iVolution: product line extension
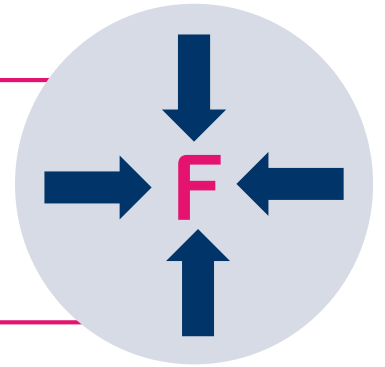
Jan Van Overbeke

iVascular®
therapies for living

The therapy: indication

Treatment of de novo or restenotic atherosclerotic lesions in peripheral arteries located under the aortic arch with a nominal diameter from 4.5 to 9.5 mm

Key features

Use in exposed arteries – iliac, superficial femoral artery (SFA) and popliteal artery

F

FLEXIBILITY

RADIAL FORCE

Stent technology

✔ **Open cell** design with **short cell length** to feature:
  – Outstanding flexibility
  – High adaptability to vessel
  – No flaking (no fish scaling effect)
  – Anti-kinking

✔ **Closed cell** in both ends for maximum control of stent release (no popping)

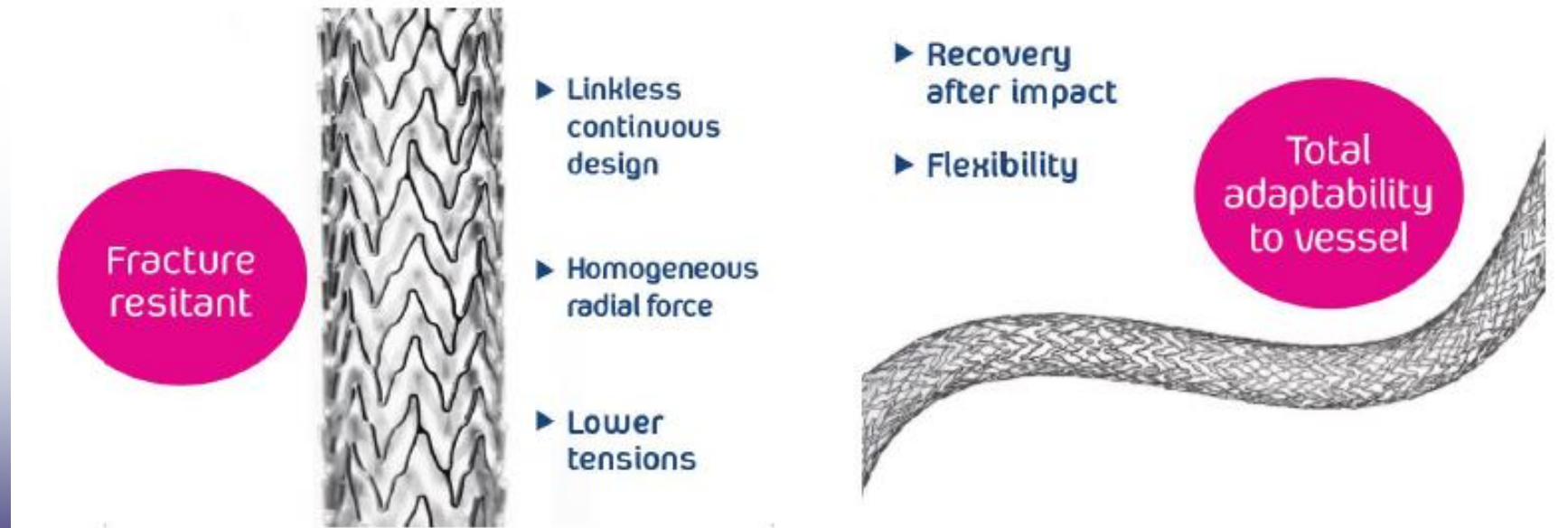✔ **4 radiopaque markers** at each end of the stent

▶ Open short-cell design

No flaking

Anti-kinking
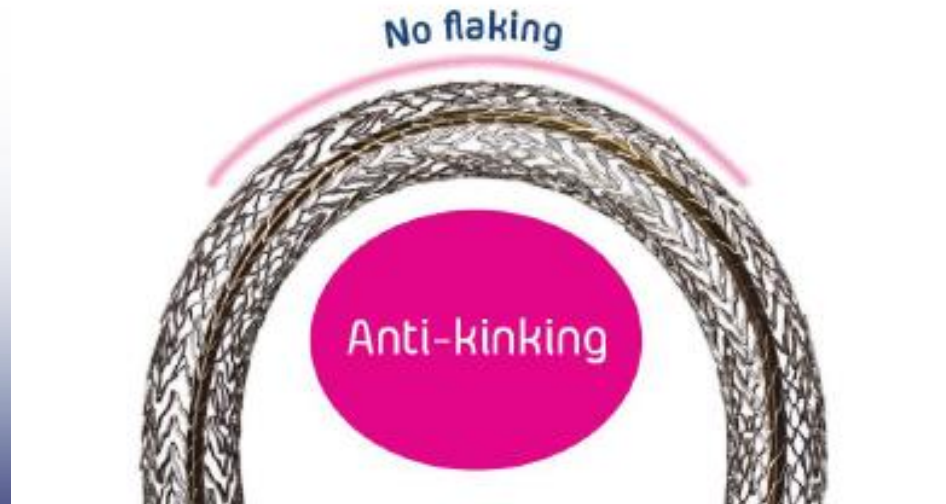
▶ 4 RO markers in either end of the stent

