

# Clinical Benefits of the Vanguard IEP Peripheral Balloon Angioplasty System with Integrated Embolic Protection from the ENTRAP Study

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# Disclosure

Speaker name:

Koen Keirse .....

I have the following potential conflicts of interest to report:

- Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)
  
- I do not have any potential conflict of interest

# Embolization during Lower Extremity Interventions

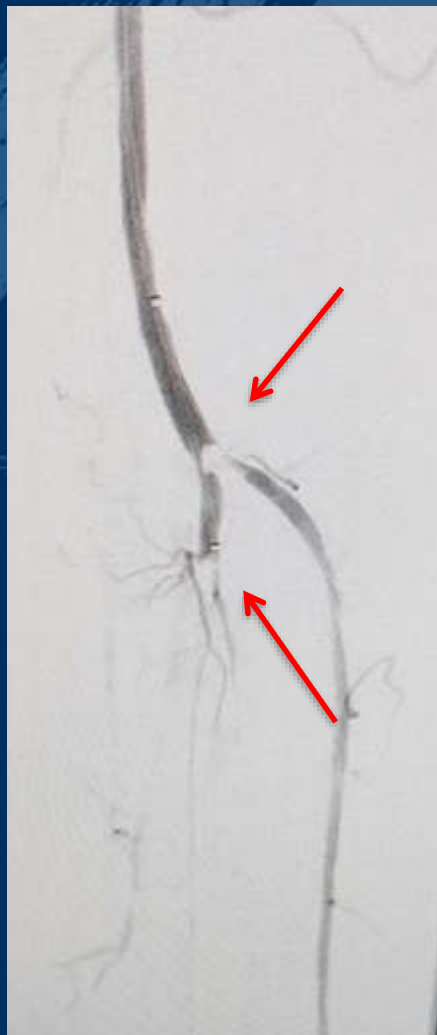
- Rates of Macro-Embolization have been described as high at 38% after Fem-Pop PTA<sup>1</sup>
- Can be associated with Limb Loss<sup>2</sup>
- Risk of limb loss may be higher in patient with poor run-off and CLI<sup>2,3</sup>
- Higher rate of embolization for in-stent restenosis and chronic total occlusions compared with stenotic lesions<sup>3</sup>
- Higher rate of embolization in TASC C and D lesions compared with TASC A and B lesions<sup>3</sup>

<sup>1</sup>J Endovasc Ther. 2008 Jun;15(3):270-6. doi: 10.1583/08-2397.1.

<sup>2</sup>Ann Vasc Surg. 2010 Jan;24(1):14-22. doi: 10.1016/j.avsg.2009.06.020. Epub 2009 Sep 11.

<sup>3</sup>J Vasc Surg. 2011 Feb;53(2):347-52. doi: 10.1016/j.jvs.2010.09.008. Epub 2010 Dec 3.

