New manufacturing process and stent design are key elements to improve clinical outcome:

the iVascular IVolution stent example

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Diclosure

Speaker's name: Peter Goverde

- **I have the following** potential conflicts of interest to report:
  - **Consulting**:

Abbott Vascular; Angioslide; Atrium Maquet Getinge group; Bard Peripheral Vascular; Cardionovum; Cordis Cardinal Health; IMDS; Ivascular; Stille; Veyran; Ziehm Imaging

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Material or Metal defects

Material or metal fatigue

Fracture

Dammage

Disaster

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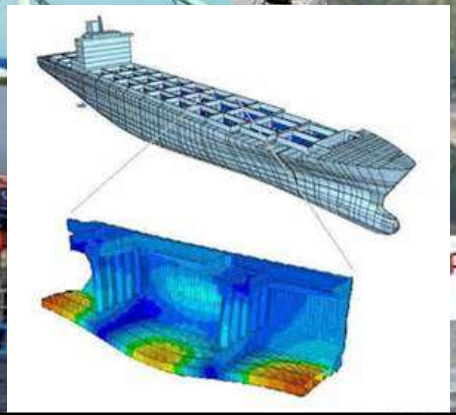

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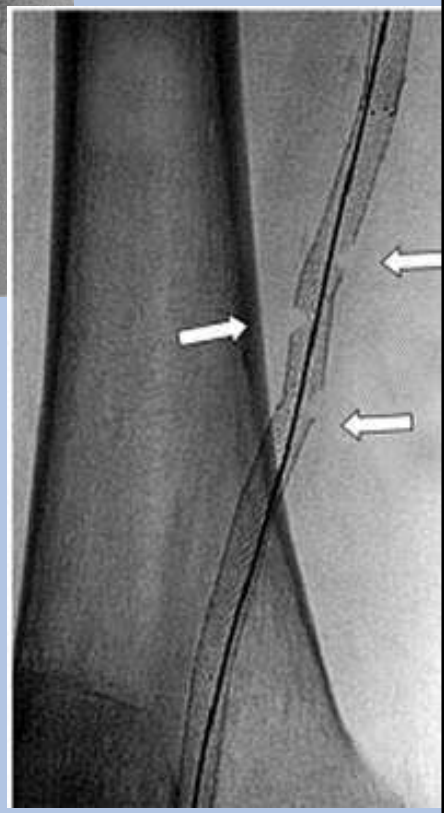
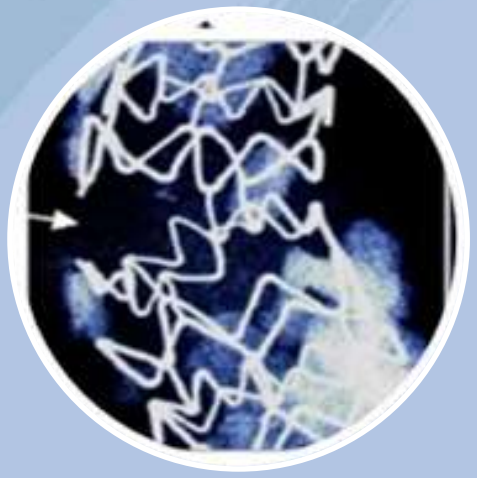
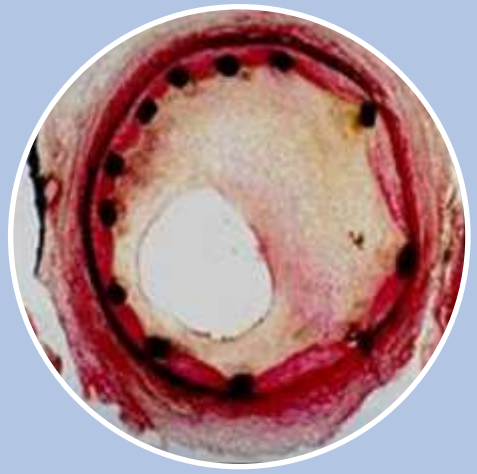


SX stent: what are the potential clinical issues?



STENT FRACTURE

THROMBUS



RESTENOSIS

IMPROVING STENT OUTCOMES

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1. Preventing restenosis

3. Limiting thrombus formation

2. Avoiding stent rupture

Can the stent production proces be an influencing factor
And can this be optimised ?

4. OPTIMAL POST PRODUCTION CONTROL

The iVascular technical solutions

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Low
1. Inflammatory reaction

- A) Radial Force
- B) Surface treatment→ passivation in order to avoid corrosion

2. Stent Fracture

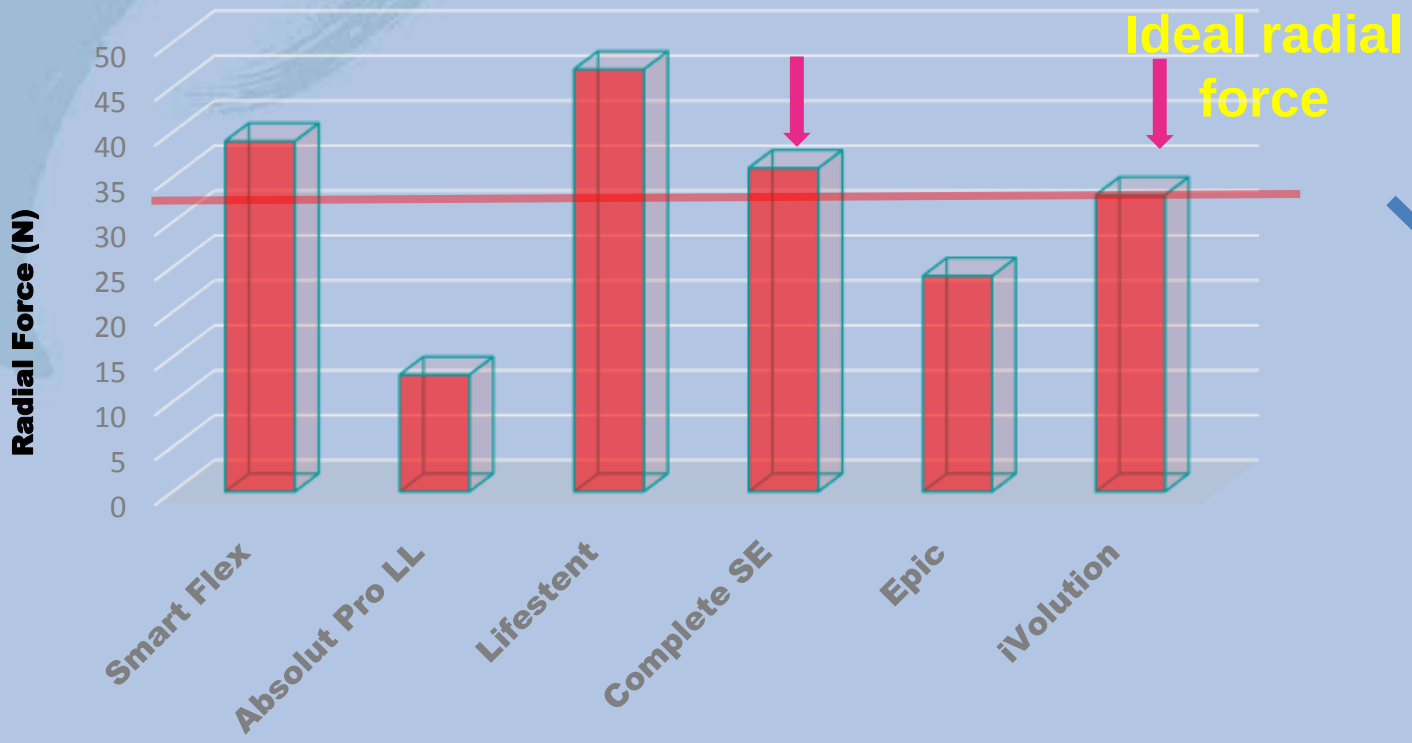
- A) The importance of stent design
- B) No inclusion (no defect) → no material weak point

