The Hairy Endograft: from concept to reality!

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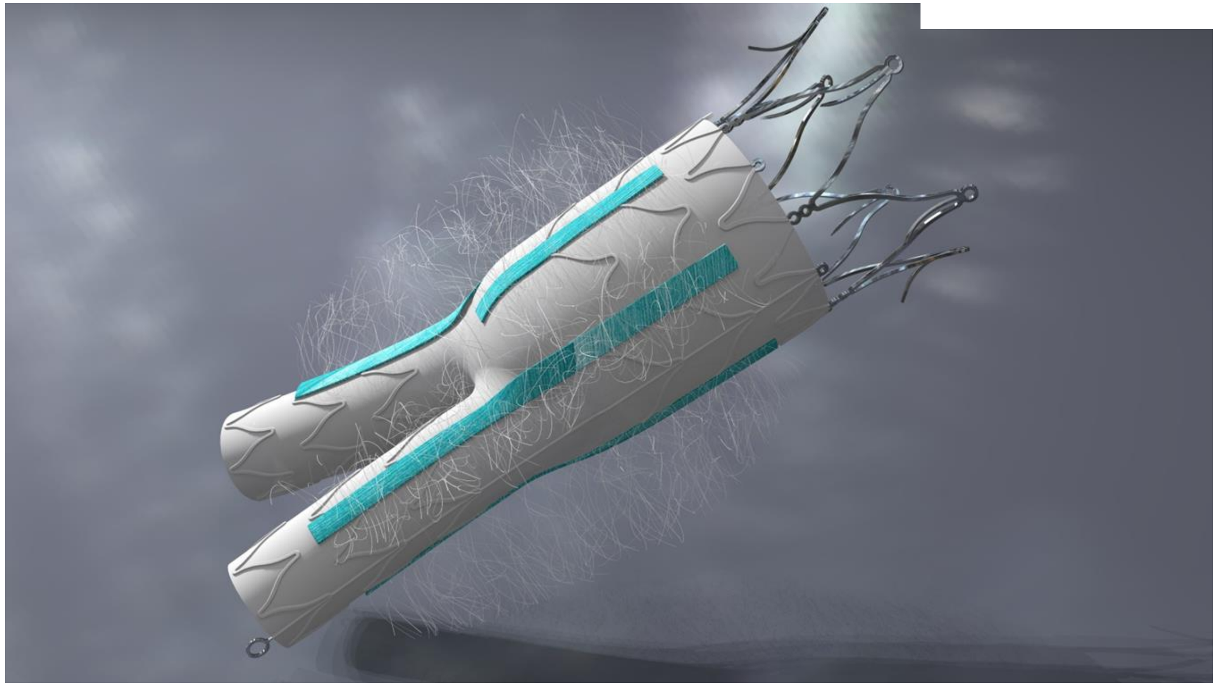
CRITICAL ISSUES
IN AORTIC ENDOGRAFTING
DECEMBER 17 - 18 2021
PULLMAN PARIS BERCY PARIS - FRANCE



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Disclaimer / Conflict of Interests

Inventor consultant and shareholder of Affluent Medical

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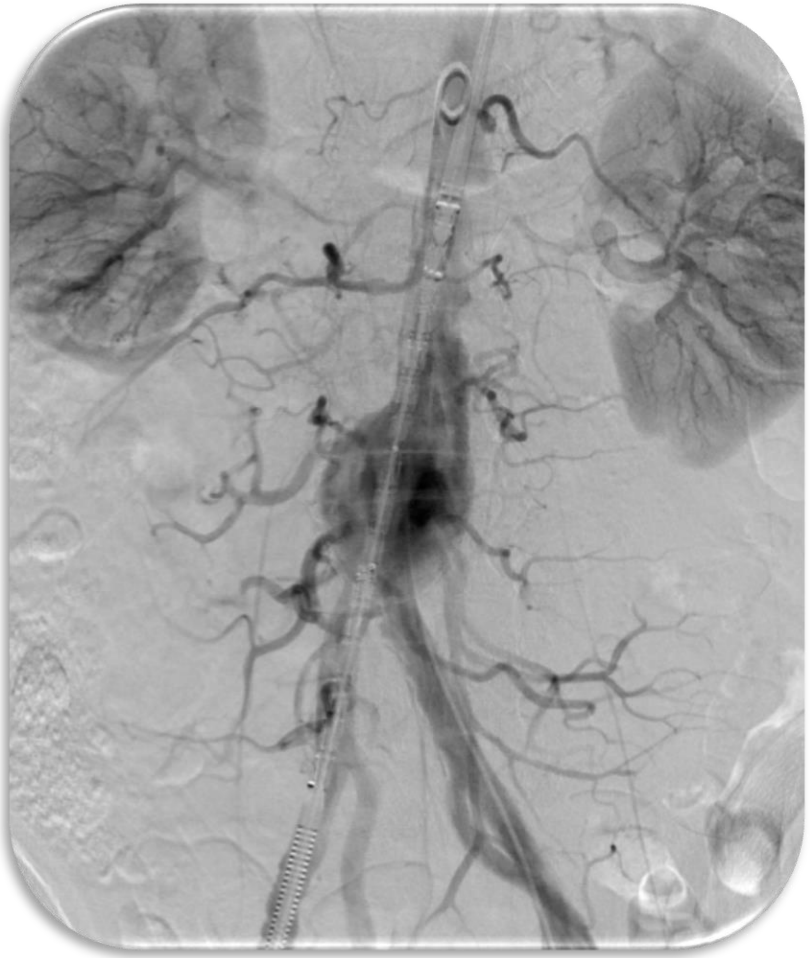
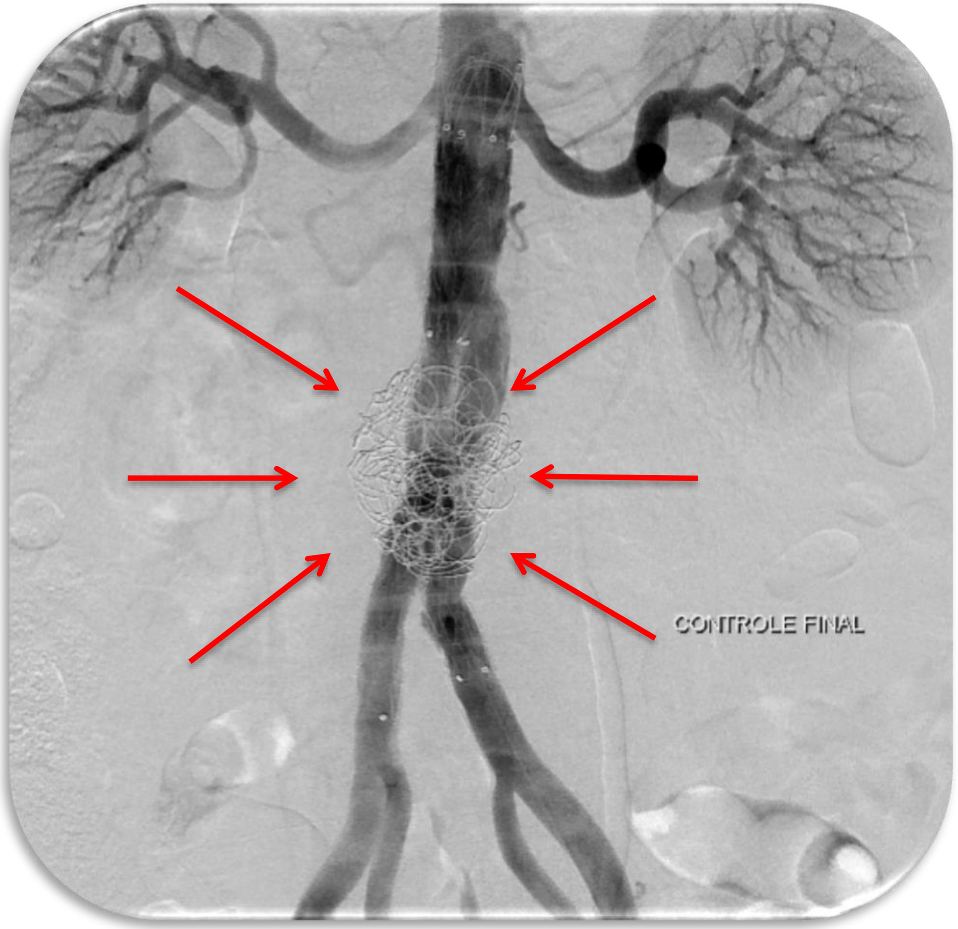
At risk patients!





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Coil embolization / PRT SCOPE 1

RANDOMISED CONTROLLED TRIAL

Prospective, Randomised Two Centre Study of Endovascular Repair of Abdominal Aortic Aneurysm With or Without Sac Embolisation

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WHAT THIS PAPER ADDS

This is the first multicentre prospective randomised trial comparing standard endovascular aneurysm repair (EVAR) with standard EVAR associated with aneurysm sac coil embolisation. Only patients at high risk of type II endoleak (EL) were enrolled. Peri-operative and two year outcomes demonstrated that aneurysm sac coil embolisation can prevent type II EL and significantly decrease re-intervention rates during follow up after EVAR. Significant aneurysm diameter and volume decrease were observed at one and two years when aneurysm sac coil embolisation was performed. Further studies are required to determine whether aneurysm sac coil embolisation could decrease the costs associated with EVAR follow up.

Objective: The benefit of aneurysm sac coil embolisation (ASCE) during endovascular aortic repair (EVAR) of abdominal aortic aneurysm (AAA) remains unclear. This prospective randomised two centre study (SCOPE 1: Sac COil embolisation for Prevention of Endoleak) compared the outcomes of standard EVAR in patients with AAA at high risk of type II endoleak (EL with EVAR with ASCE during the period 2014–2019.
Methods: Patients at high risk of type II EL were randomised to standard EVAR (group A) or EVAR with coil ASCE (group B). The primary endpoint was the rate of all types of EL during follow up. Secondary endpoints included freedom from type II EL related re-interventions, and aneurysm sac diameter and volume variation at two year follow up. Adverse events included type II EL and re-interventions. CTA and Duplex ultrasound scans were scheduled at 30 days, six months, one year, and two years after surgery.
Results: Ninety-four patients were enrolled, 47 in each group. There were no intra-operative complications. At M1, 16/47 early type II EL occurred (34%) in group A *vs.* 2/47 (4.3%) in group B ($p < .001$). At M6, 15/36 type II EL (41.7%) occurred in group A *vs.* 2/39 (4.26%) in group B ($p < .001$). At M12, 15/37 type II El (40.5%) occurred in group A *vs.* 5/35 (14.3%) in group B ($p = .018$). At 24 months, 8/32 type 2 El (25%) occurred in group A *vs.* 3/29 (6.5%) in group B ($p = .19$). Kaplan–Meier curves of survival free from EL and re-interventions were significantly in favour of group B ($p < .001$). Aneurysm sac volume decreased significantly in group B compared with group A at M6 ($p = .081$), at M12 ($p = .004$), and M24 ($p = .001$).
Conclusion: For selected patients at risk of EL, ASCE seems effective in preventing EL at one, six, and at 12 months. However, the difference was not statistically significant at 24 months. ASCE decreases the re-intervention rate two years after EVAR. A significantly faster aneurysm volume shrinkage was observed at one and two years following surgery. (SCOPE 1 trial: NCT01878240)

Keywords: Aneurysm, Embolisation, Endoleak, Endovascular, Prevention
Article history: Received 28 February 2020, Accepted 16 November 2020, Available online XXX

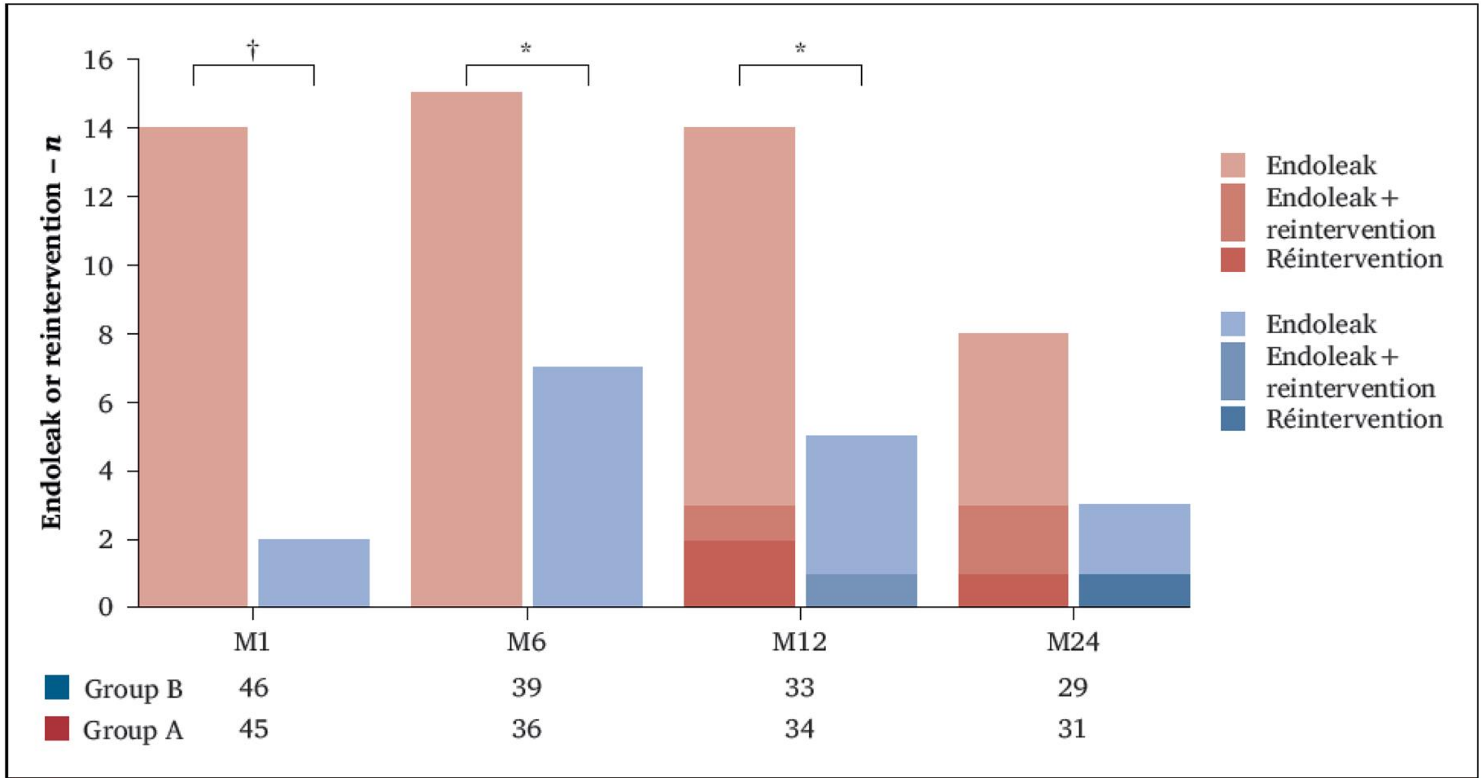
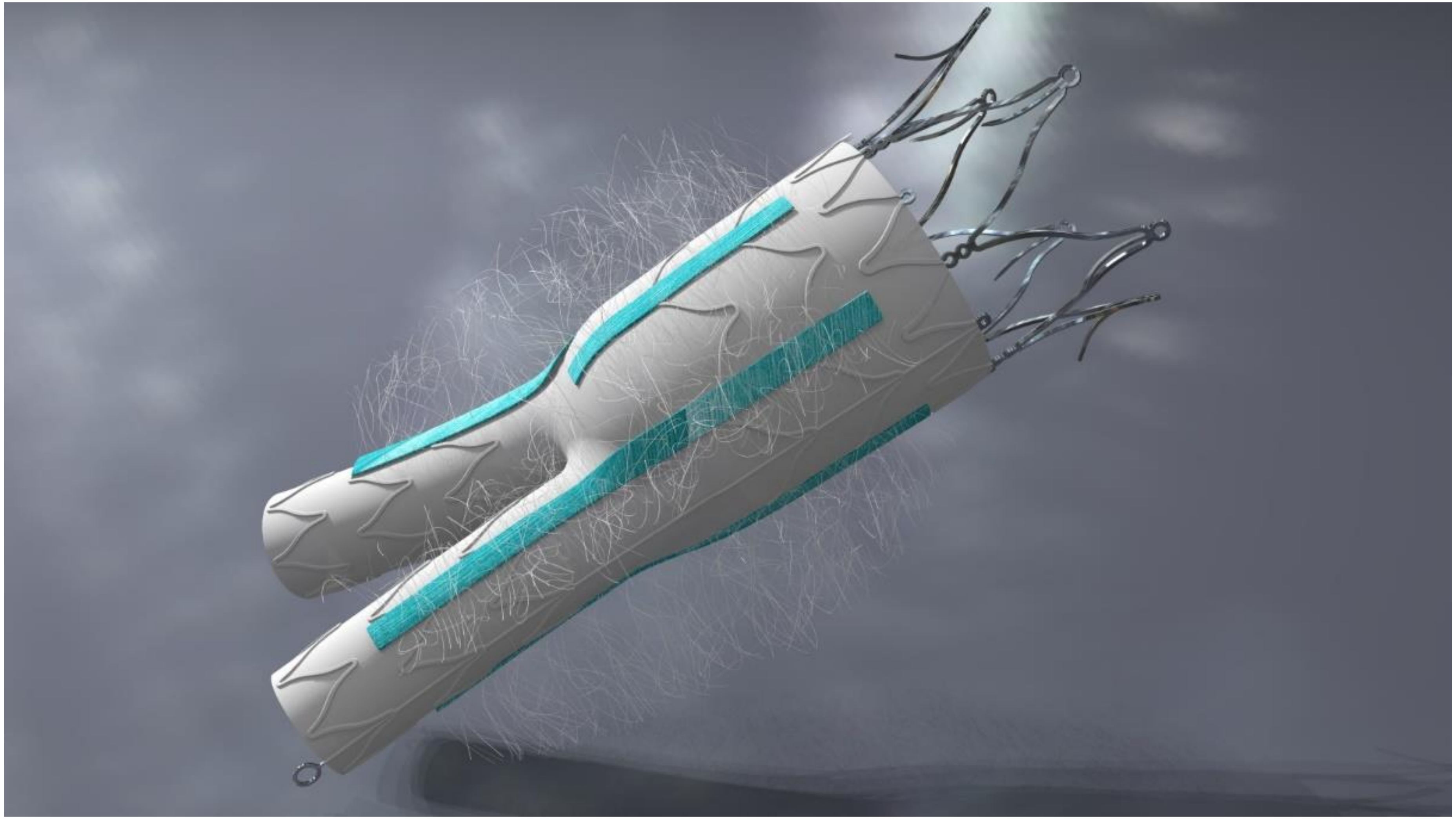


Figure 2. Primary outcome events including type II endoleaks and re-interventions for patients with endovascular aneurysm repair without (group A) or with sac embolisation with coils (group B). $^{*}p < .05$; $^{\dagger}p < .001$.

