Introducing dual layer micromesh, a new era in fempop interventions

DIDACTICS
DEVELOPMENT
DISTRIBUTION

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Disclosure slide

Speaker name: Koen Deloose, MD

❑ I have the following potential conflicts of interest to report:

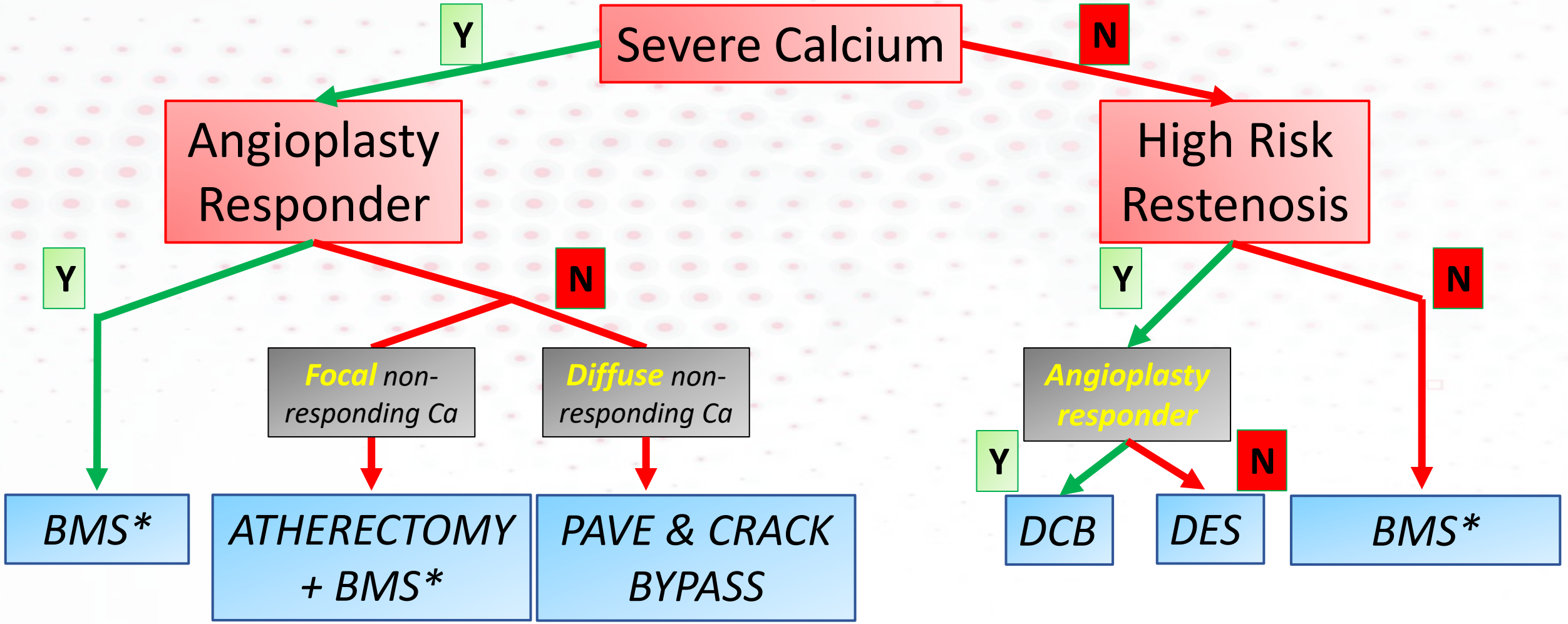
☒ Consulting: Abbott, Asahi, Biotronik, Boston Scientific, CTI vascular, CyndRX, GE Healthcare, Gore, iVascular, Terumo

❑ Stockholder of a healthcare company
❑ Employment in industry
❑ Owner of a healthcare company
❑ Other(s)