Smooth
3. endothelialization to prevent thrombus

- A) Stent design to enhance blood flow hemodynamics
- B) Perfect surface finishing→ electro polishing

KEY POINT 1: Equilibrated radial force

- To maintain the artery open
- **Without applying high permanent stress on artery wall**



1. Preventing restenosis

KEY POINT 2: Surface treatment = passivation

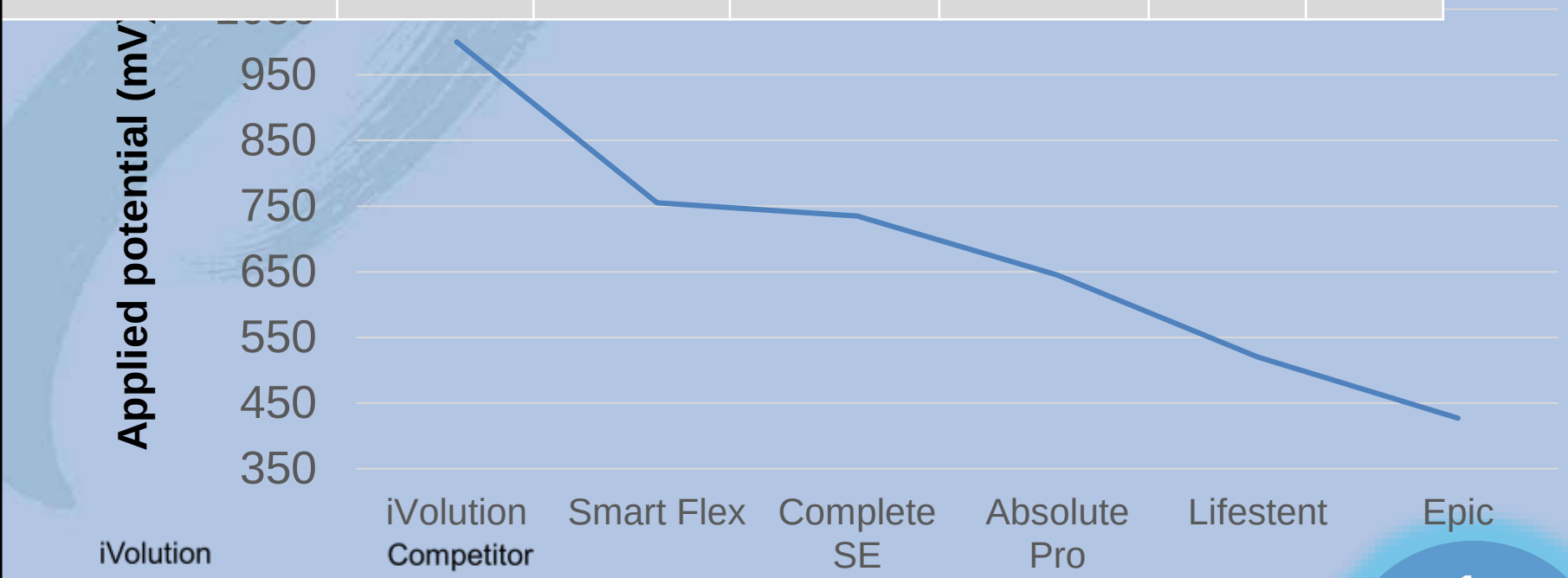
- To avoid corrosion and Nickel release
- Ultra thin layer of TiO2 on stent Surface after electro polishing
- Key: adequate thickness of TiO2, or reverse effects

Thickness (nm)	>3500	420	130	5
Cracks	Very high	Medium	Medium	No
Corrosion resistance	Very low	High	Medium	Very high
Nickel on surface	Yes, many	Yes	Yes	No

Best option according to FDA conducted studies

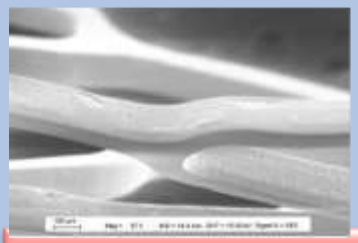
- Corrosion analysis to test the passivation layer (to avoid corrosion)
  1. Pitting corrosion test: conducted following the ASTM F2129 to evaluate the corrosion resistance of a stent
  2. SEM analysis: to reveal the weak points in corrosion through images

	iVolution	Smart Flex	Complete SE	Absolout Pro	Lifestent	Epic
Applied potential (mV)	>1000	755	735	645	520	427
Remarks	No break	Break	Break	Break	Break	Break



iVolution

Competitor



Lowering inflammatory reaction

1. Preventing restenosis

2A. the importance of stent design

Best resistance to fracture = stent design without bridges nor direct connections (J.Endovascular Ther2010 – Muller-Hulsbeck Comparison 2nd generation stents for application in SFA)