Fabre, Ejves, 2021

An innovative endograft with thrombogenic fibers that ensures a complete sac thrombosis and promotes sac shrinkage

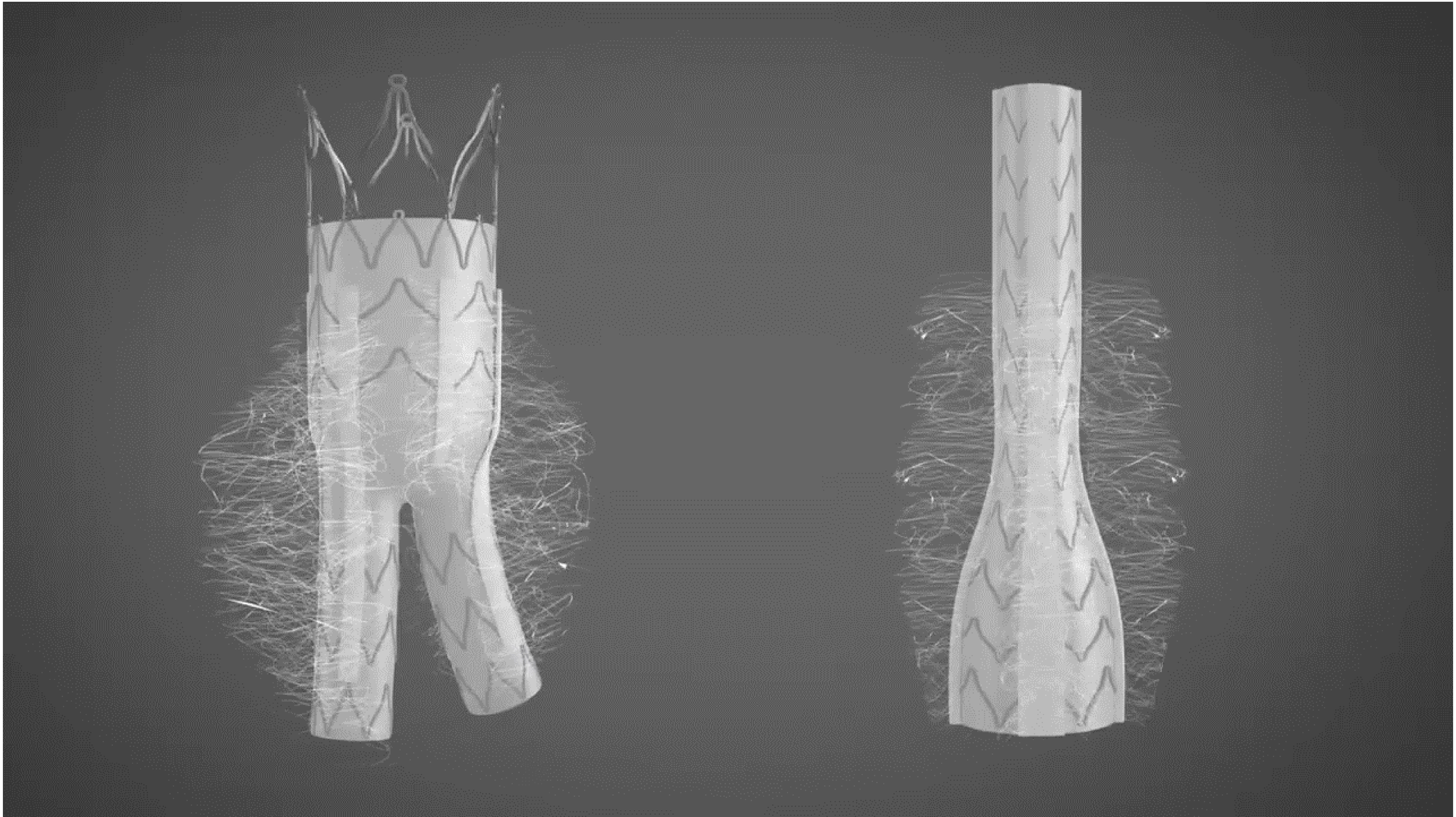


The Concept

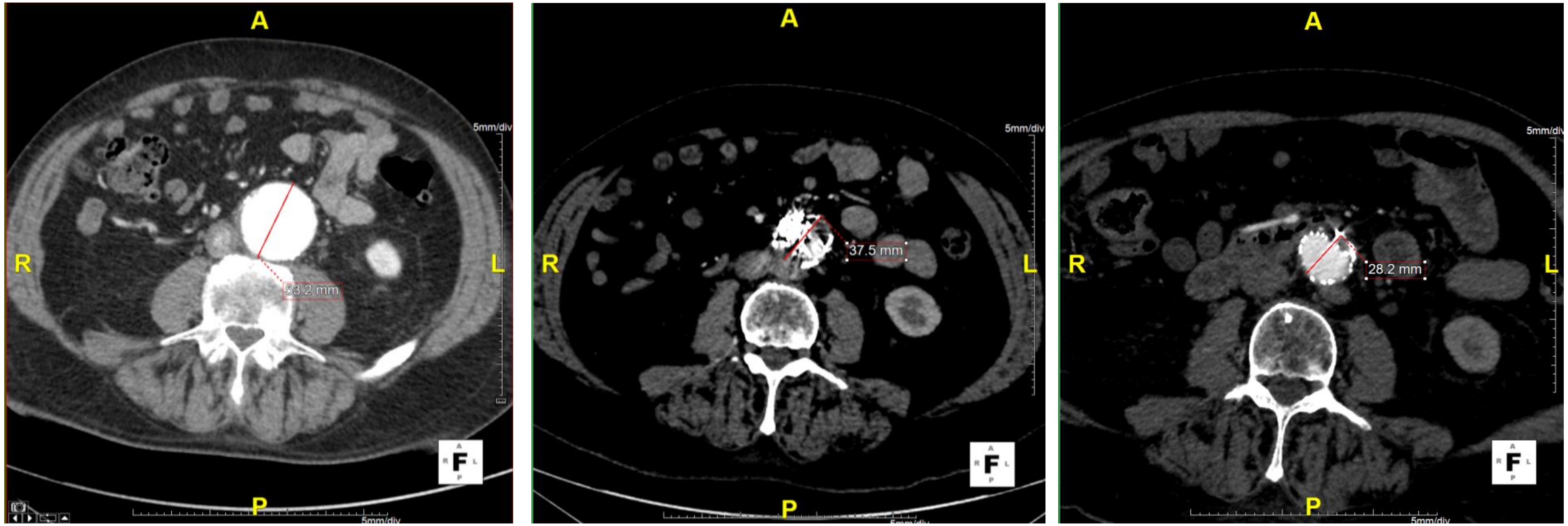
Integrate into one low profile device and the thrombogenic fibers of the coils, eliminating the metal support of the coils

- Without impacting any feature/performance of the EVAR device
- Without changing the standard EVAR procedure in any aspect, including duration
- Without increasing costs in a significant way
- Without adding risks

KARDIOZIS Prototype



SCOPE 1 prospective randomized study
Patient group II / EVAR + Coils embolization



Before EVAR 53.2 mm	After 1 year 37.5 mm	After 2 years 28.2 mm

Shrinkage of the AAA
In at risk patient for Endoleak

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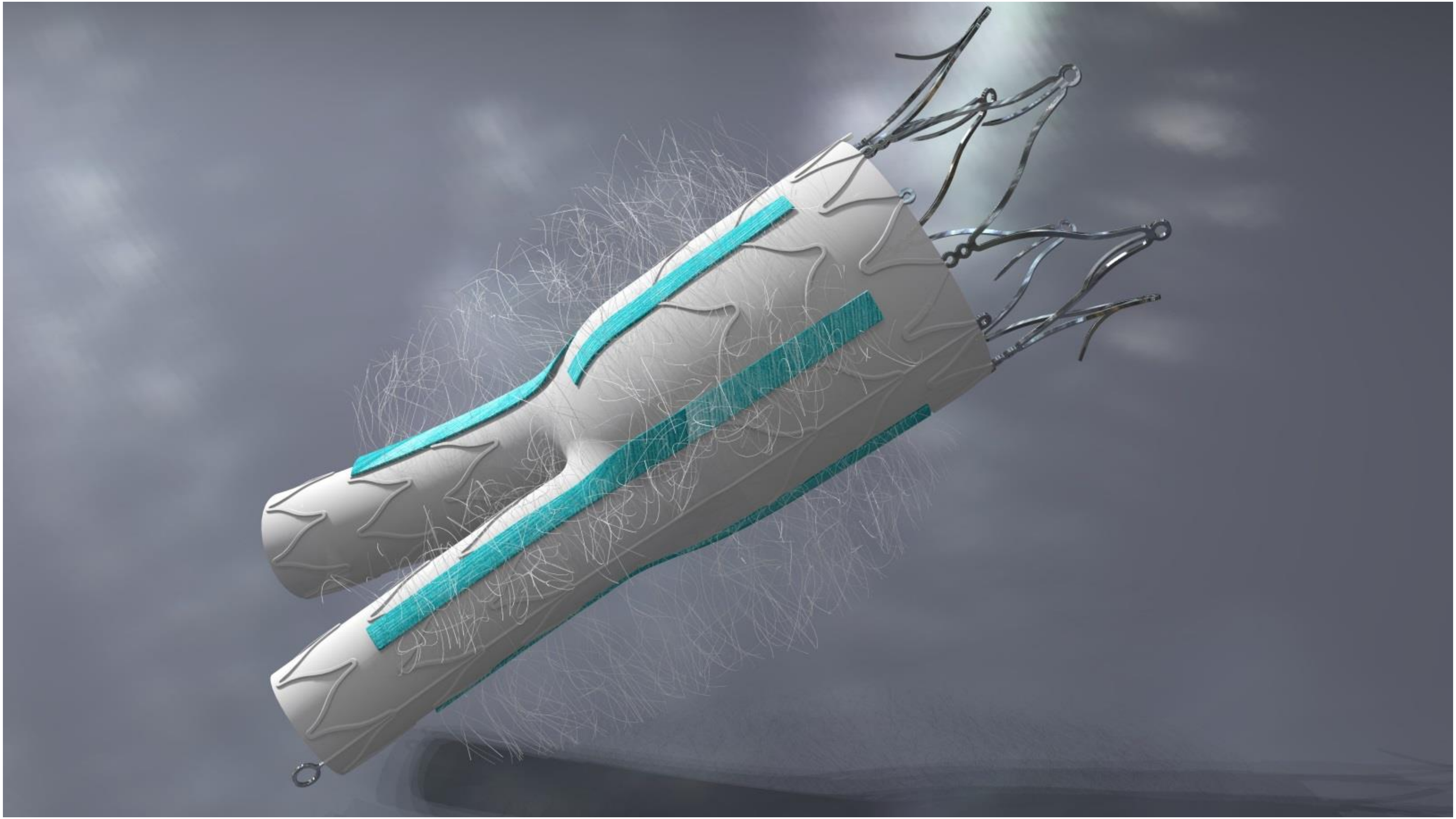
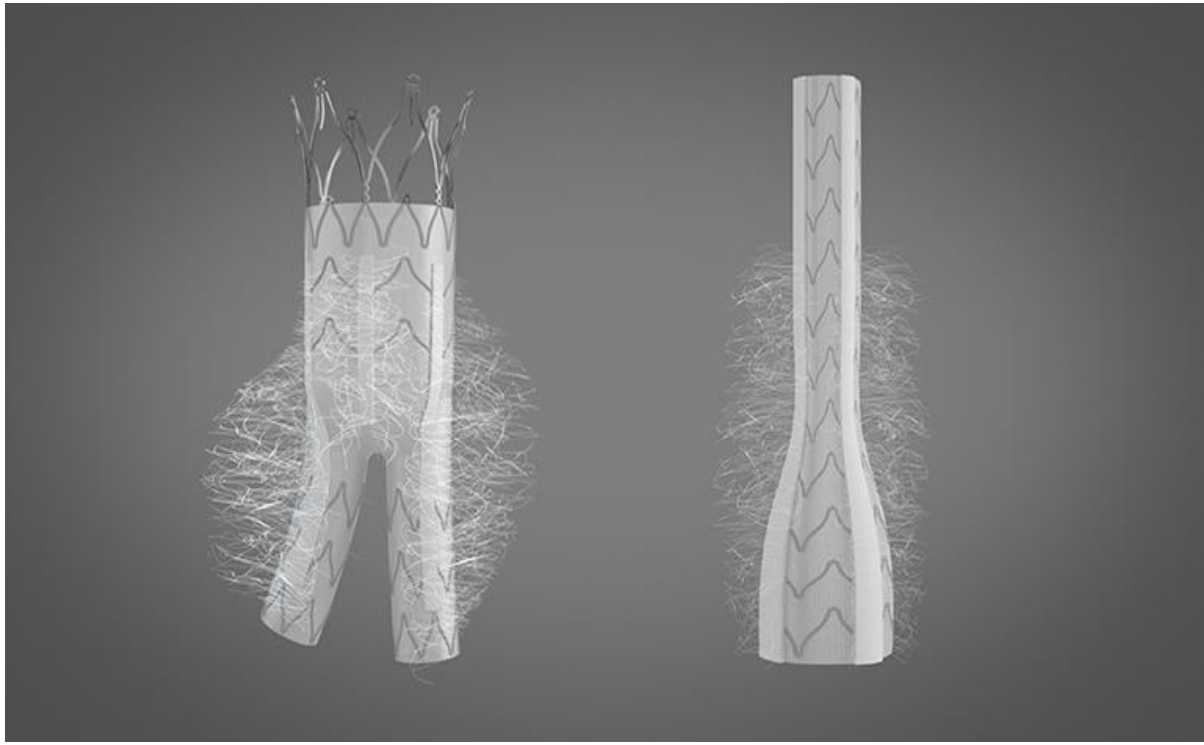


4 EVAR ® stent graft

- Classic stent graft combined with an external thrombogenic fibered coating
- 7 Patents filed: 2020 -2040
  - Fibers 5
  - DS 1
  - Prostheses 1
- Assembly of 2 medical devices with a Classic endoprosthesis + Thrombogenic fibers from coils
- No drug, no biological activity



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WO2013182614A1 Patent

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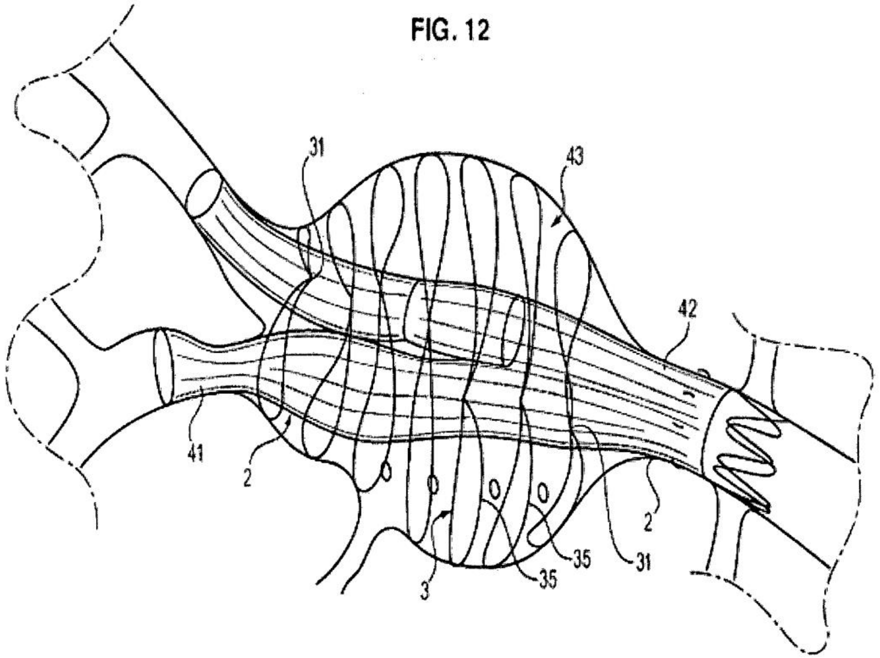
FIG. 12



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A61F 2/24 (2006.01) *A61F 2/966* (201 3.01)
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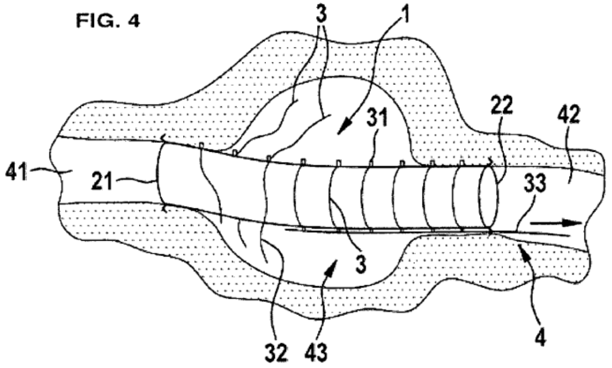
(54) **Title:** ENDOPROSTHESIS AND DELIVERY DEVICE FOR IMPLANTING SUCH ENDOPROSTHESIS

FIG. 4



13/182614 A1

(57) **Abstract:** The invention relates to an endoprosthesis (1), in particular a vascular or cardiac endoprosthesis (1), having a body

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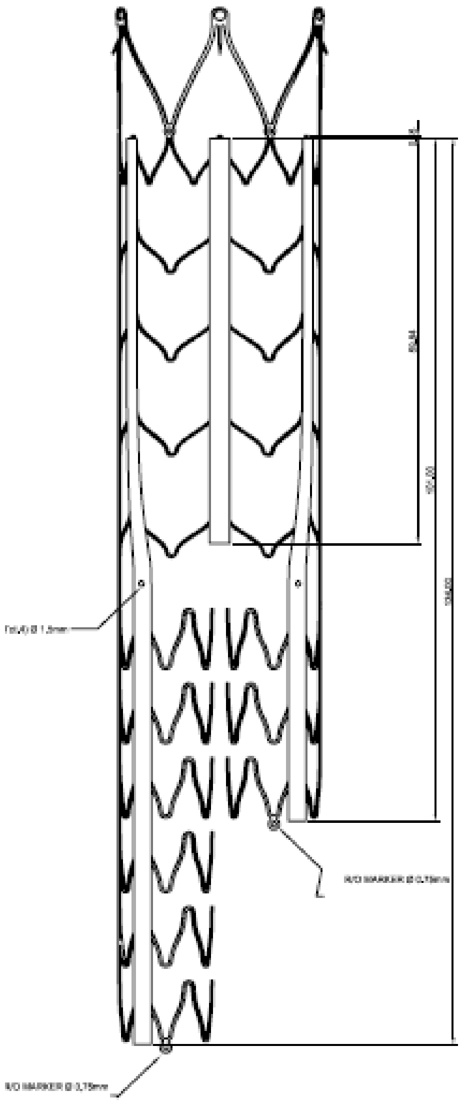
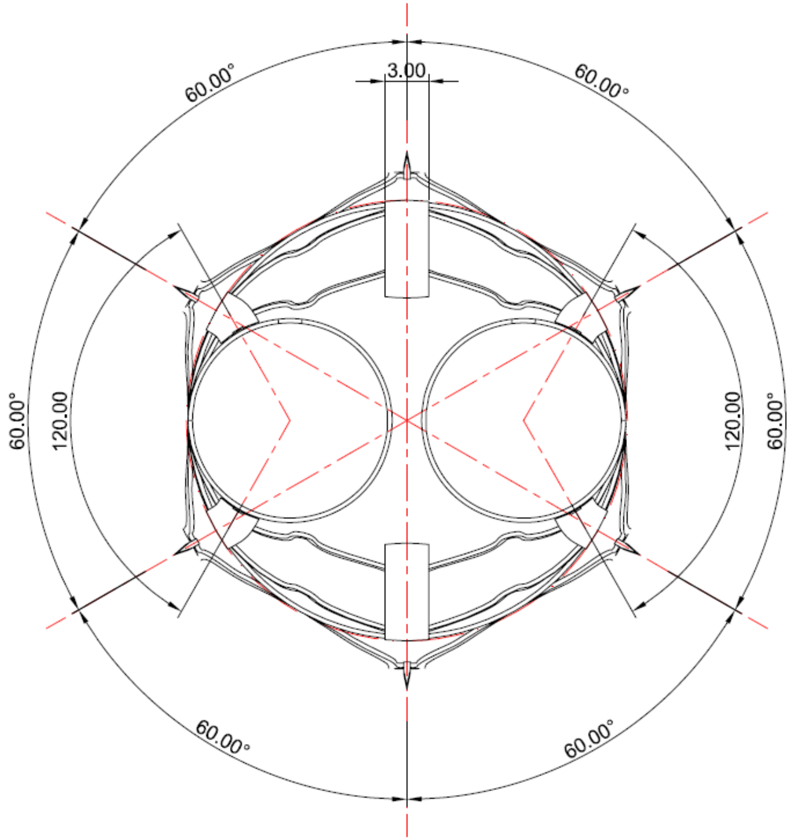
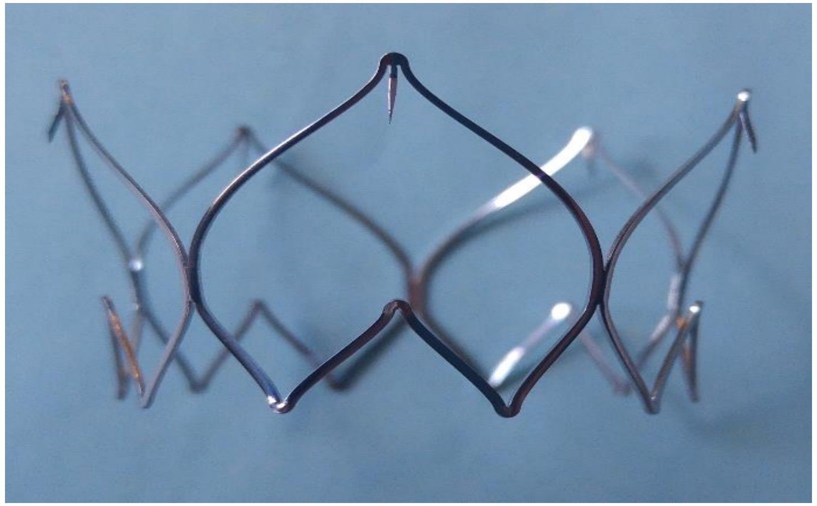
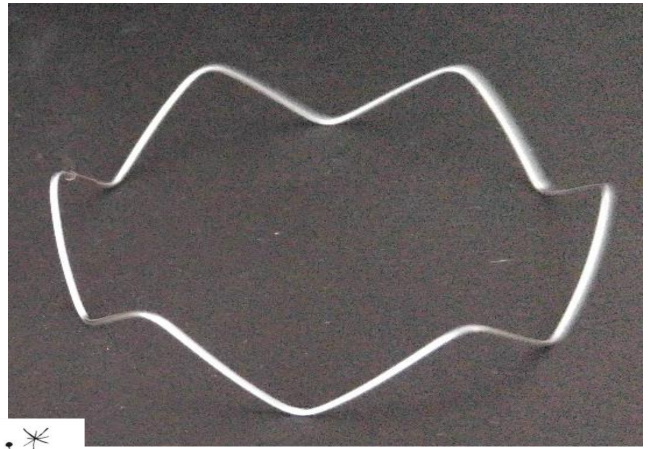
Stent graft design / main features Summary