High visibility

scular.global

Stent technology

✓ **Continuous design.** Links are extensions of struts for more homogeneous distribution of stress and less risk of fracture
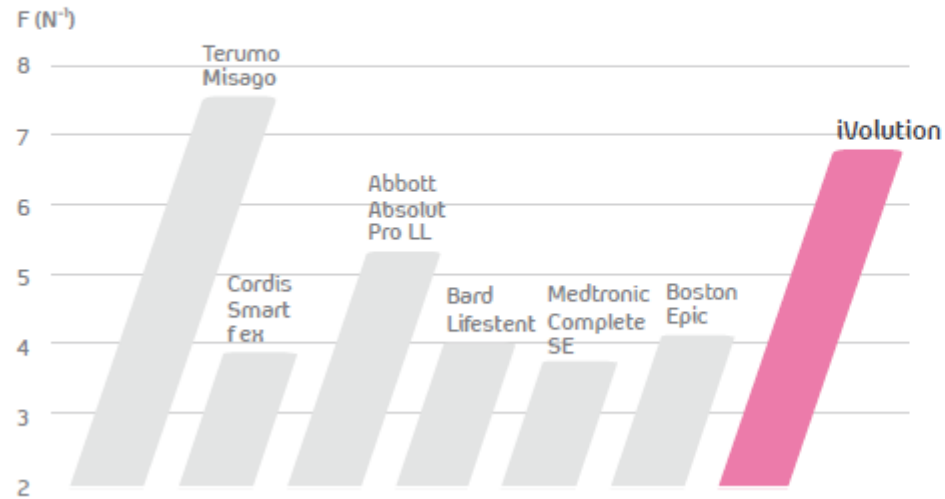
✓ High arterial wall coverage
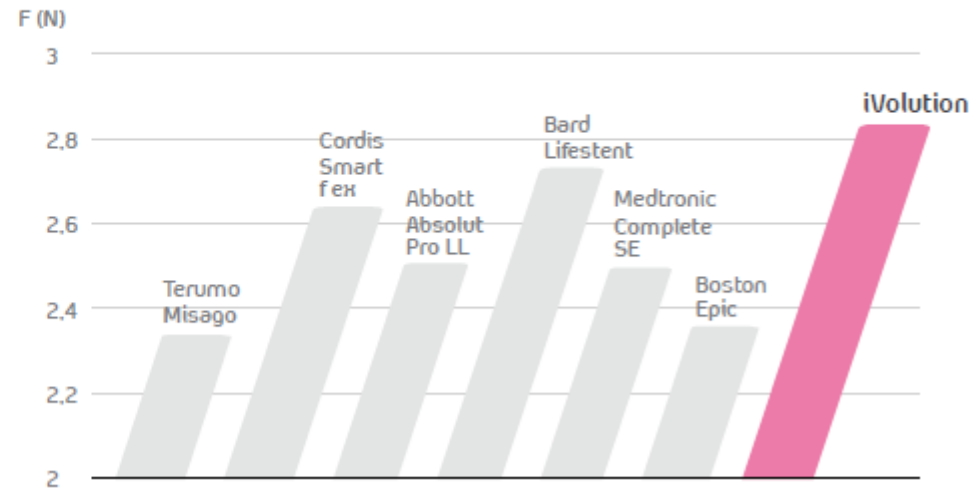✓ Perfect recovery after impact
✓ Best-in-class radial force

Fracture resitant

▶ Linkless continuous design

▶ Homogeneous radial force

▶ Lower tensions

▶ Recovery after impact

▶ Flexibility

Total adaptability to vessel

vascular.global

Stent technology

Balance between adaptability and arterial support

Delivery system

Delivery system

Ergonomic handle

Scroll: Precision

Pull-back: quickness

Dual delivery system

iVolution: Self-expanding nitinol stent system
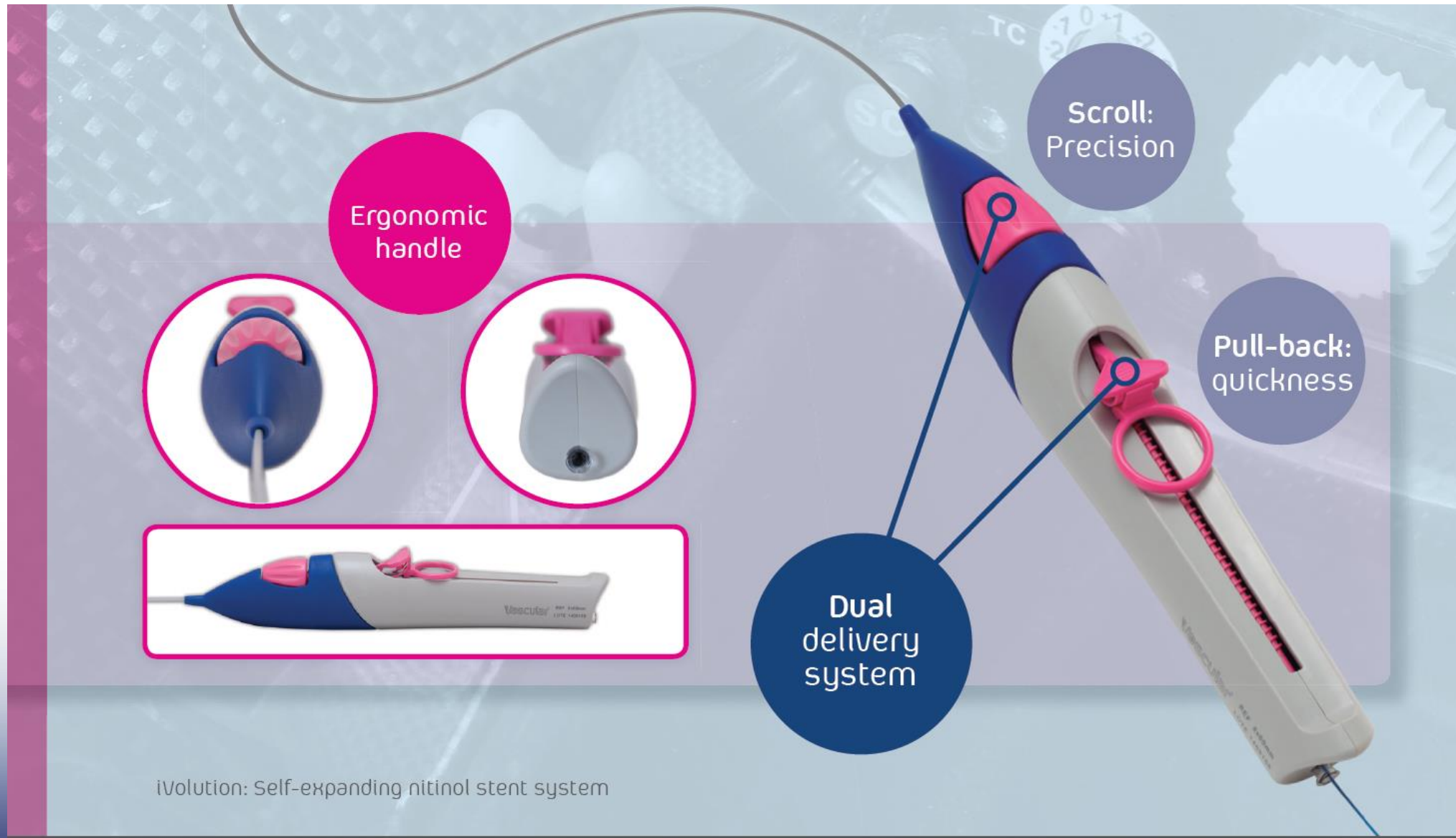
Delivery system