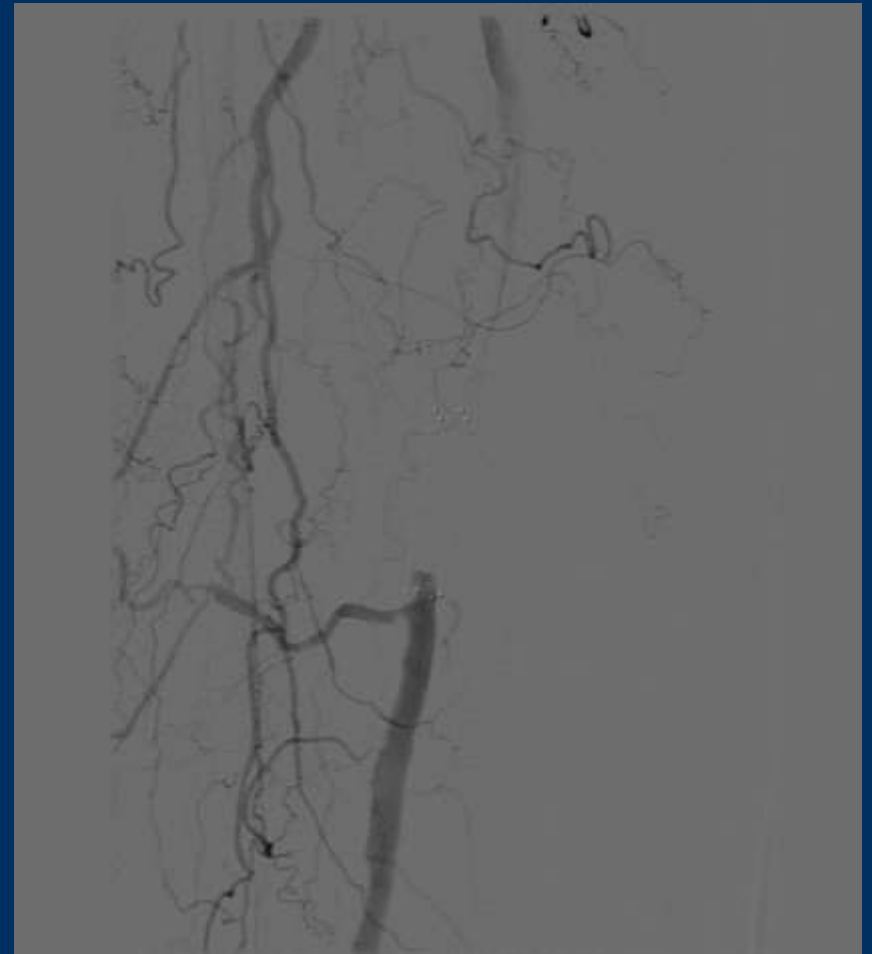
# Embolization after SFA PTA



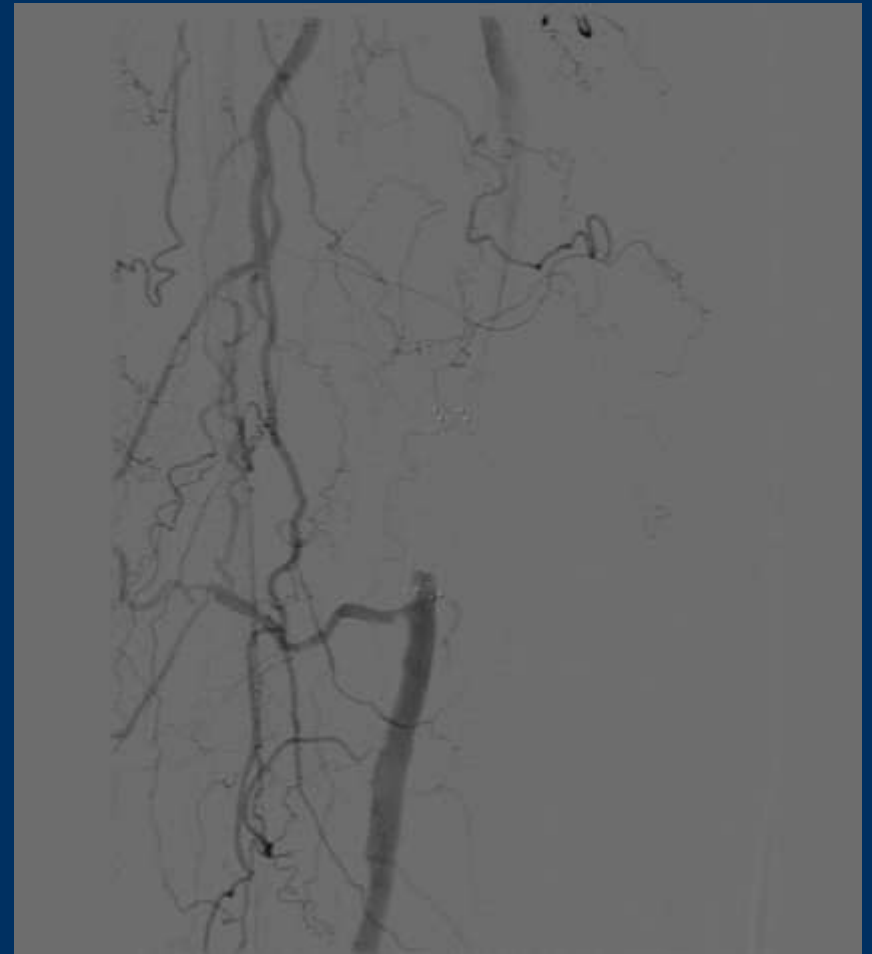
