



**UKS**  
Universitätsklinikum  
des Saarlandes

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ST. FRANZISKUS-HOSPITAL  
MÜNSTER

# ***Multicentre post-market experience with the Indigo thrombectomy system for acute ALI***



Re-**O**pen Registry

The logo for the Re-Open Registry features a stylized orange and blue catheter or aspiration device. The word "Re-Open Registry" is written in a sans-serif font, with "Re-", "en", and "Registry" in black, and "O" in red.

# Re-**O**pen Registry

To evaluate **safety** and **efficacy** of  
***vacuum-assisted aspiration thrombectomy***  
in patients suffering  
***acute lower limb ischemia*** (<14 days)

# Re-O<sub>2</sub>en Registry

Retrospective

multicenter registry (N = 44)

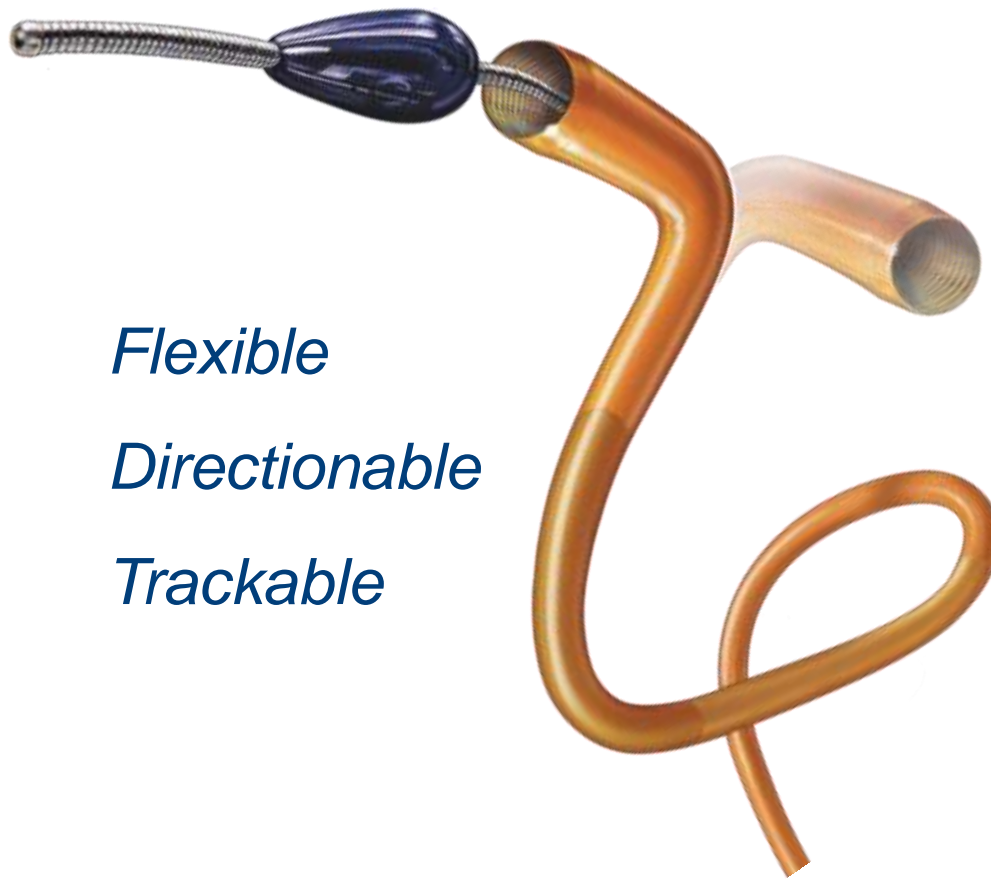
core-lab adjudicated

N = 400 patients

# Re-Open Registry

<i>Preston Royal</i>	<i>UK</i>	<i>Bella Huasen</i>	<i>San Andrea</i>	<i>IT</i>	<i>Michele Rossi</i>
<i>St. Thomas' London</i>	<i>UK</i>	<i>Robert Morgan</i>	<i>Latina Hospital</i>	<i>IT</i>	<i>Giovanni Bertoletti</i>
<i>Imperial College</i>	<i>UK</i>	<i>Mo Hamady</i>	<i>Vancouver General</i>	<i>CA</i>	<i>Darren Klass</i>
<i>Queen's London</i>	<i>UK</i>	<i>Giuseppe</i>	<i>Chicago</i>	<i>USA</i>	<i>Kumar Madassery</i>
<i>Taunton Hospital</i>	<i>UK</i>	<i>Katharine Lewis</i>	<i>Michigan</i>	<i>USA</i>	<i>Jihad Mustapha</i>
<i>Plymouth University</i>	<i>UK</i>	<i>Richard Miles</i>	<i>Auckland City Hospital</i>	<i>NZ</i>	<i>Andrew Holden</i>
<i>Inverness Hospital</i>	<i>UK</i>	<i>Michael Ashcroft</i>	<i>Hanoi University</i>	<i>VN</i>	<i>Luan Nguyen</i>
<i>Alexandra Hospital</i>	<i>UK</i>	<i>David Flowers</i>	<i>Bankok University</i>	<i>TH</i>	<i>T Benyakorn</i>
<i>Hull Hospital</i>	<i>UK</i>	<i>Raghu L</i>	<i>Bankok Siriraj Hospital</i>	<i>TH</i>	<i>Chumpol Wongwanit</i>
<i>Chester Hospital</i>	<i>UK</i>	<i>Gerard Doyle</i>	<i>Cali Hospital</i>	<i>CO</i>	<i>Carlos Gonzalez</i>
<i>Sheffield Hospital</i>	<i>UK</i>	<i>Trevor Cleveland</i>	<i>Brazil</i>	<i>BR</i>	
<i>Oxford Hospital</i>	<i>UK</i>	<i>Raman Uberoi</i>	<i>Liverpool Sydney</i>	<i>AU</i>	<i>Mark Schlapoff</i>
<i>Birmingham Hospital</i>	<i>UK</i>	<i>Ian McCafferty</i>	<i>Charles Gairdner Perth</i>	<i>AU</i>	<i>Ricky Kwok</i>
<i>Liverpool Hospital</i>	<i>UK</i>	<i>Usman Shaikh</i>	<i>The Mater Sydney</i>	<i>AU</i>	<i>Steve Dubenec</i>
<i>Manchester University</i>	<i>UK</i>	<i>Nimral Kikani</i>	<i>Rotterdam Maastad</i>	<i>NL</i>	<i>Imani Farshad</i>
<i>St.Franziskus Münster</i>	<i>DE</i>	<i>Theodosios Bisdas</i>	<i>Eskilstuna Hospital</i>	<i>SE</i>	<i>Mats-Ola Eriksson</i>
<i>Homburg Hospital</i>	<i>DE</i>	<i>Alexander Massmann</i>	<i>Uppsala University</i>	<i>SE</i>	<i>Martin Bjorck</i>
<i>Mühlheim Hospital</i>	<i>DE</i>	<i>Claus Nolte Ernsting</i>	<i>Belfast Hospital</i>	<i>IR</i>	<i>Daniel Conroy</i>
<i>Bordeaux Hospital</i>	<i>FR</i>	<i>Clement Marcelin</i>	<i>Kuopio Hospital</i>	<i>FI</i>	<i>Hannu Manninen</i>
<i>Nimes Hospital</i>	<i>FR</i>	<i>Nicolas Louis</i>	<i>Helsinki University</i>	<i>FI</i>	<i>Kimmo Lappalainen</i>
<i>San Camillo Rome</i>	<i>IT</i>	<i>Nicola Mangialardi</i>	<i>Ryhad Hospital</i>	<i>SA</i>	<i>Abdul Alvi</i>
<i>Tor Vergata Rome</i>	<i>IT</i>	<i>Giovanni Pratesi</i>	<i>Warsaw</i>	<i>PO</i>	<i>Jaroslaw Miszczuk</i>