Nitinol laser cut stent





PTFE suturless Graft 9 Prototypes

- Suturless
- Multilayer
- ePTFE
- Nitinol:
  - Laser-cut
  - Wire

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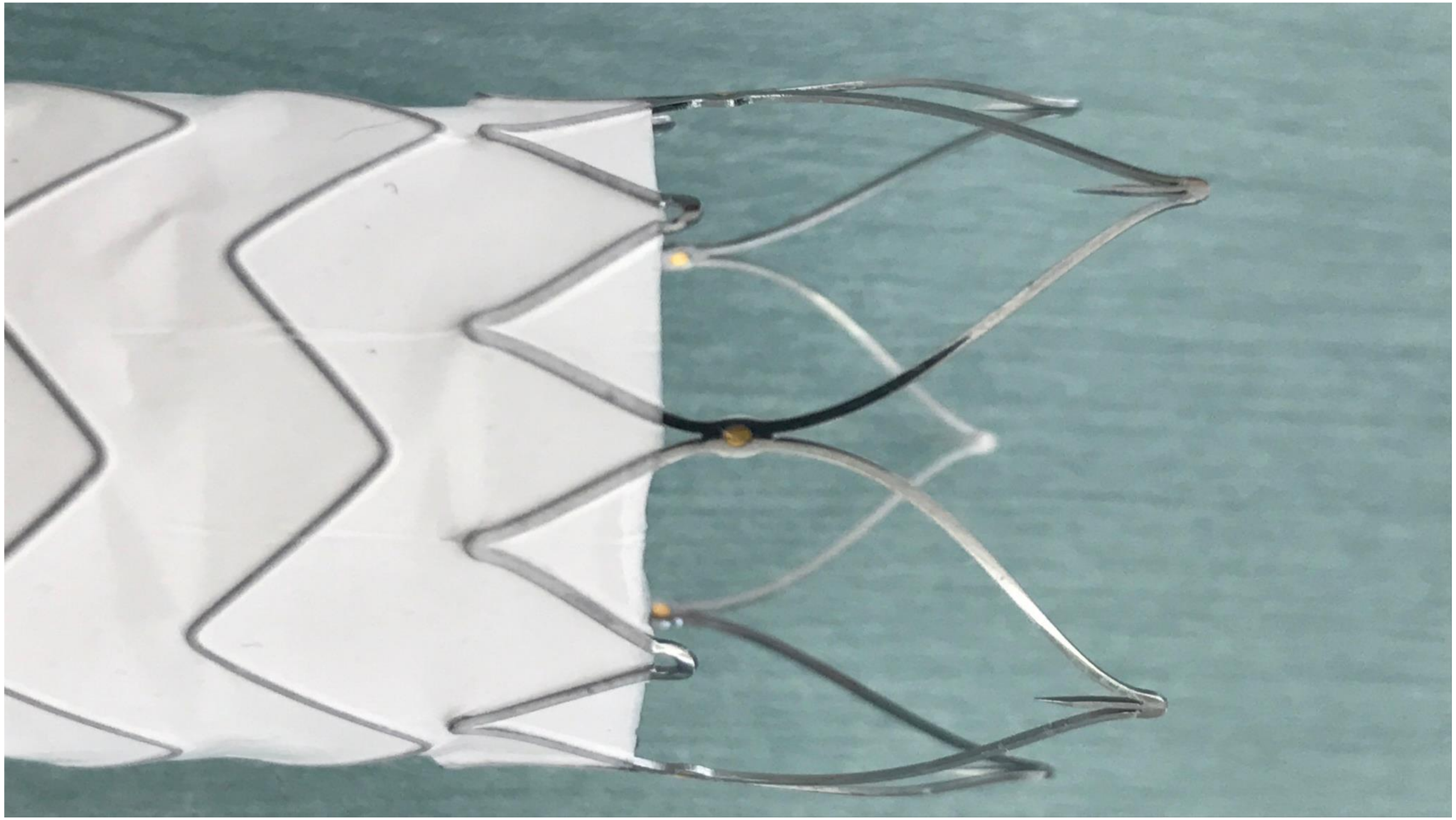
Proximal seal / Anchoring



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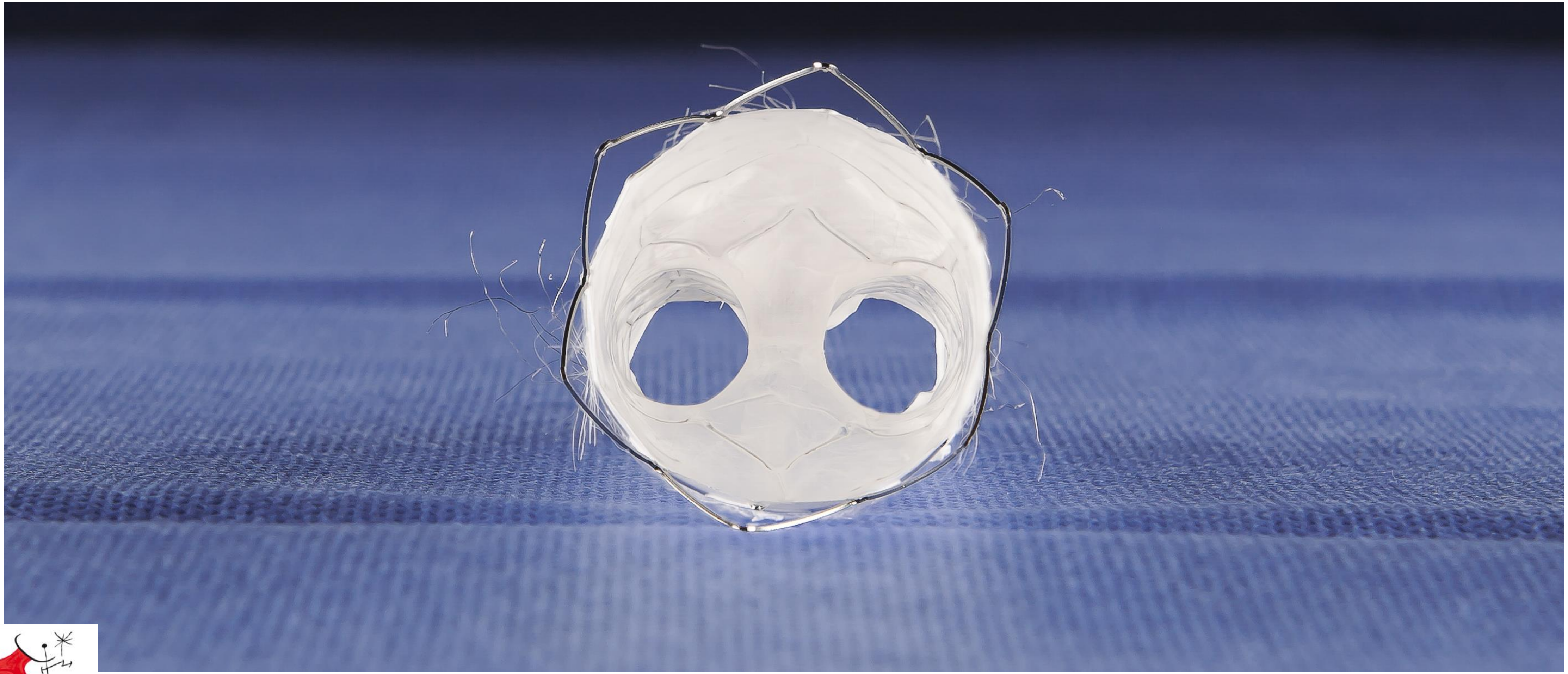
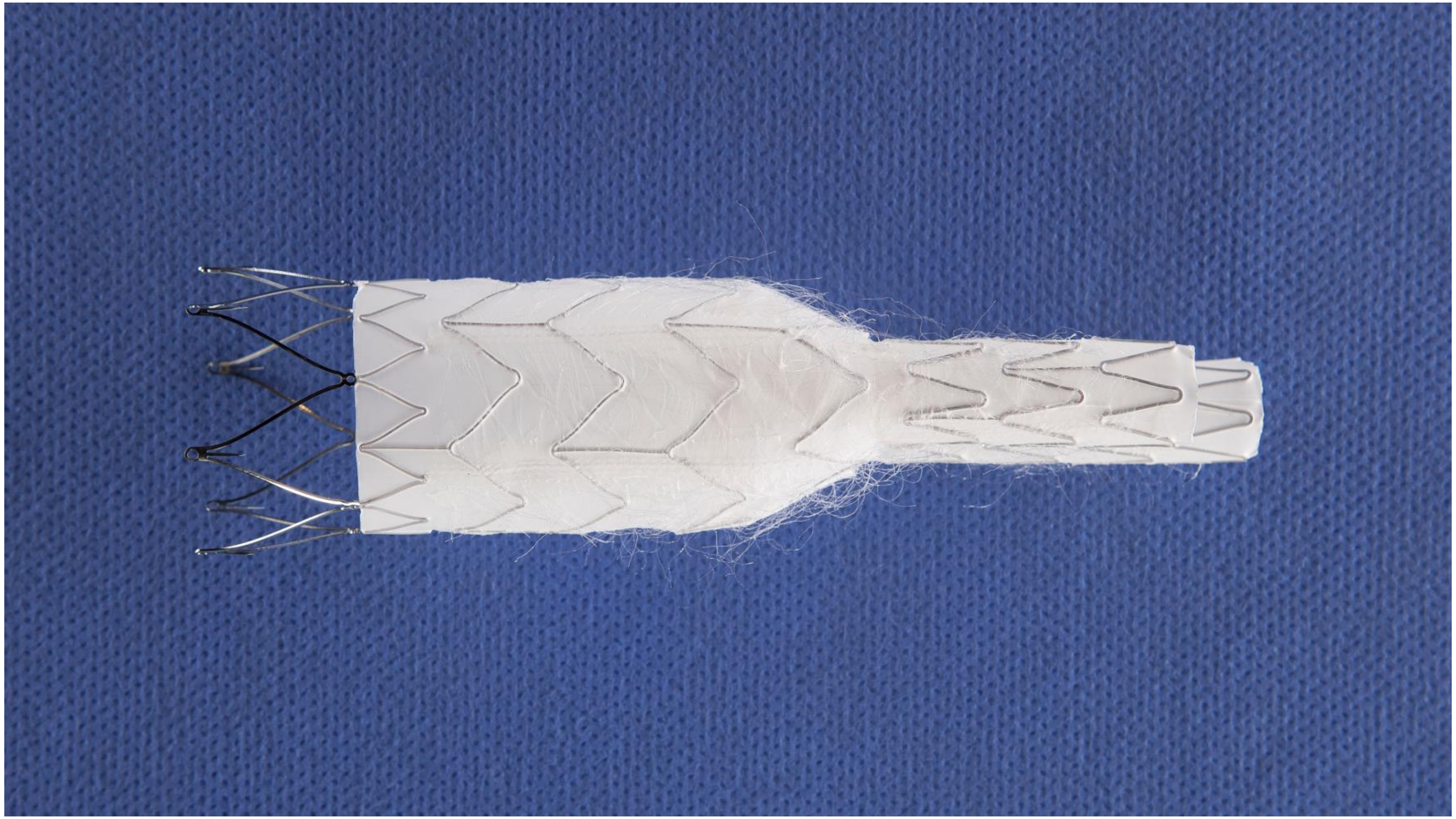
Ergonomic designed graft





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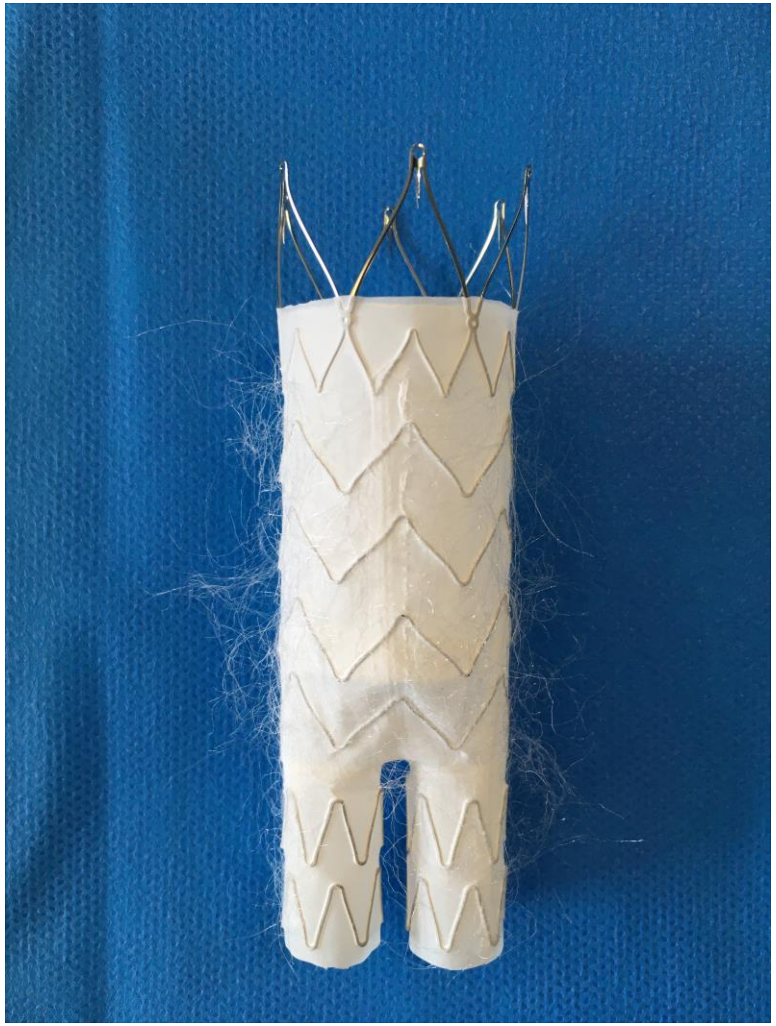

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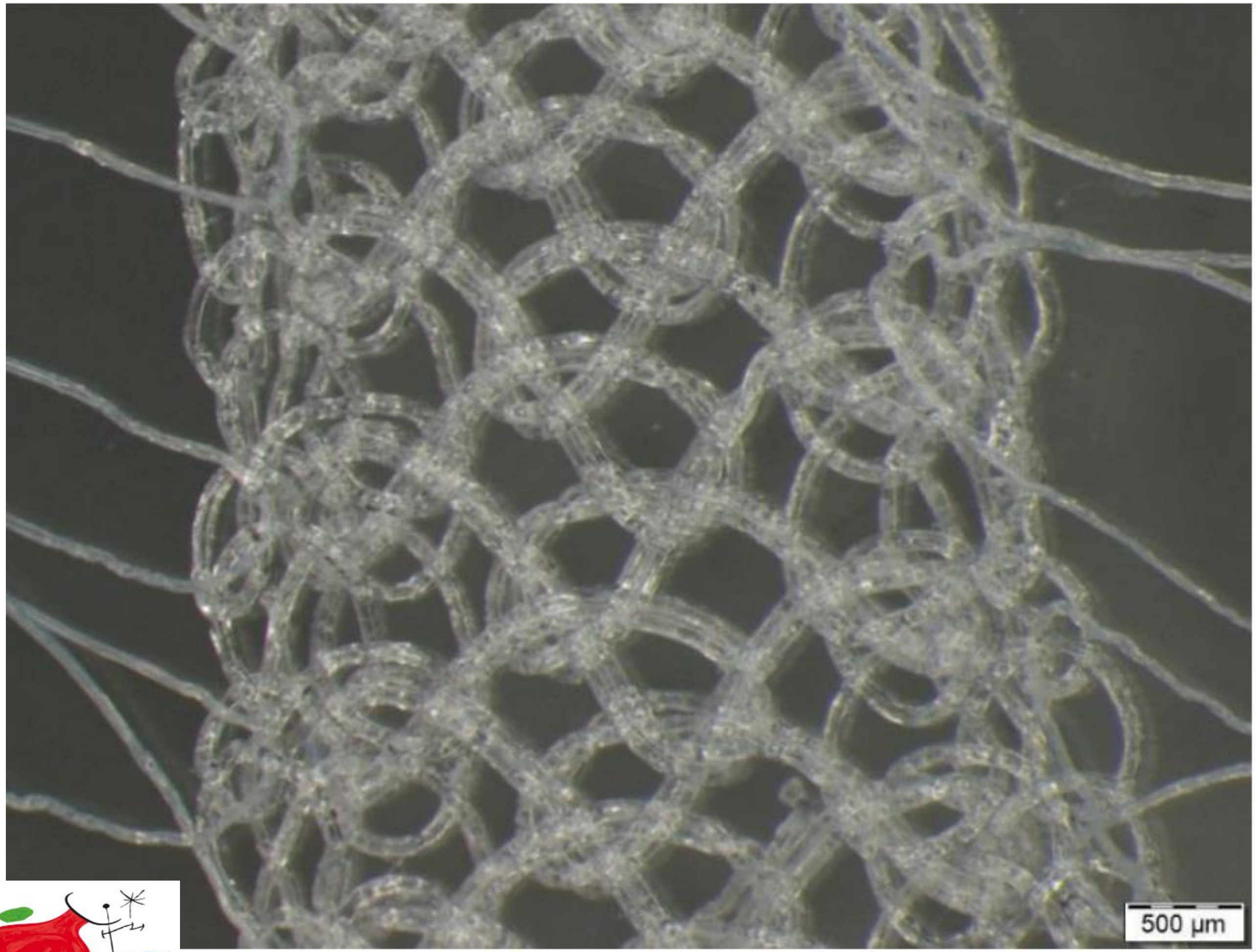
Thrombogenic fibers