# Aspiration Thrombectomy after SFA PTA



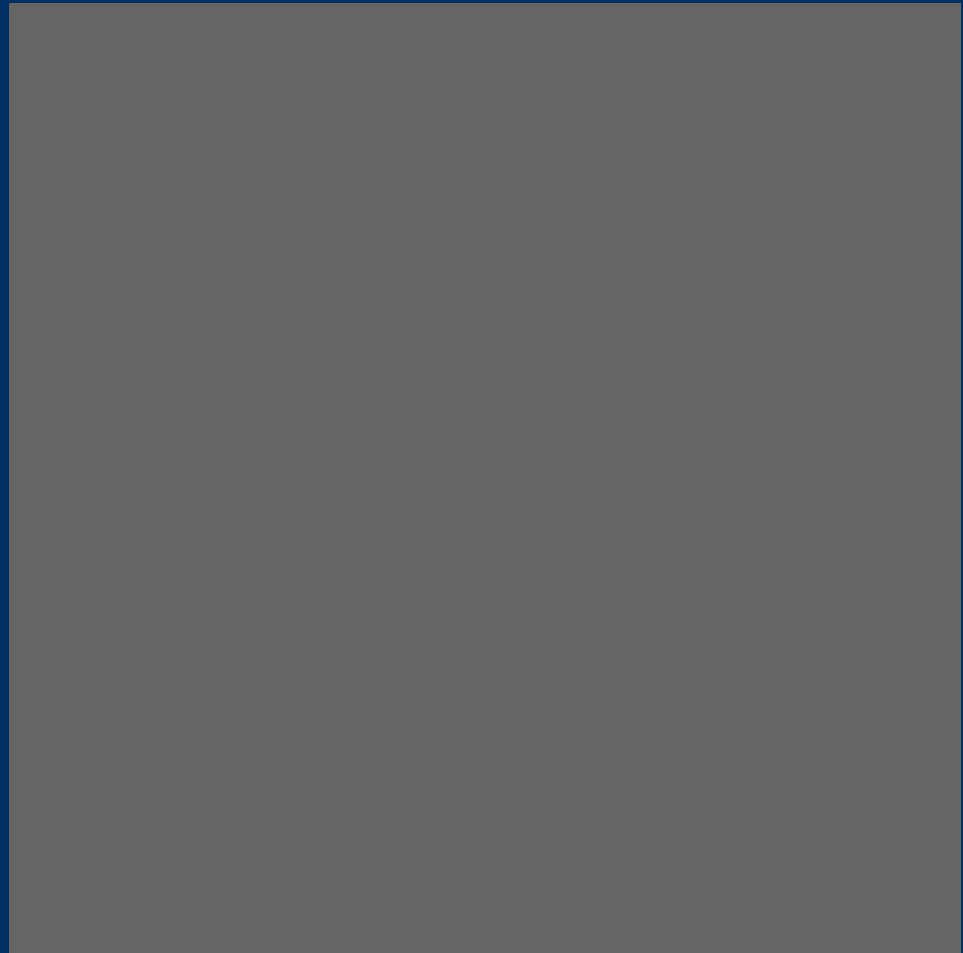
# Embolization after SFA