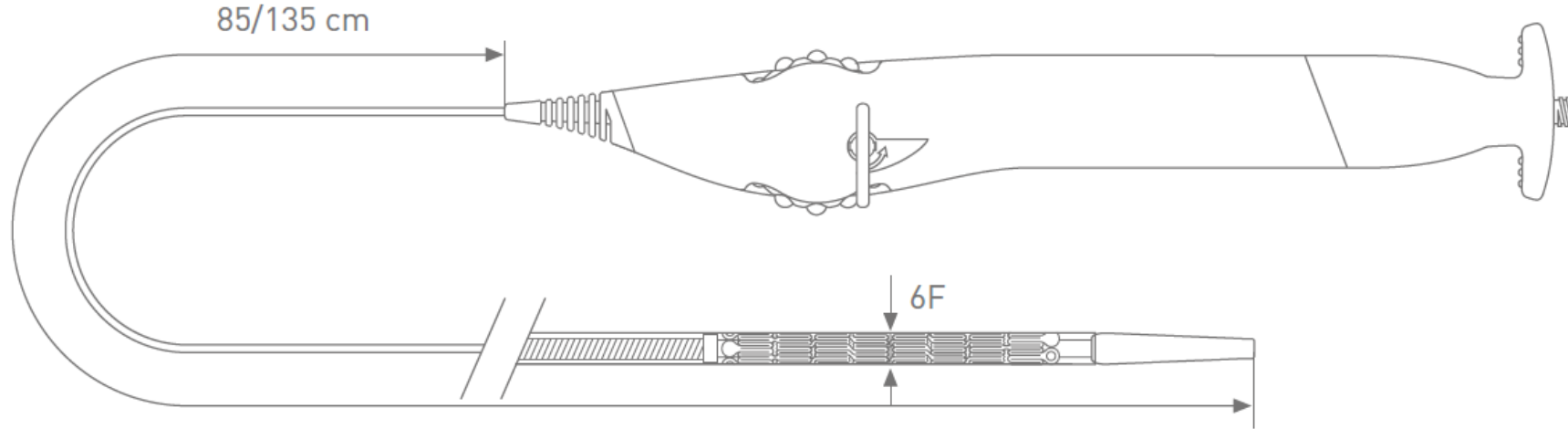
Distal segment:  
Transparent cover for stent location

**Easy track and reliable lesion crossing.** Provided by the use of a flat wire braiding, which optimizes push / flex performance of the catheter shaft also in cross-over procedure the risk of kinking is reduced.