✓ **Triple sheath** design for a comfortable and safer delivery

✓ **High visibility**
  - **2 radiopaque markers** on the catheter to limit the stent
  - **1 extra marker** on the **moving sheath** for continuous visibility of the delivery

✓ **PTFE- coated retrievable sheath** for a smooth delivery

✓ **Non-traumatic soft tip**

✓ **Fully compatible with 6F introducer** for all stent sizes

therapies for living
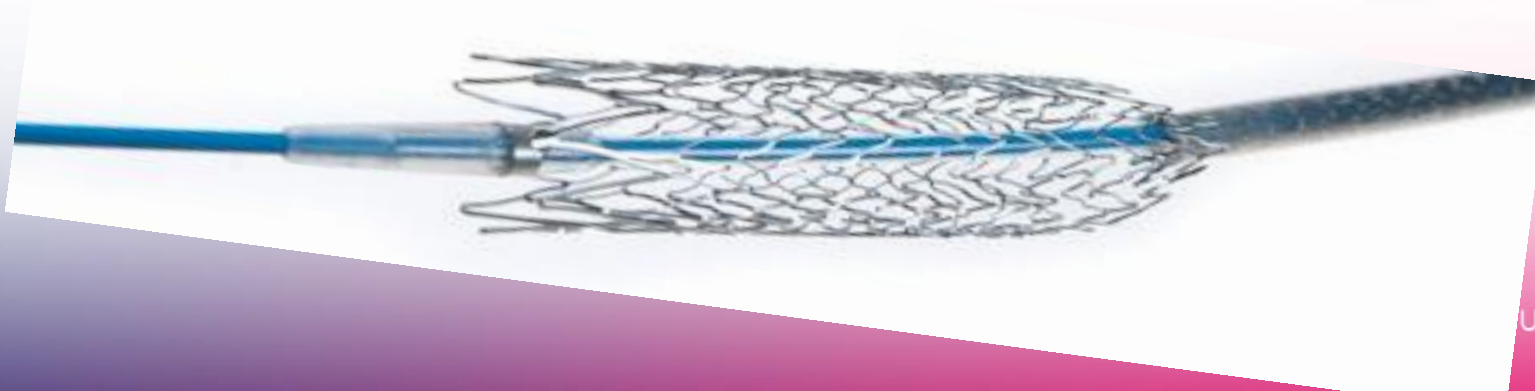
General features

- Nitinol stent
- Triple sheath catheter
- Catheter length: 80 and 140 cm
- Compatible with 6F introducers
- Compatible with 8F guiding catheters
- Compatible with 0.035'' guidewires

- 4 RO markers in each end of the stent
- 2 RO markers in the catheter
- 2 handles sizes:
  - Small (L: 40 mm – 100 mm)
 - Large (L: > 100 mm)

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Key to success: deployment tips & tricks

Keep control while delivering

1. Choose the correct length of the delivery device, according to the situation of the lesion

2. Introduce the triple sheath into the hemostasis valve of the introducer

3. Keep the system stretched (tensed)

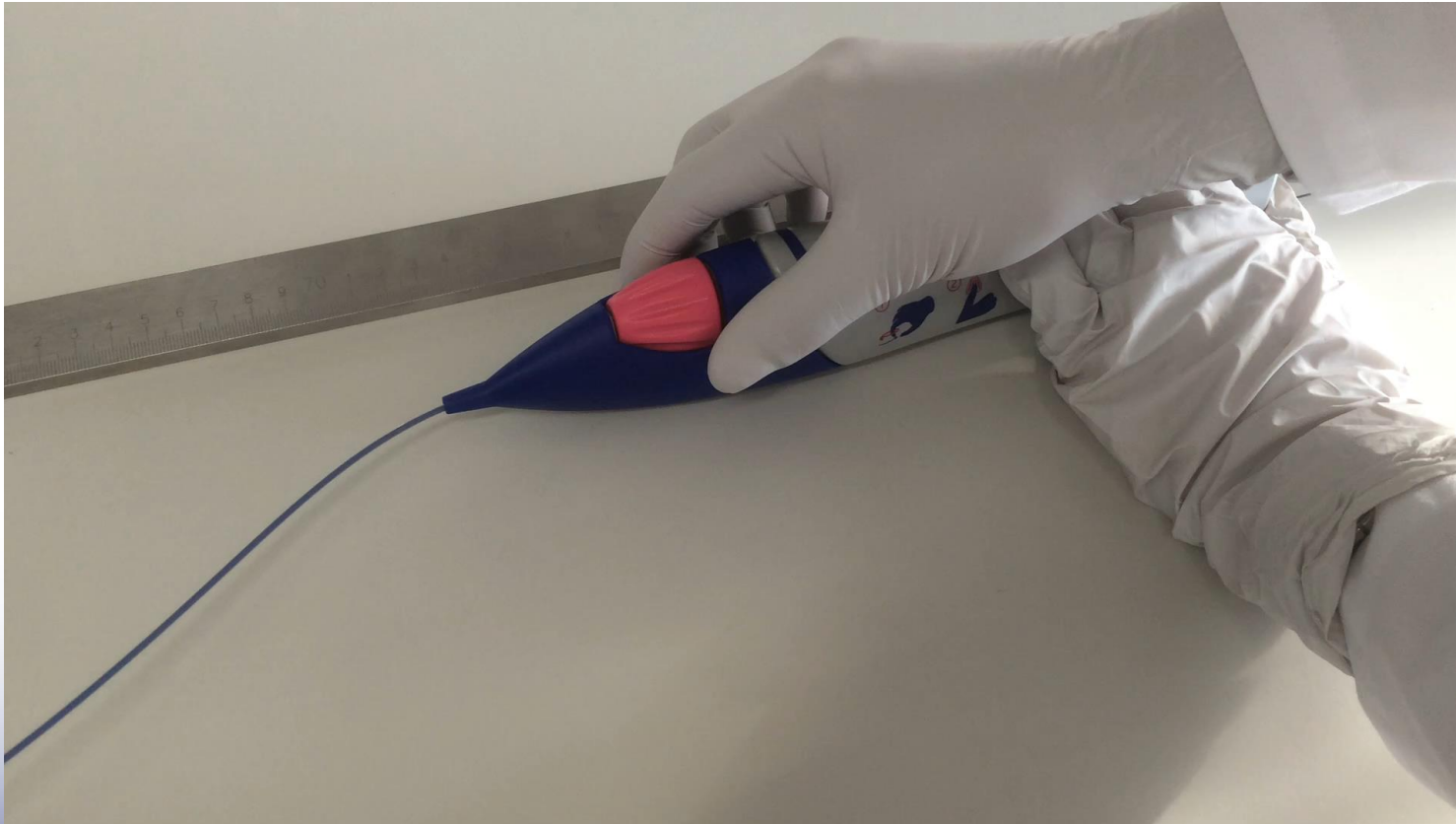4. Try not to move the handle while delivering