CTO PTA



# Embolization after SFA CTO PTA



# Embolization after SFA CTO PTA

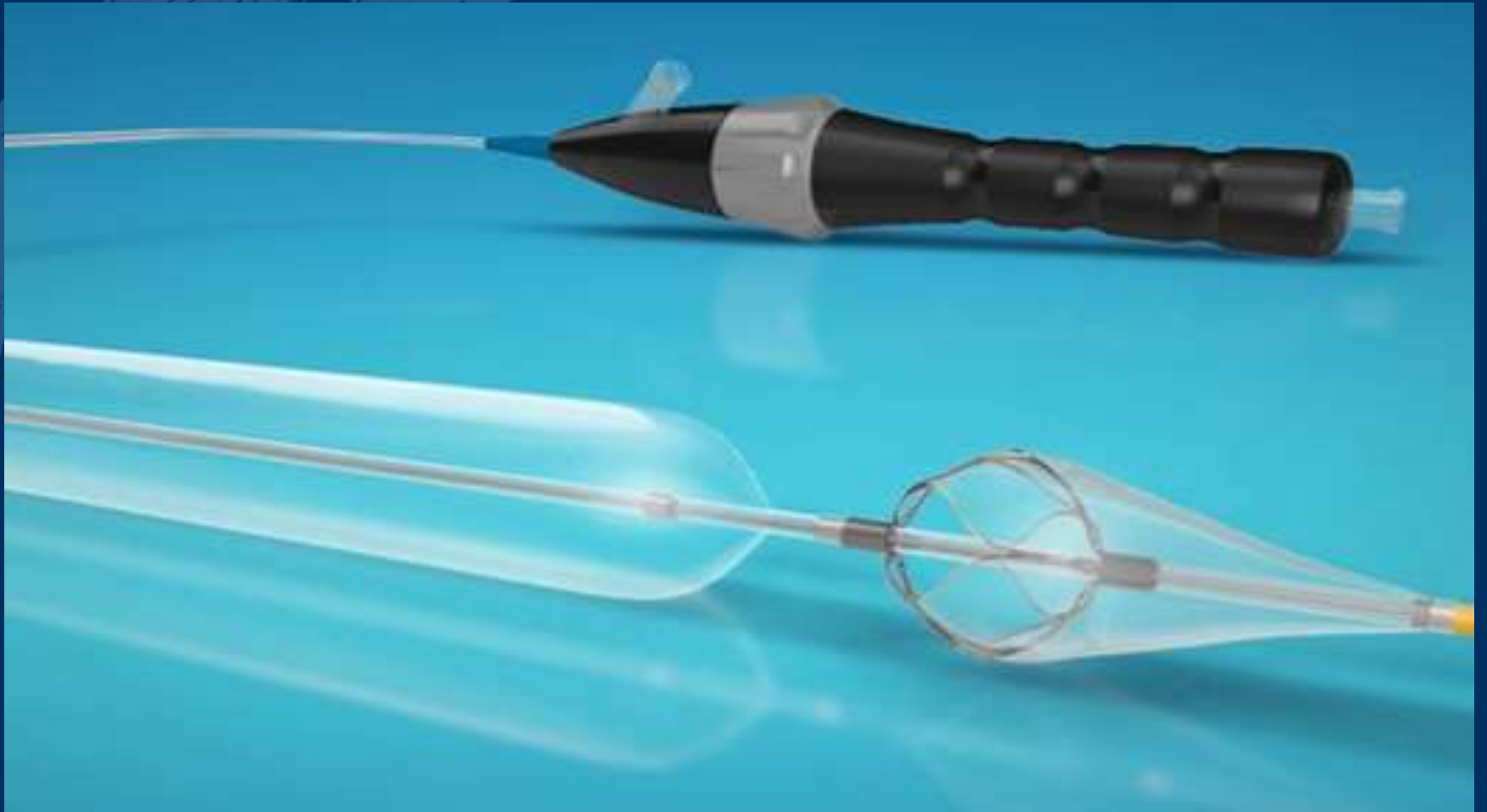