ig 5. (i), ZA00462 central spine view

Fiber sample

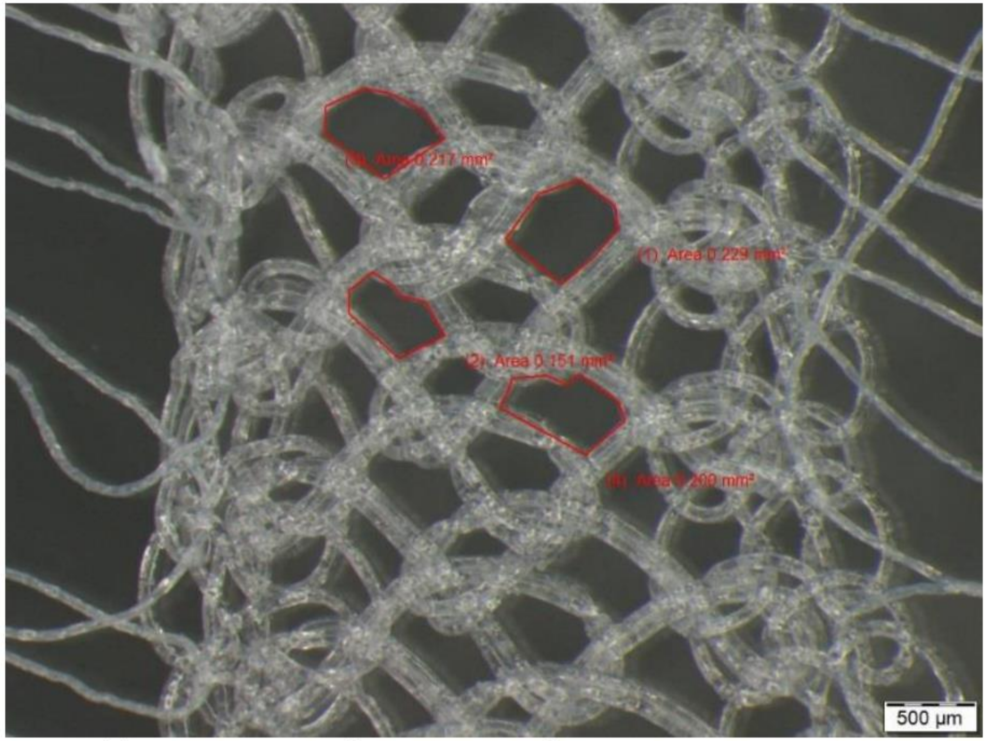


Fig 5. (ii), ZA00462 central spine view with open pore area measurements

Fiber strips

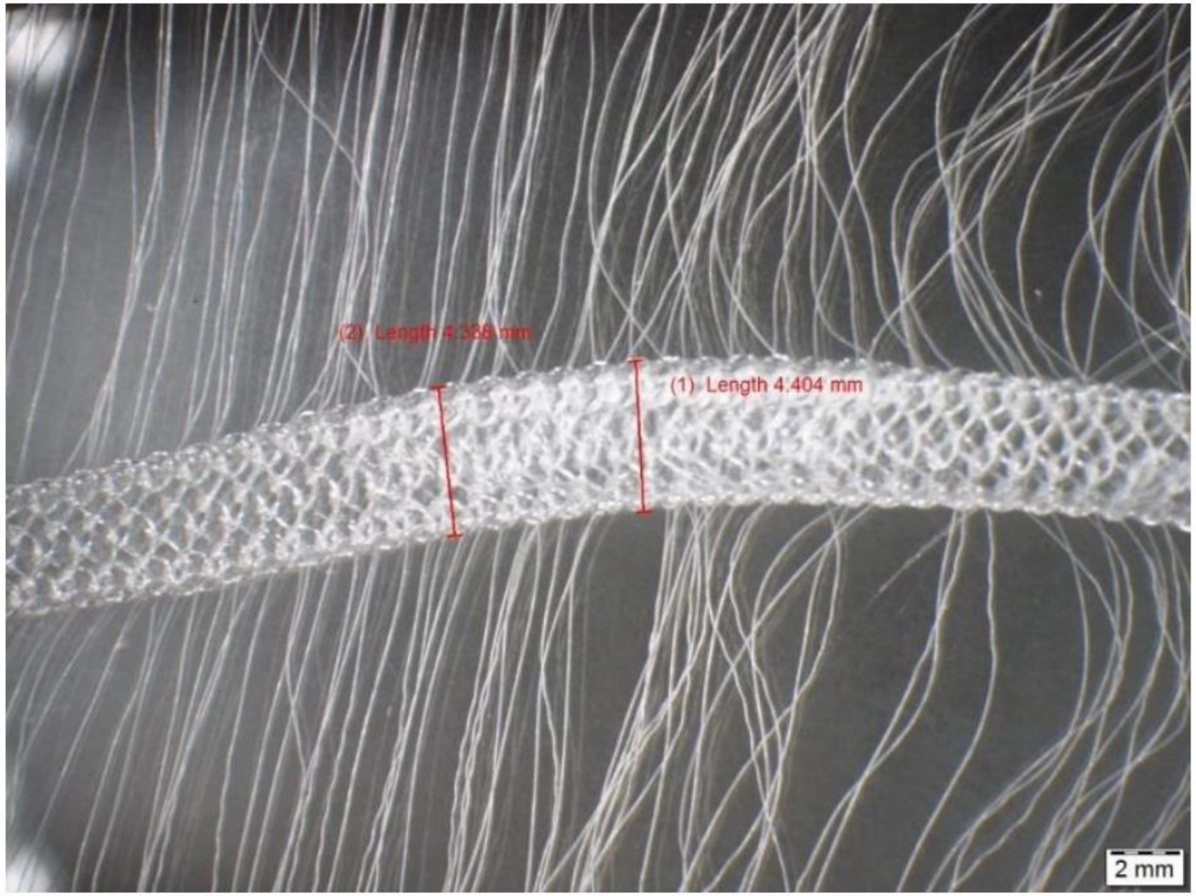


Fig 5. (iii), ZA00462 centre spine view with spine width measurements

View of the PTFE fiber strip technique

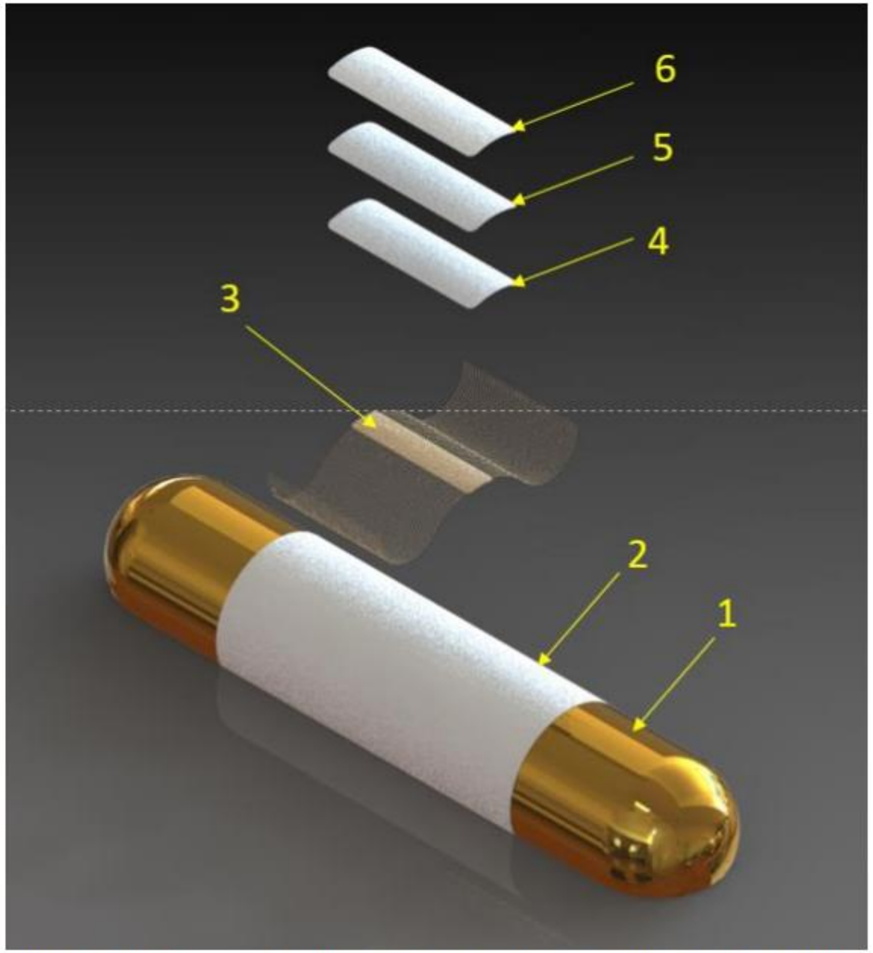


Fig. 8. Expanded view of the components used in method 1: 1 -Mandrel, 2 -Inner BioWeb Wrap, 3 - PET Fibre strip, 4- BioWeb Strip #1, 5- BioWeb Strip #2, 6 - BioWeb Strip #3.

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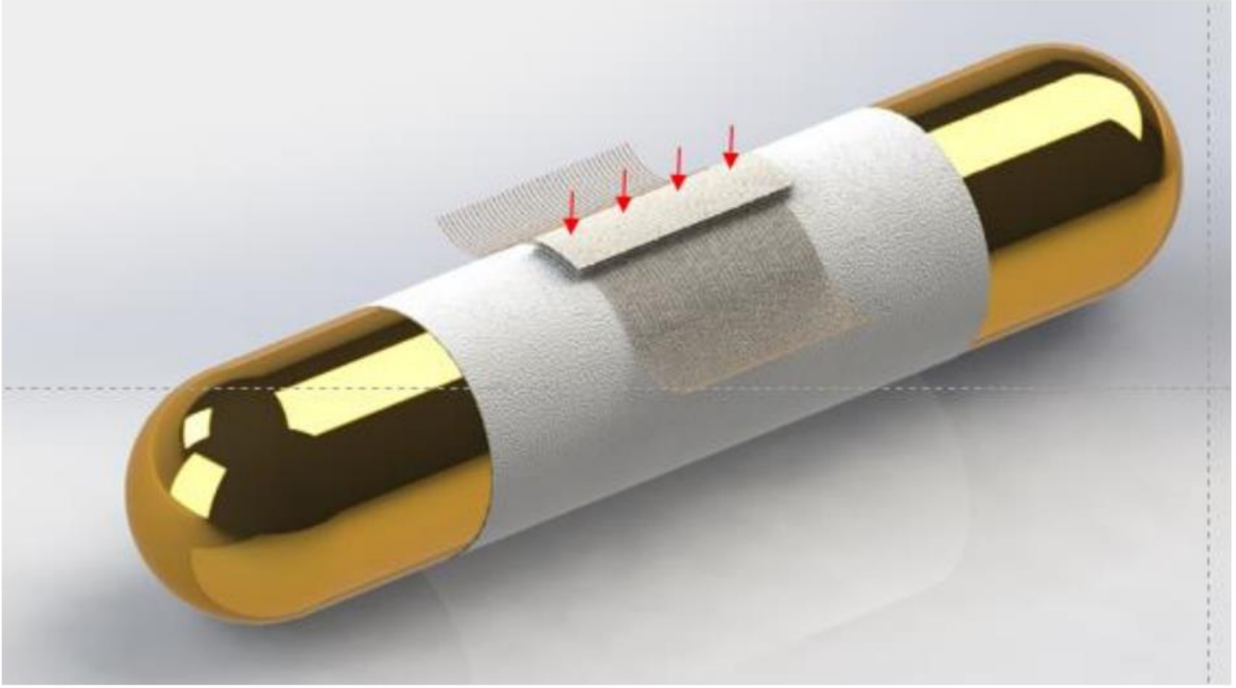

Fig. 9. Illustration of the assembled components in method 1.

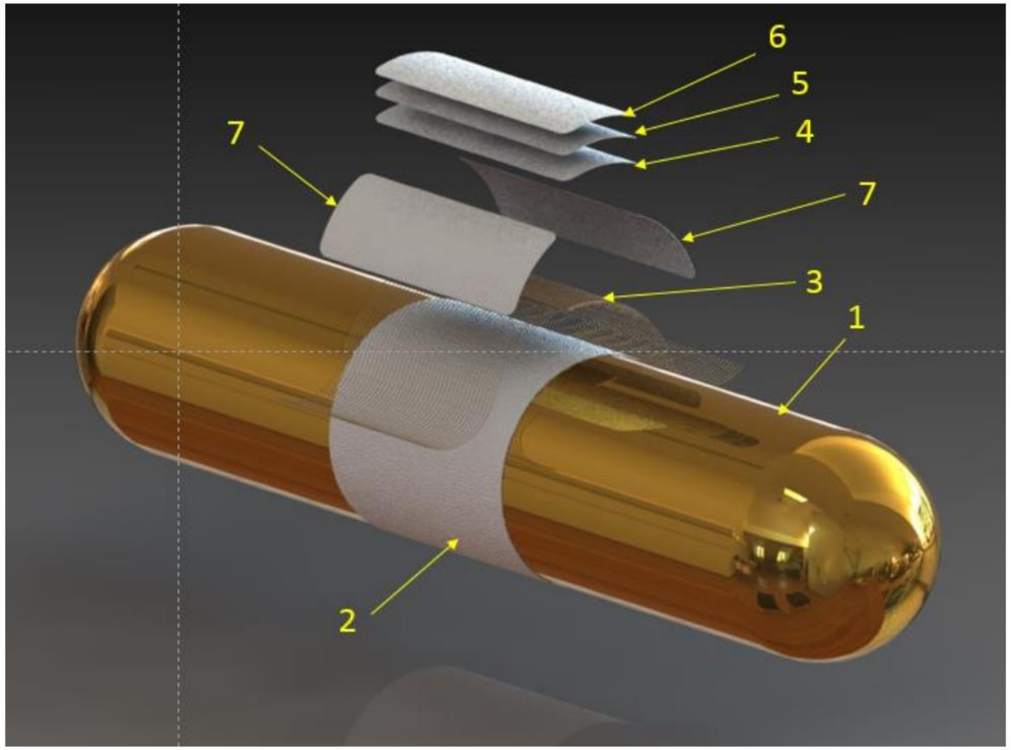

Fig. 11. Expanded view of the components used in method 2: 1 – Mandrel, 2 - Inner BioWeb Wrap, 3 - Pet Fibre strip, 4 - BioWeb Strip #1, 5 - BioWeb Strip #2, 6 - BioWeb Strip #3, 7 - PET Tape.

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Fiber tension testing

Fig. 28. Tensile Tester Set-Up

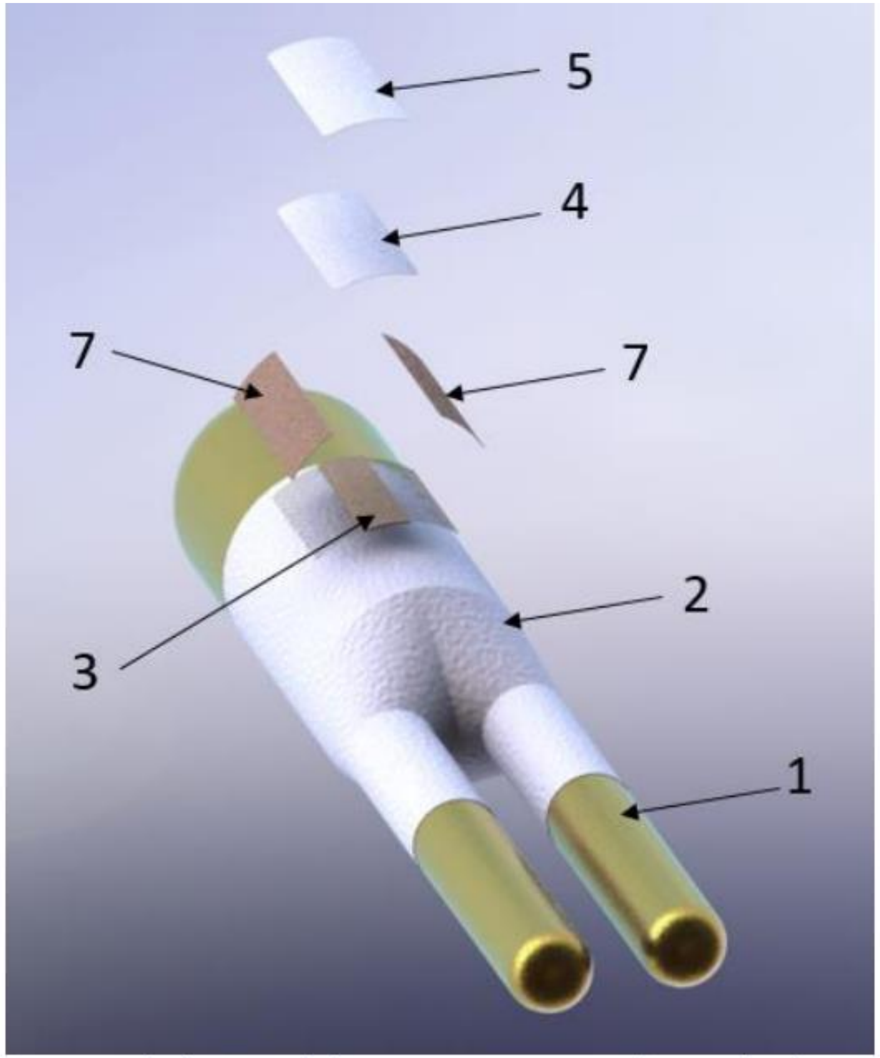

Fig. 30. Expanded view of the components used in method 5:
ǀrel, 2 – Bifurcated encapsulated frame per fig 29,
p, 4 - BioWeb Strip #1, 5 - BioWeb Strip #2, 7 - PET Tape.