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AVOID SHORTENING ON EXPANSION

Evaluate the different ways for delivering de stent
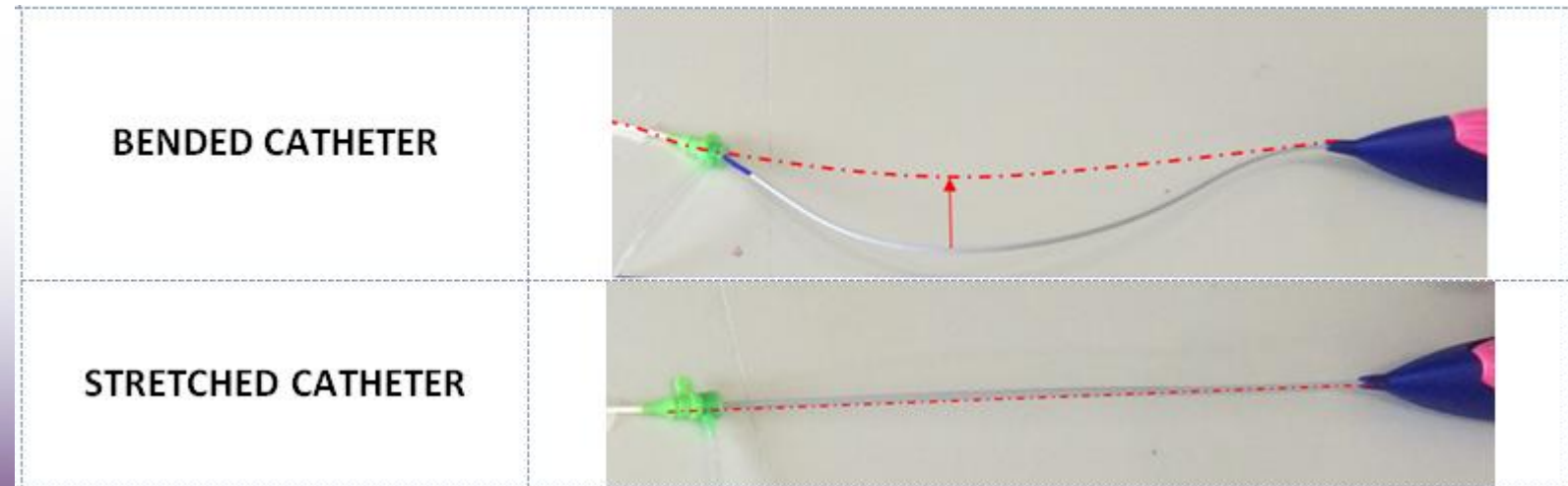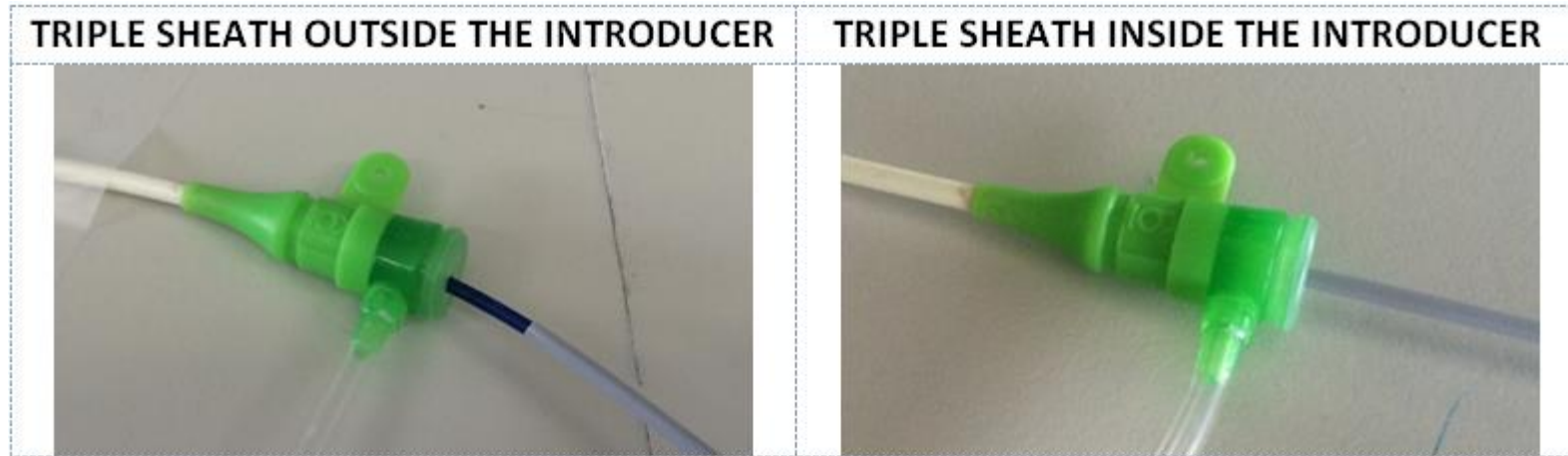
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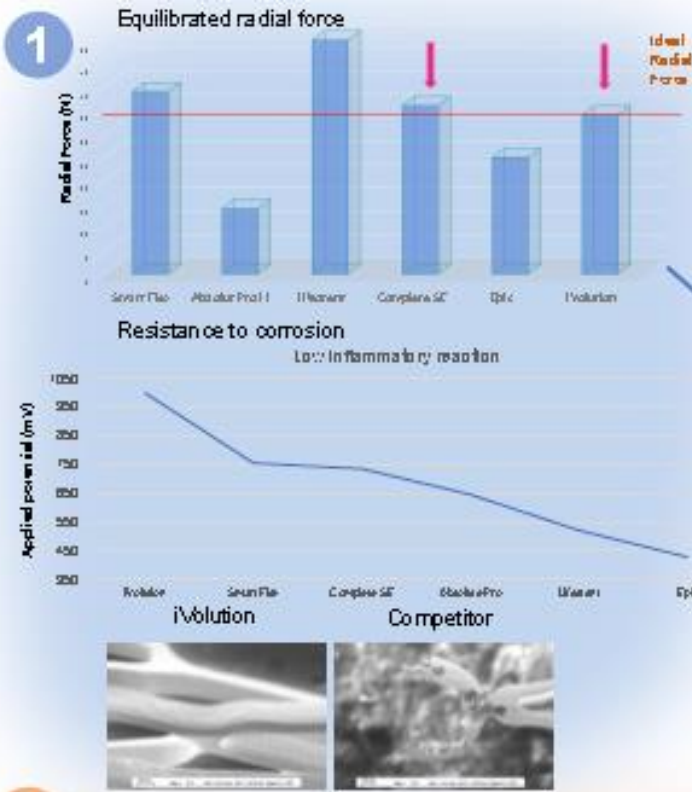## TEST DEMO