*Clot engagement*



*Flexible*

*Directionable*

*Trackable*

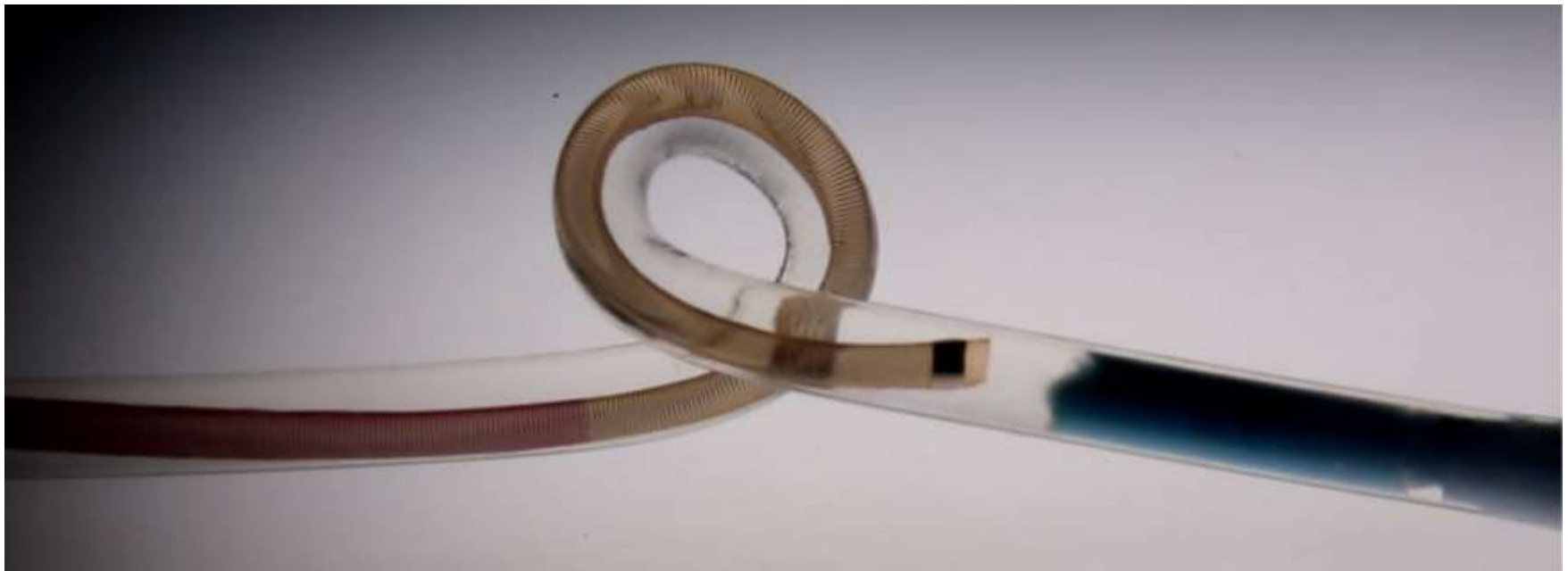
***Penumbra Indigo-System***



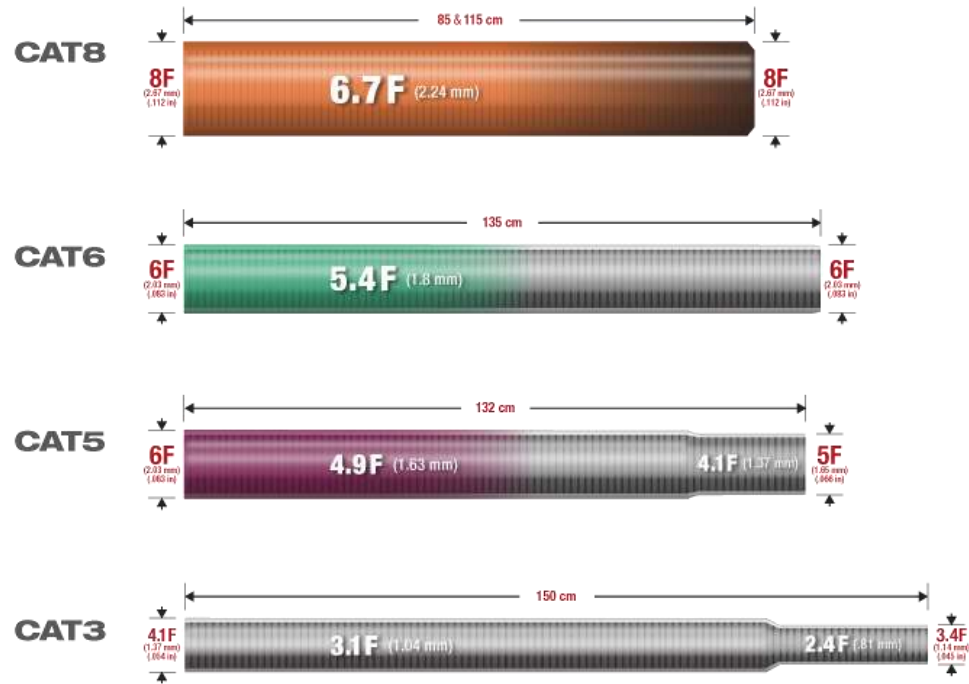
*vacuum pump & canister*