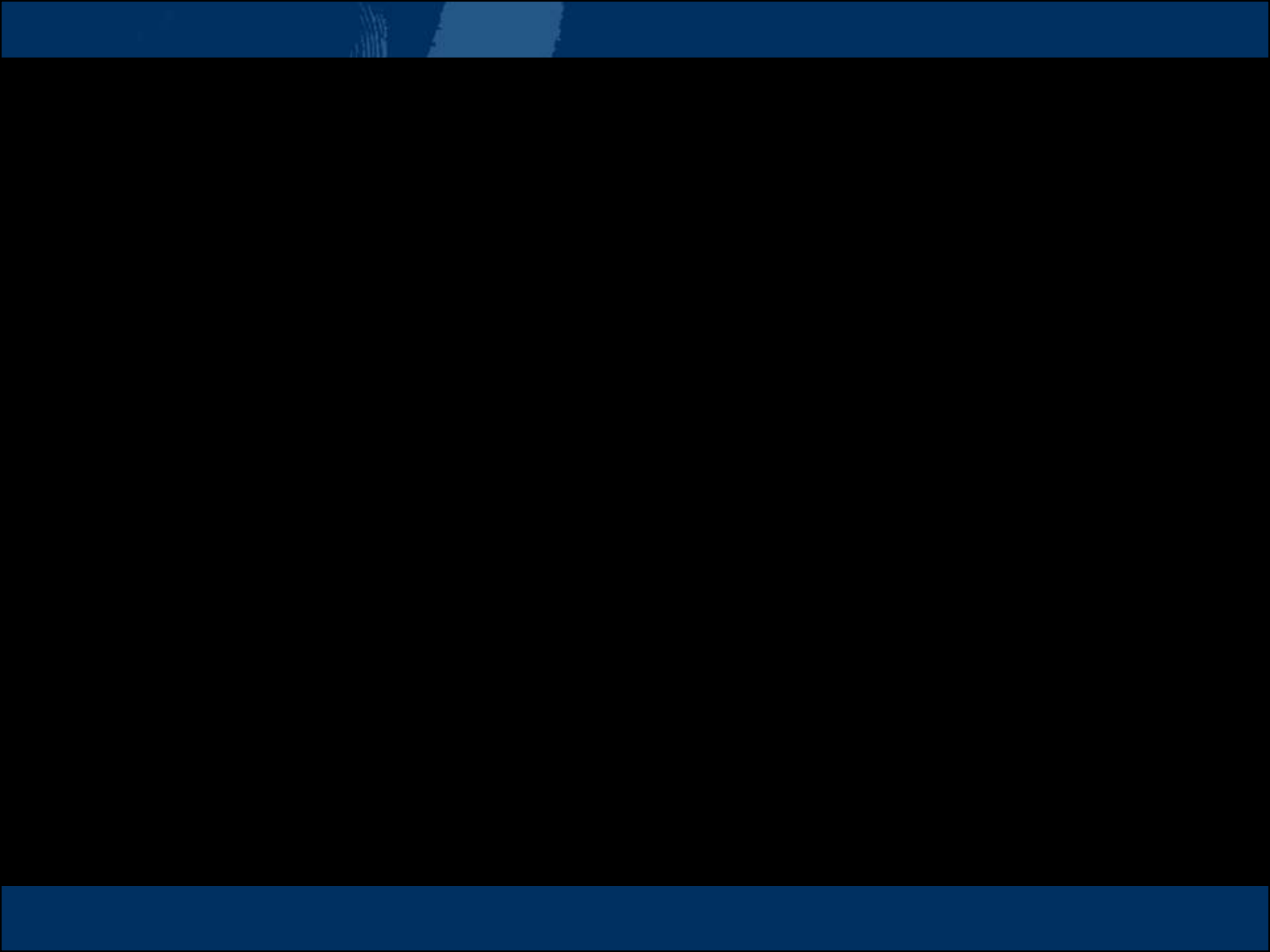


# Embolization after SFA PTA



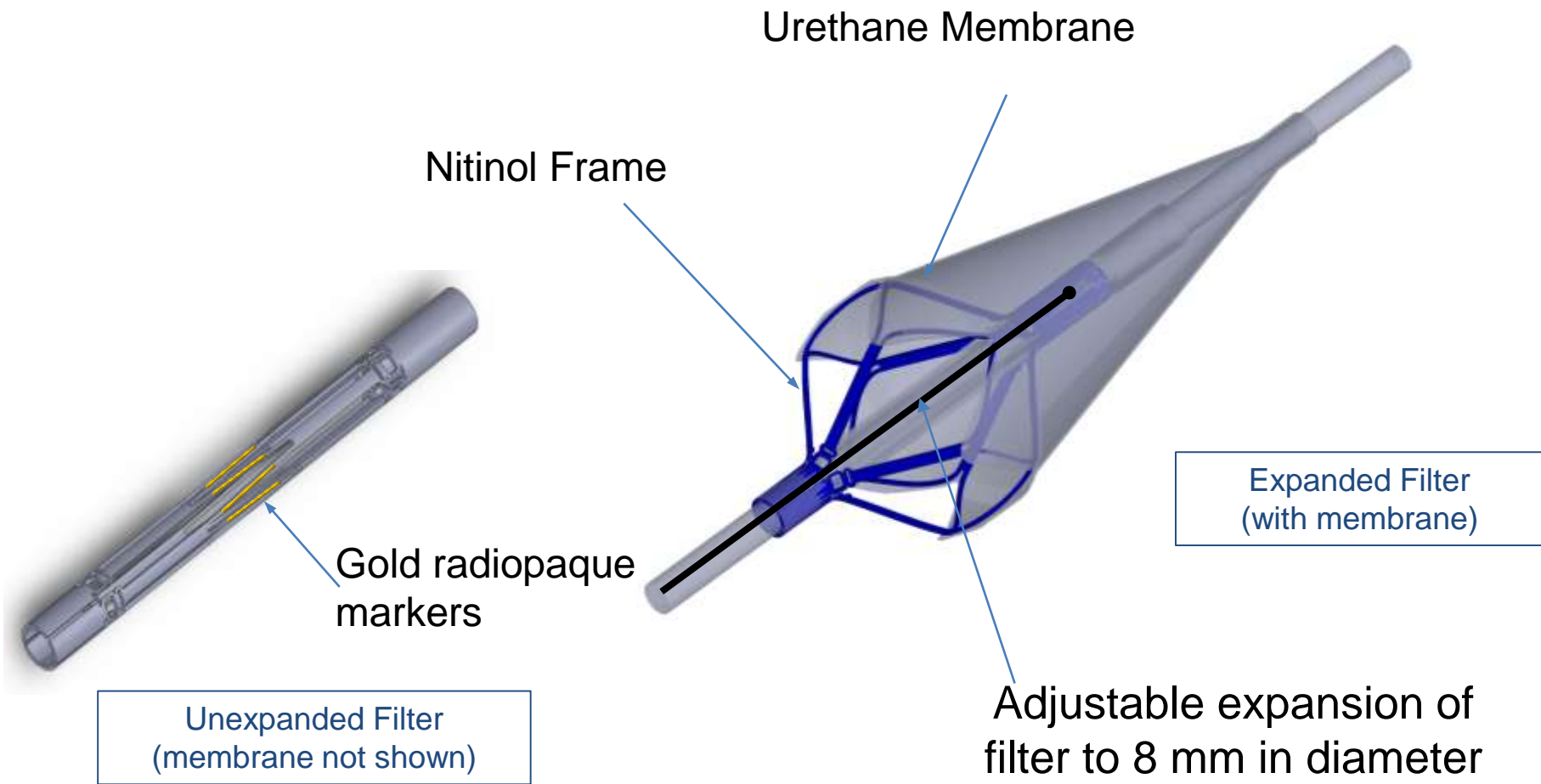
# Vanguard IEP Peripheral Balloon Angioplasty System with Integrated Embolic Protection