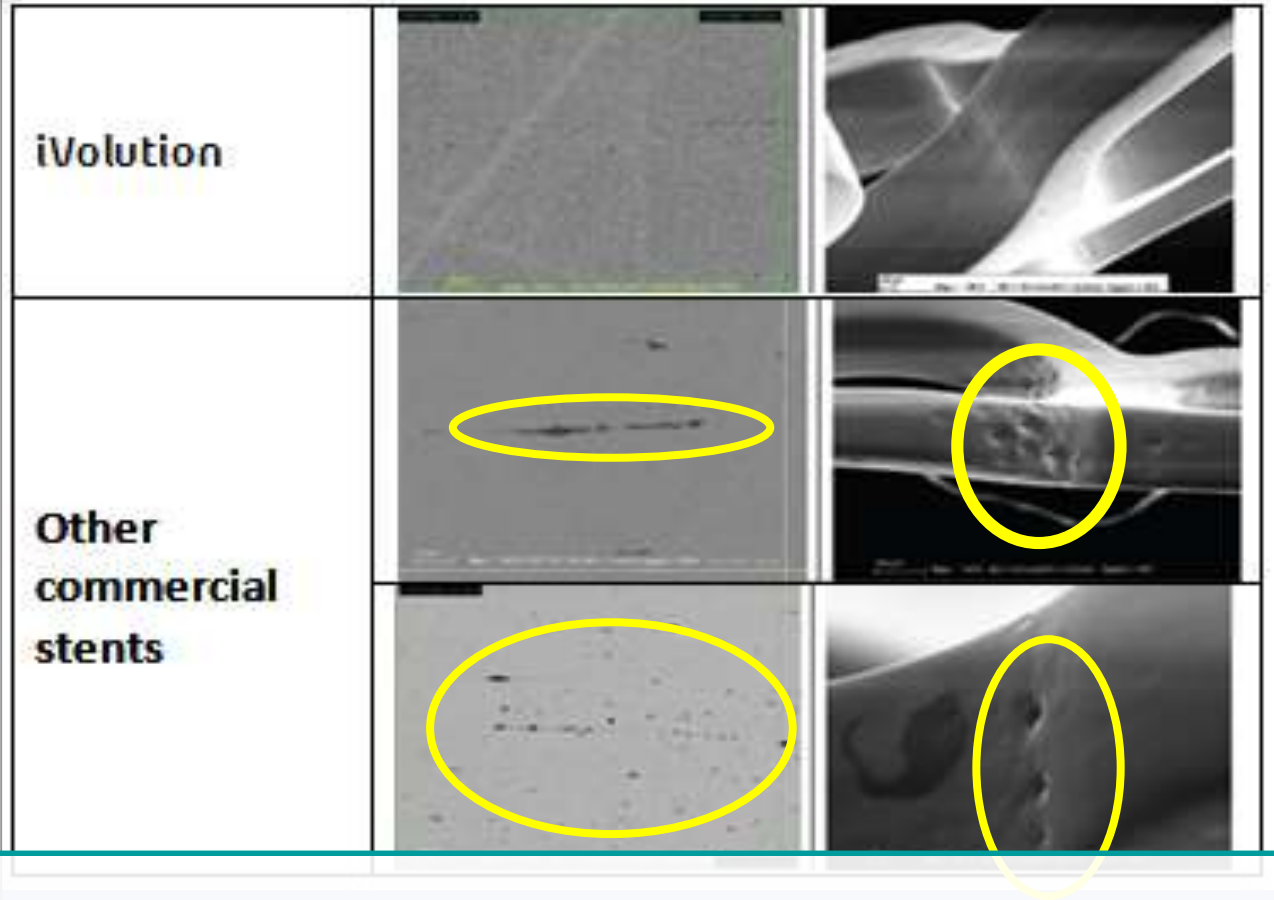
- iVolution stent doesn't have bridges
- Continuous design
- Open cell design with short cell length

2B. Optimal quality of material

- **No inclusions (no defects) = absence of weak point in the material**
- There can be different kinds of inclusions in the nitinol tube:

OXYGEN: very hard	**CARBIDES: soft**
Surface TiO_2 **Passivation in contact with the atmosphere** **Wall thickness of the layer**	**TiC** **Happens if the alloy is manufactured in a graphite kettle**
Inside $Ti_4Ni_2O_x$ **Happens during ingot manufacturing** **Can create tunnels during tube extrusion**	
> Decreased resistance to fatigue, corrosion and ductility	**> Fractures on the line of the inclusion**

No inclusions (no defects)



The **absence of inclusions in the tube** of the final stent are key to ensure the quality of the stents and **to avoid the risk of fractures**