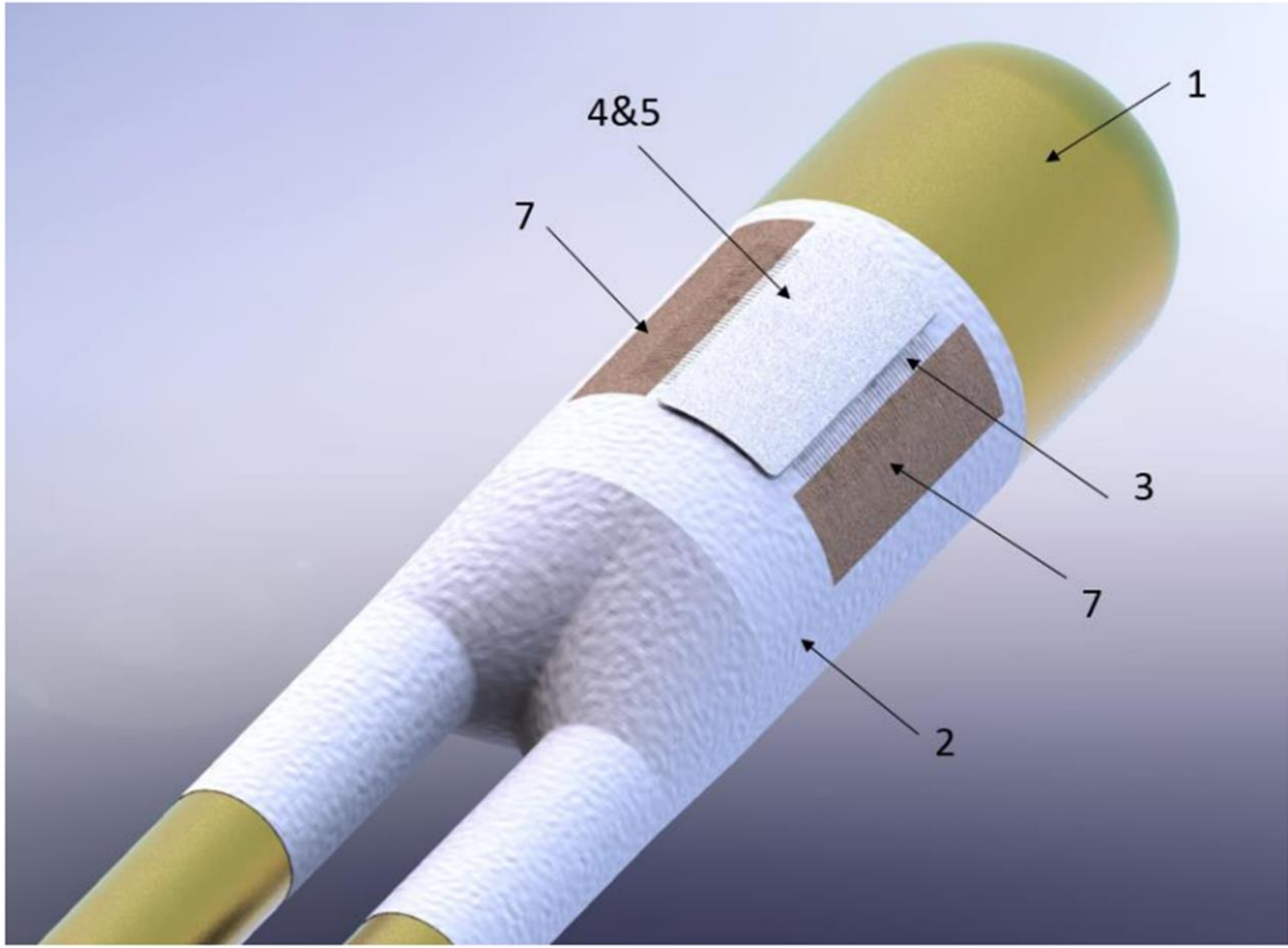

Fig. 31. Illustration of the Bifurcated finished assembly using method 5

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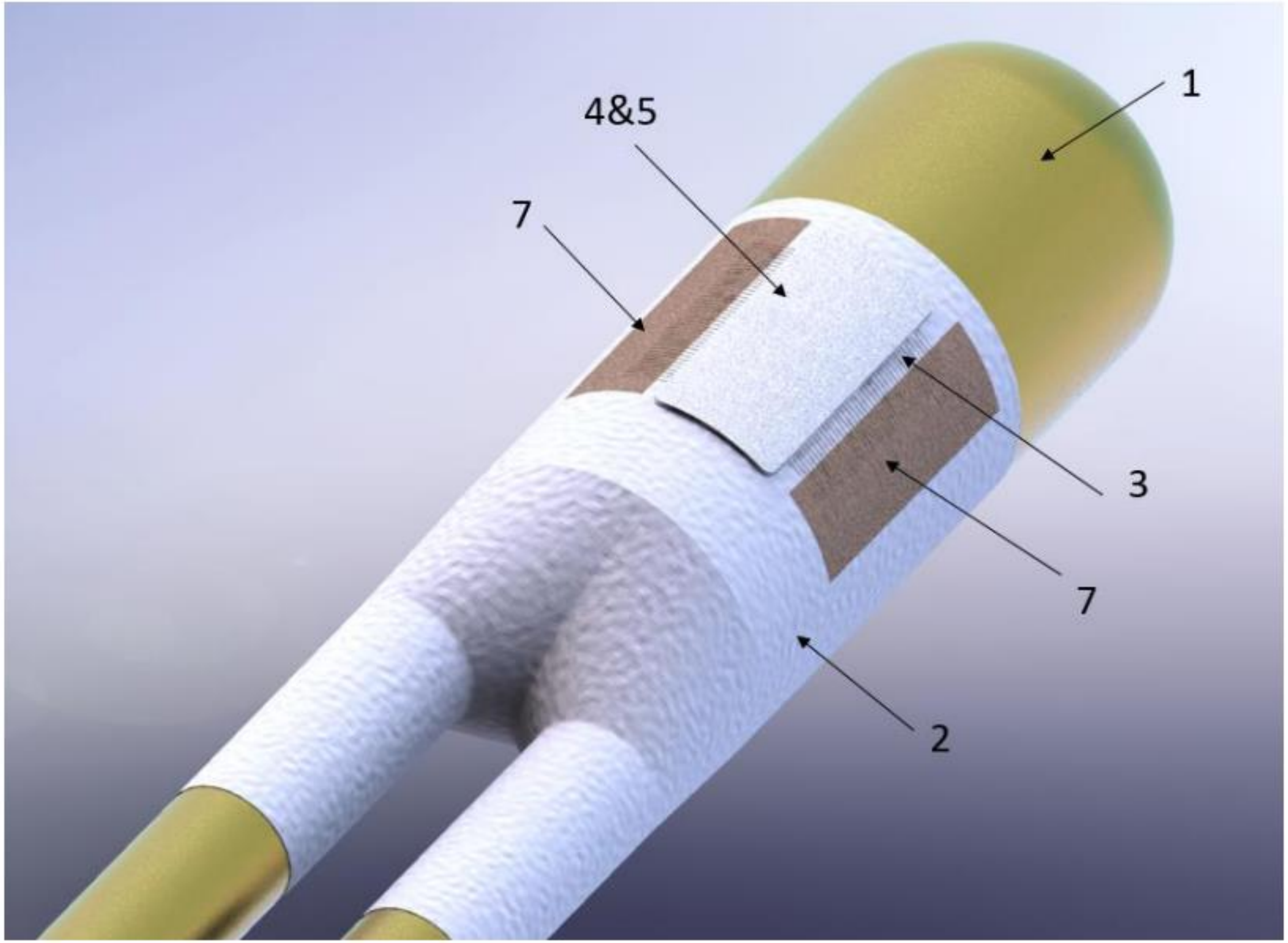
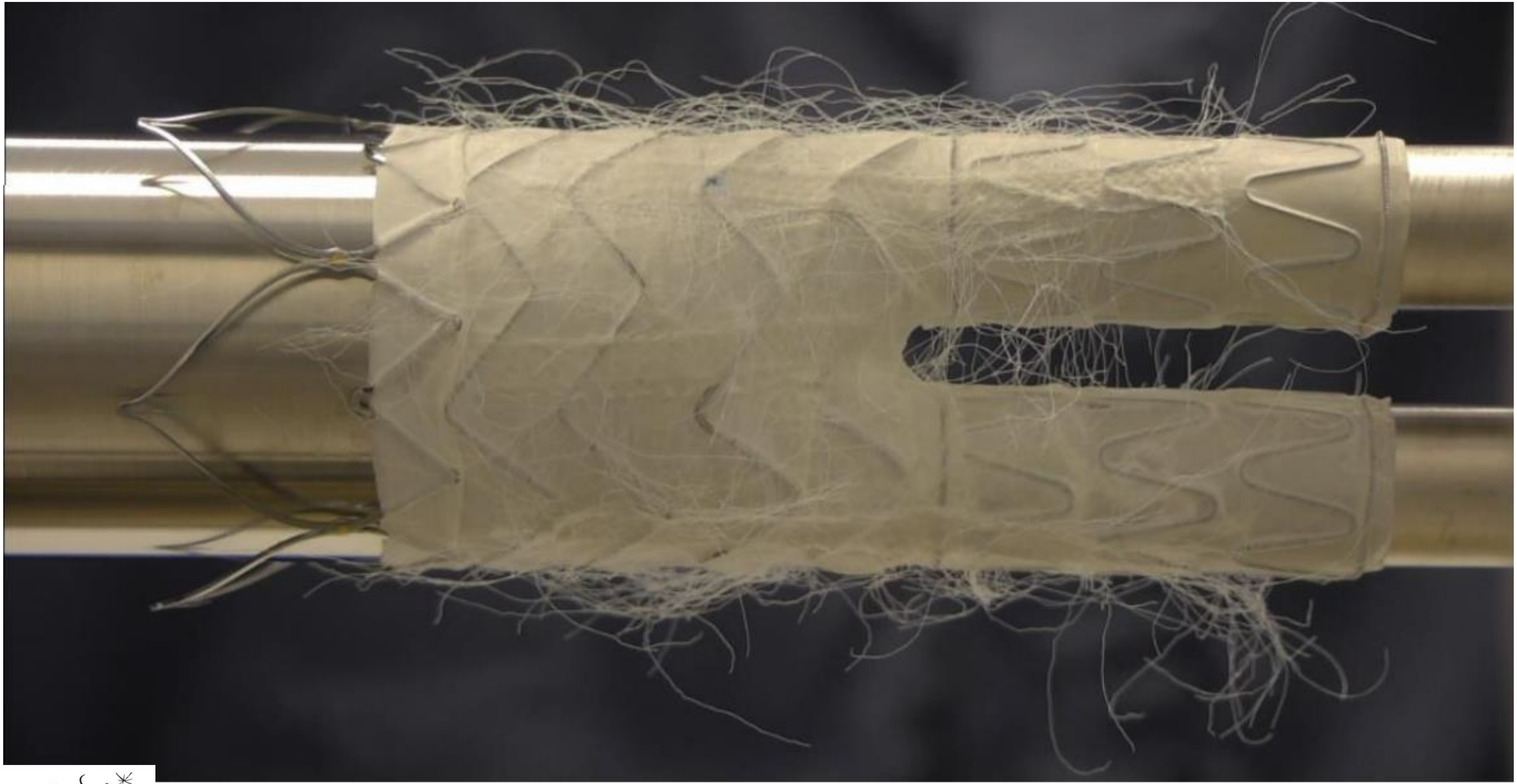


Fig. 31. Illustration of the Bifurcated finished assembly using method 5



: Frontal view of Bifurcated Body with longitudinal fibre integration.

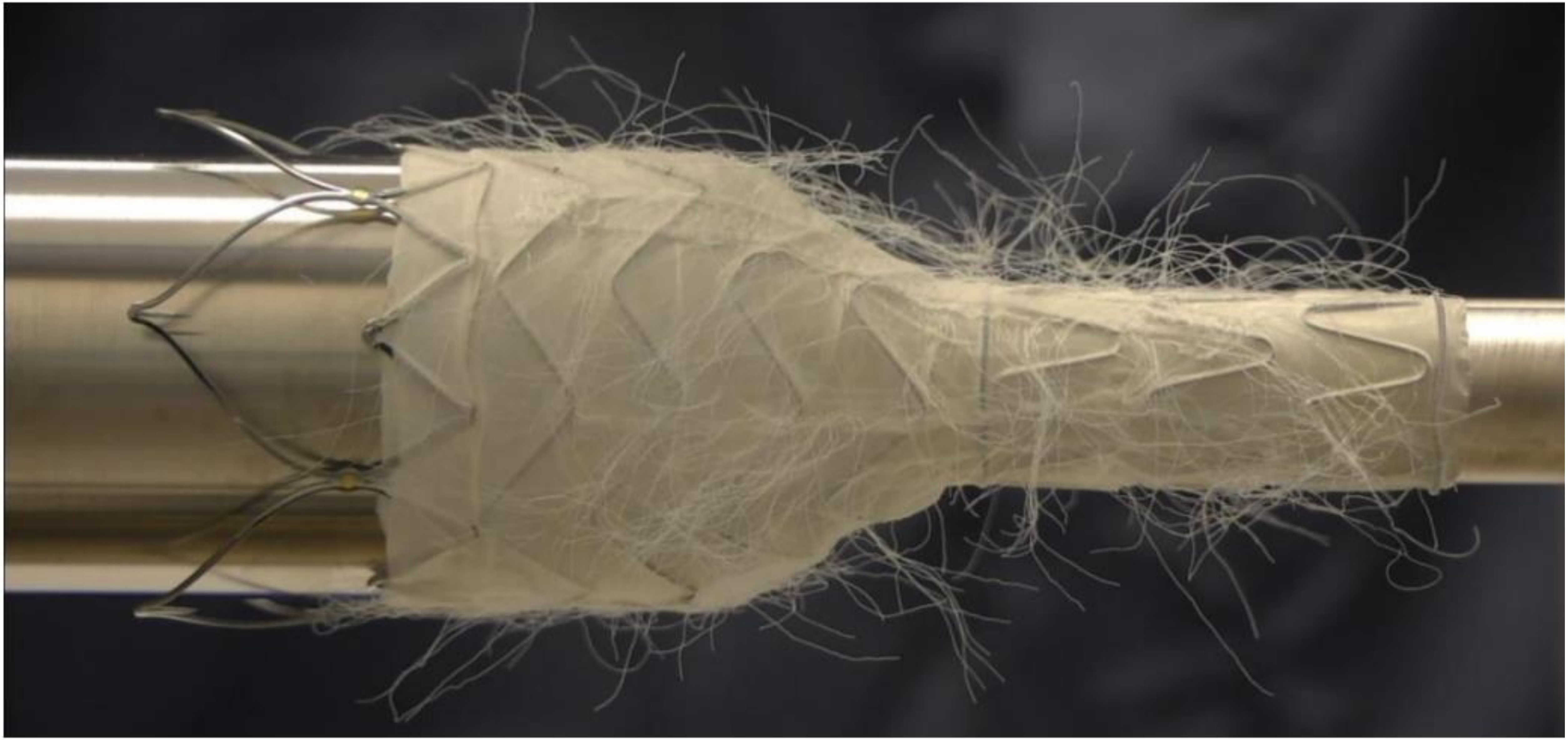
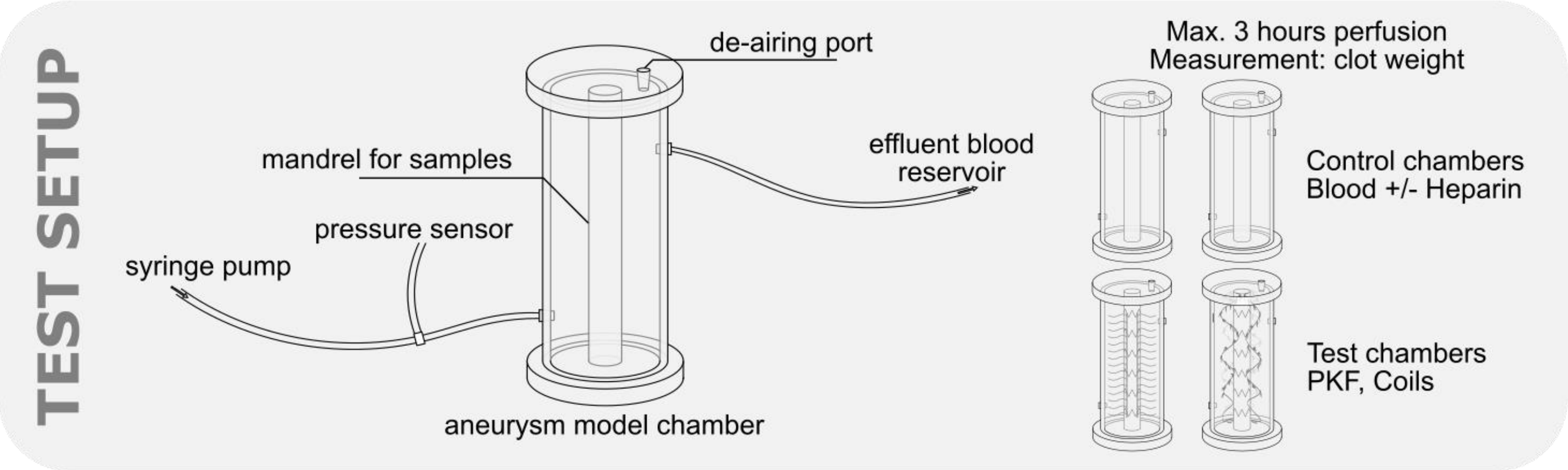


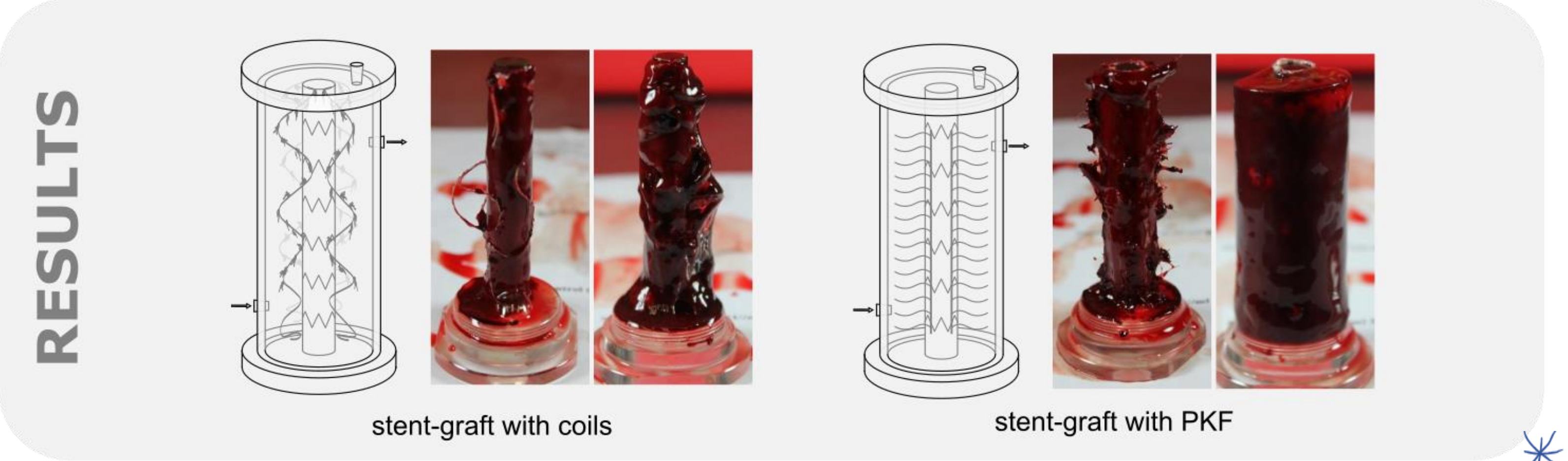
Fig 2: Side view of Bifurcated Body with longitudinal fibre integration.

Bifurcted integrated graft

Fig. 32. Bifurcated encapsulated frame with Integrated Longitudinal Fibre.