❑ I do not have any potential conflict of interest

CURRENT FEMOROPOPLITEAL PRACTICE

"3 questions/answers"- based treatment algorithm

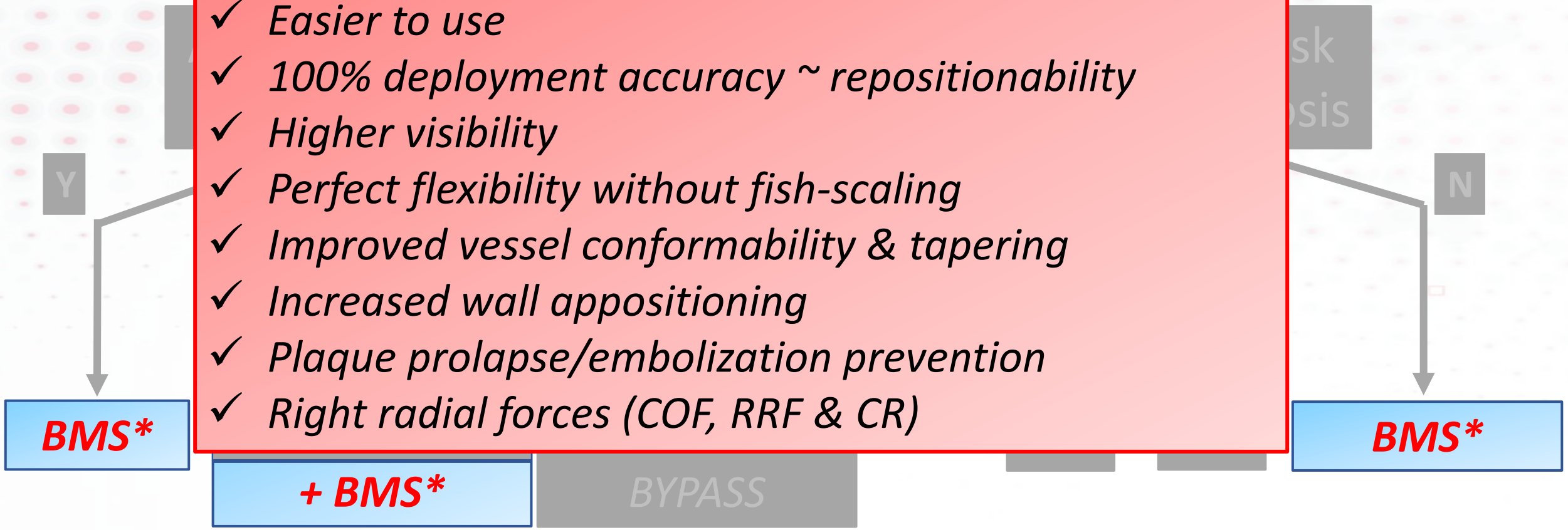


CURRENT FEMOROPOPLITEAL PPRACTICE

“3 questions/answers”- based treatment algorithm

BMS * = next generation

- ✓ *Easier to use*
- ✓ *100% deployment accuracy ~ repositionability*
- ✓ *Higher visibility*
- ✓ *Perfect flexibility without fish-scaling*
- ✓ *Improved vessel conformability & tapering*
- ✓ *Increased wall appositioning*
- ✓ *Plaque prolapse/embolization prevention*
- ✓ *Right radial forces (COF, RRF & CR)*



Based on these requirements and the good experiences in the carotid area….