2B. Optimal quality of material

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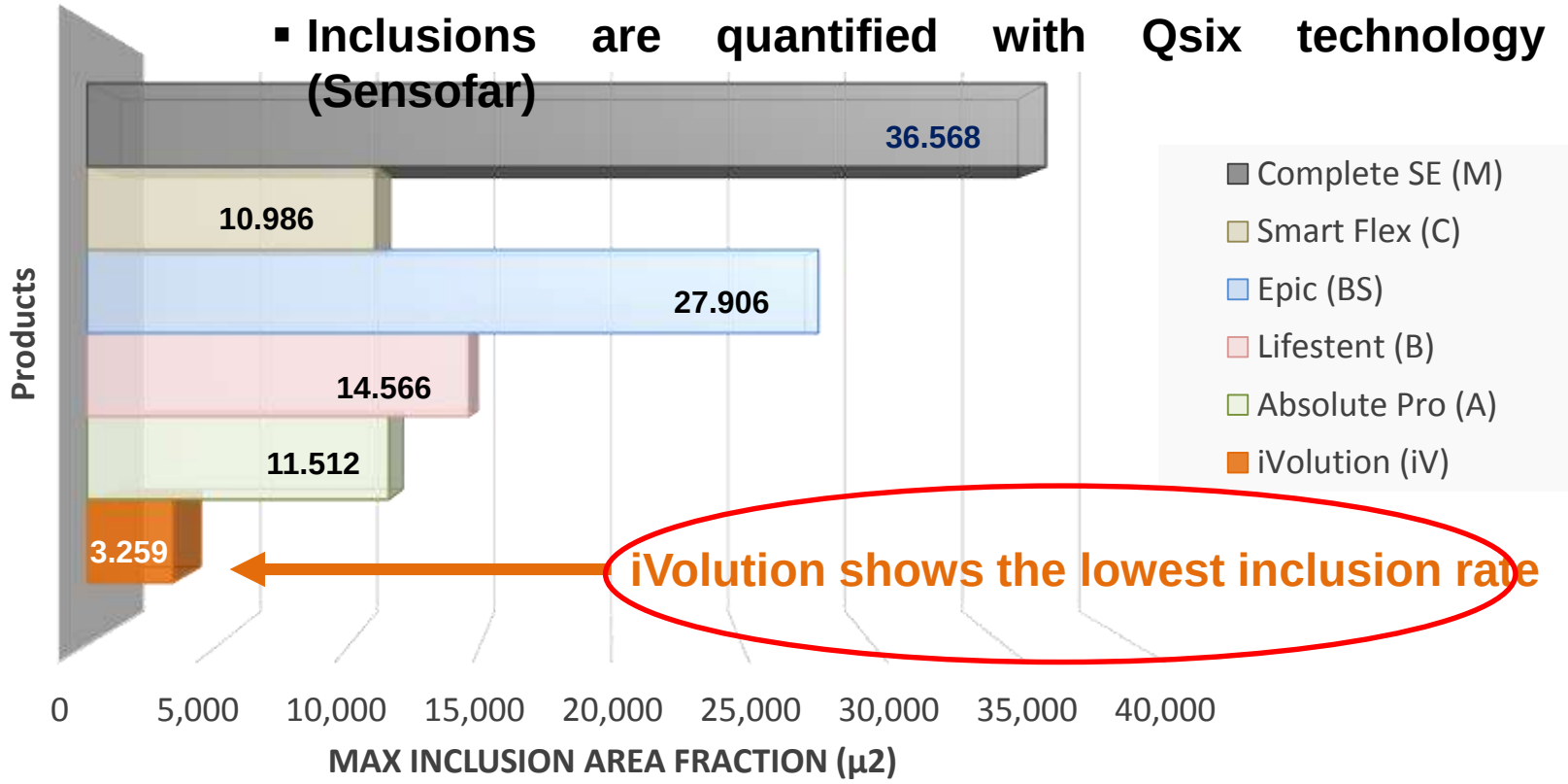
- 6 stents are evaluated during comparative bench tests
- Inclusions are quantified with Qsix technology (Sensofar)



3A. Stent design enhancing flow hemodynamics

6 stent designs have been evaluated during 4 sets of comparative bench tests, to assess:

- **1st flexibility : Stent ability to adapt to the vessel anatomy:**
- **2nd flexibility test : Stent ability to recover its shape after impact**
- **Kinking test**
- **Stent resistance to bending**

3A. Stent design enhancing flow hemodynamics

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FLEXIBILITY is defined as the stent ability to adapt to the anatomy of the treated artery without compromising the function of the implant.

The more flexible, the more adaptability to the vessel.

HIGH FLEXIBILITY STENTS	SEMI FLEXIBLE STENTS		NOT FLEXIBLE STENTS
			
iVOLUTION - iVASCULAR	ABSOLUT PRO LL - ABBOTT	COMPLETE SE - MEDTRONIC	EPIC - BS
Pictures property of the Paris Institute of Technology			
	LIFESTENT - BARD	SMART FLEX - CORDIS	

3A. Stent design enhancing flow hemodynamics

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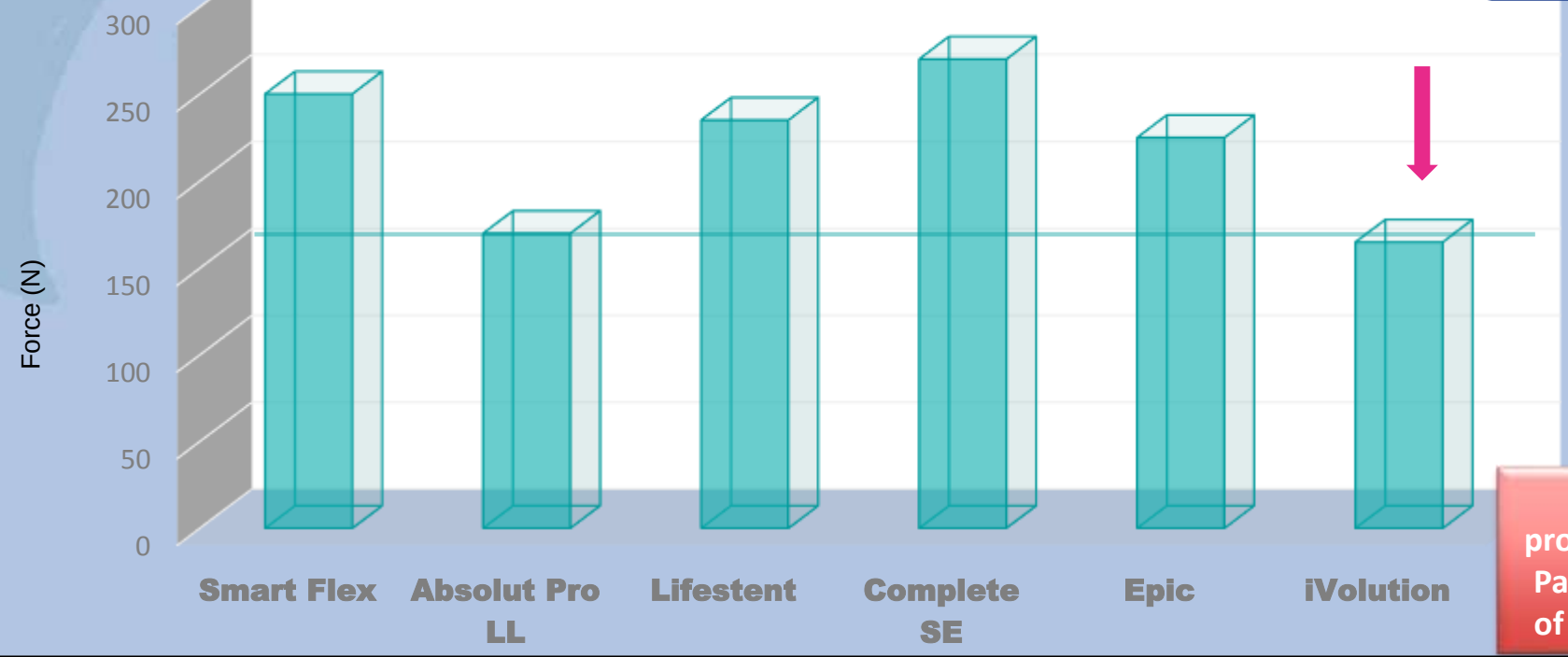
FLEXIBILITY as the capability of not modifying the treated vessel. The lower is the force of the stent, higher flexibility and better adaptability to the vessel anatomy.