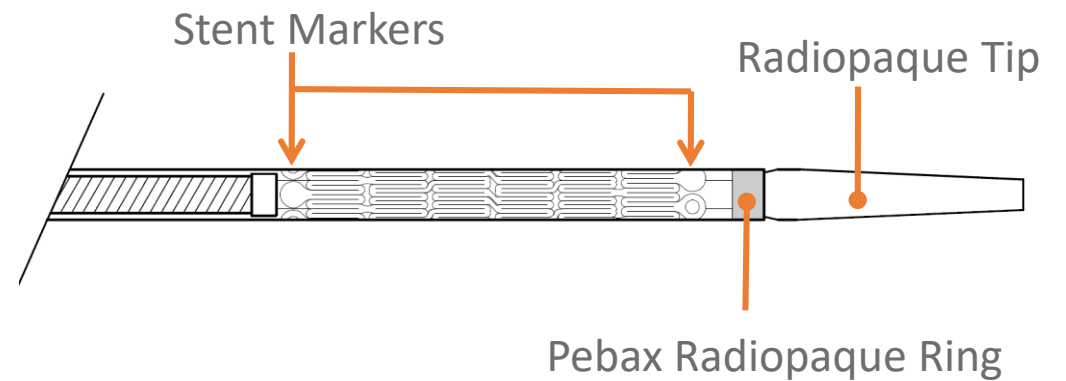
# Easy Flype & Easy HiFlype

## Delivery system – radiopacity



## Over the wire (OTW) catheter

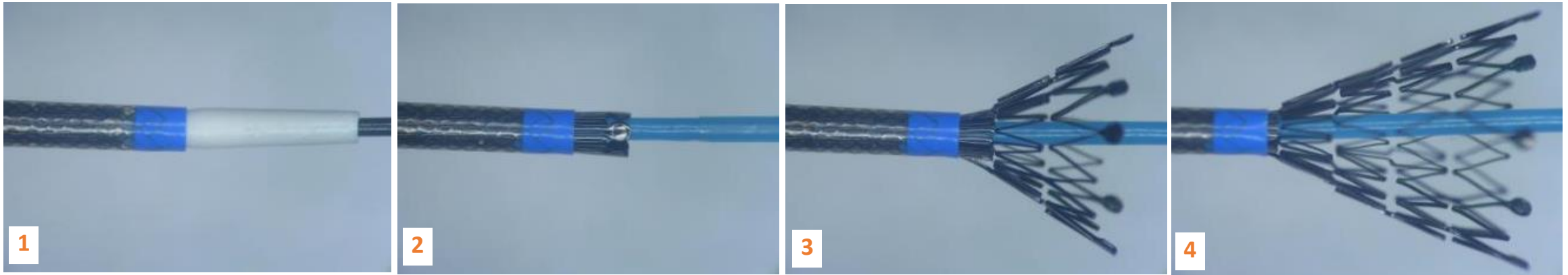
It's extremely important to know the portion of the stent already deployed. Thanks to the pebax radiopaque ring, positioned at the extreme part of the retractile sheet, you have under your eyes this information.