Renzan™
Peripheral Vascular Stent System

BMS * = next generation

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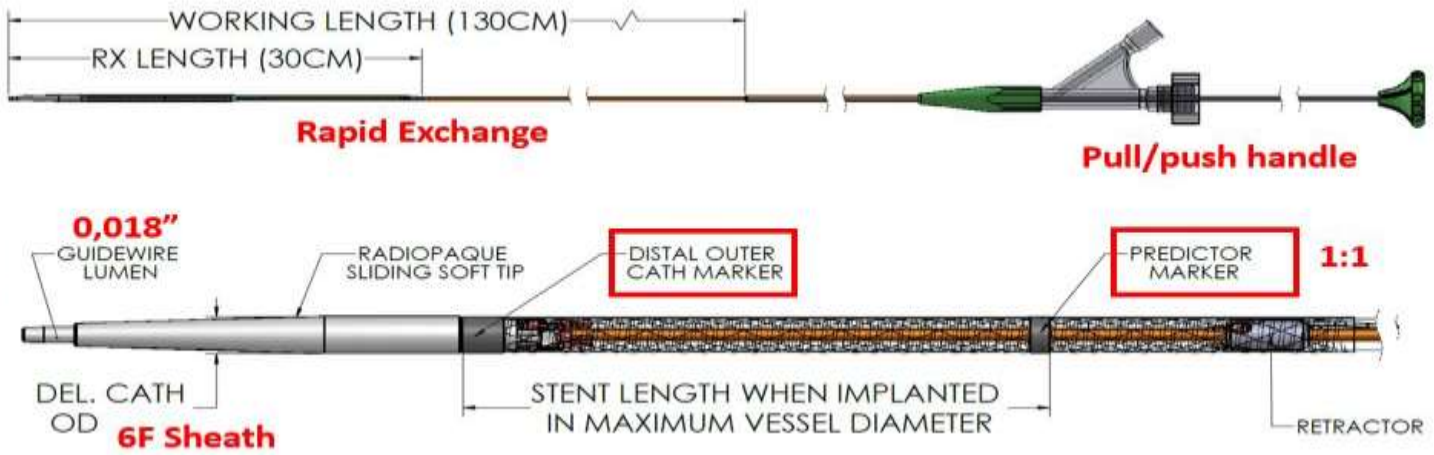