# ***Vacuum-assisted Aspiration-Thrombectomy***

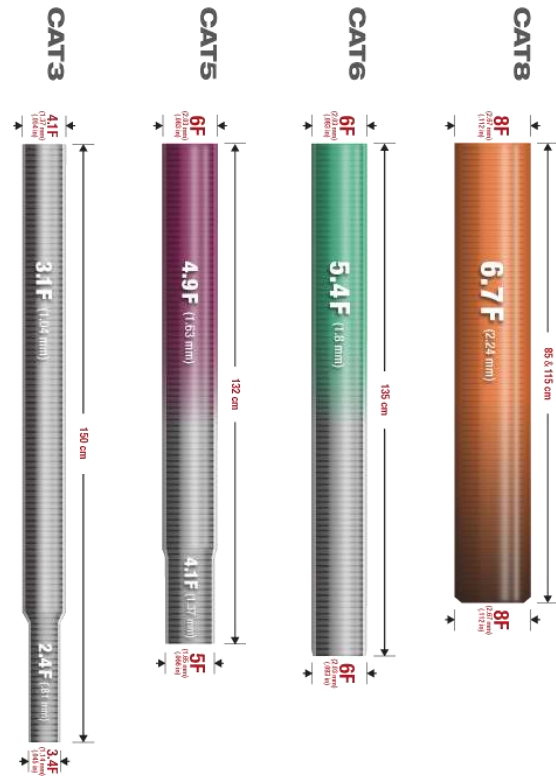
- *Extraction large clot in short time*



*Penumbra Indigo*





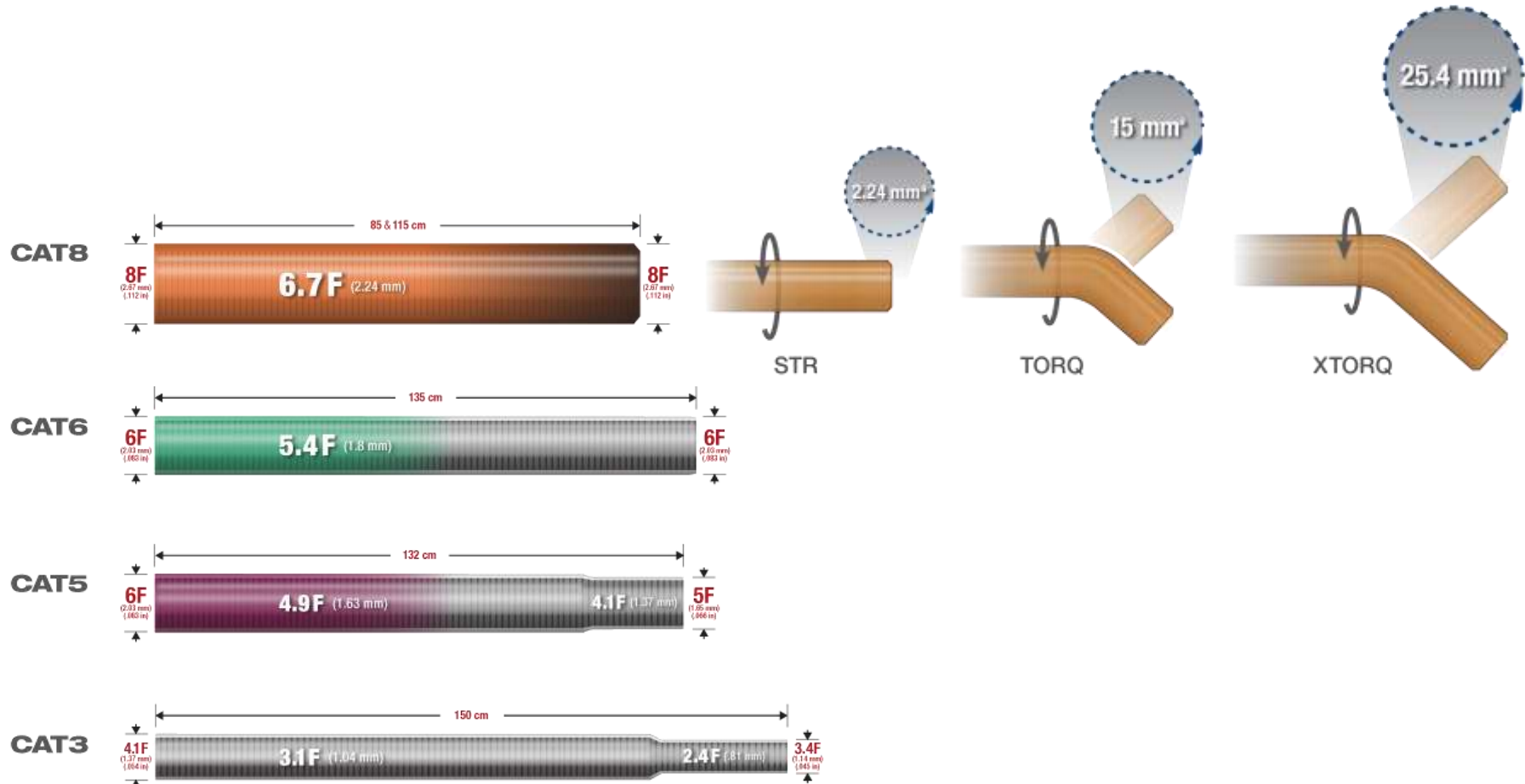


*Coaxial-technique*

**CAT5, CAT6 into CAT 8**

**CAT3 into CAT5 & 6**





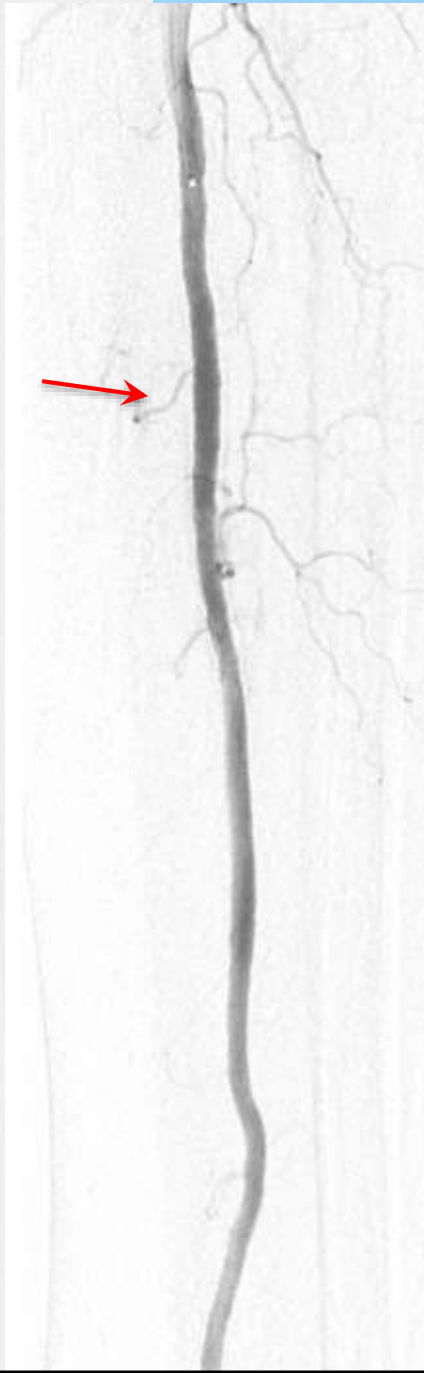


WW: 1024WL: 512

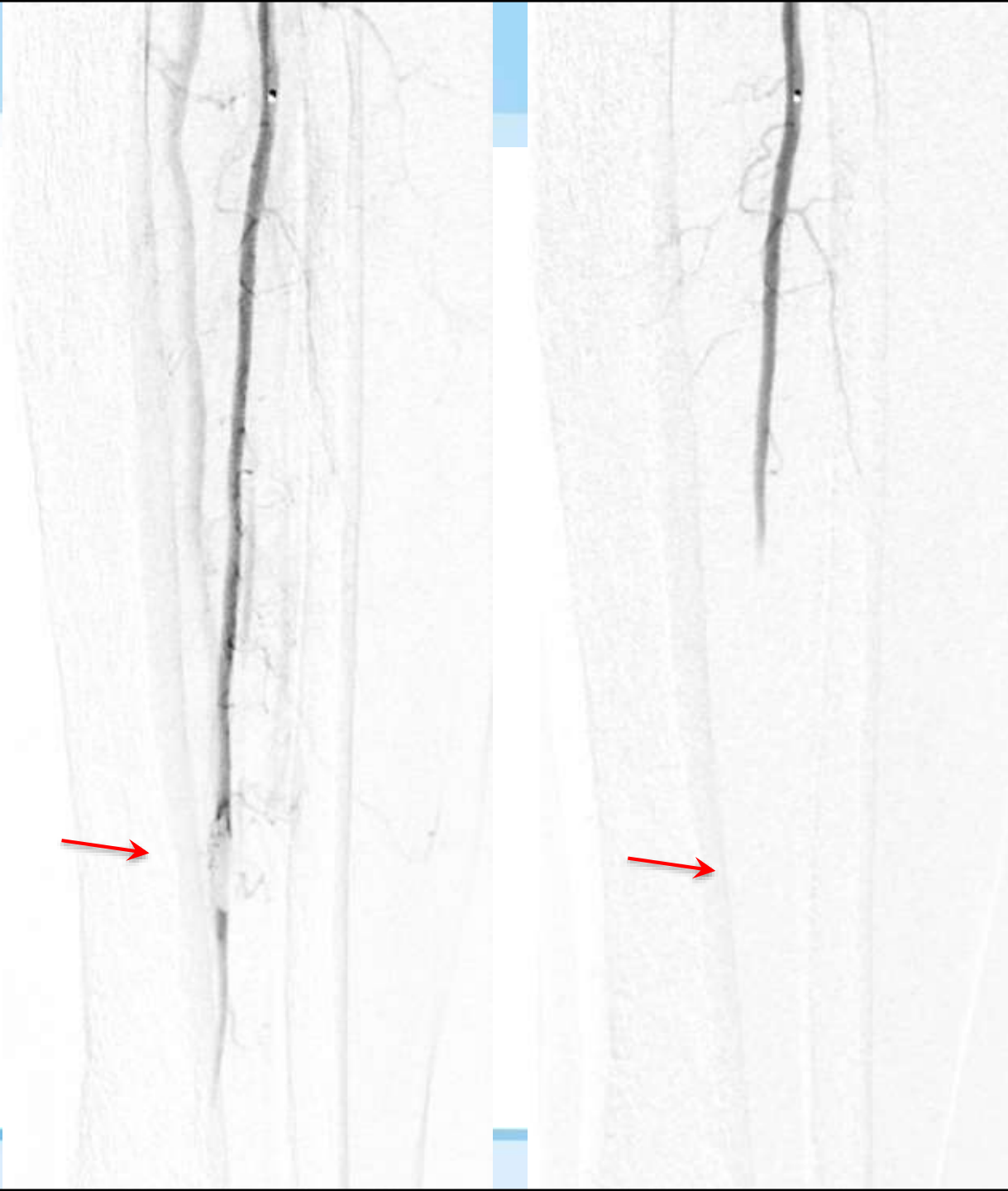
*CAT3 in plantar arch*



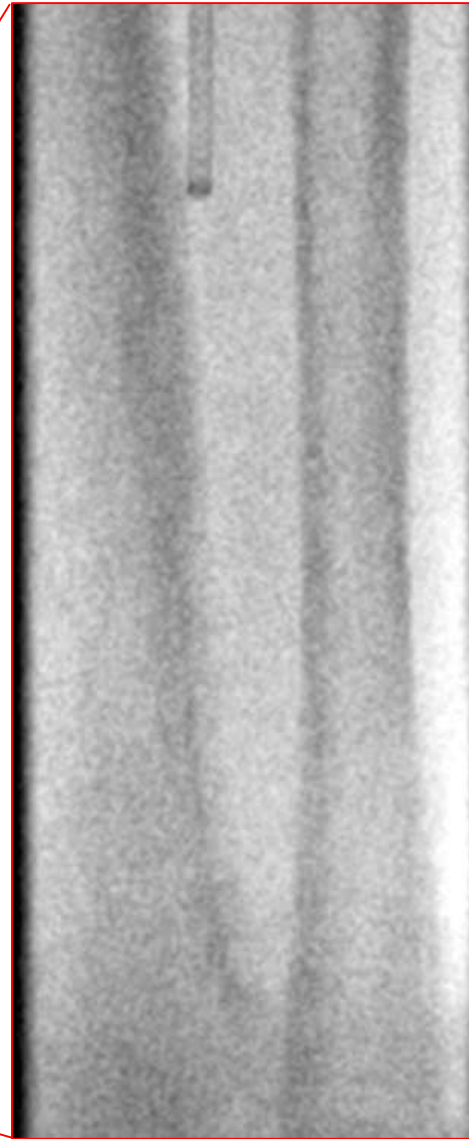
*Thrombembolism*  
*A. tibialis ant. + A. fibularis*