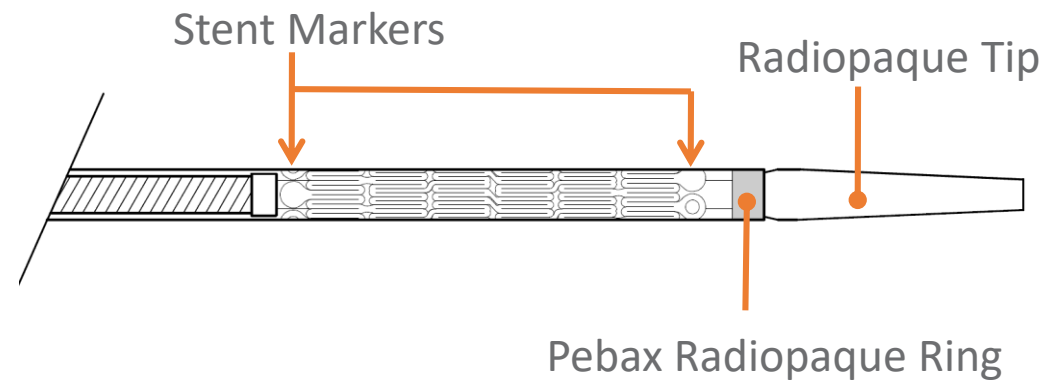
# Easy Flype & Easy HiFlype

## Delivery system – radiopacity



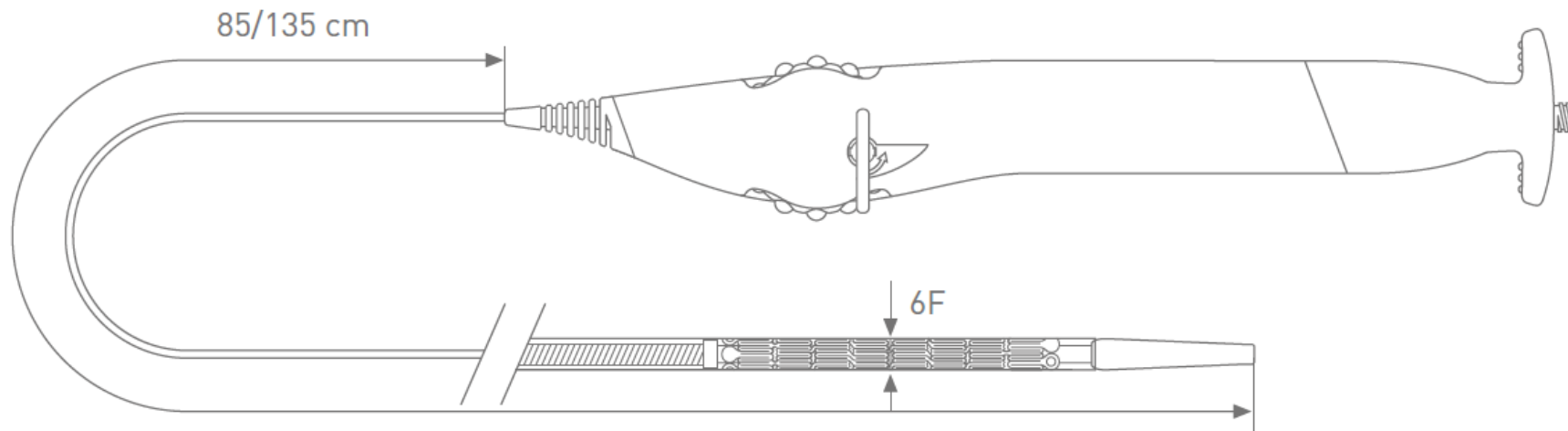
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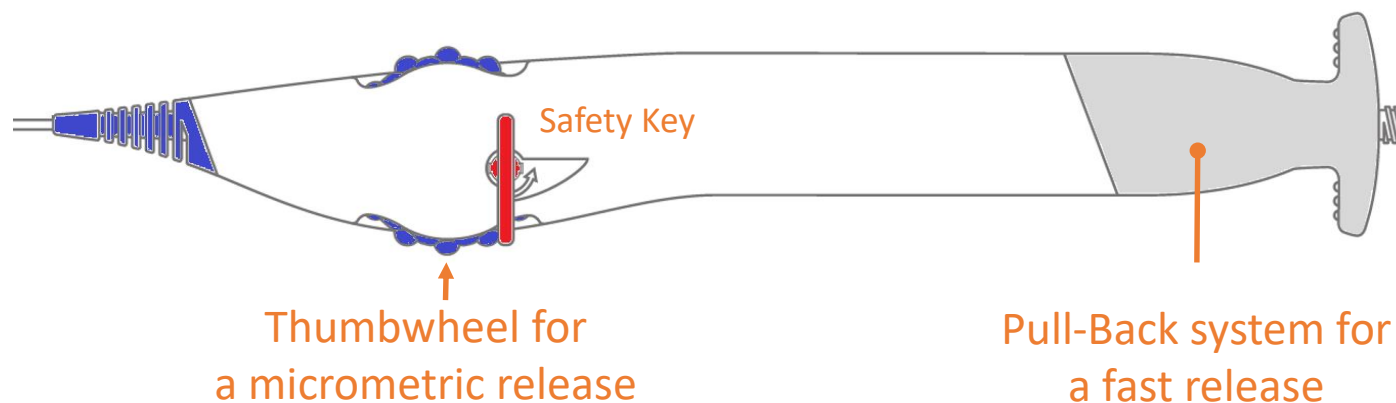


# Easy Flype & Easy HiFlype

Delivery system – single hand delivery system



Over the wire (OTW) catheter with single hand dual release system



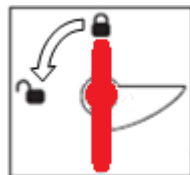
# Easy Flype & Easy HiFlype

Single hand dual delivery system: safety key

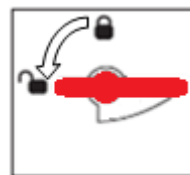


The system is locked to avoid any unintentional stent release in a wrong position.

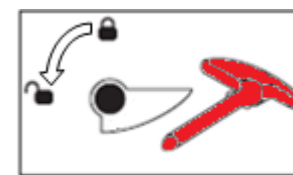
To unlock the release system: turn the safety key on the handle in the direction of the arrow (anticlockwise) to unlock it, then pull it out completely:



Locked system



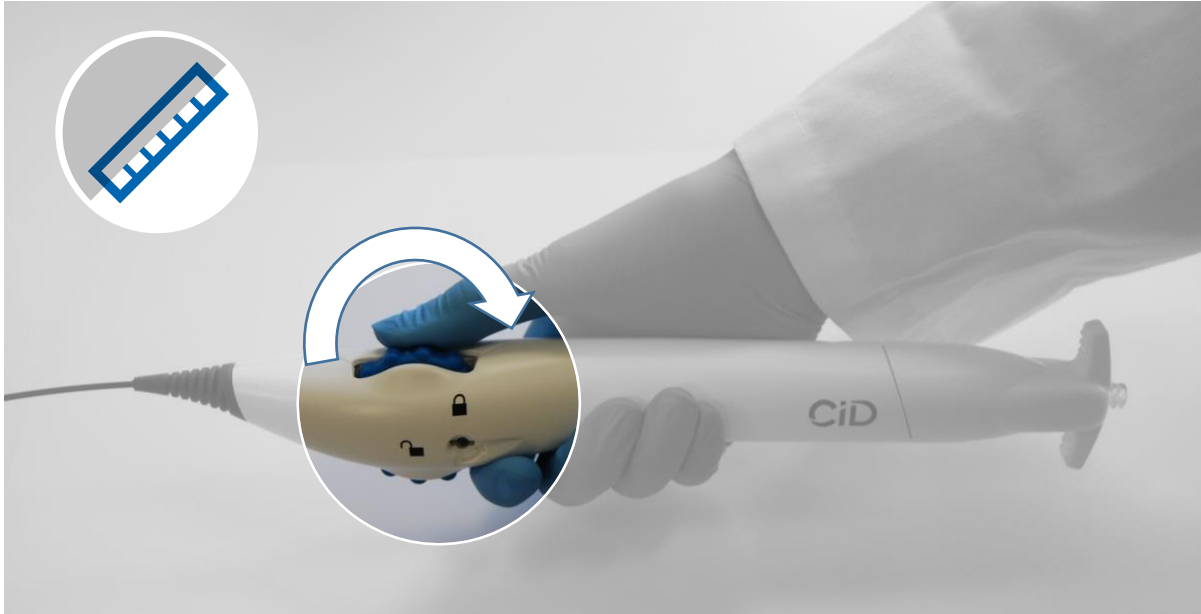
STEP 1  
Unlock the key



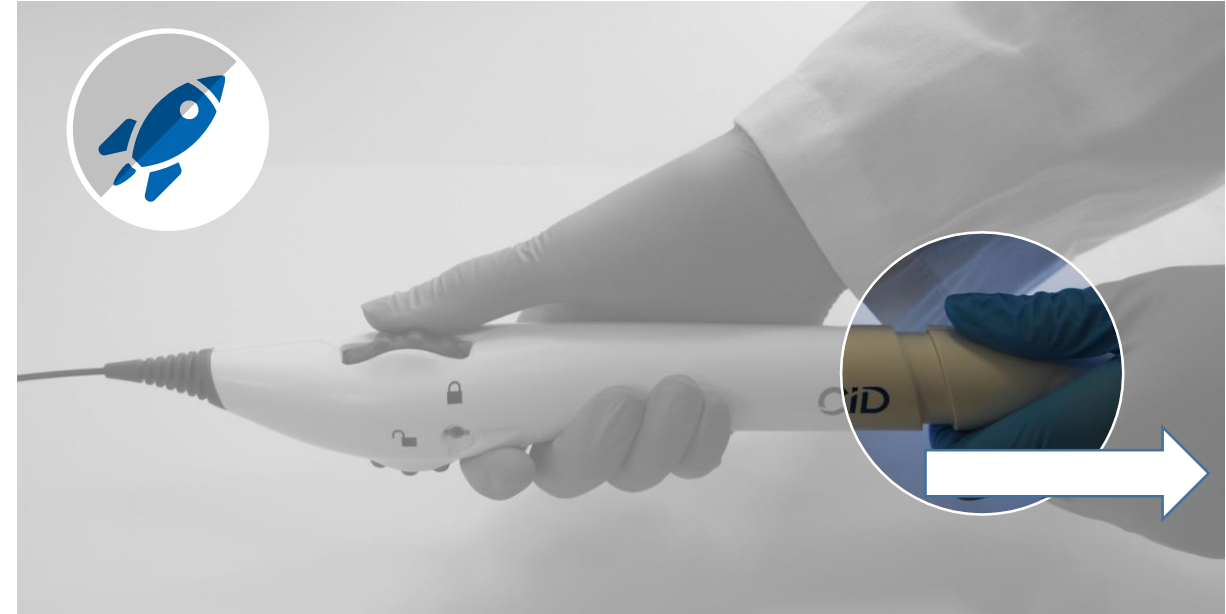
STEP 2  
Extract the Key  
READY TO RELEASE