- Triple sheath outside the introducer / system bended

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TEST DEMO

- Triple sheath inside the introducer / system straight

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New manufacturing process and stent design are key elements to improve clinical outcome:
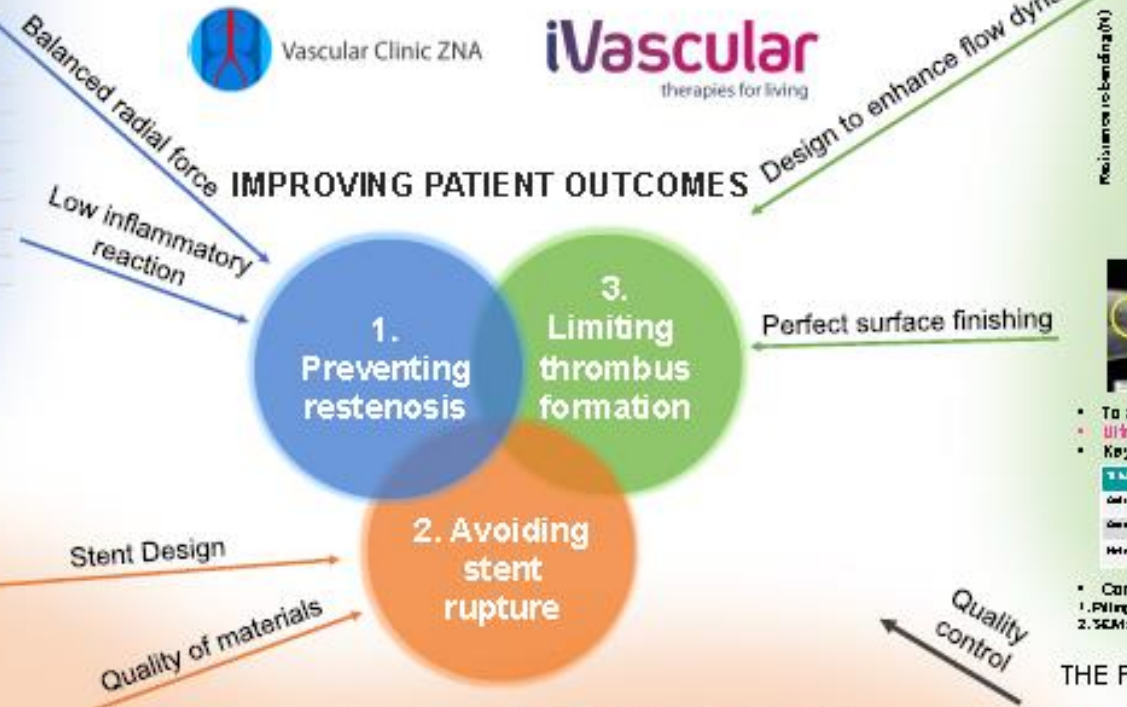
The iVascular SX stent example

P.Goverde MD, K. Lauwers MD, L. Helsloot MD, K.Taeymans MD, P.Verbruggen MD (Vascular Clinic ZNA, Antwerp, Belgium)
R.Sun, R.Prince (Paris Institute of Technology, Paris, France)

Vascular Clinic ZNA
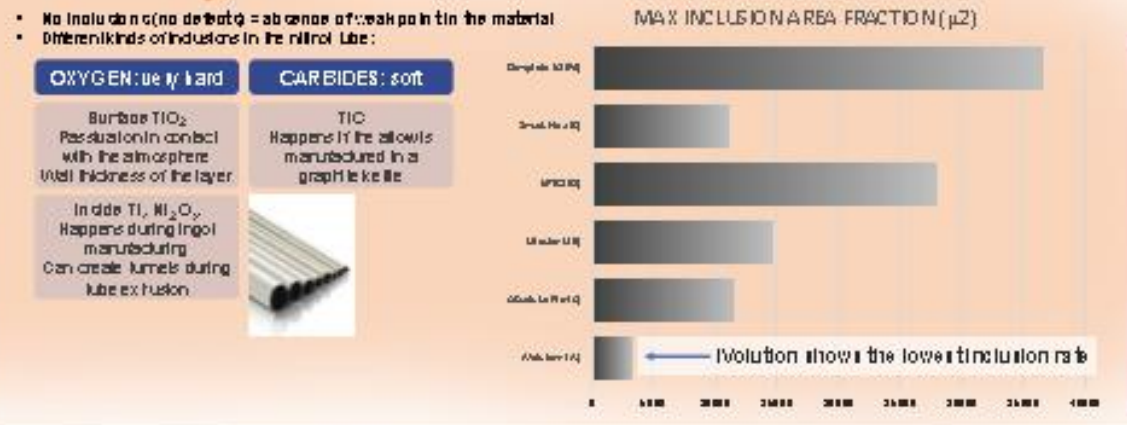
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IMPROVING PATIENT OUTCOMES