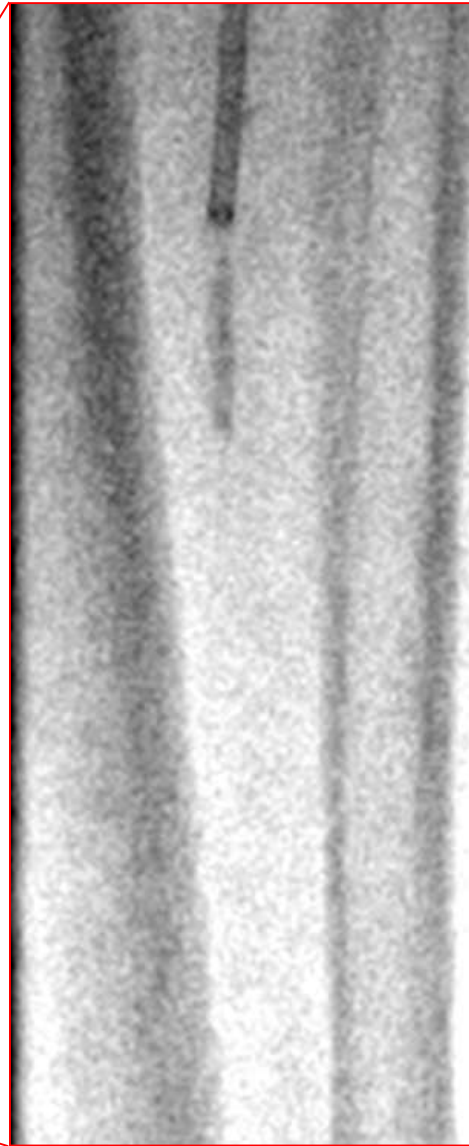
*A. tibialis ant.*



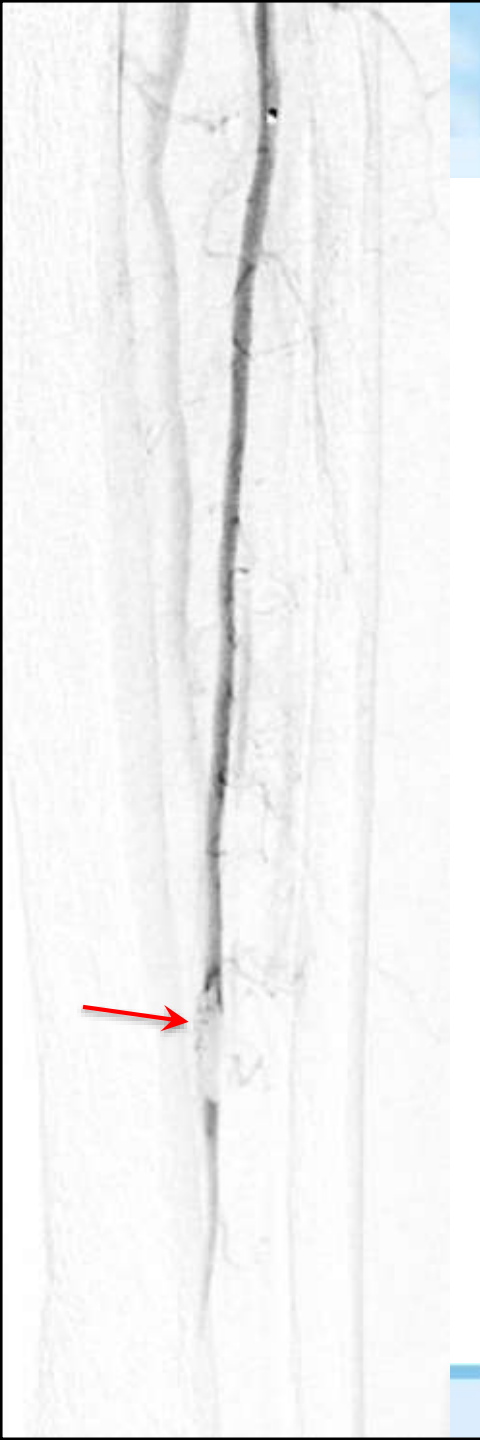
*A. fibularis*