# Easy Flype & Easy HiFlype

Single hand dual delivery system: micrometric release and fast release

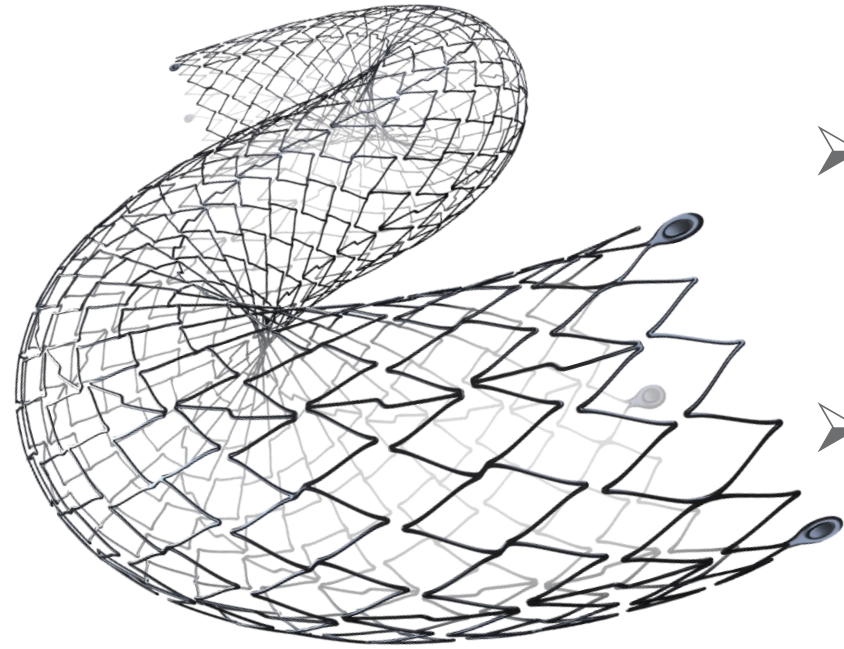


With the thumbwheel you can use just one hand and obtain a **micrometric release**! Thanks to the gear reduction 3:1, each “click” (thumbwheel movement) releases less than 1 mm stent!



Once the stent is anchored to the vessel wall, with the Easy Flype & Easy HiFlype handle, you can decide to have a **fast release** of the stent with the pull-back system (1:2 gear multiplier).

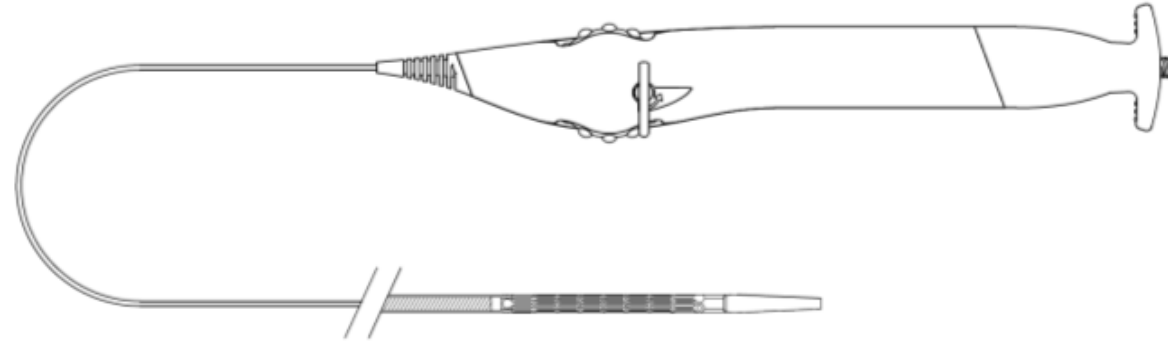
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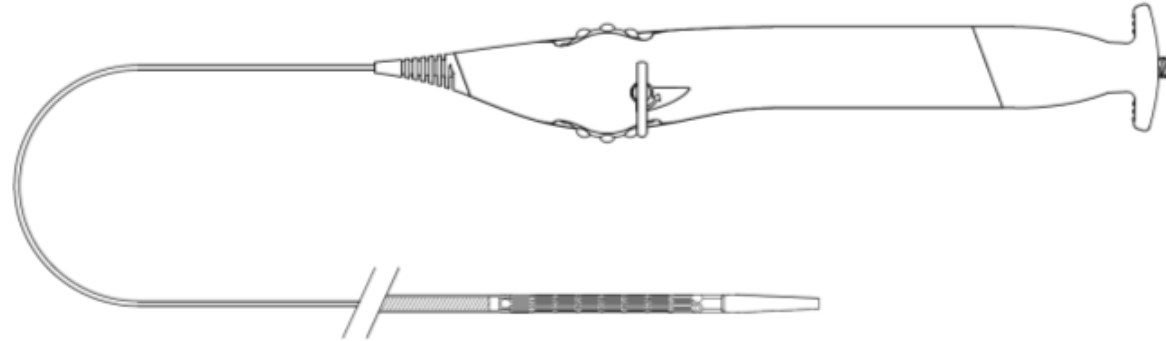