3A. Stent design enhancing flow hemodynamics

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KINKING:

- **The radius at which the stents looses its structure**
- **Stent ability to adapt to the curvatures.**

ABSOLUT PRO LL
ABBOTT

SMART FLEX -
CORDIS

LIFESTENT - BARD

iVOLUTION - iVASCULAR

EPIC - BS

COMPLETE SE –
MEDTRONIC

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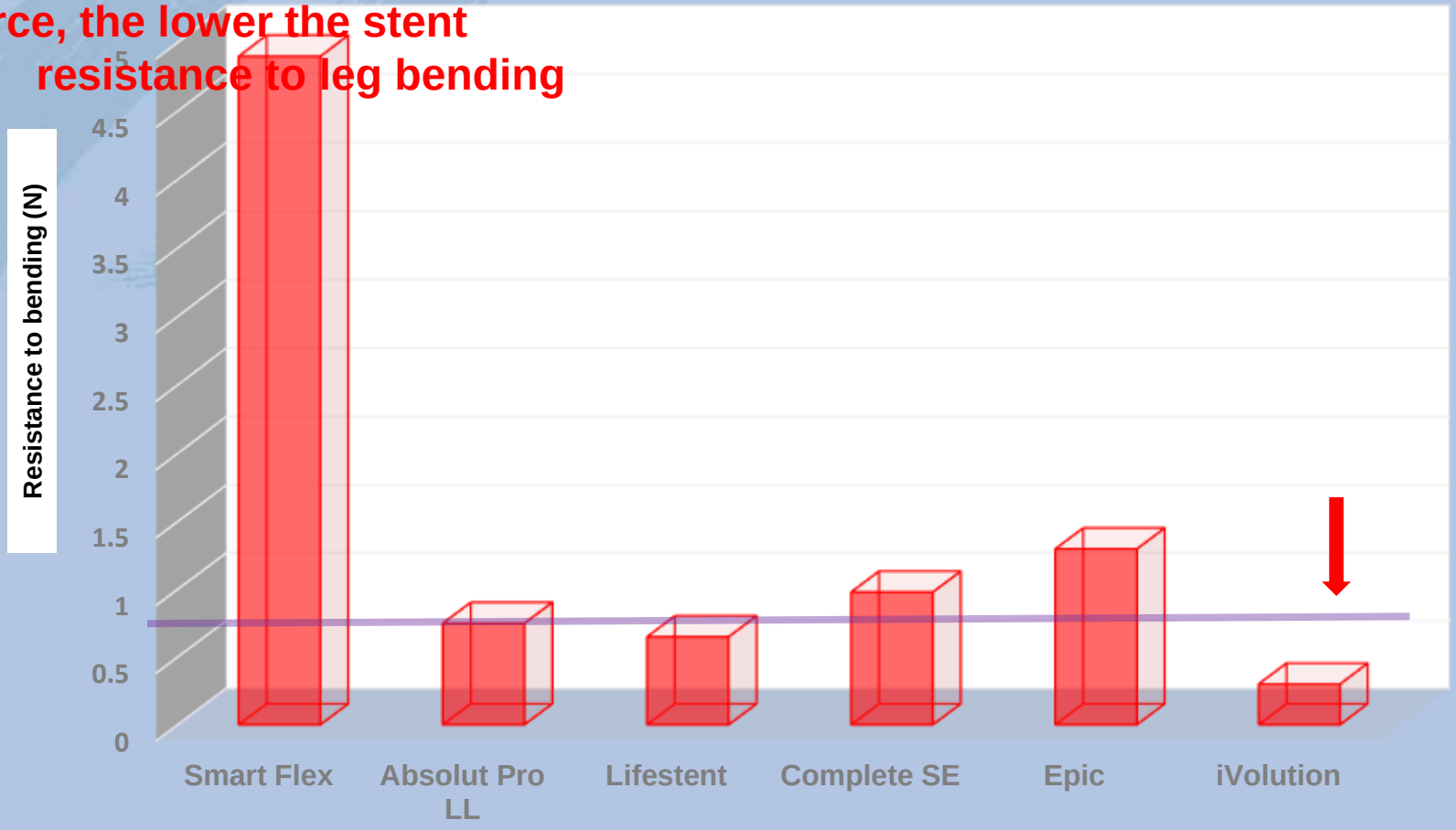
3A. Stent design enhancing flow hemodynamics

RESISTANCE TO BENDING is the measure of the stretching and shortening forces at which the stent is subjected to. **The larger the force, the lower the stent resistance to leg bending**



3B. Perfect surface finishing Importance of Electro Polishing

Diagn Interv Radiol 2015; 21: 403–409

Comparative study of the corrosion behavior of peripheral stents in an accelerated corrosion model: experimental *in vitro* study of 28 metallic vascular endoprostheses

PURPOSE

Clinical cases of stent-fractures show that **corrosion behavior might play a role in these fractures**. Implanted *in vivo*, especially in combination with other implanted foreign materials, these metallic products are exposed to special conditions, which can cause a process of corrosion. Here, we aimed to test the corrosion potential of stents made of different materials in an *in vitro* setting.