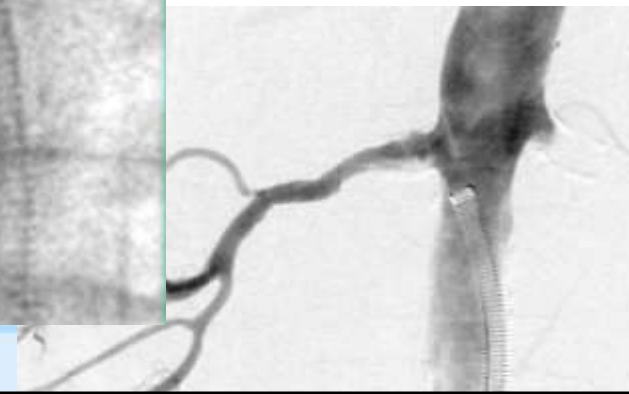
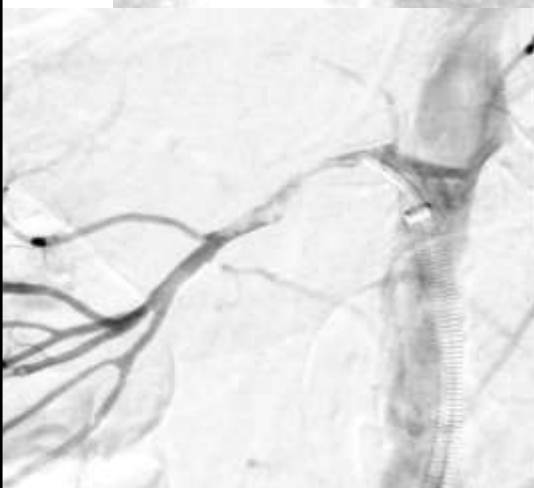
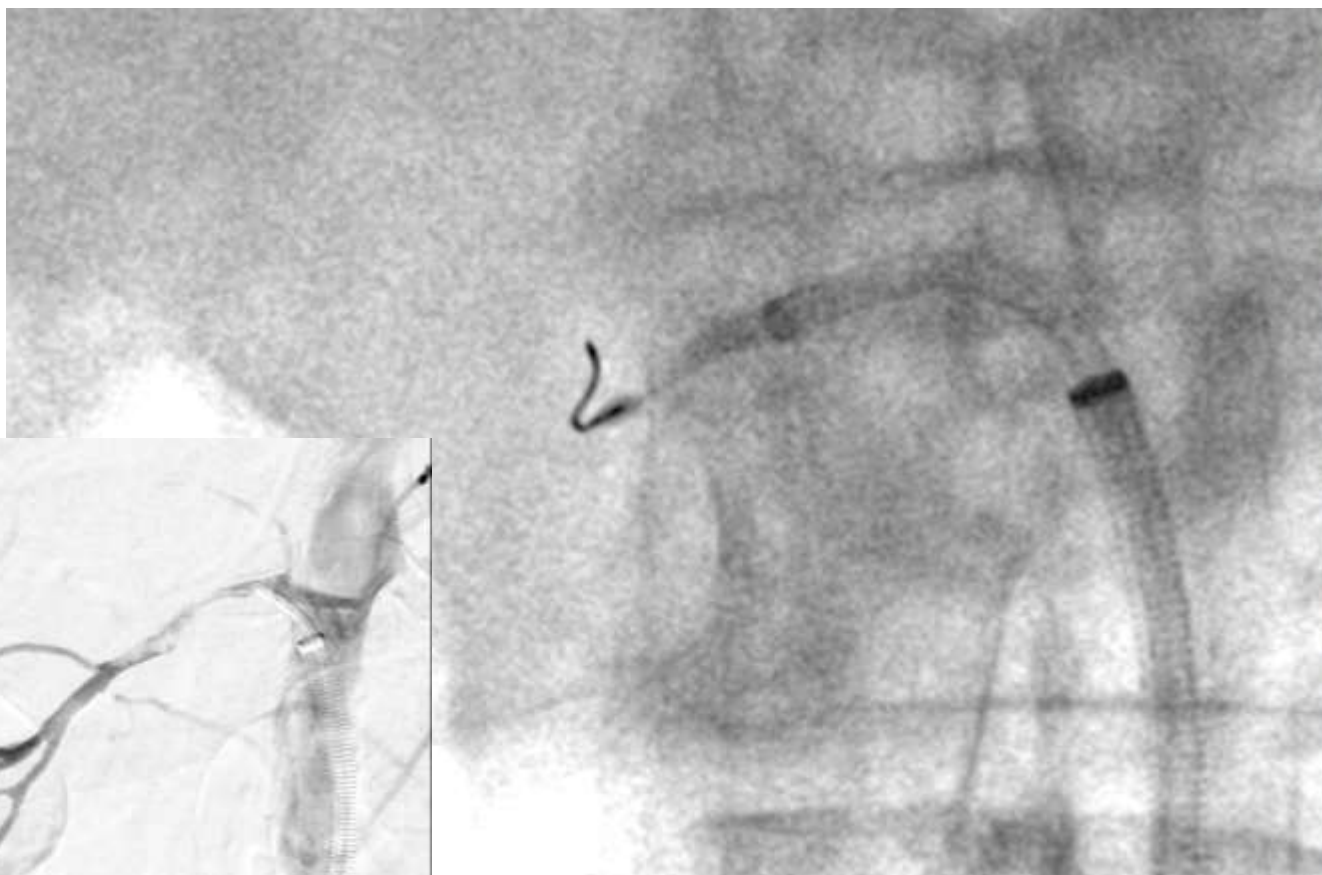