# Easy Flype Technical Specifications



PERIPHERAL STENT	
Stent Diameters:	6 - 8 mm
Stent Lengths:	20 - 150 mm
Stent material:	Nickel titanium alloy (nitinol)
Strut surface coating:	Bio Inducer Surface
6 tantalum radiopaque markers	
DEVICE SPECIFICATIONS	
Over The Wire (OTW)	
Introducer sheath compatibility:	6F
Guidewire compatibility:	0.035"
Usable Catheter Length - UCL:	85 & 135 cm

# Easy HiFlype Technical Specifications



PERIPHERAL STENT	
Stent Diameters:	9 - 12 mm
Stent Lengths:	20 - 100 mm
Stent material:	Nickel titanium alloy (nitinol)
Strut surface coating:	Bio Inducer Surface
6 tantalum radiopaque markers	
DEVICE SPECIFICATIONS	
Over The Wire (OTW)	
Introducer sheath compatibility:	6F
Guidewire compatibility:	0.035"
Usable Catheter Length - UCL:	85 & 135 cm

# Easy Flype & Easy HiFlype



## ORDER INFORMATION EASY HIFLYPE

### USABLE CATHETER LENGTH 85 CM

$\varnothing$ (mm) \ L (mm)	20	40	60	80	100
9.00	ICEF9020S	ICEF9040S	ICEF9060S	ICEF9080S	ICEF90100S
10.00	ICEF10020S	ICEF10040S	ICEF10060S	ICEF10080S	ICEF100100S
12.00		ICEF12040S	ICEF12060S	ICEF12080S	ICEF120100S

### USABLE CATHETER LENGTH 135 CM

$\varnothing$ (mm) \ L (mm)	20	40	60	80	100
9.00	ICEF9020L	ICEF9040L	ICEF9060L	ICEF9080L	ICEF90100L
10.00	ICEF10020L	ICEF10040L	ICEF10060L	ICEF10080L	ICEF100100L
12.00		ICEF12040L	ICEF12060L	ICEF12080L	ICEF120100L

# Easy Flype & Easy HiFlype

## ORDER INFORMATION EASY FLYPE

### USABLE CATHETER LENGTH 85 CM

$\varnothing$ (mm) \ L (mm)	20	40	60	80	100	120	150
6.00	ICEF6020S	ICEF6040S	ICEF6060S	ICEF6080S	ICEF60100S	ICEF60120S	ICEF60150S
7.00	ICEF7020S	ICEF7040S	ICEF7060S	ICEF7080S	ICEF70100S	ICEF70120S	ICEF70150S
8.00	ICEF8020S	ICEF8040S	ICEF8060S	ICEF8080S	ICEF80100S	ICEF80120S	ICEF80150S

### USABLE CATHETER LENGTH 135 CM

$\varnothing$ (mm) \ L (mm)	20	40	60	80	100	120	150
6.00	ICEF6020L	ICEF6040L	ICEF6060L	ICEF6080L	ICEF60100L	ICEF60120L	ICEF60150L
7.00	ICEF7020L	ICEF7040L	ICEF7060L	ICEF7080L	ICEF70100L	ICEF70120L	ICEF70150L
8.00	ICEF8020L	ICEF8040L	ICEF8060L	ICEF8080L	ICEF80100L	ICEF80120L	ICEF80150L

# Easy Flype & Easy HiFlype

Easy Flype & Easy HiFlype

CoCr St

CLINICAL Focus

System

BIS coating



# Easy Flype & Easy HiFlype

**“** The Isthmus Logic balloon expandable stents are well designed stents which offer adequate radial forces to overcome severe and calcified iliac stenosis. **”**  
*Dr. Rutger Brans*