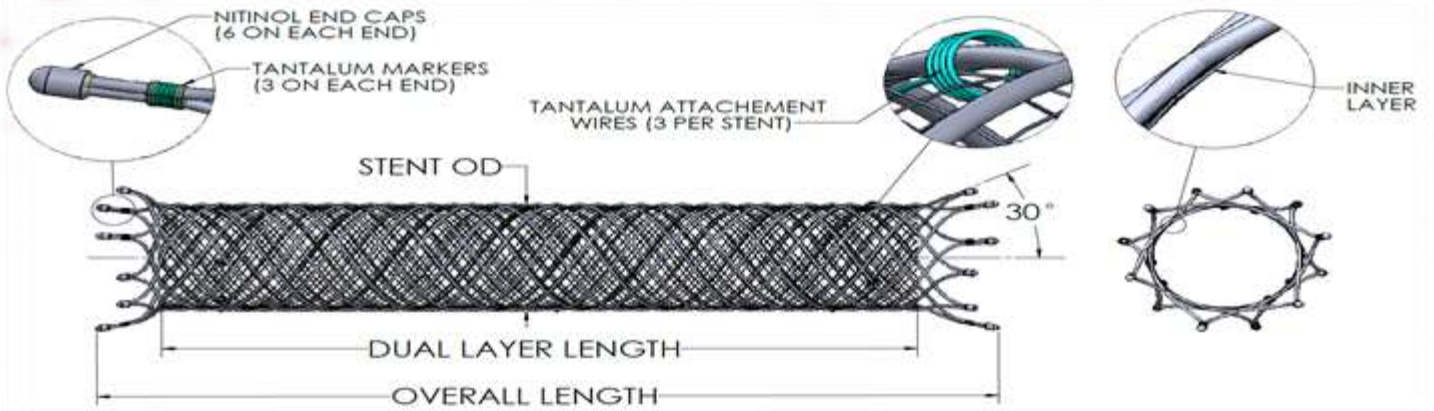
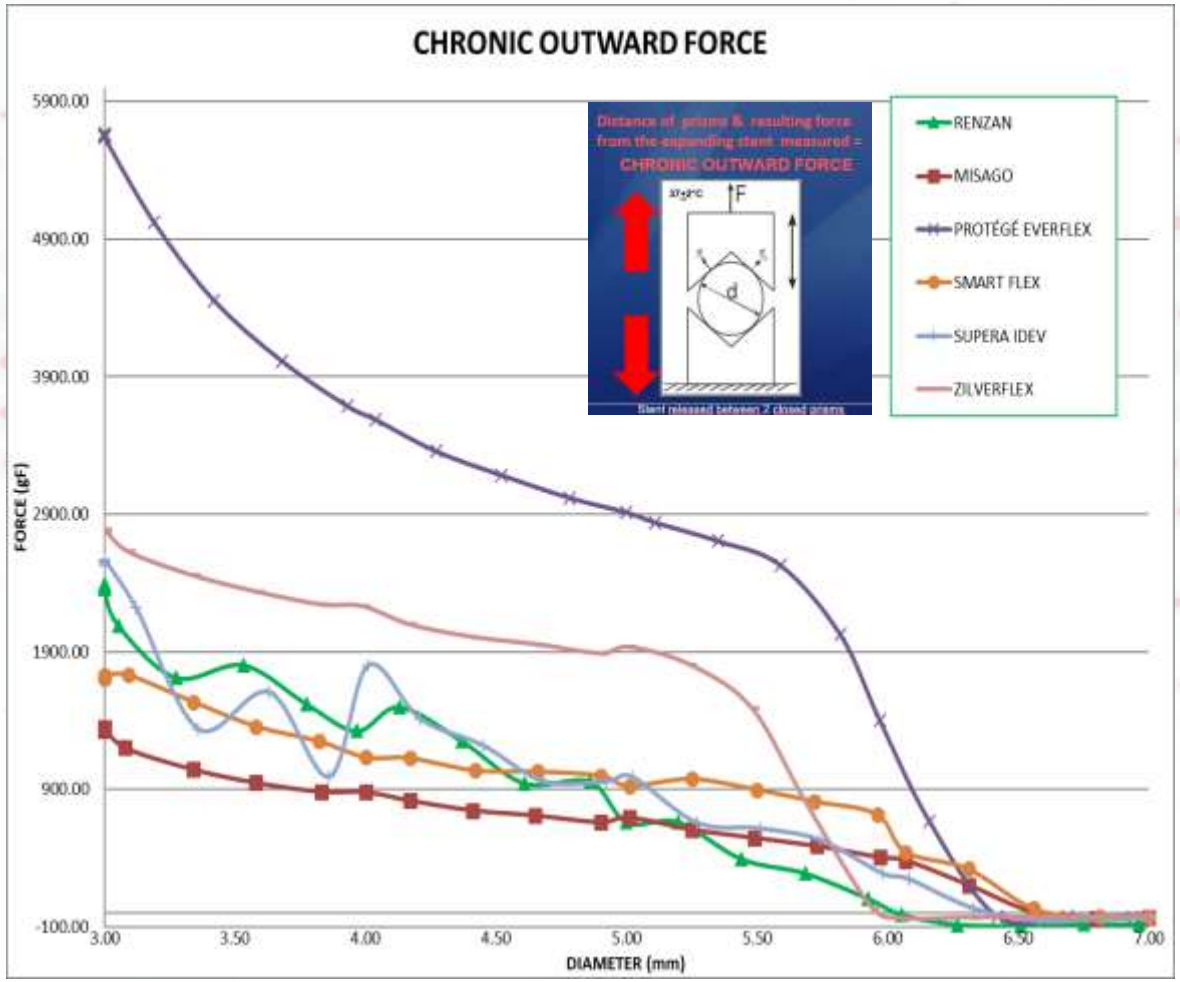
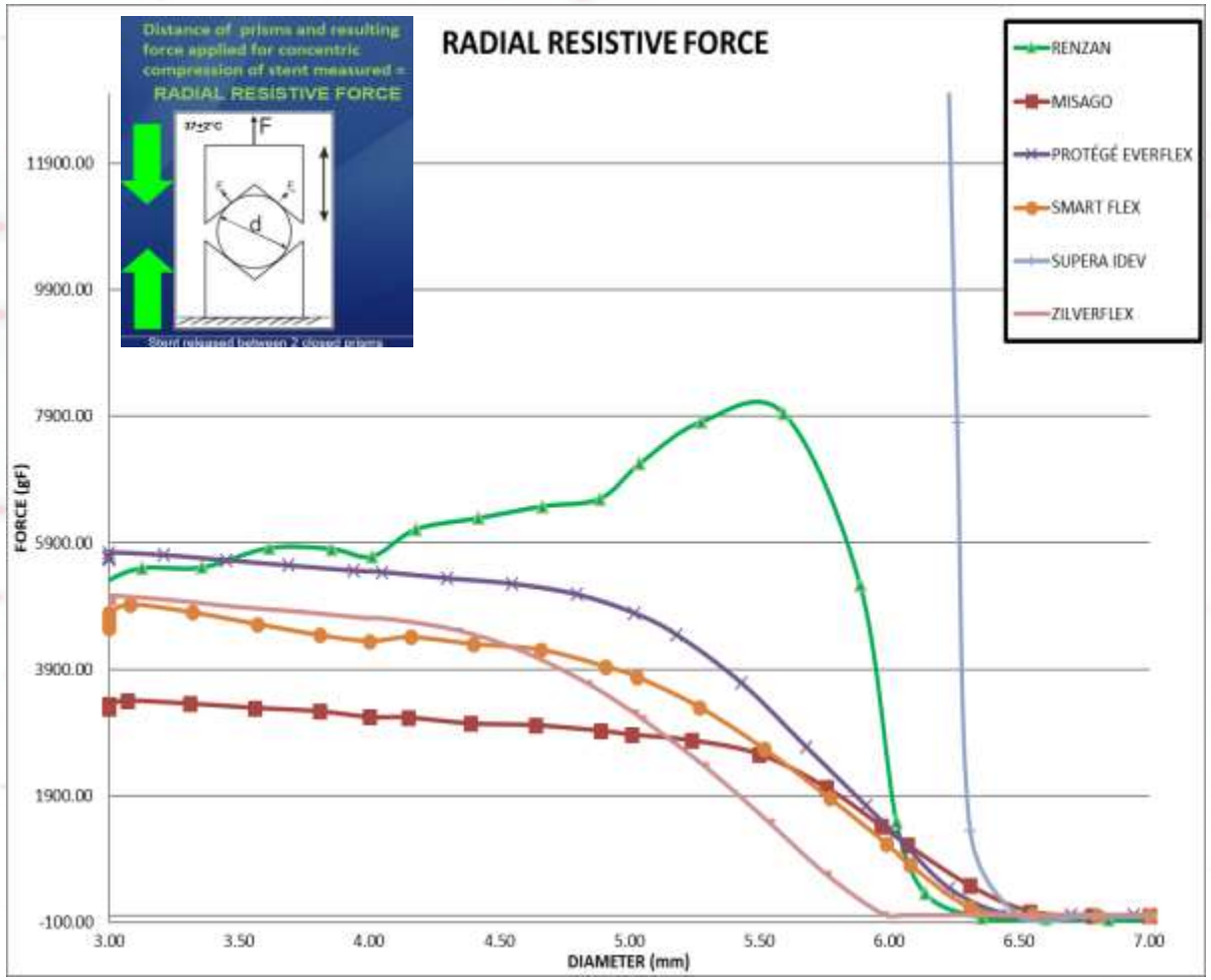