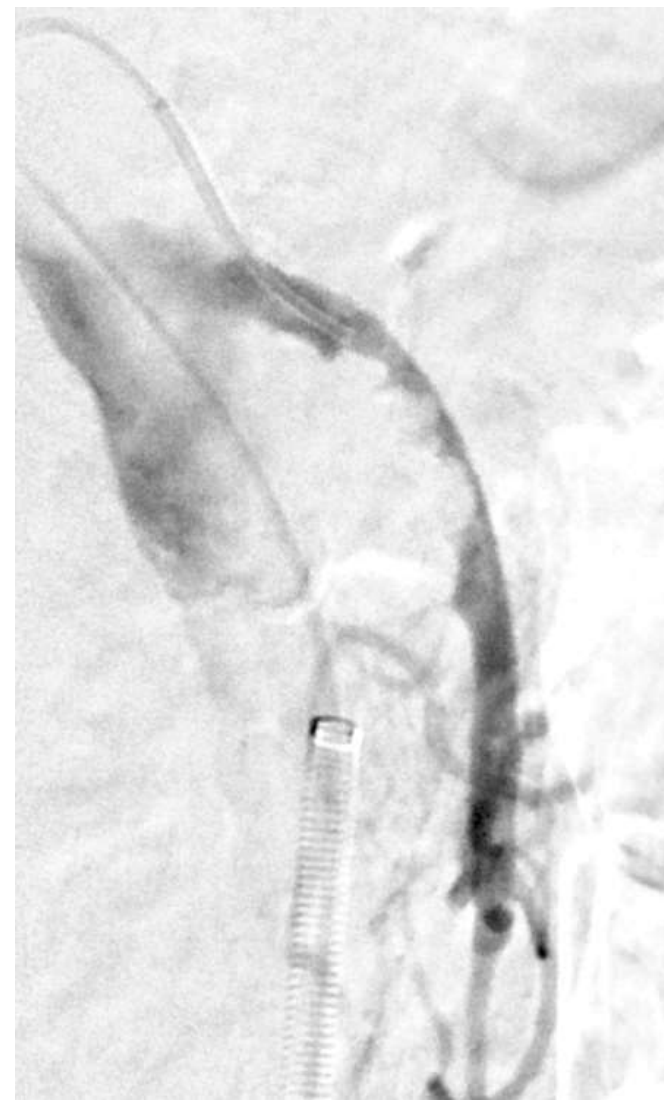
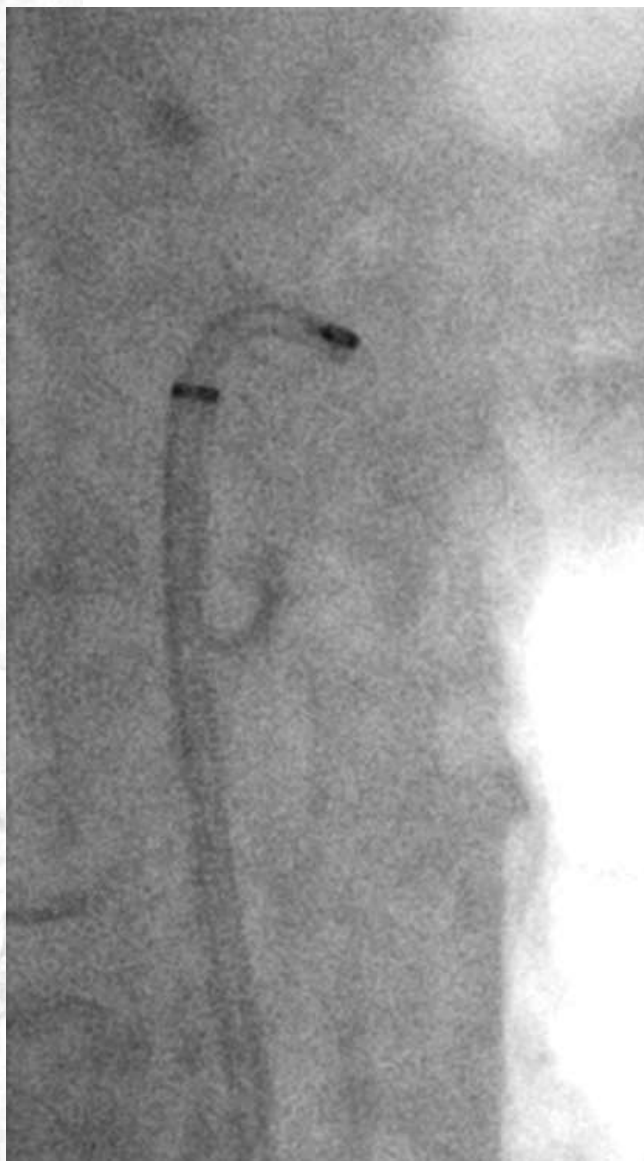
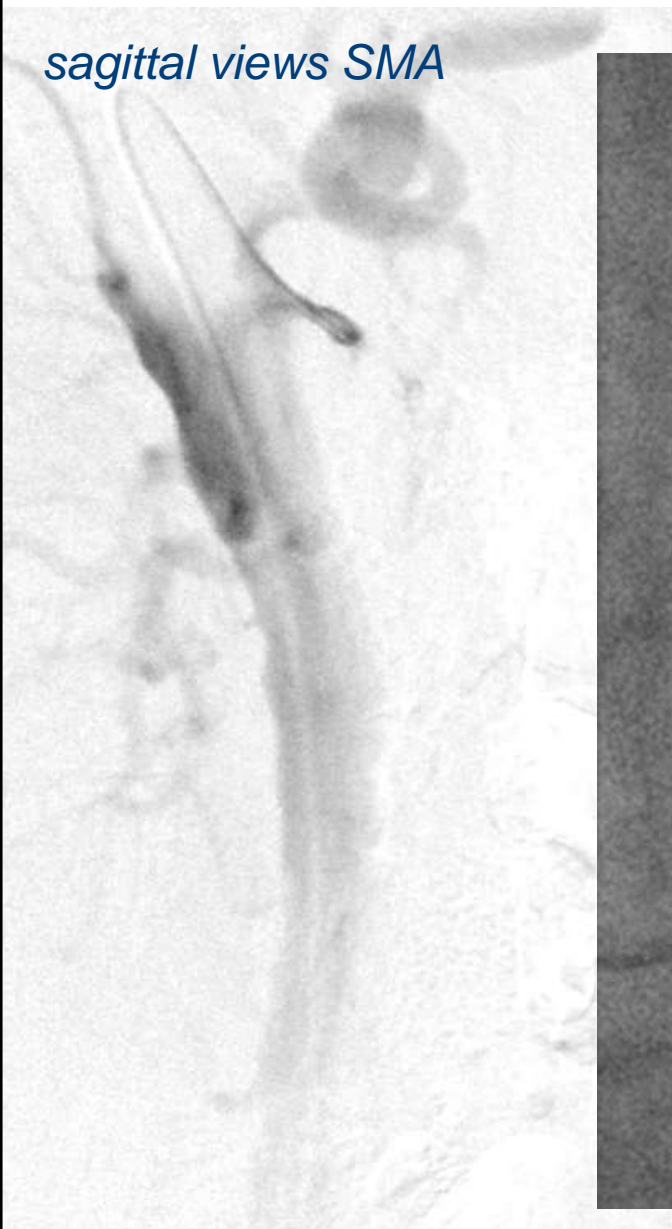