CONCLUSION

The analysis of corrosion behavior may be useful to select the right stent fulfilling the individual needs of the patient within a large number of different stents. **Electropolished stents showed the best results**

3B. Perfect surface finishing Importance of Electro Polishing

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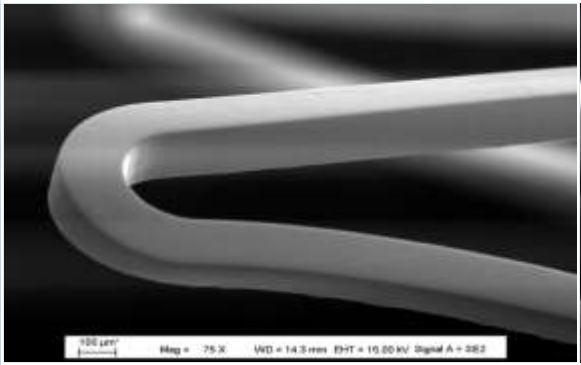
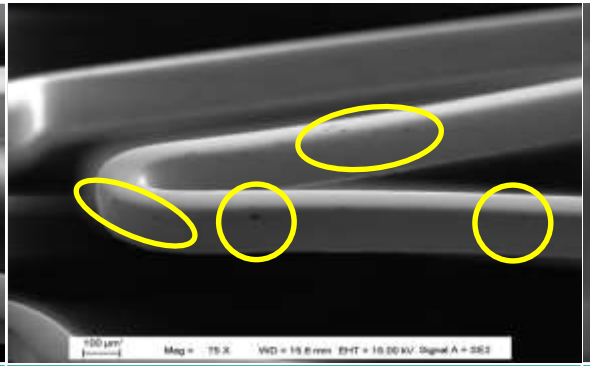
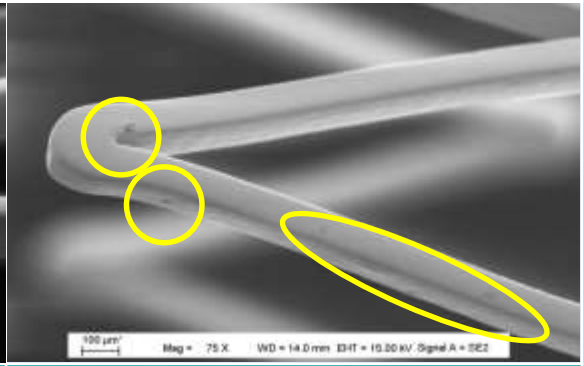
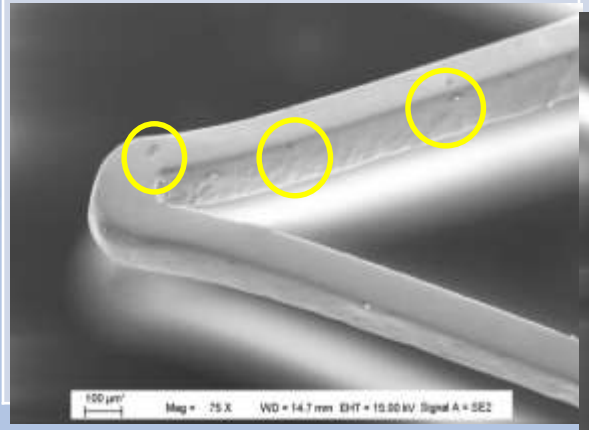
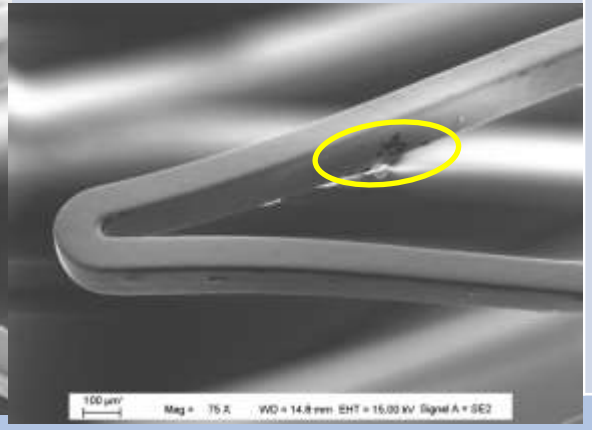
iVolution	Absolute Pro	Lifestream
		
Epic	**Smartflex**	**Complete SE**
		

Magnification 75 X

3B. Perfect surface finishing Importance of Electro Polishing

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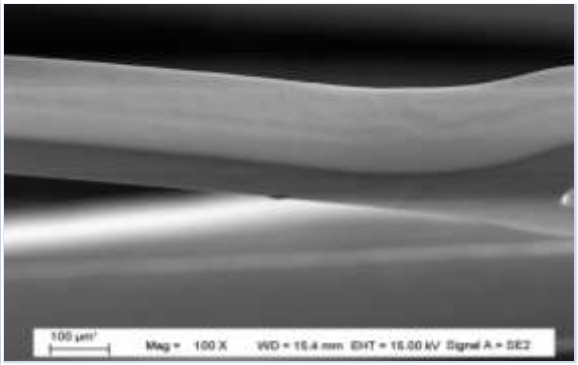
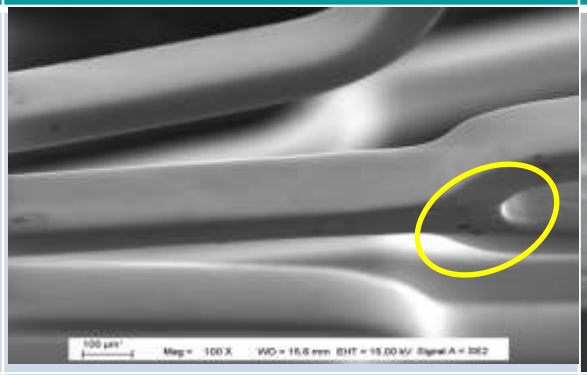
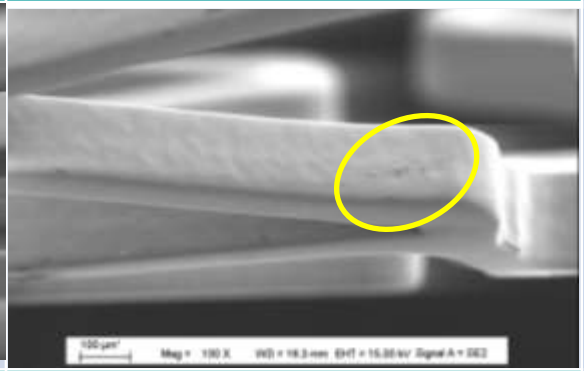
iVolution	Absolute Pro	Lifestream
		