In-vitro assessments of clot elicitation by thrombogenic fibers vs. embolization coils





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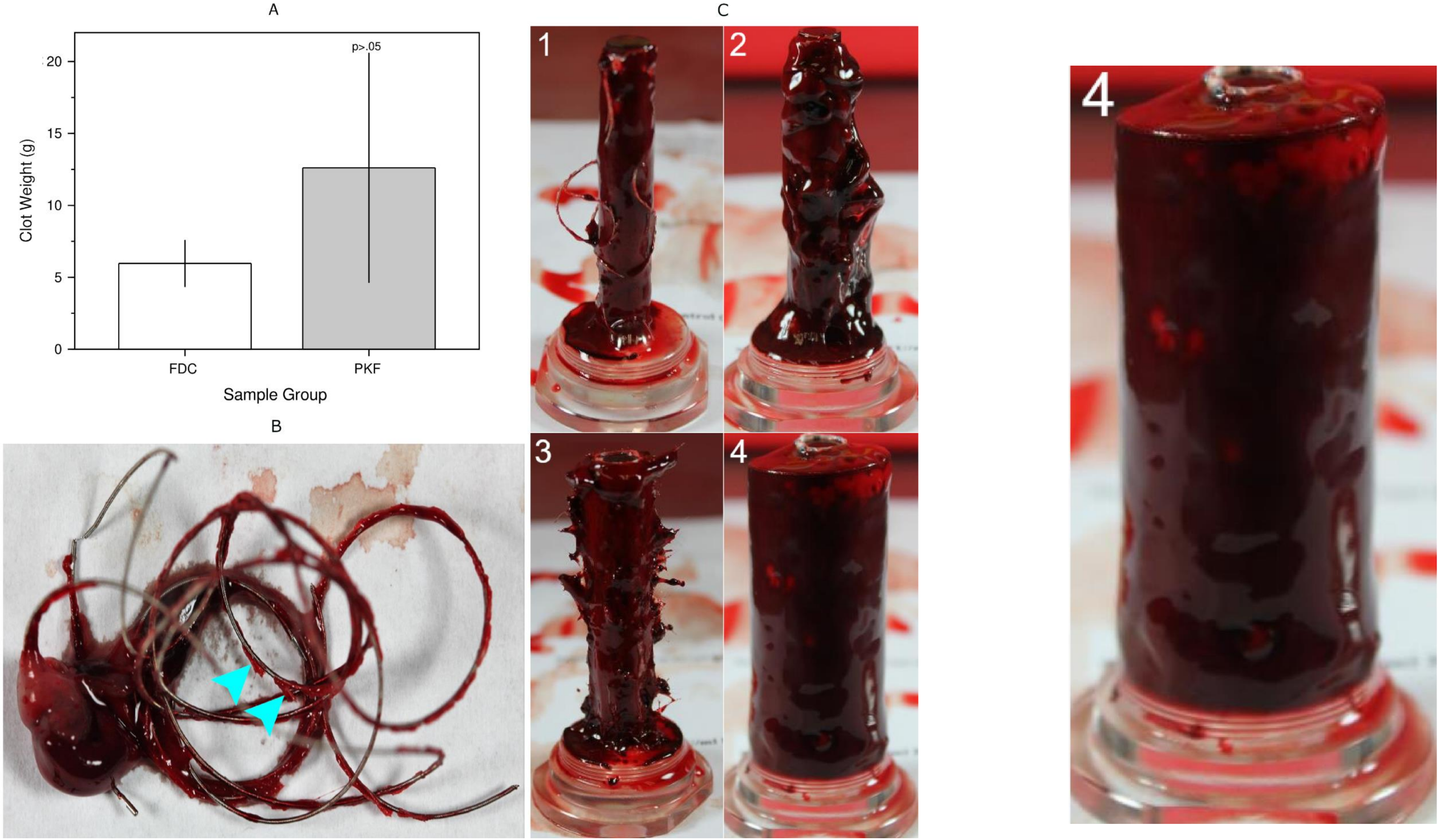
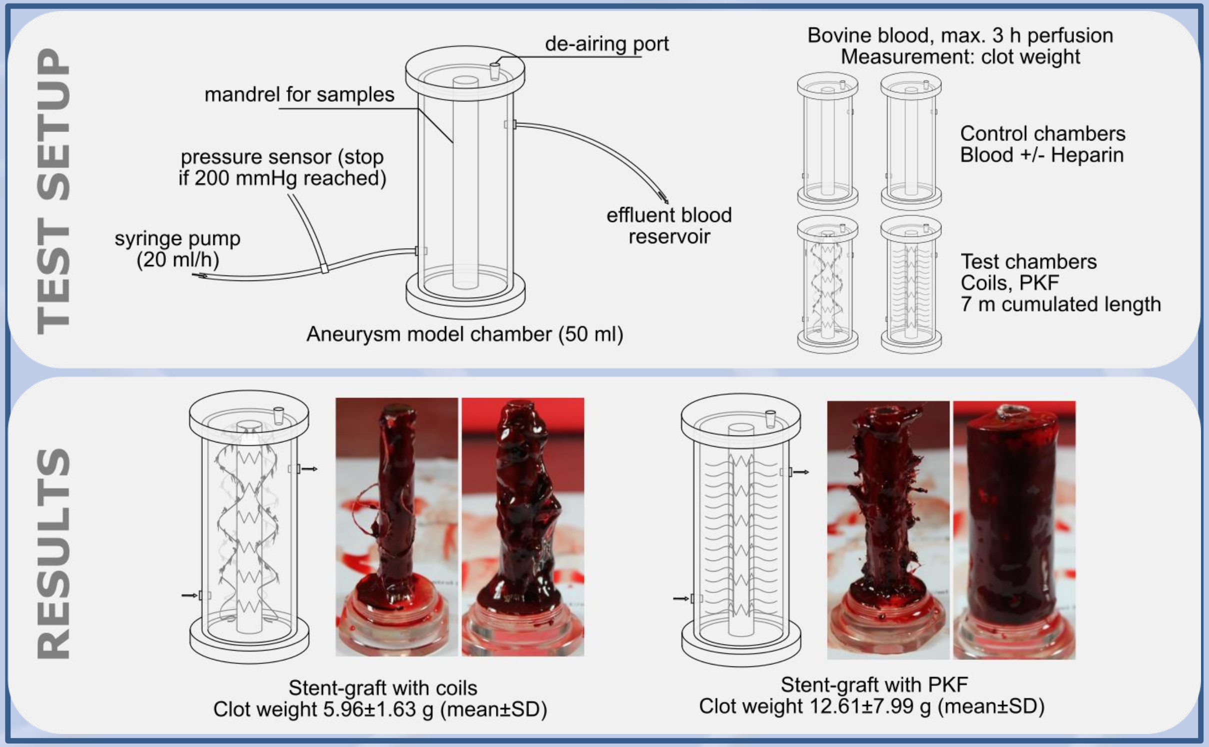

A
p>.05
Clot Weight (g)
20
15
10
5
0
FDC
PKF
Sample Group
B
C
1
2
3
4
4

In-vitro assessments of clot elicitation by thrombogenic fibers vs. embolization coils

- Model aneurysm chamber with type II endoleak
- Stent-graft with Patented Kardiozis Fibers (PKF) vs. stent-graft with embolization coils
- Two-step assessment: static & dynamic systems



- Equivalent lengths of PKF and coils induce equivalent thrombosis
- Successful use of perfused aneurysm chamber model
- Total embolization seen with PKF
- Next step: further clinical investigations

A stent-graft with PKF elicits at least as much clot as coils dispersed in an aneurysm model chamber.

ASAIO Journal
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Stentgraft crimping /Delivery system

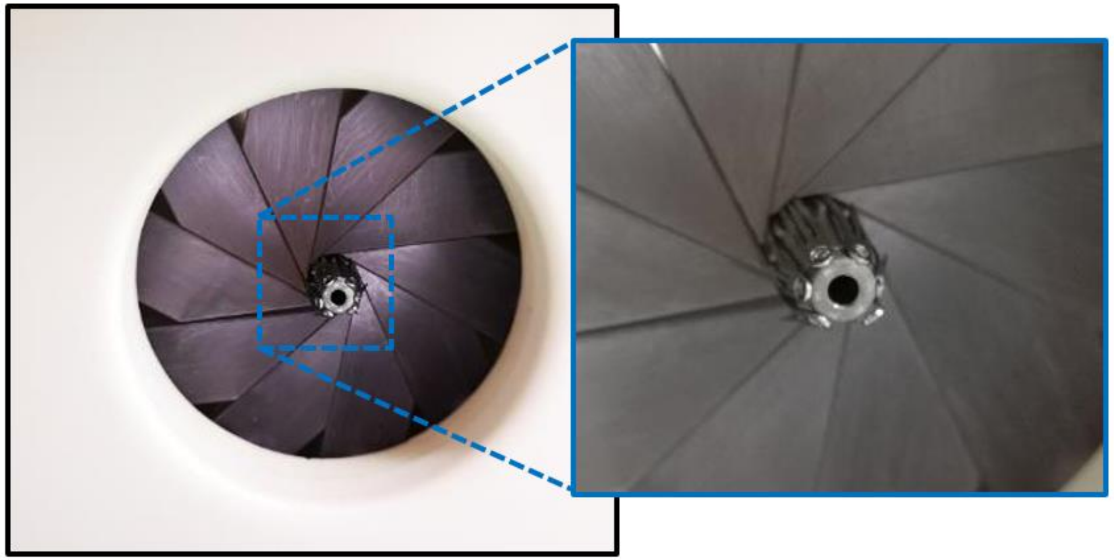


Figure 3: crimped prosthesis and stent stopper engaged outside the crimping head.

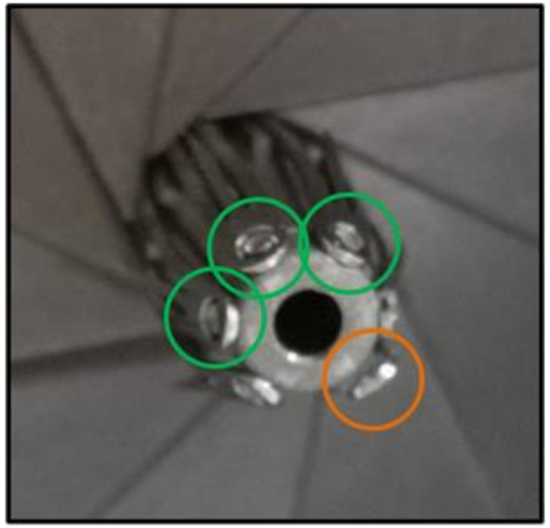


Figure 8: *correctly (GREEN) and un-correctly (ORANGE) matching teeth an*

PTFE damage

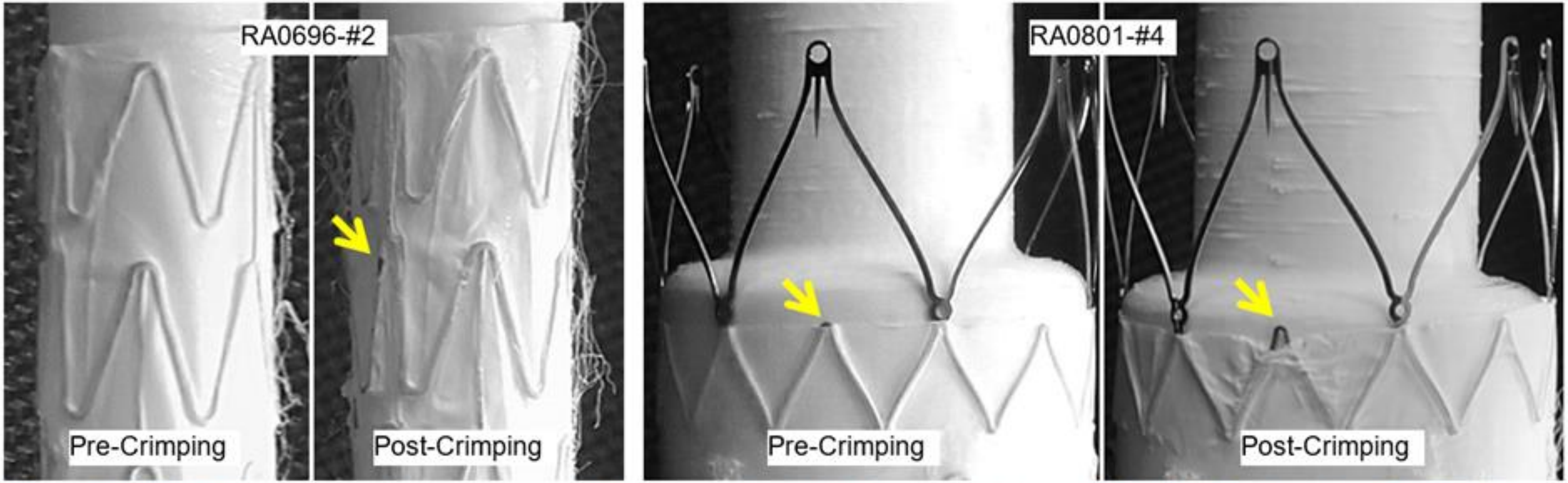
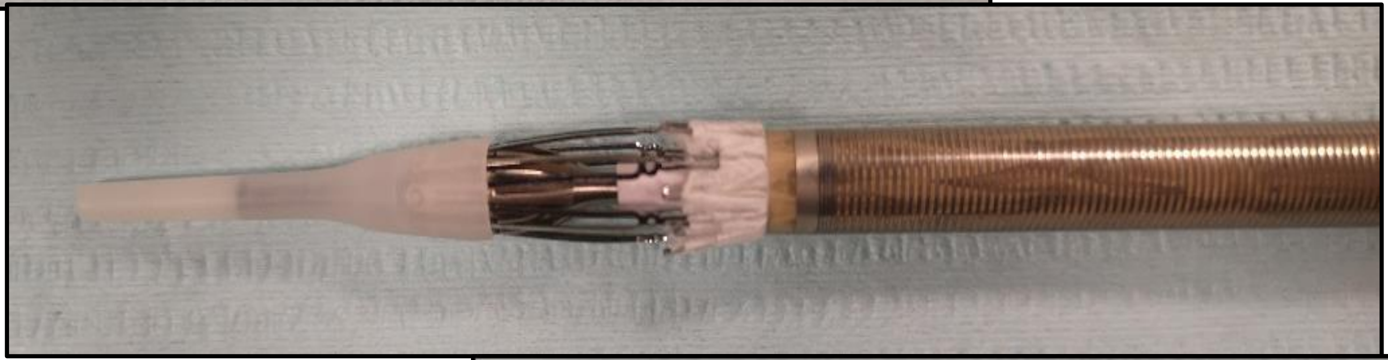


Figure 3: PTFE damage on two representative sample. Left: Leg prototype RA0696-#2, showing PTFE damage (yellow arrow) and slight PTFE crumpling. Right: Bifurcated body prototype RA0801-#4, showing pre-existing PTFE defect pre-crimping, with damage post-crimping (yellow arrows).



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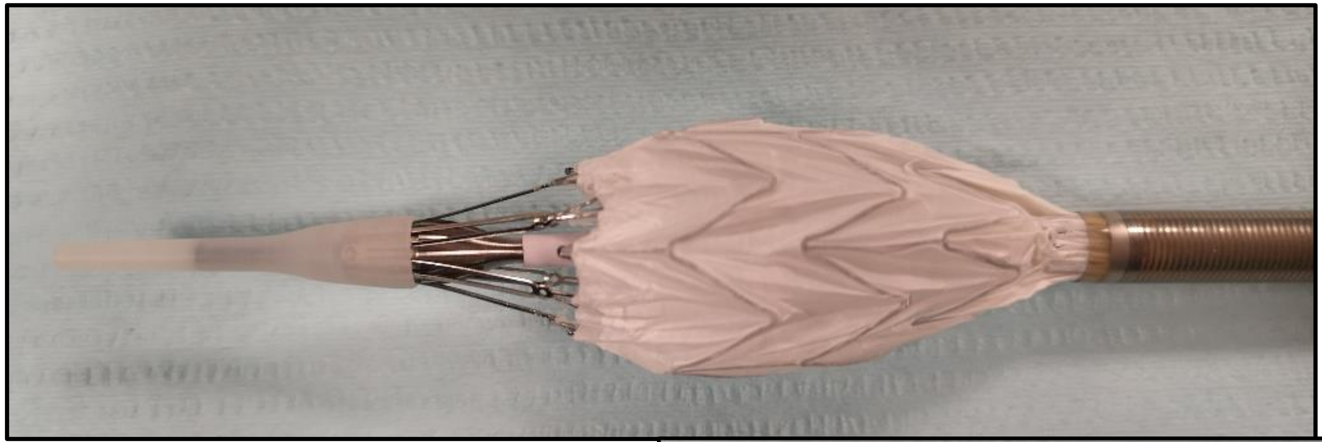

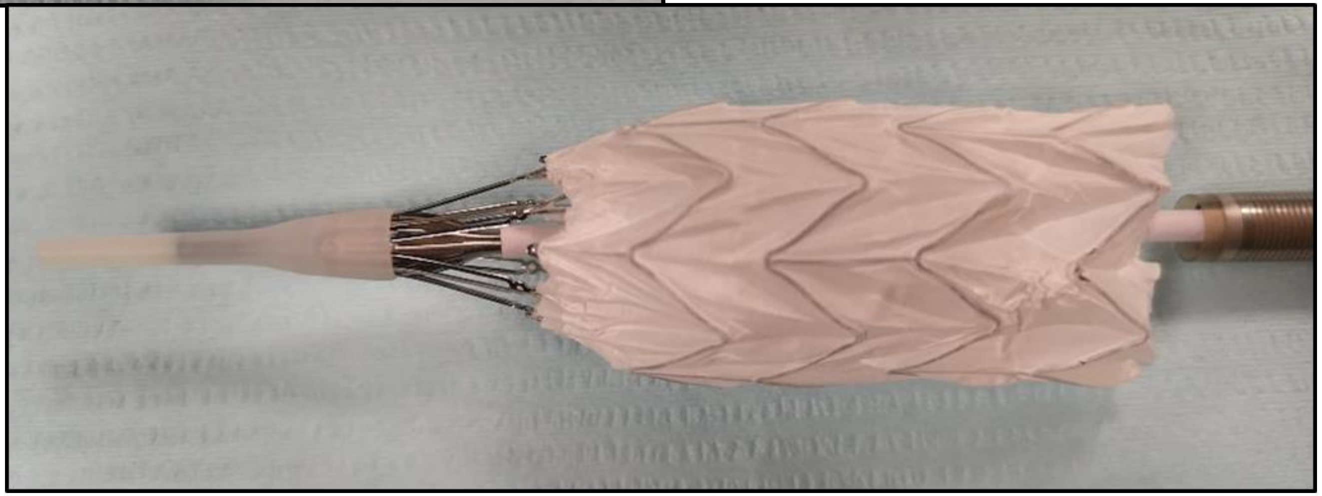

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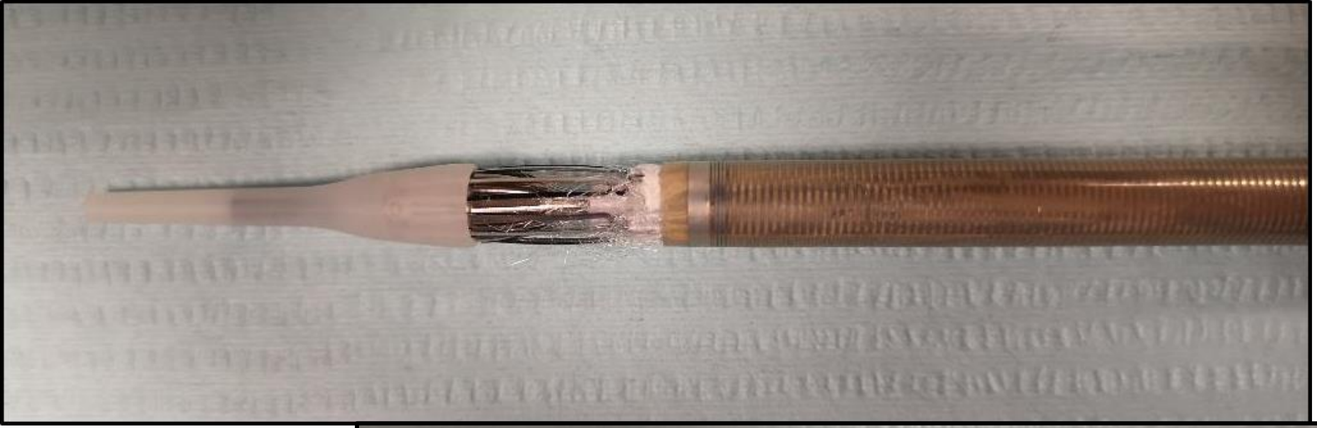