Balanced radial force

Low inflammatory reaction

Design to enhance flow dynamics

Perfect surface finishing

Stent Design

Quality of materials

Quality control

1. Preventing restenosis

3. Limiting thrombus formation

2. Avoiding stent rupture

1

Equilibrated radial force

Radial Force (N)

Ideal Radial Force

Serum Flex · Absolute Pro II · Ultrasmart · Complete SE · Epic · iVolution

Resistance to corrosion

Low inflammatory reaction

Applied potential (mV)

Protubo · Serum Flex · Complete SE · Absolute Pro · Ultrasmart · Epic

iVolution   Competitor

2

Best resistance to fracture = stent design without bridges nor direct connections (J.Endovascular Ther 2010-Muller-Huisbeck Comparison 2nd generation stents for application in SFA)
- iVolution stent doesn't have bridges
- Continuous design
- Open cell design with short cell length

2 types of Fatigue Tests to prove design concept

Test case scenario:
- Stent d 8 mm
1. 10 samples tested simultaneously
2. Stent is implanted into a mock vessel with inner diameter of 7.5mm
3. Controlled pressure is induced to the artery to simulate deformation
4. 400 M cycles are applied
- Results:
1. After the test, no damage nor fractures were observed
2. iVascular stent radial durability = 400 million of cycles

Fracture Risk

Safety Zone

- No inclusions (no defects) = absence of weak point in the material
- Different kinds of inclusions in the nitinol tube:

OXYGEN: very hard

Surface TiO₂
Passivation in contact with the atmosphere
Wall thickness of the layer

Inside Ti, Ni₂O₃
Happens during ingot manufacturing
Can create tunnels during tube extrusion

CARBIDES: soft

TiC
Happens if the allow is manufactured in a graphite kettle

MAX INCLUSION AREA FRACTION (µ2)

Complete (CM)
Serum Flex (V)
Epic (CG)
Ultrasmart (M)
Absolute Pro (V)
Absolute (V) — iVolution shows the lowest inclusion rate

3

Flexibility to adapt to the anatomy of the treated artery without compromising the function of the implant

Competitor   iVolution

Ability to adapt to the curvatures

Competitor   iVolution

Resistance to bending (N)

Serum Flex · Absolute Pro II · Ultrasmart · Complete SE · Epic · iVolution

Competitor   iVolution

- To avoid corrosion and Nickel release
- Ultra thin layer of TiO₂ on stent surface after electro polishing
- Key: adequate thickness of TiO₂ or reverse effects

- Corrosion analysis to test the passivation layer (to avoid corrosion)
1. Pitting corrosion test conducted following the ASTM F 2129 to evaluate the corrosion resistance of a stent.
2. SEM analysis to reveal the weak points in corrosion through images

4

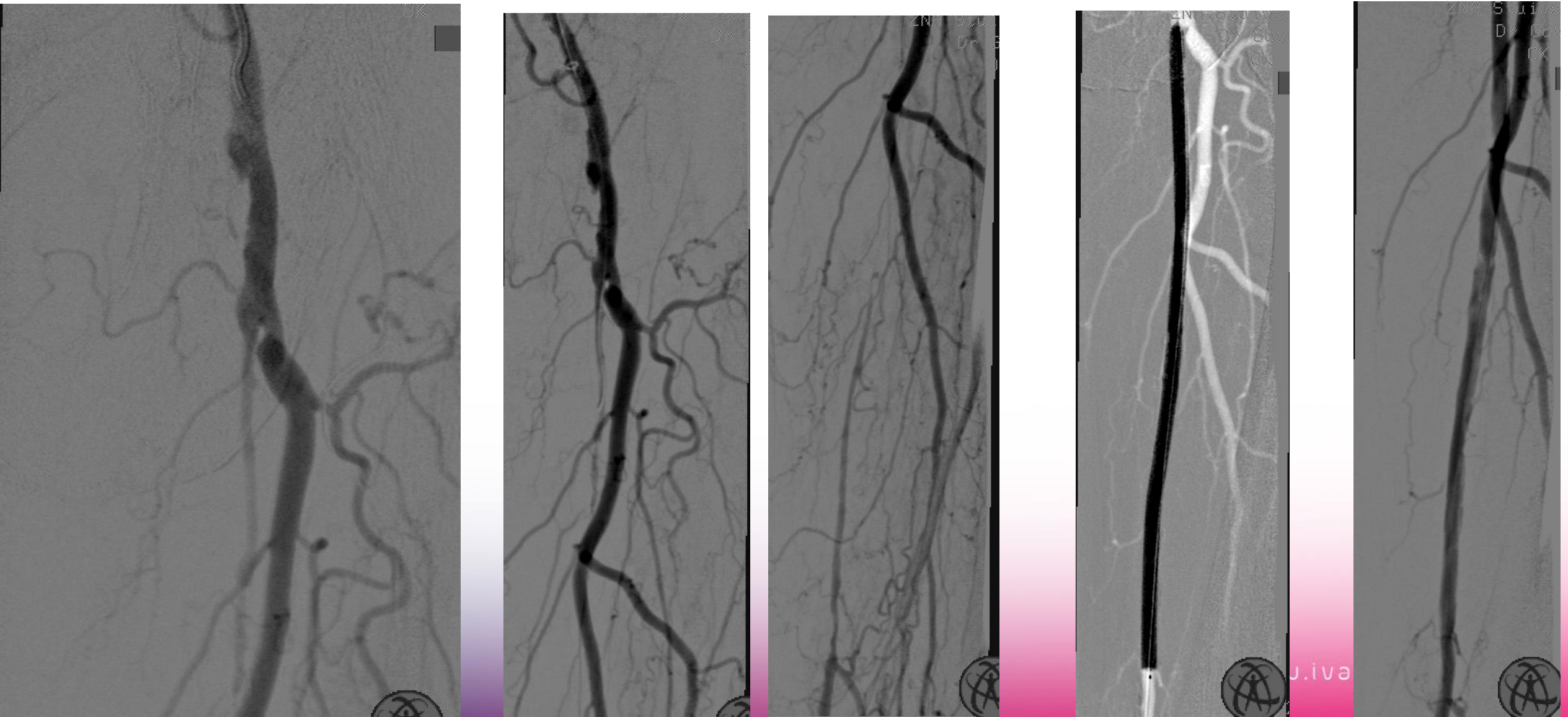**THE FIRST COMPANY TO CONTROL ALL STENT UNITS**