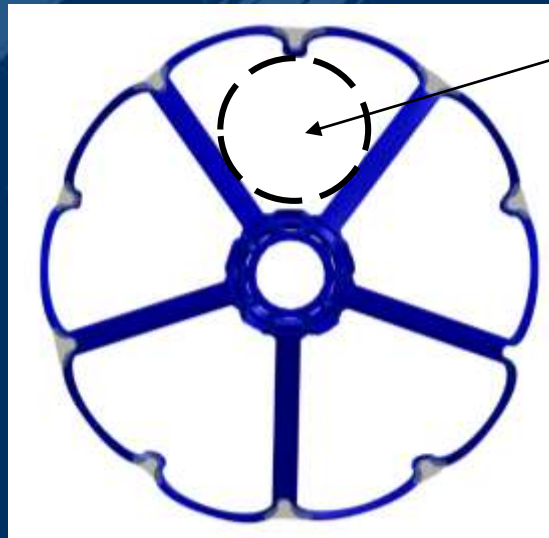


# Vanguard System Design Features

- First system for lower extremities in which PTA balloon and EPD are coupled on same catheter
- **Filter expandable to 8.0 mm by operator based on patient anatomy**
- Sheathless Design
- Over-the-Wire PTA balloon catheter
  - .018" Guidewire Compatible
  - 6 French Sheath Compatible
  - Balloon Diameters 4 – 8 mm
  - Balloon Lengths: 40, 80, 120, 200 mm
- Filter membrane with 150 micron pores



# Embololic Capture



2.5 mm  
diameter  
inlet



150 um  
filter holes

# Capture Efficiency

- Bench Testing
- 93.1% Capture Efficiency Testing
- 212 – 250  $\mu\text{m}$  particles
- Minimal disruption of blood flow

Captured  
Fluorescent  
Particles



# ENTRAP Study

A Single-Arm, Multicenter Study for the Lower *Extremities* using the VaNguard IEP™ Peripheral Balloon Angioplasty System with InTegRAted Embolic *Protection*

- prospective, non-randomized, study with follow-up to 30 days to determine acute safety, acute device performance and clinical performance

Primary Safety Endpoint	Freedom from MAE, defined as death, amputation and target vessel revascularization (TVR) at 30 days post-procedure.
Primary Efficacy Endpoint	Procedural Success, defined as <50% residual stenosis without any MAE (death, amputation or TVR) prior to hospital discharge.
Secondary Endpoints	<ol style="list-style-type: none"><li>1. Technical success, defined as successful delivery, balloon inflation and deflation, subsequent EPD deployment and retrieval of the intact device.</li><li>2. Change in Ankle-Brachial Index (ABI) from baseline, discharge and 30 days.</li><li>3. Rutherford-Becker (RB) Improvement (<math>\geq 1</math>) at 30 days.</li><li>4. Filter content analysis post-removal</li></ol>



# ENTRAP Study Sites

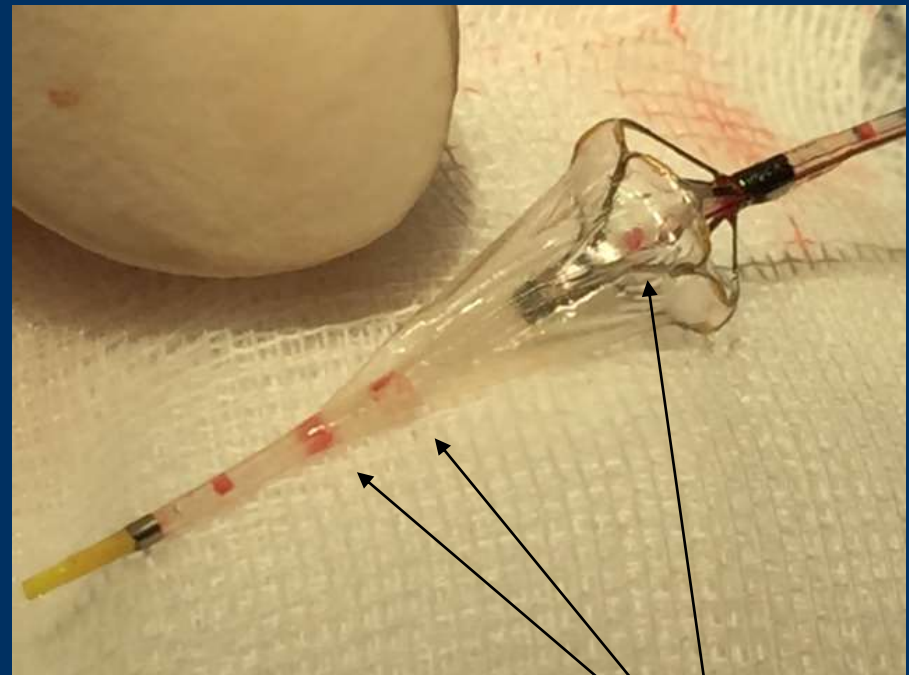
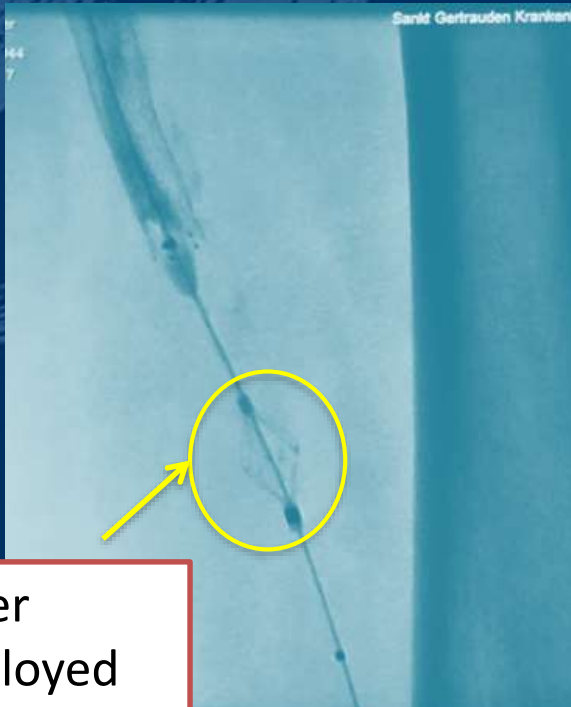
- Up to 130 subjects will be enrolled at sites in Germany and Belgium