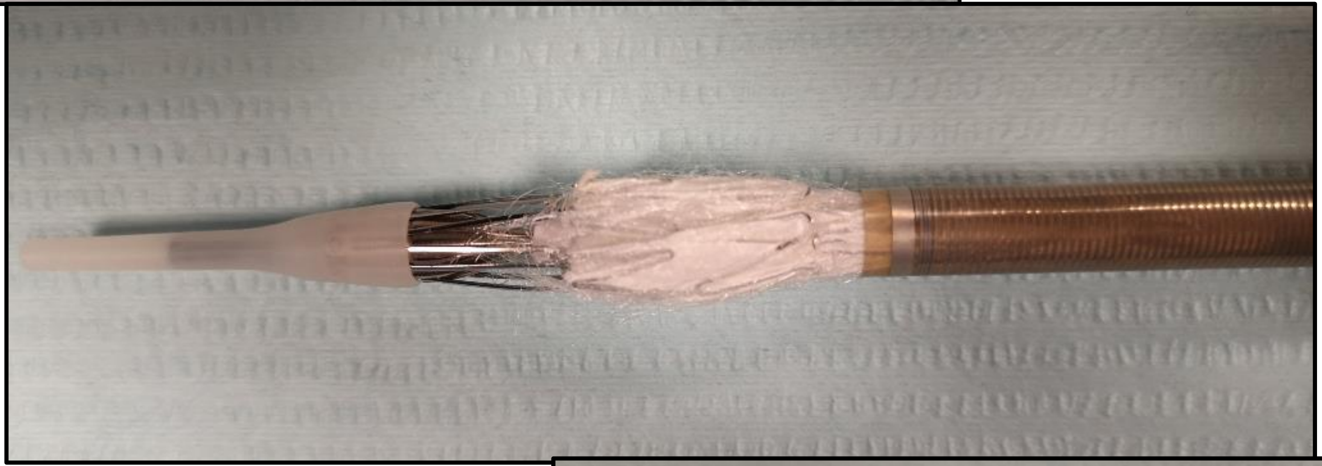

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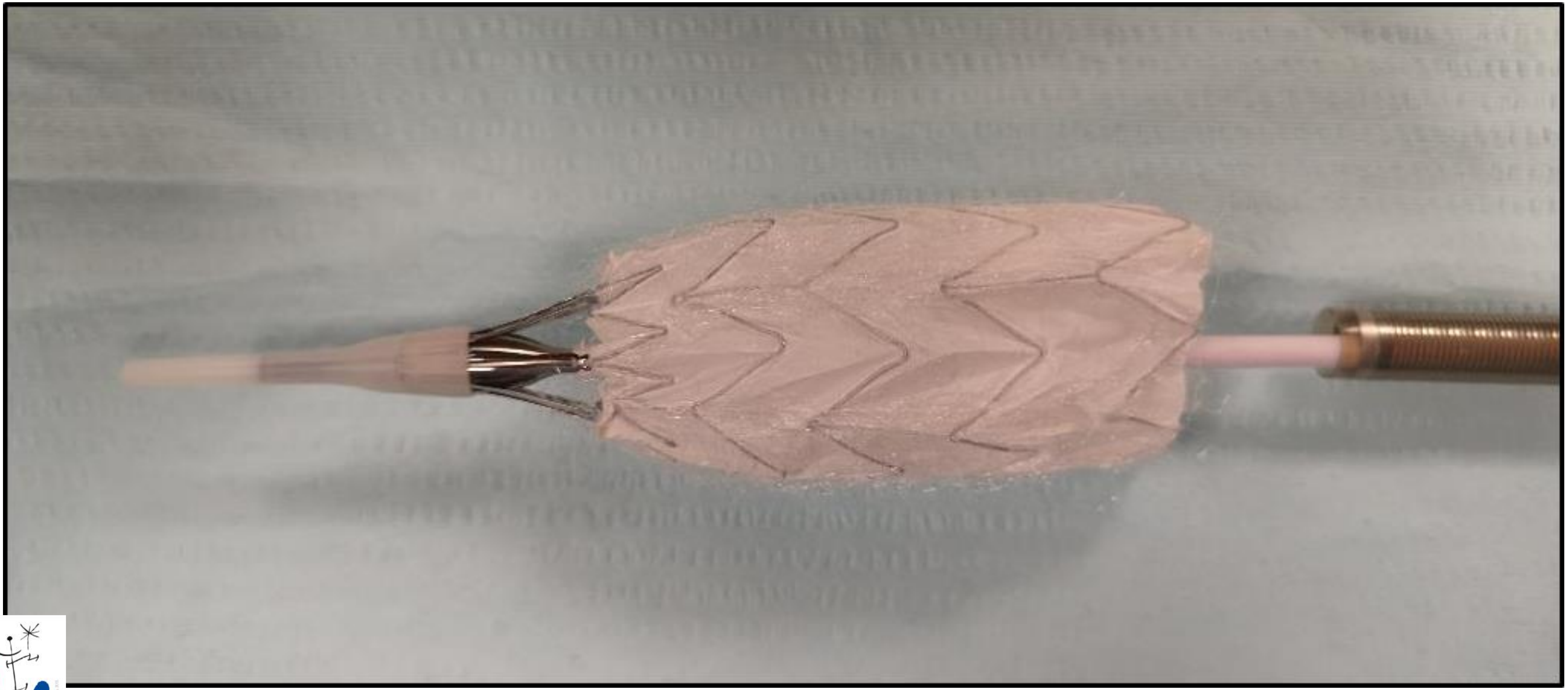

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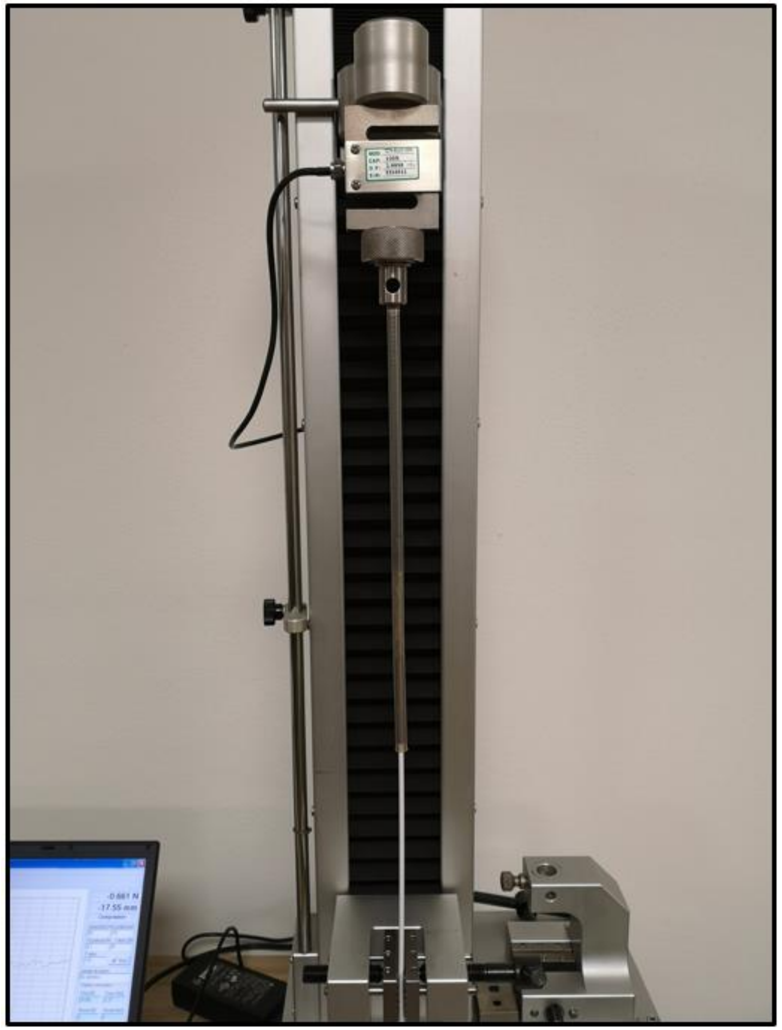
Delivery System Film

Sliding force test / Stentgraft



Stent	Sample ID	Configuration	Crimping	Deployment	Friction force	Visual Inspection
KZ_RD_A_STENT_Rev01	#2	4+4 PFTE wraps (6 fibers strips)	PASS*	PASS*	PASS	No fiber detachment
KZ_RD_A_STENT_Rev01	#4	4+4 PFTE wraps (no fibers)	PASS	PASS	PASS	No fiber detachment
KZ_RD_A_STENT_Rev01	#6	6+6 PFTE wraps (no fibers)	PASS	PASS	PASS*	No fiber detachment

** With Comments/Observations*

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PTFE wear after testing

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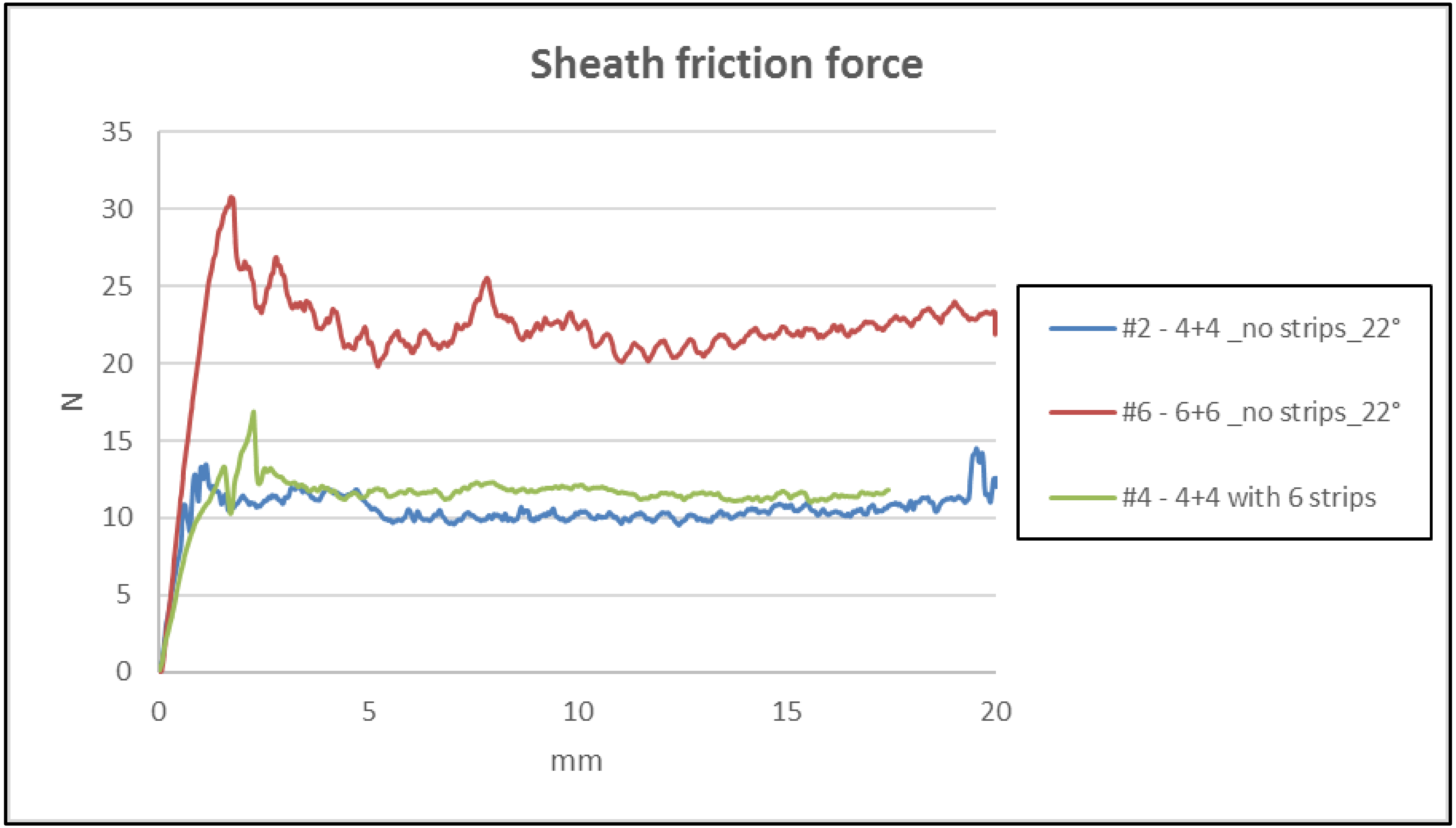
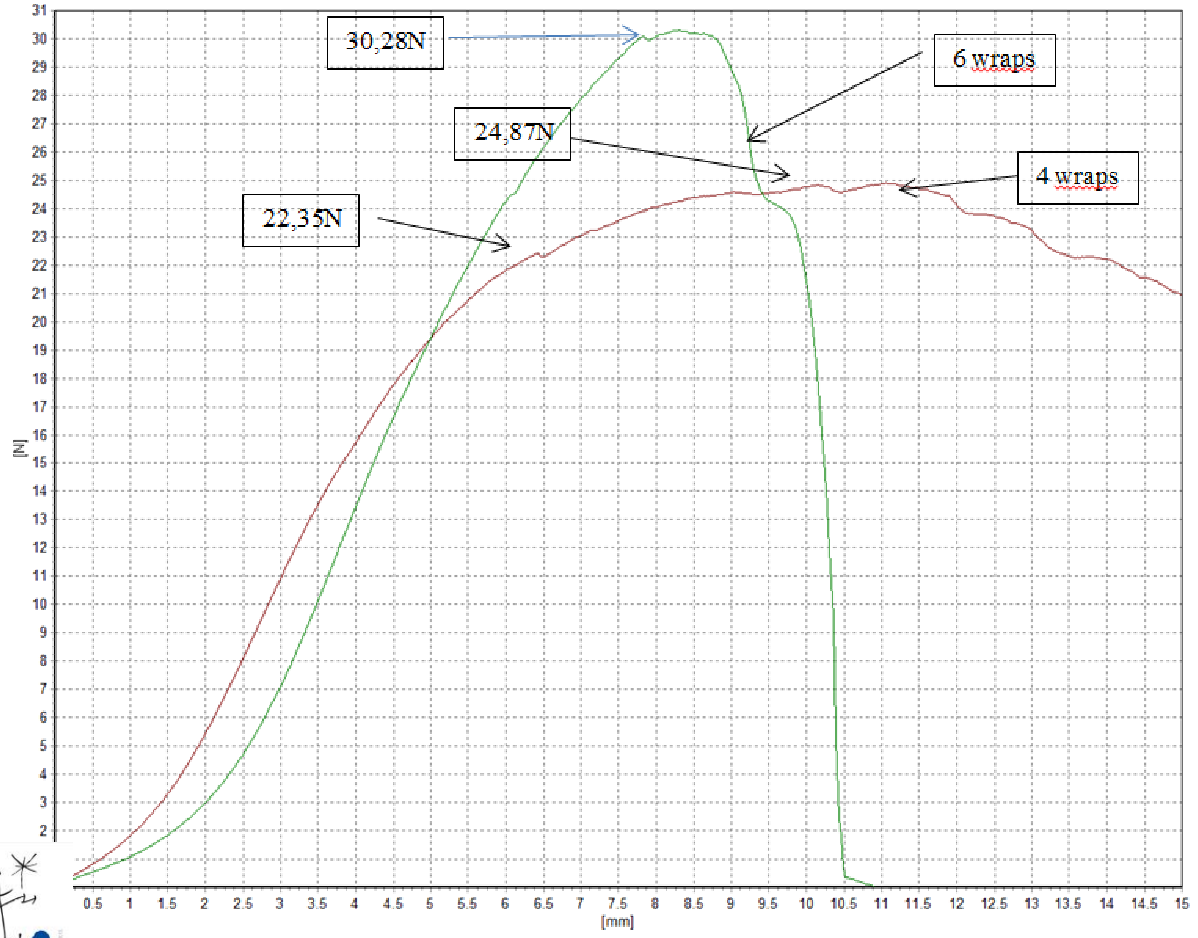
Sheath friction force



Tensile strength results



ISO 25539-1: 2017

Cardiovascular implants -

Endovascular devices - Part 1:

Endovascular prostheses (ISO

25539-1:2017) § 8.4 “Reporting”;

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Evaluation test Crimping

<u>Test Protocol</u>

Crimping test to verify pull force trend

Diameter 18Fr

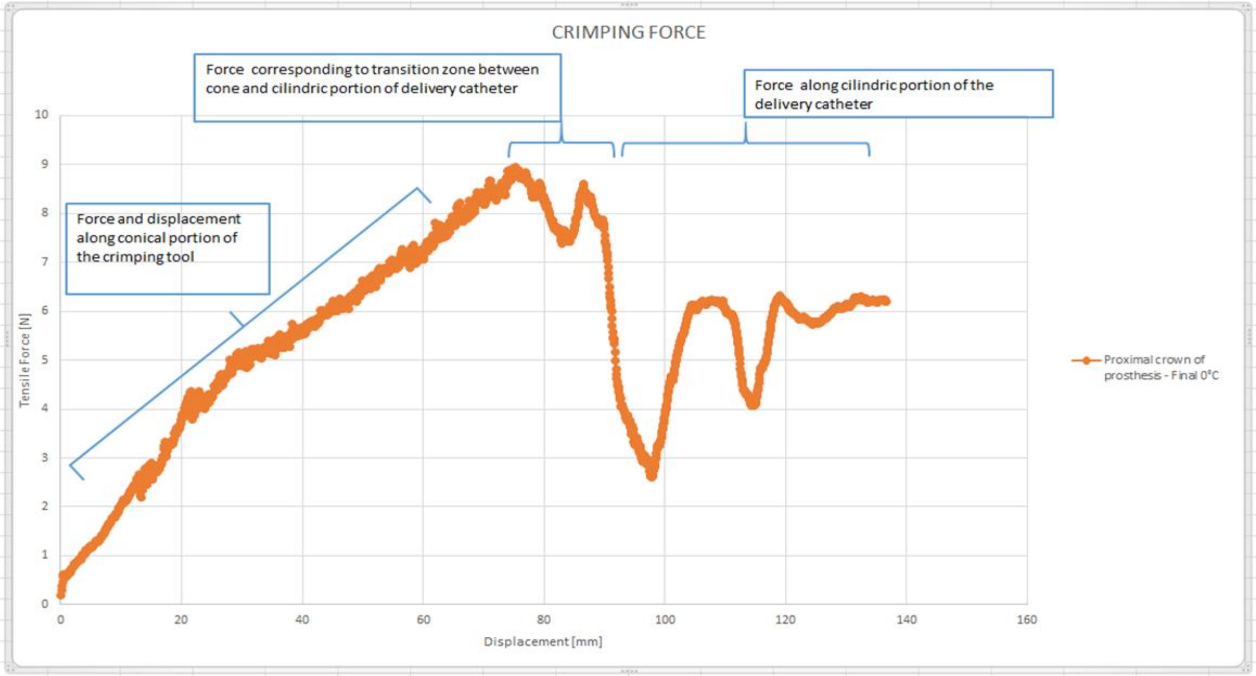
Crimping method: conical shape tooling

Temperature:0°C

Constant speed:50mm/min
Maximum displacement:200mm

Evaluation results: Crimping Test

<u>Crimping test performed only on the renal upper ring</u>



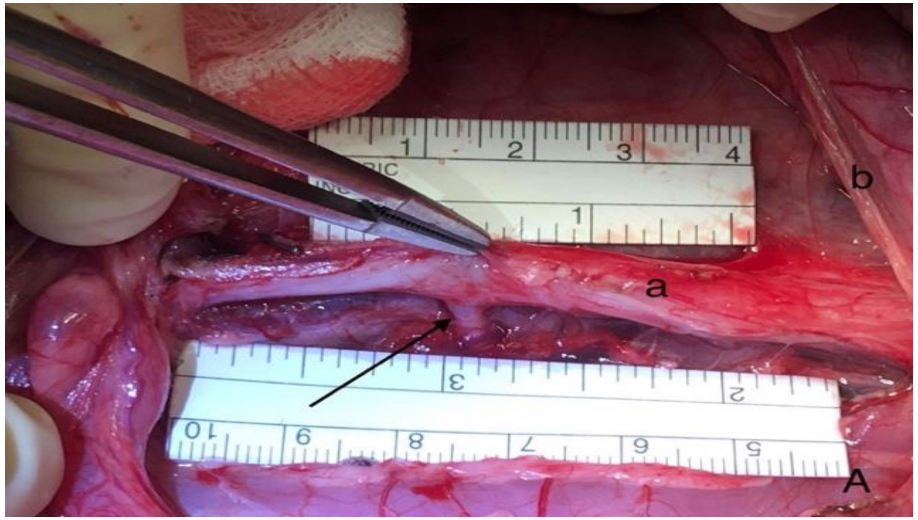
Max pull force 9N

Kardiozis

Stengraft / Kardiozis Low profile 14 fr / 25 mm

In vivo / Animal study

- AAA model with type 2 Endoleak



Diaz, *J. Vasc. Surg*, 2004

Chaer, *J. Vasc. Surg.* 2006

Rhee, *J. Vasc. Surg,* 2005

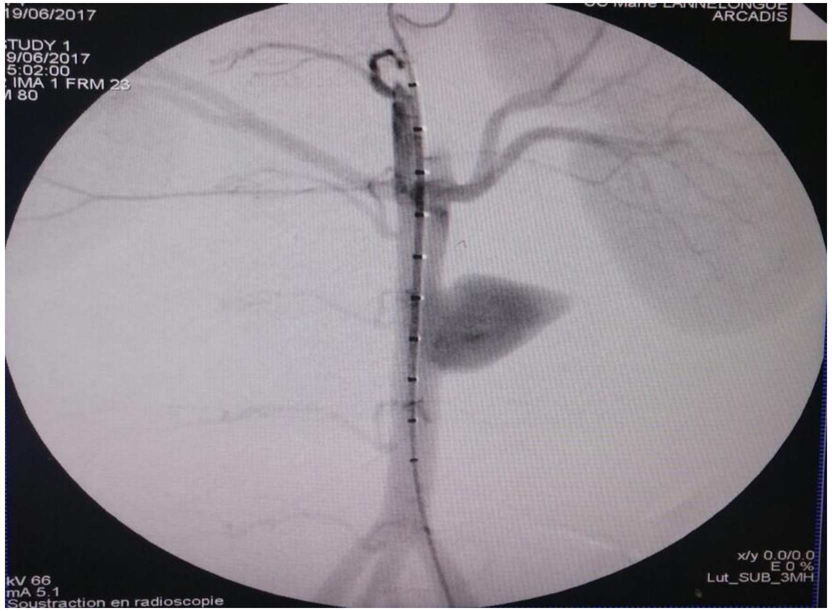
)04

Model improvment

- Major T2EL
- Anterior feeding artery / IMA

Material / Methods

- T2EL evaluation / Groups:
    - Contrast Echo doppler
    - Arteriography
    - Surgical analysis
    - Pressure measurment