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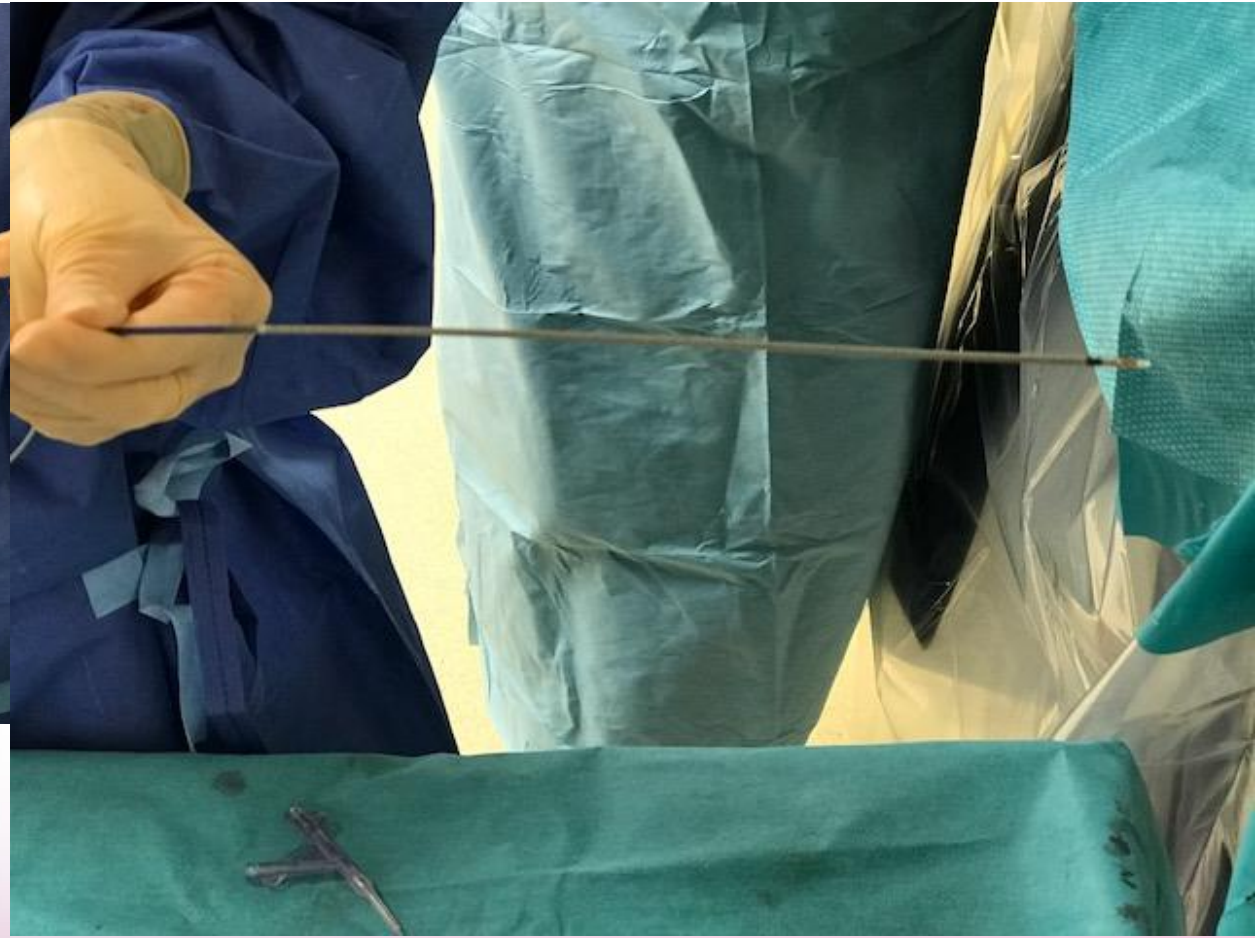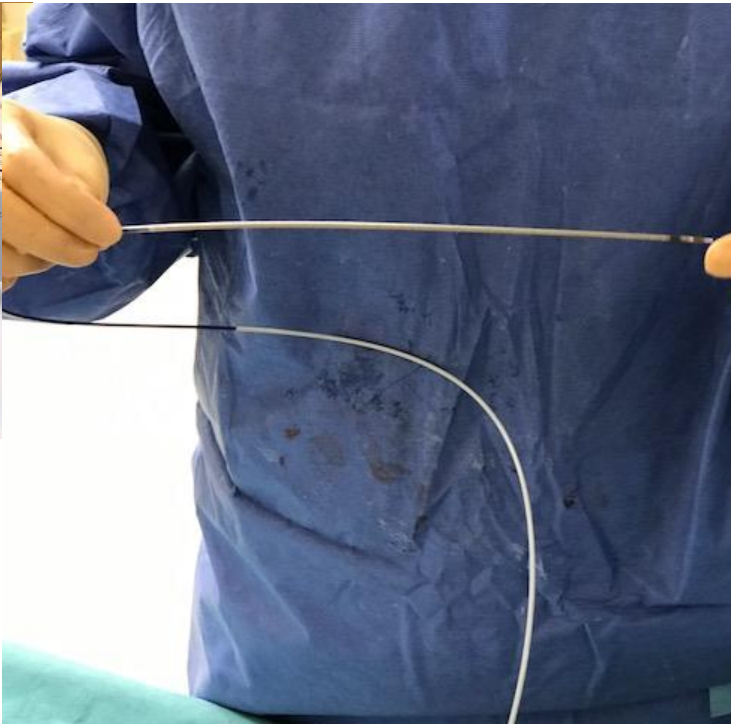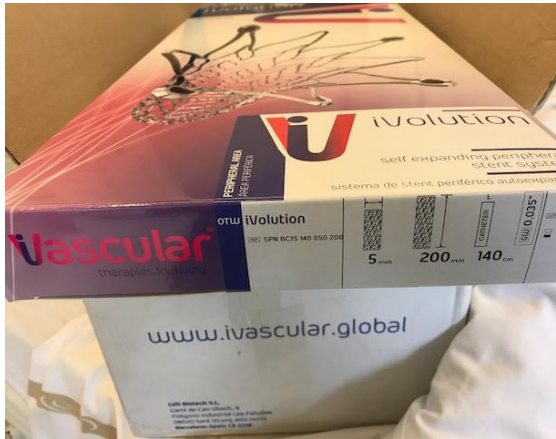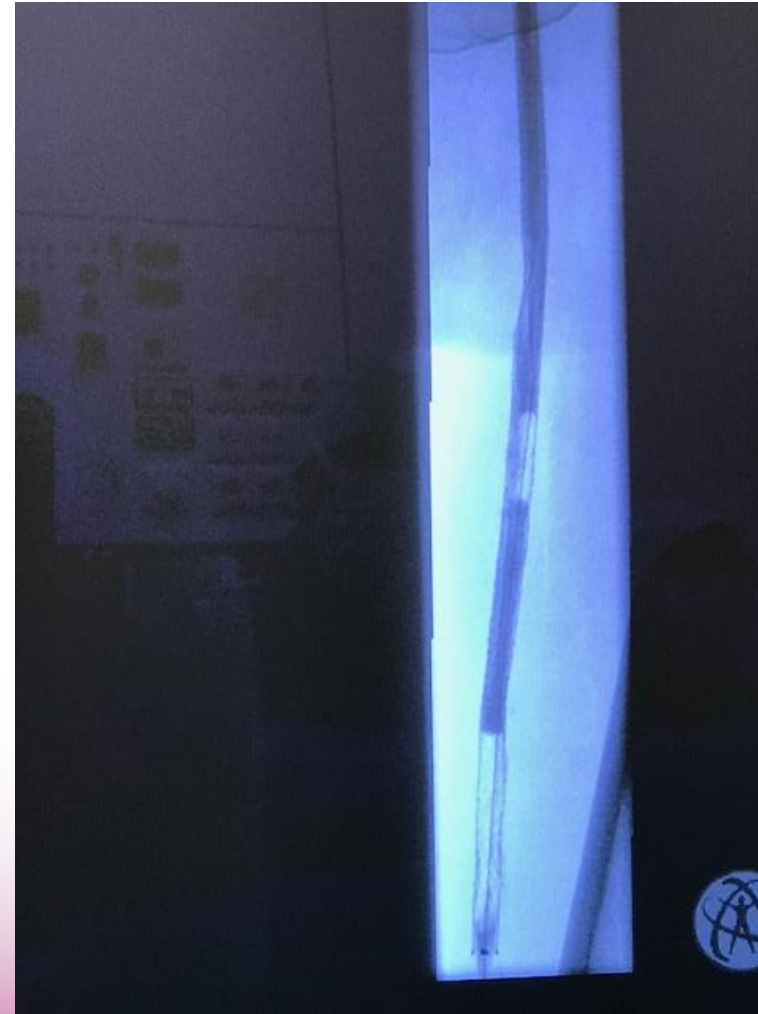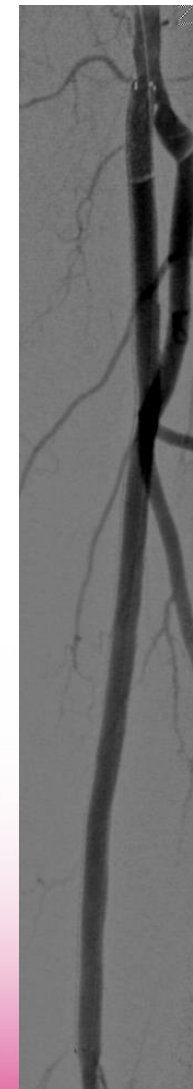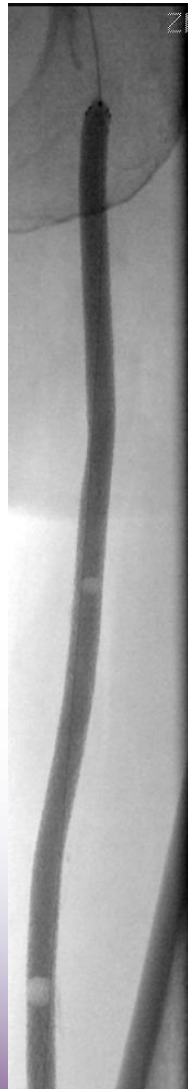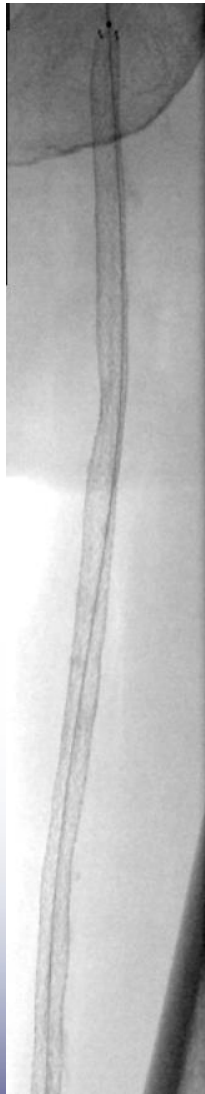# iVolution 200mm