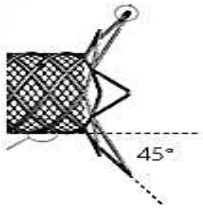
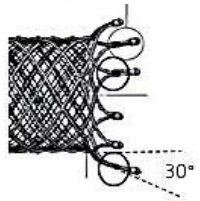
RENZAN radial forces



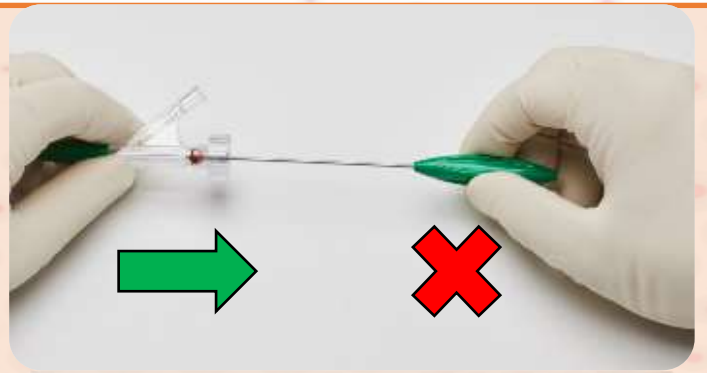
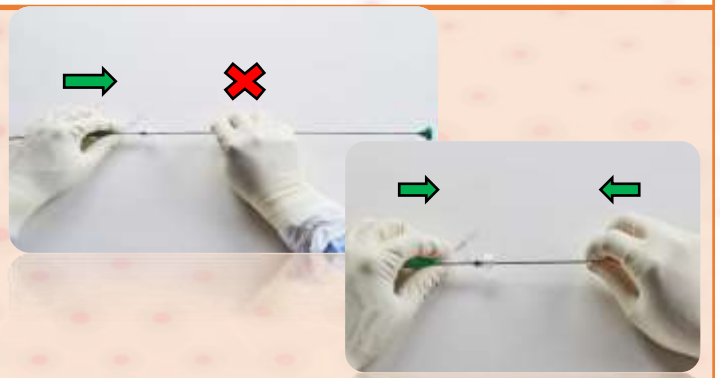
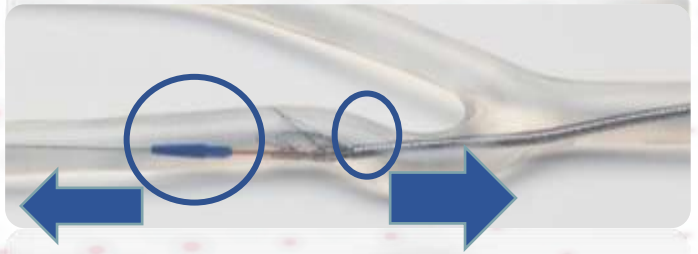
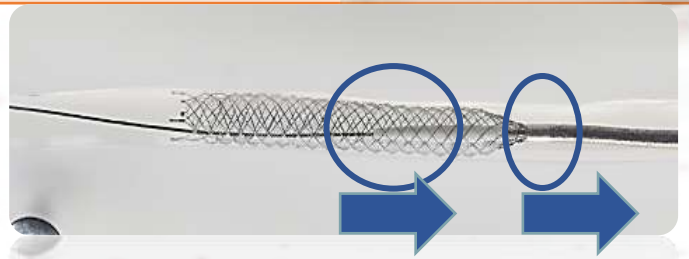
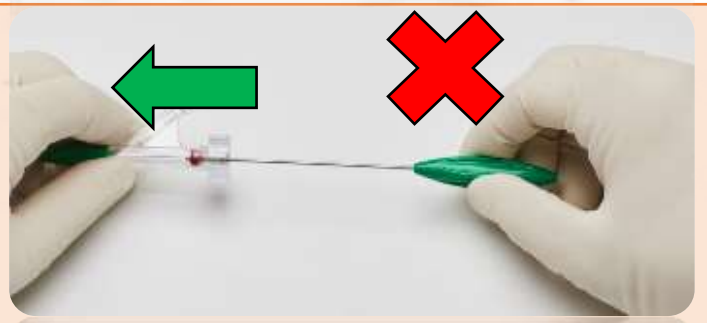


Data on file at MicroVention. TR17-120 ,TR16-272. Renzan stent (n=30), Supera stent (n=5), Other brand stents (n=2)

Some differences between ROADSAVER & RENZAN

	ROADSAVER	RENZAN
Platform (Inch – French)	0.014 Guide Sheath: 5Fr Guide Catheter: 7Fr	0.018 Guide Sheath: 6Fr Guide Catheter: 8Fr
Working lengths (cm)	143	130
Delivery catheter	Coil reinforcement	Coil & Braid reinforcement
RX length (cm)	25	47
Stent sizes (mm)	Diameter 5-10 Length 22-47	Diameter 5-8 Length 40-100
Flare configuration	 No nitinol end cap 1 marker distal flared end 45° flared angle 5-8 mm flare length	 6 nitinol end caps 3 markers flare ends 30° flared angle 5mm flare length
Stent pore size (µm)	375-700	330-440