**“** Due to the particular position at the carrefour level, and in consequence the kissing stent technique, we decided to use two Isthmus Logic devices which have platinum markers at the stent ends. **”**  
*Dr. Roberto Cancellieri*

**“** The Easy HiFlype nitinol stent appears to be a valid option that offers an adequate radial force, to maintain the lumen free of lesions, combined with a good flexibility to all forces applied. **”**  
*Dr. Eric Ducasse*

**“** We chose to use the Isthmus Logic which accelerates the rate of endothelialization and reduces thrombogenicity due to the presence of the Bio-Inducer Surface coating. **”**  
*Dr. Alberto Giammarino*

**“** Isthmus Logic balloon expandable stents offer a good scaffolding and precise positioning. **”**  
*Dr. Rytis Kaupas*

**“** Alvimedica stents were selected because of their Bio Inducer Surface coating. **”**  
*Dr. Sergei A. Piskunov*

**“** The Bio Inducer Surface coating accelerates the strut coverage, reduces the thrombogenicity, and seals against metal ions release. **”**  
*Dr. Nicola Troisi and Dr. Leonardo Ercolini*

**Clinical Focus** 2016 Edition

A selection of clinical cases and references on endovascular treatment of iliac arteries with Easy HiFlype or Isthmus Logic stent

Iliac Endovascular Treatment is nowadays considered standard of care for simpler lesions, and many clinicians prefer to treat even the most complex lesions with an initial percutaneous attempt. The aggressive use of endovascular techniques has demonstrated acceptable results in patients whose physiology may not permit open-surgery revascularization. The goal of this Alvimedica Clinical Focus is to share different clinical experiences in iliac arteries lesion treatment promoting different approaches and results.

**“** This compilation, performed by physicians to physicians, provides a very useful technical tool in the treatment of the very distal vessels. **”**

In the clinical cases described in this issue physicians used Isthmus Logic balloon expandable stent or Easy HiFlype Self Expanding stent selecting the right stent for the right lesion and the right anatomy.

*Prof. Gioacchino Coppi*

 Alvimedica

# Clinical Focus



**Clinical Focus**

A selection of clinical cases and references on endovascular treatment of Superficial Femoral Artery with Easy Flype Stent.

This booklet is a selection of interesting cases for the endovascular treatment of superficial femoral artery sharing clinical experiences in stenting with Easy Flype system. Due to the chronic nature of peripheral arterial disease and the high restenosis rate, a variety of strategies have been tried over the past several years and the clinical trials on stents clearly indicate improving outcomes in the SFA treatment. In this clinical focus the selected cases analyze the complexity of the SFA disease and promote different techniques of revascularization requiring the usage of the stent. Thus, correct and efficient endovascular techniques in those cases illustrate some key feature of Easy Flype stent, such as the right balance of radial force and flexibility especially in high-calcified lesions.

*Prof. Dirk Schenert*

This collection of case studies has also the aim to be a dedicated technical tool for endovascular treatment of lower limb vessels.

Alvimedica

The Clinical Focus has the objective to present how challenging cases have been treated by recognized European KOLs with the implantation of Easy Flype and Easy HiFlype stents in order to show the benefits this device can bring to patients.

# Clinical Focus

The best feedbacks we can have about Isthmus Logic comes from the users:



*Dr. Med. Hans  
Krankenberg*

Easy Flype stent combined good flexibility and adequate radial force in calcified lesions having also the benefit of a pure carbon coating for a better biocompatibility.

Easy Flype stent presented a good balance between flexibility and radial force in calcified lesions adding the benefit of a pure carbon coating for a better biocompatibility.



*Dr. Enrico  
Maria Marone*

# Clinical Focus



The Easy Hiflype nitinol stent appears to be a valid option that offers an adequate radial force, to maintain the lumen free of lesions, combined with a good flexibility to all forces applied. In addition specific carbon coating may improve biocompatibility and avoid recurrence of restenosis or acute thrombosis during follow-up.

The implantation of an Easy HiFlype Nitinol stent resulted in a favorable clinical and economic result. Easy HiFlype stent demonstrates an adequate radial force balanced with a good flexibility plus the unique benefit of a pure carbon coating to improve biocompatibility