1. Diaz, *J. Vasc. Surg*, 2004
2. Chaer, *J. Vasc. Surg.* 2006
3. Rhee, *J. Vasc. Surg,* 2005

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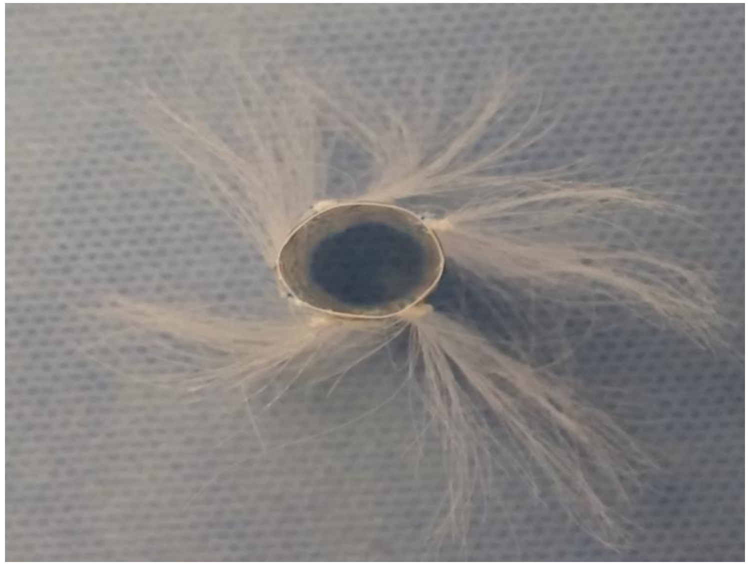
Material / Methods

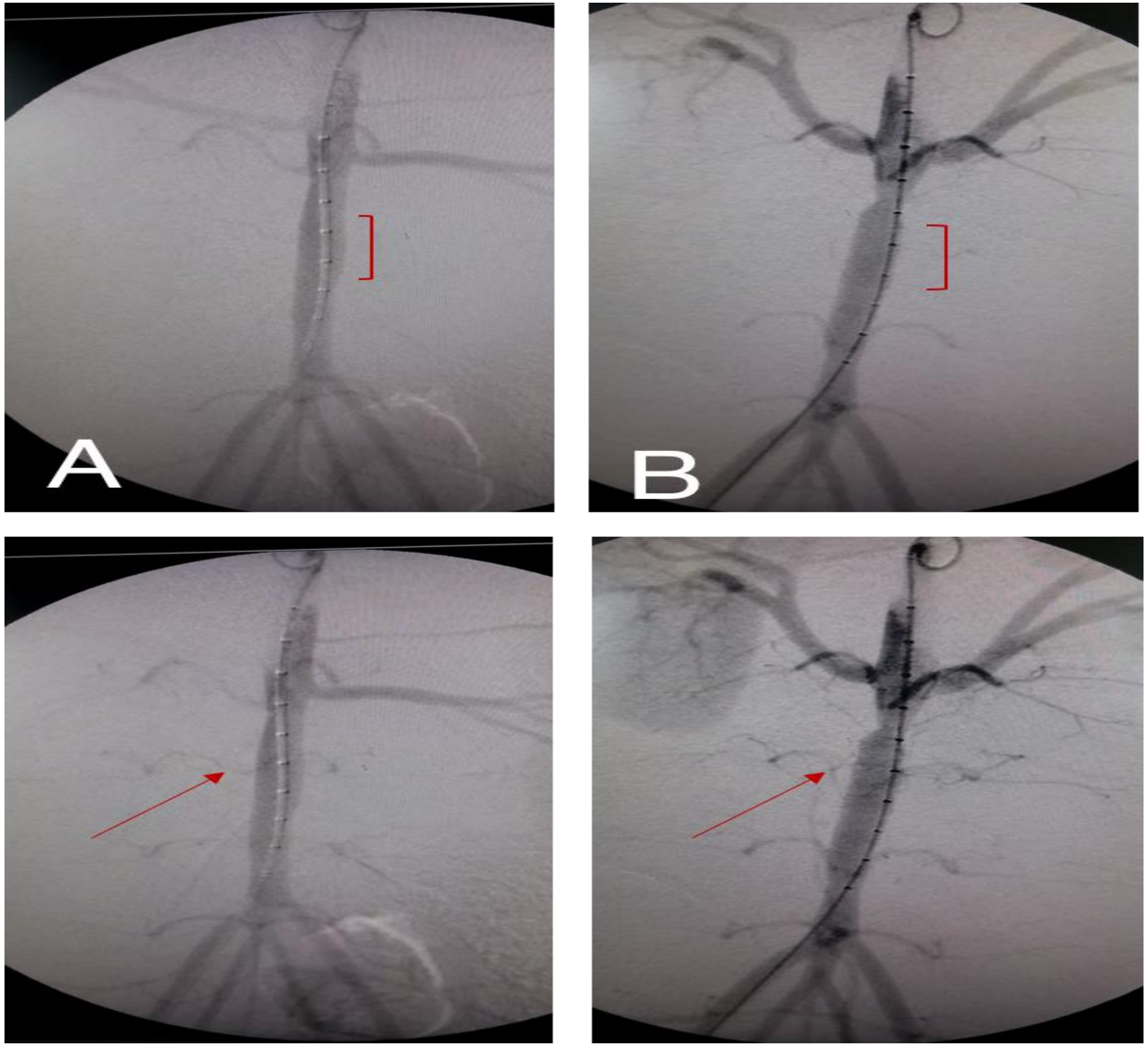
- Standart group: Covered PTFE Stent Fluency (Bard)
- Kardiozis stengraft:
  - PTFE EVAR stentgraft
  - Thrombogenic fibers



Arteriography

No difference between 2 groups:

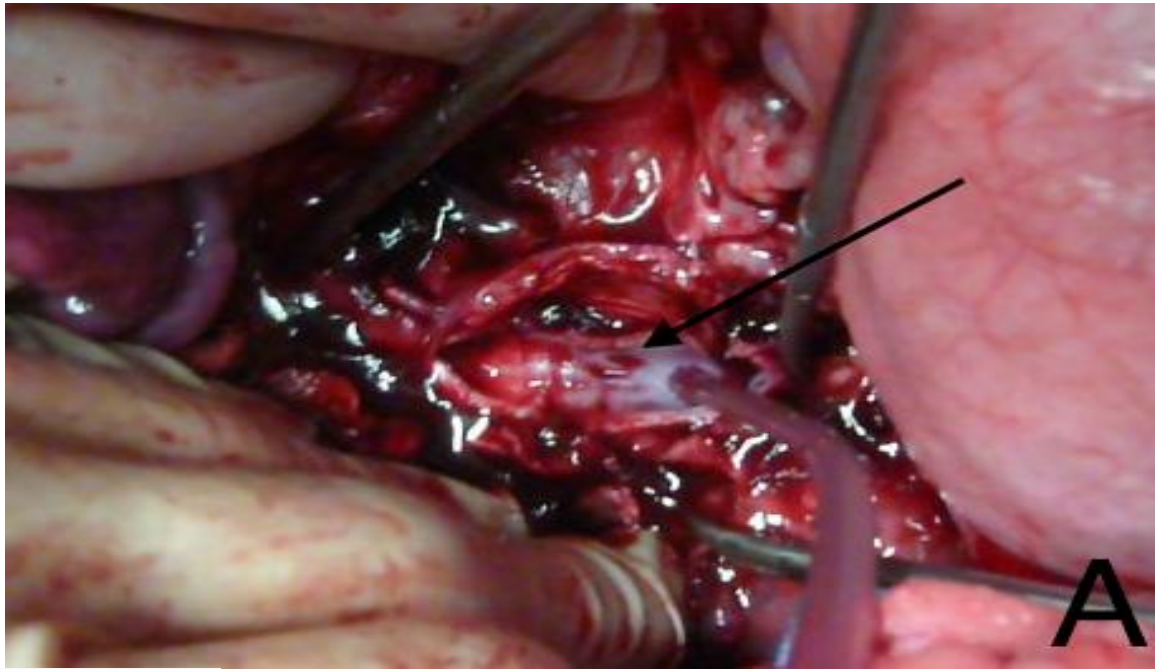
- Lombar arteries Opacification
- No AAA sac opacification

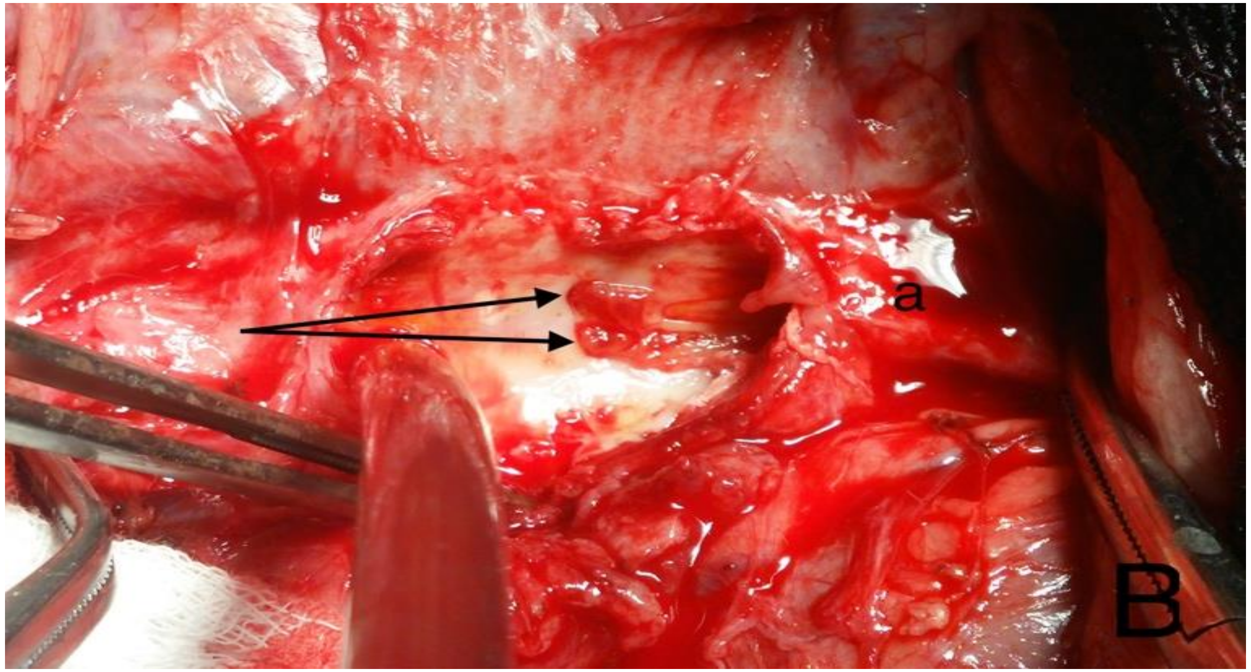


Back bleeding

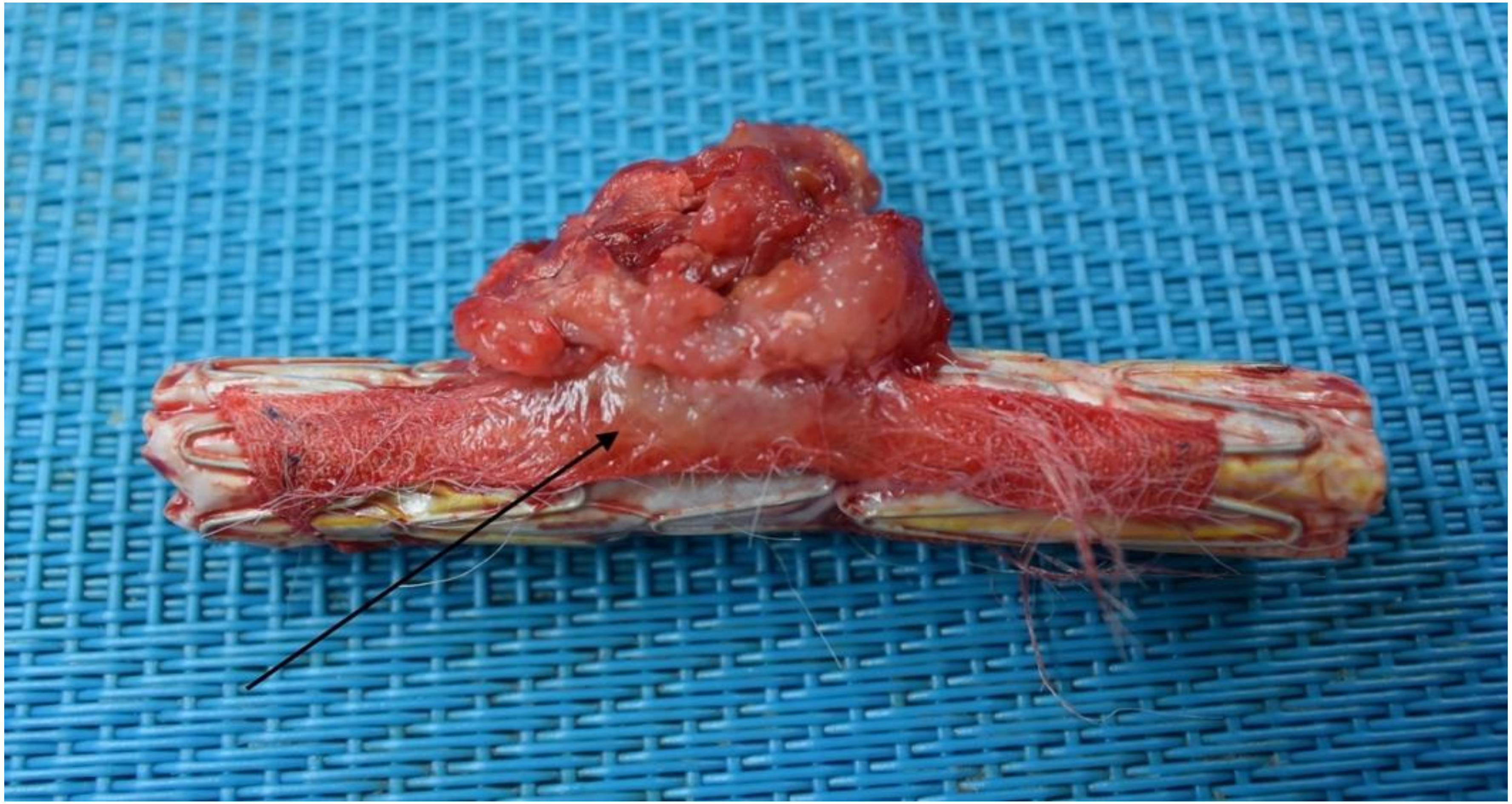
- A: Control Group : back bleeding 5 cases upon 6

- B: Fibered group: Thrombosis all lombar arteries





Morphological analysis after removal



Conclusions

- This novel concept consists of one device that integrates current EVAR technologies with thrombogenic fibers
- In vitro tests confirm the validity of the concept, showing better results than coils alone
- The fiber technology can improve EVAR long-term patient outcome without adding any extra burden, resulting in decreased patient monitoring costs, mortality and reintervention rate.
- The strips of fibers could be also fixed on the external part of all grafts

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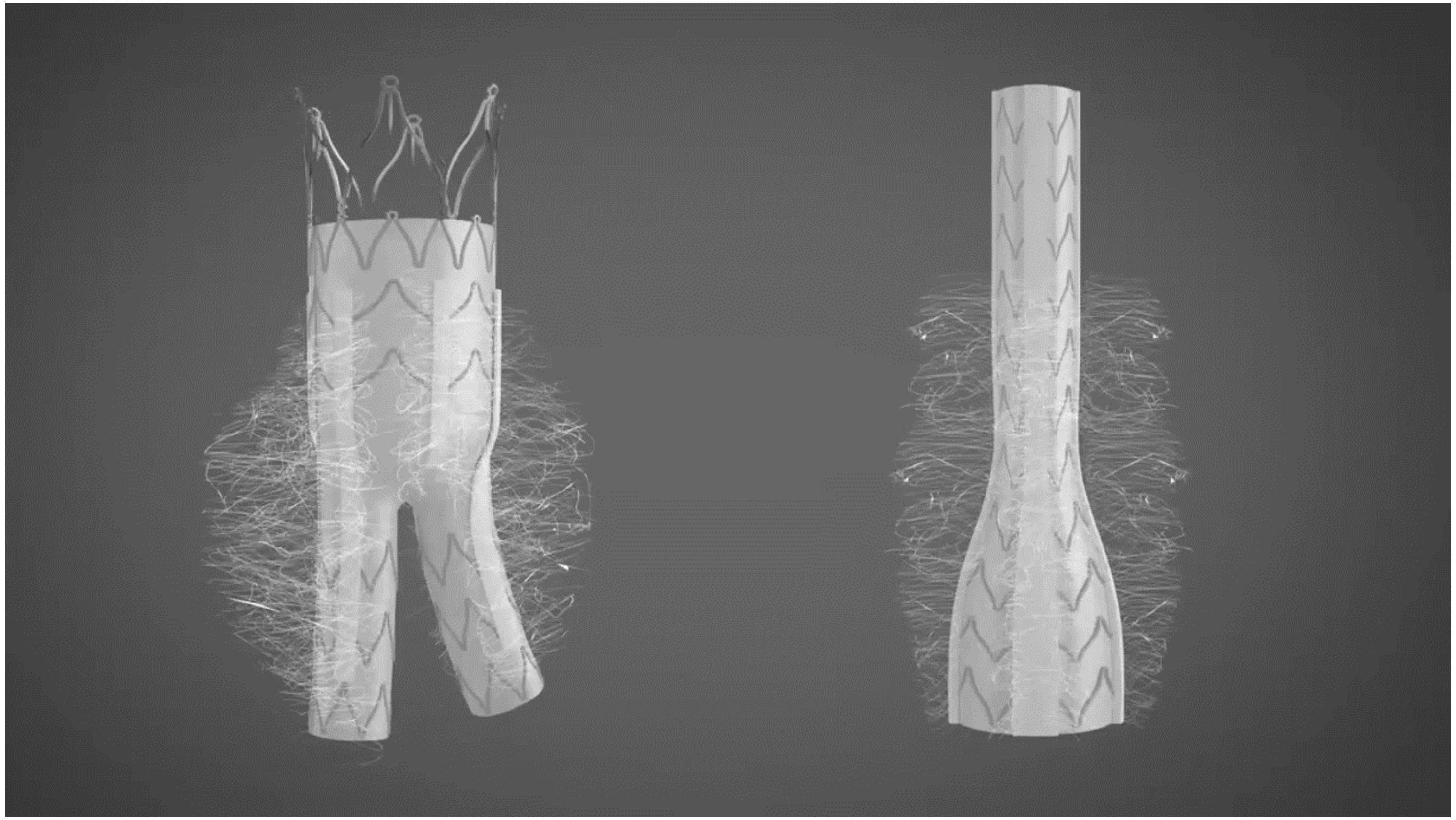
Are you ready to use it?



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