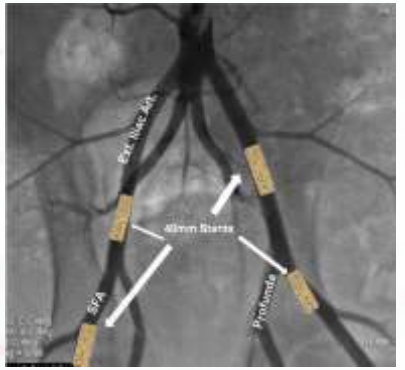
Some differences between ROADSAVER & RENZAN

	ROADSAVER	RENZAN
DEPLOYMENT		
DELIVERY SYSTEM MOVEMENT		
RE-SHEATHING		

Experiences with RENZAN

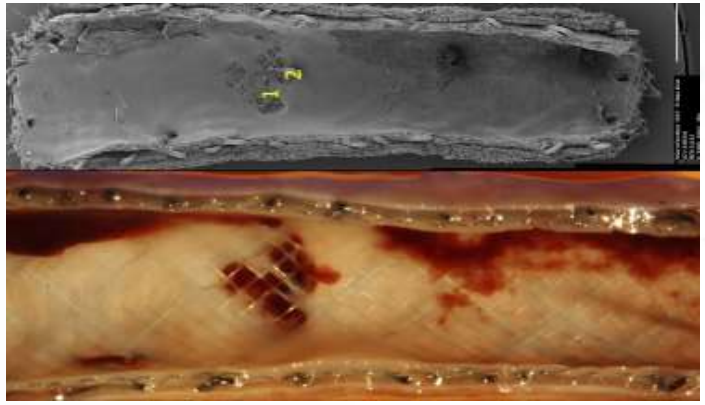
- 2 ovine models, 3 stent implantations (SFA/iliac)
- 4 Yucatan swine models, 4 stent implantations (SFA/iliac) per animal

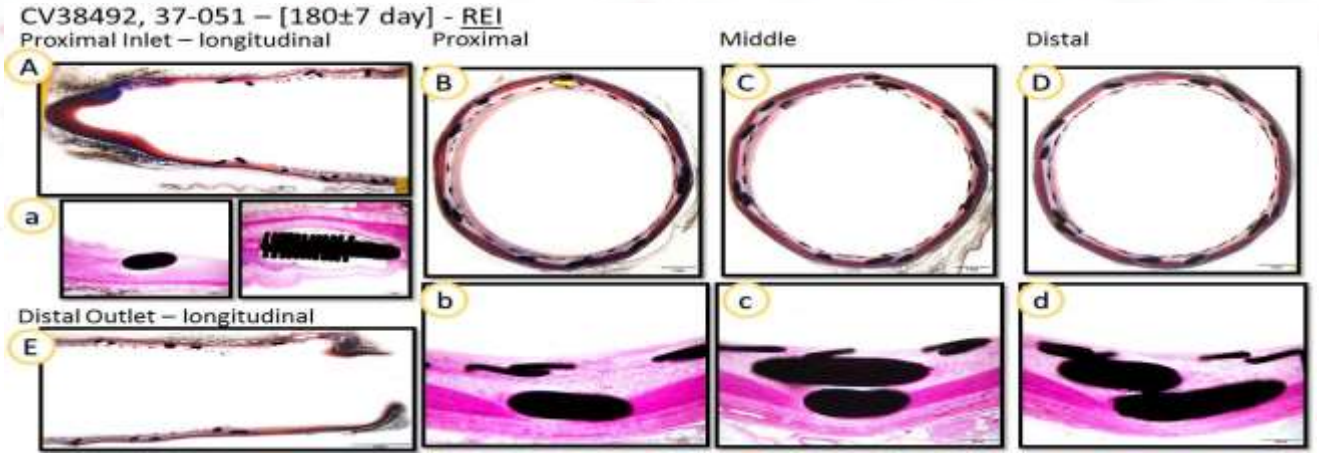
  @30-60-180 days :



-> **macroscopically** : Good Stent Radiopacity, No Flow Issues, Side Branches Patent, Stents Well Apposed to Vessel Wall, No Migration

-> **histology** : minimal vessel injury, minimal inflammation, stent almost fully incorporated, organized neo-intima/SMC