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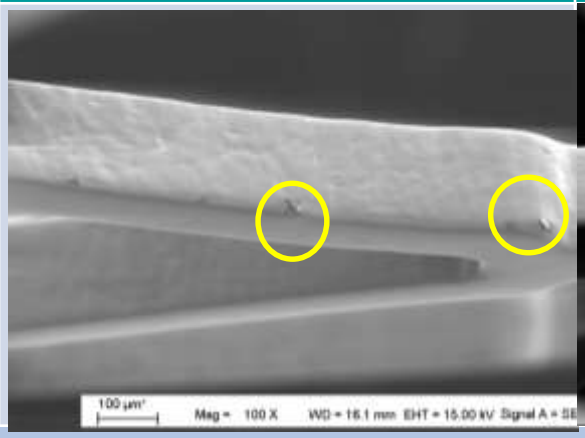	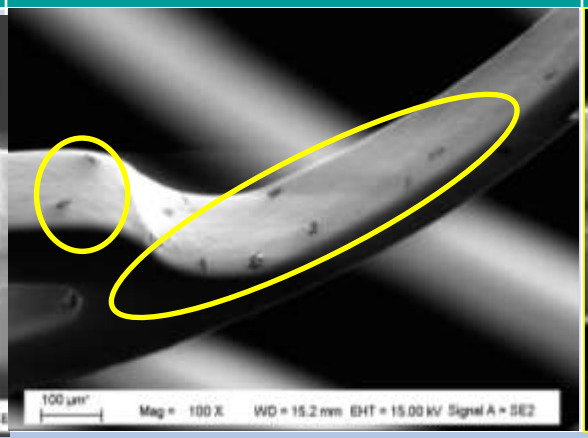	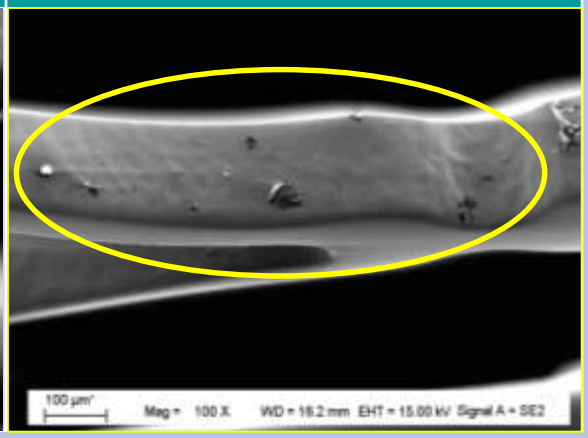

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The iVascular technical solutions

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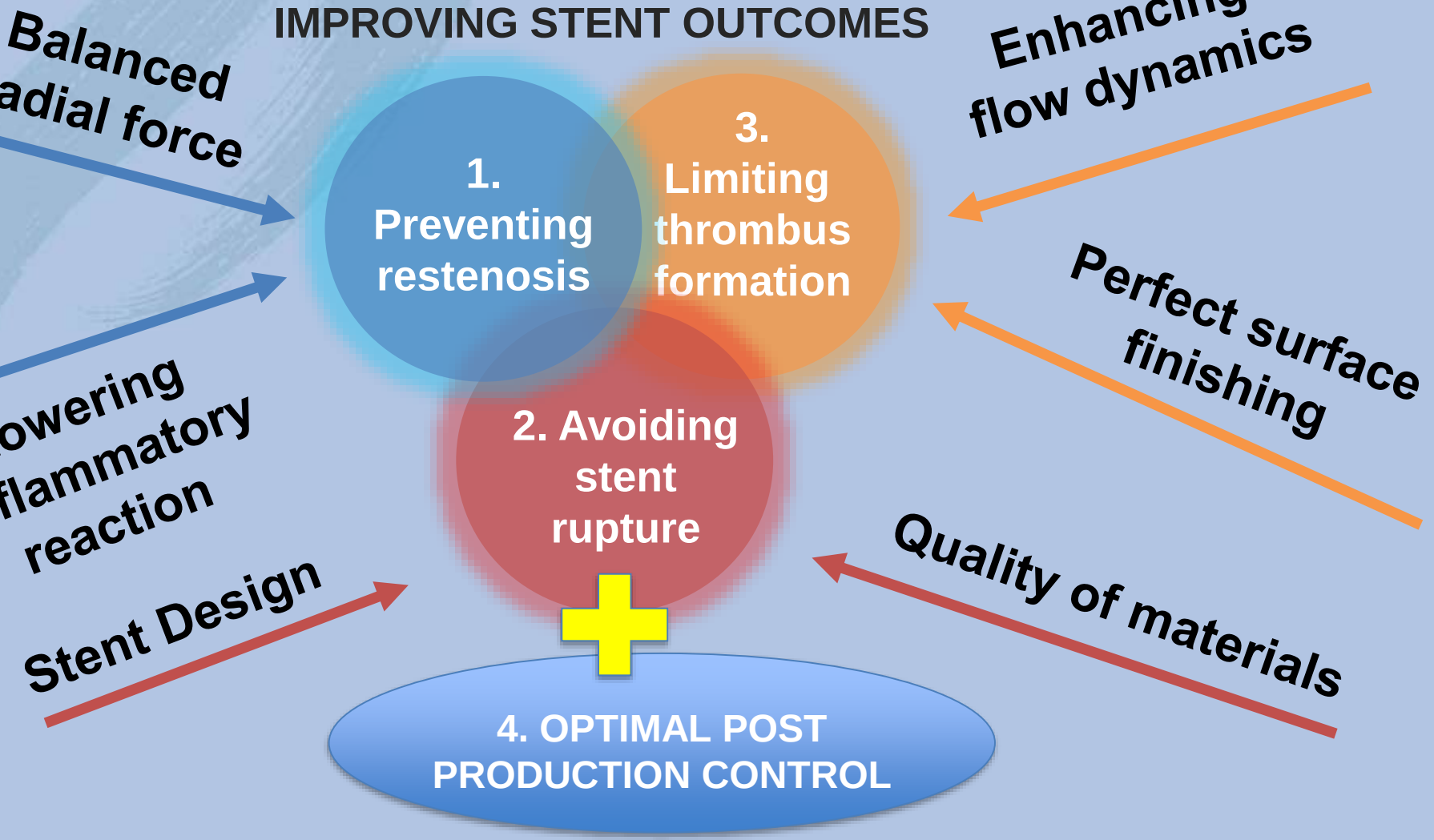