Investigator	Site
Prof. Thomas Zeller, MD Coordinating Principal Investigator	Bad Krozingen, Germany
Ralf Langhoff, MD	Berlin, Germany
Prof. Dierk Scheinert, MD	Leipzig, Germany
Prof. Stefan Müller-Hülsbeck, MD	Flensburg, Germany
Koen Deloose, MD	Dendermonde, Belgium
Jürgen Verbist, MD	Bonheiden, Belgium
Lieven Maene, MD	Aalst, Belgium
Koen Keirse, MD	Tienen, Belgium

# Risk of Distal Embolization during LE Vascular Interventions

<b>High Risk of Embolization</b>	<b>High Consequence of Embolization</b>
Visible Thrombus in Vessel	Critical Limb Ischemia
Acute Limb Ischemia	Single Vessel Run-off
Chronic Total Occlusions	Diabetes Mellitus
Ulceration/Calcification	Severe/Diffuse Pedal Disease
Long Lesions	Multi-level Disease
In-stent Restenosis	End-Stage Renal Disease

# Vessel Prep in Patient with High Embolic Risk: Vanguard IEP System in SFA



Images courtesy of Ralf Langhoff, M.D.  
Sankt Gertrauden Krankenhaus, Berlin, Germany

# Vanguard IEP Peripheral Balloon Angioplasty System with with Integrated Embolic Protection Filter

*Vanguard IEP<sup>®</sup> Peripheral Balloon  
Angioplasty System with Integrated Embolic  
Protection*

# Vanguard Size Matrix

VANGUARD IEP System Sizes		Available Catheter Length (cm)	Balloon Length (mm)				Sheath Compatibility	Filter Length (mm)	Filter Diameter (mm)
			40	80	120	200			
Balloon OD (mm)	4.0	135	X	X	X	X	6F	16	Adjustable up to 8 mm
	5.0	135	X	X	X	X	6F		
	6.0	135	X	X	X	X	6F		
	7.0	80, 135	X	X	X		6F		
	8.0	80, 135	X	X	X		7F		

The Vanguard IEP Peripheral Balloon Angioplasty System with Integrated Embolic Protection is indicated for peripheral vascular percutaneous transluminal angioplasty (PTA) and capture and removal of embolic material during angioplasty for the femoral, iliac, popliteal and profunda arteries.

# Conclusions

- Distal embolization can result in occlusion of distal vessels, lower extremity ischemia, tissue loss and amputation
- Not all patients have the same risk of distal embolization
- A novel balloon with integrated embolic protection and adjustable filter size may help mitigate the risk of distal embolization in high-risk patients



Thank You

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