Feedback from the field

Occlusion proximal & mid left SFA : Luminor & Ivolution 200mm

Occlusion proximal & mid left SFA : Luminor & Ivolution 200mm

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Occlusion proximal & mid left SFA : Luminor & Ivolution 200mm

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Summary

		Flexibility	Resistance to bending	Artery straightening	Resistance to impact	Radial force	Global punctuation
iVascular	iVolution	6	6	7	7	7	33
TERUMO	Misago	7	7	7	1	3	25
Cordis	Smart Flex	2	1	3	5	4	15
Abbott	Absolute Pro	5	4	5	4	1	19
BARD	Lifestent	3	5	5	6	2	21
Medtronic	Complete	1	3	3	3	6	16
Boston Scientific	Epic	4	2	1	2	5	14

Competition

- Everflex (MDT):   200mm (6&7mm diameter)

- Life stent solo (Bard):   200mm (6&7mm diameter)

- Sinus superflex (Optimed):   180mm (6&7 mm diameter)

- Supera (ABT):   200mm (5&6mm diameter)

- Misago stent (Terumo) :   recalled from the market

- Epic (BSC) :   120mm max length

Feedback Dr Goverde

The iVolution 200 mm :

"a very nice extension of the iVolution portfolio with a reliable delivery device that can guarantee you an very accurate placement without the risk of elongation"

"Together with the excellent characteristics of the existing iVolution stents makes it a "need to have on the shelf" "