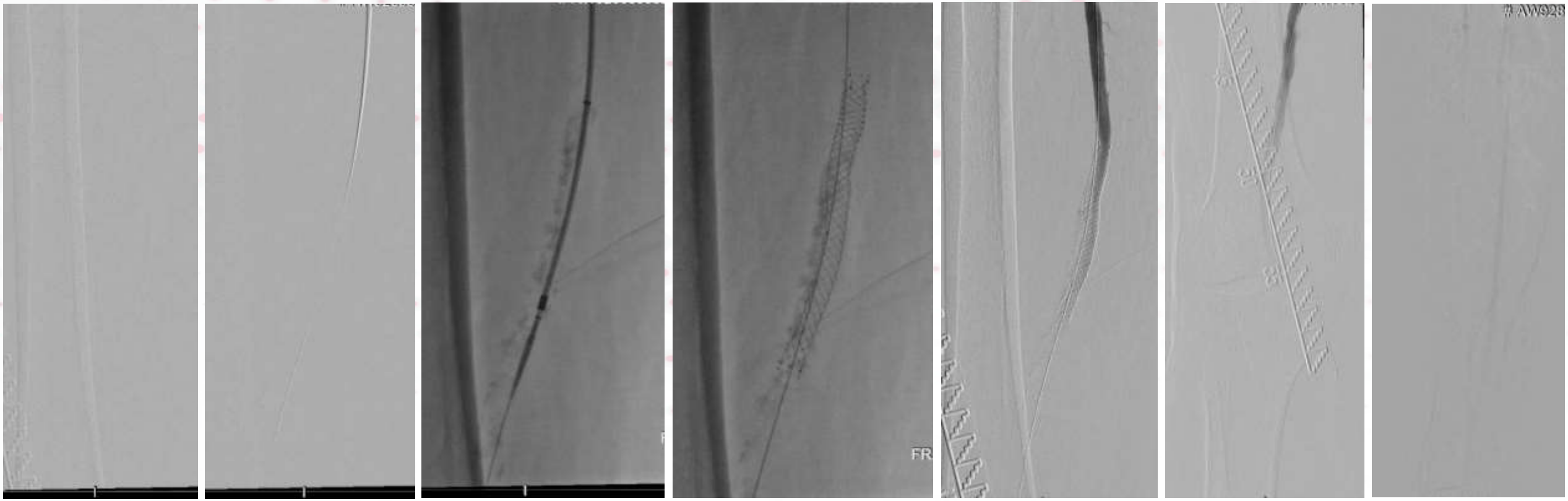




Data on file at MicroVention. TR16-098

Experiences with RENZAN

- First in man experiences (Belgium, Germany and France)



DUS FU @12 months : ABI 1,00 – Rutherford 0 - normal triphasic signal pre-intra-post stent

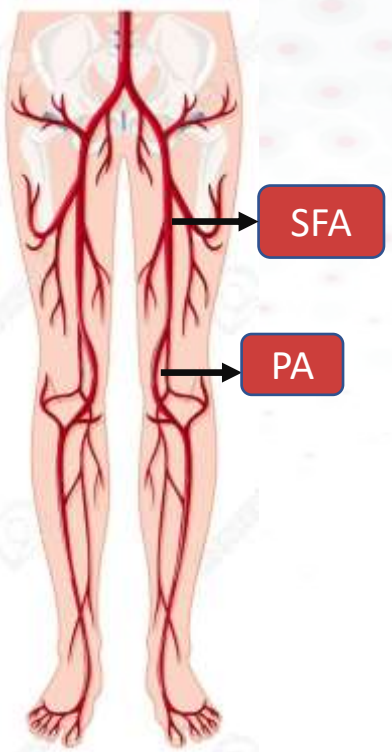
RENZAN – study : PRIZER

- Prospective, Multicenter, **P**ost-market, Single a**R**m study, to conf**I**rm the performance of the Ren**Z**an™ Peripheral Stent System in treating subjects with Sup**E**rficial Femoral and/or Popliteal a**R**tery disease

135 subjects

90 FEM-POP cases
SFA – P1

45 POP cases
P1-P3



Objectives

Primary: Confirm safety and efficacy of the Renzan™ when used for SFA and/or POP disease treatment

Secondary: Primary patency of the artery @ 12MFU compared to results from clinical tirals using similar metallic scaffolds

Follow-up period

36 months

PRIZER : Eligibility criteria

INCLUSION CRITERIA

- Rutherford 2-5
- ABI ≤ 0,9
- SFA and/or POP
- > 50% stenosis
- 40mm ≤ LL ≥ 140mm
- 4,0mm ≤ RVD ≥ 7,0mm
- Successful 1:1 predilatation

EXCLUSION CRITERIA

- Use of debulking devices, DCB
- Stent placement across SFA/DFA bifurcation
- Stent placement within 1cm of another stent
- In-stent restenosis
- stent overlap
- Acute thrombus

PRIZER : procedural overview

1. Procedural medication = SOC
2. Approach = contralateral or antegrade
3. Baseline procedural angiography = core lab guidelines
4. Significant ipsilateral iliac lesions should be treated succesfully (≤30% RS) prior to treatment of the TL
5. Mandatory vessel preparation of TL (POBA 1:1 RVD)