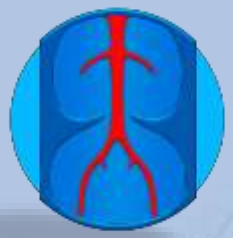

Post production control

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- **Post production analysis & control :**
  - **As important as the optimal production line**
  - **Mostly done by randomised control**
  - **Mostly done by human inspection**
  - **Not every stent will be controled**
  - **Thus failure can slip through**

SENSOFAR MEDICAL

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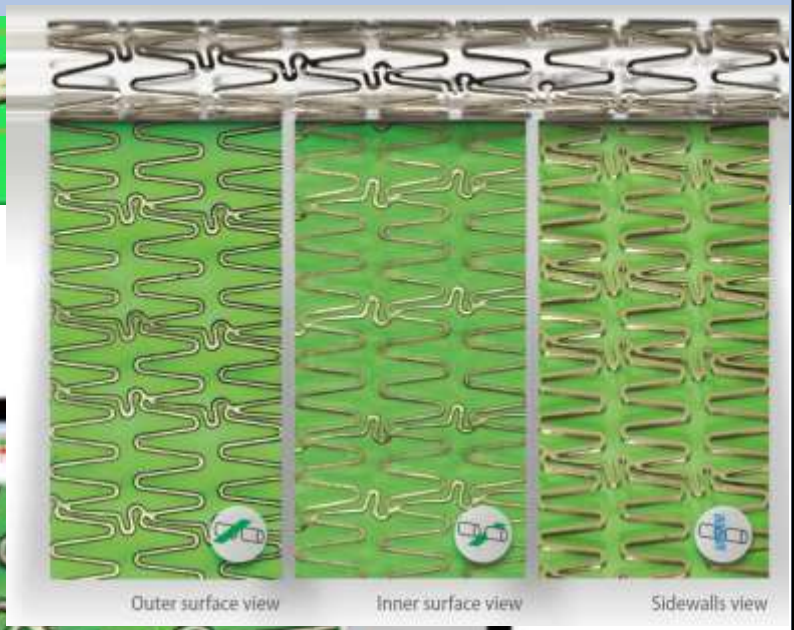

Q six

Post production control

Q six

The Q six is able to simultaneously acquire and analyze images of the outer and inner surfaces as well as the sidewalls of the stent structure at a rate ranging from 5 mm^2/s to 20 mm^2/s.

- High NA optical design, premium CF60-2 Nikon objectives
- multi-million pixel imaging array
- unique combination of light sources provide extremely sharp views of the complete stent surface with unprecedented real color, resolution and contrast.

- High-resolution imaging and 3D optical measurement allow for complete surface inspection of the stent structure, reducing
  - Errors
  - quality control costs
  - inspection time

  - making the task of acceptance faster, easier and more reliable

Post production control

SENSOFAR MEDICAL

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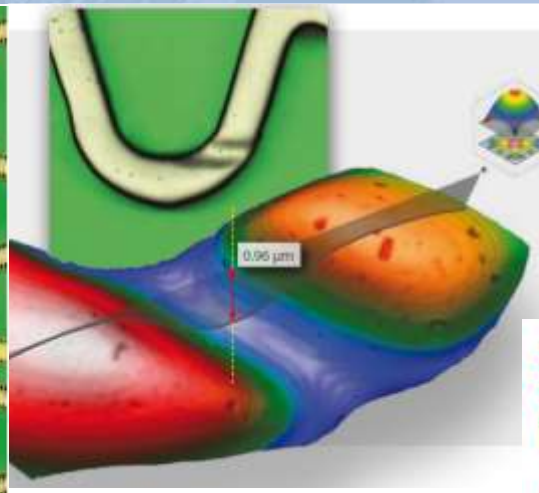
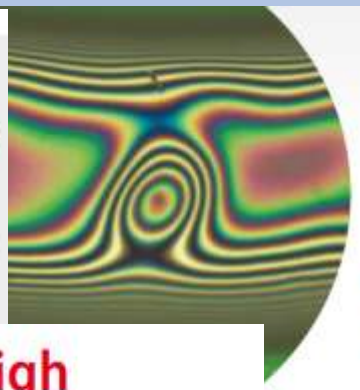


Surface topography

Verify the depth of scoremarks or scratches of your stents. 3D Topography of a defect can be obtained in seconds with a lateral resolution of 0.5 microns and a vertical resolution of 1nm.



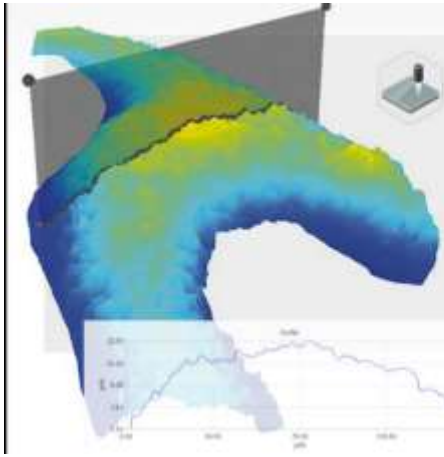
3D modes

Overcoming the limits of 2D Imaging

Non-contact optical 3D profiling using Sensofar's proven Vertical Scanning Interferometry (VSI) technology.

Extremely high inspection rate

UP TO 1 CORONARY STENT PER MINUTE



Mapping the thickness of coatings

Check the performance of your process and coating uniformity. Thickness of optically transparent coatings is mapped all across the width of the struts with a lateral resolution of 0.5 microns and a vertical resolution of 2 nm in just a few seconds. The minimum value of the thickness that can be measured is approximately 3 microns.

Surface roughness

Check the quality of your electro-polishing process. Standard surface texture parameters are measured according to ISO 25178. The operator can select areas of measurement at the outer surface of the stent and filtering parameters.

Conclusions

iVascular technical solutions to improve SX stent clinical outcomes

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Fracture risk	✓ **Optimal stent design** ✓ **Controlled manufacturing process to prevent material defect and weak points**
Smooth endothelialization to prevent thrombus	✓ **Optimal design to respect artery and blood flow hemodynamics** ✓ **Ideal surface finishing**
Low Inflammatory reaction	✓ **Balanced radial force** ✓ **Stent passivation to prevent corrosion**
Post production control	✓ **Qsix control of outer/inner/side surfaces** ✓ **EVERY PRODUCED STENT IS INSPECTED**

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Thank you for your attention!

New manufacturing process and stent design are key elements to improve clinical outcome:

the iVascular IVolution stent example

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