→ Successful ≤20% RS

6. Renzan™ stent implantation (Stent 1:1 RVD)
7. Post-dilatation = optional with POBA
8. Closure = approved VCD

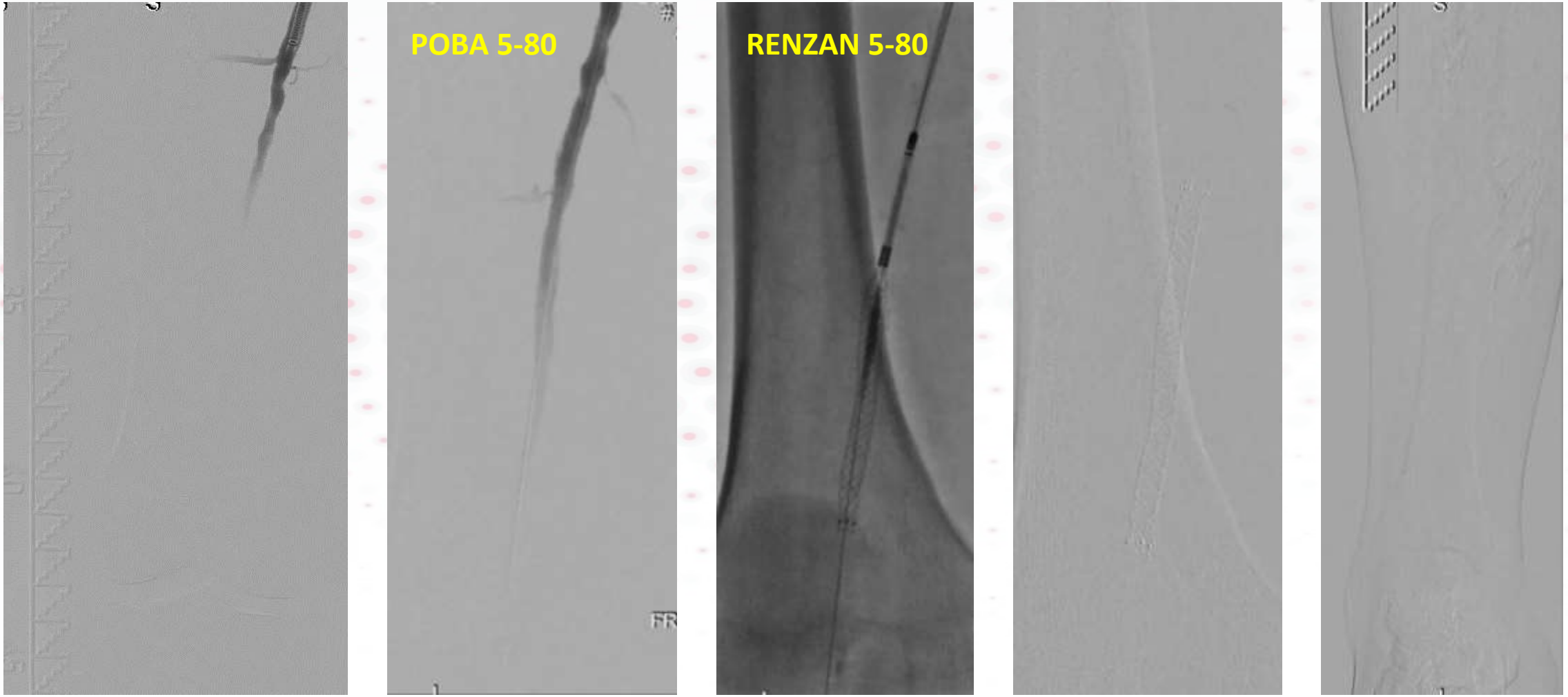
PRIZER : Timeline

Assessment Schedule (Timeframe window)	Baseline hospitalization			Follow-Up Hospital (site) visit		
Event/Activity	Pre-Procedure	Index Procedure*	Post Procedure Pre-Discharge	1 month (± 7 days)	6 months (± 30 days)	1, 2, 3 years (± 30 days)
Informed Consent	X					
Medical History	X					
Inclusion/Exclusion criteria	X	X				
Medication	X	X	X	X	X	X
Physical Examination	X		X	X	X	X
Rutherford-Becker Classification	X		X	X	X	X
Ankle-Brachial Index (ABI)	X		X	X	X	X
Walking Impairment Questionnaire (WIQ)	X			X	X	X
European Quality of Life-5 Dimensions (EQ-5D) Questionnaire	X			X	X	X
Laboratory Tests	X					
Duplex Ultrasound (DUS)				X	X	X
Angiography		X				
Adverse Events		X	X	X	X	X

* Prior to stent implantation it is mandatory to properly prepare the vessel achieving 1:1 stent to vessel sizing (≤ 10% residual stenosis as per operator's assessment), without using adjunctive debulking devices.

** Core laboratory guidelines

An enrollment….



Conclusions

- Bare metal stenting still plays an important role in a standard femoropopliteal treatment algorithm
- Next generation BMS require 100% deployment accuracy, perfect flexibility, conformability and wall appositioning, embolization prevention and the right radial forces (COF, RRF & CR)
- Although based on design principles of the successful carotid stent Roadsaver, some important differences deserve attention, especially in deployment-resheathing technique
- Initial animal and FIM experiences are extremely promising
- The **PRIZER prospective multicenter trial** will show us in the near future if the RENZAN stent can confirm its promising role in modern SFA-Popliteal stenting.