*Penumbra Indigo CAT 8  
& SEP 8*

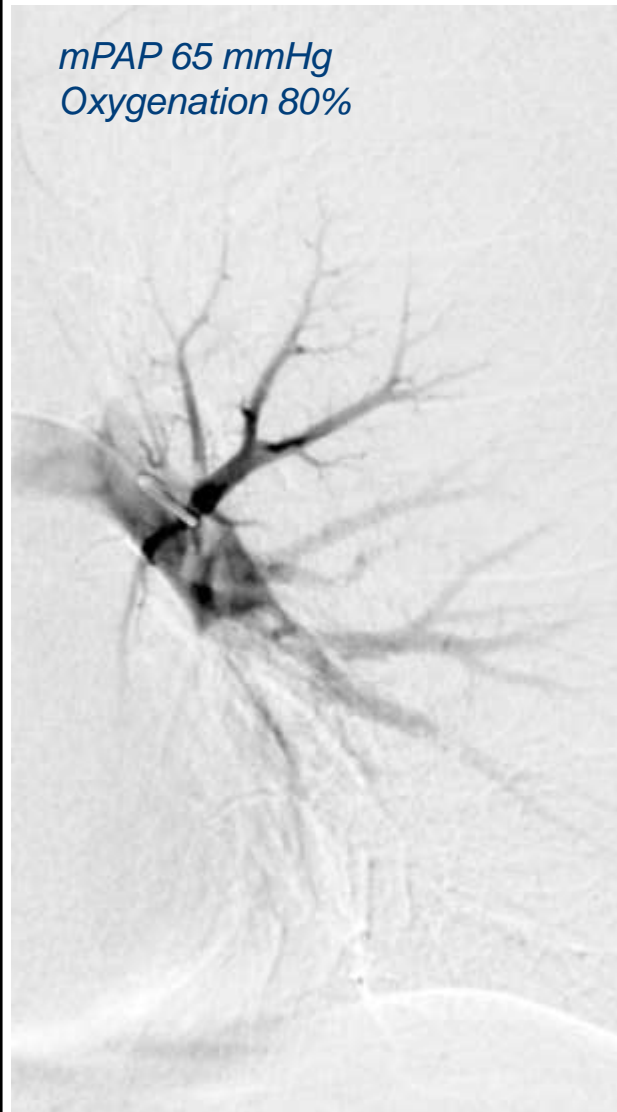


*sagittal views SMA*

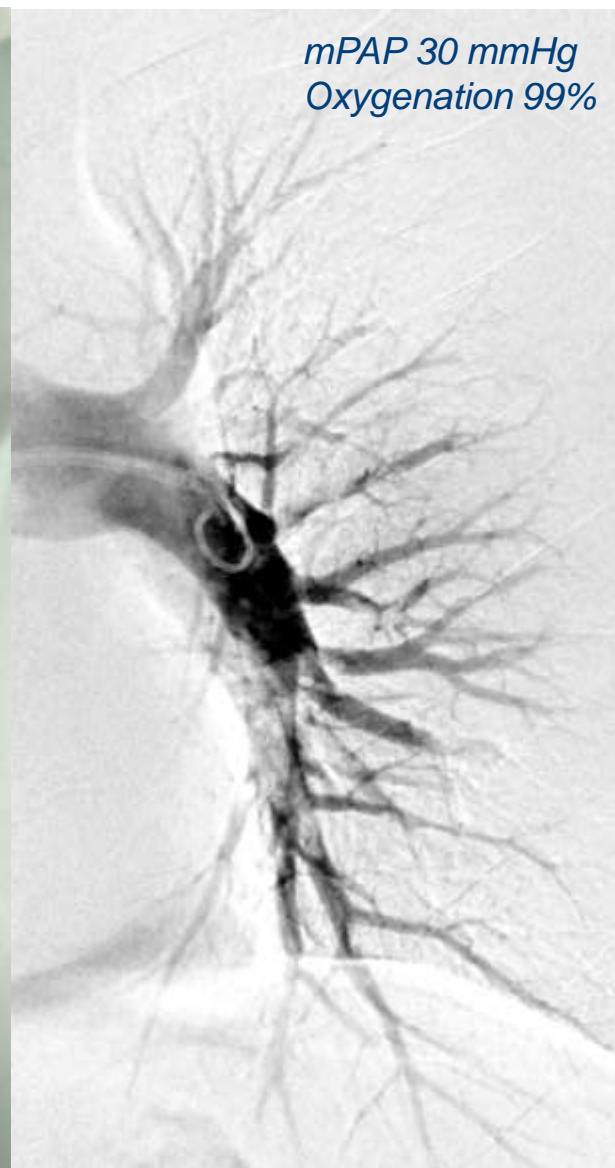




*mPAP 65 mmHg  
Oxygenation 80%*



*mPAP 30 mmHg  
Oxygenation 99%*





# *Objectives*

## *Primary outcome*

- **technical success**  
restoration antegrade flow  
without lysis/alternative revascularization strategies

## *Secondary outcomes*

- blood transfusion
- in-hospital re-intervention
- major adverse events



# Results

N = 158 patients with 12 months follow-up

Primary technical success 100%

iliacs 8F/6F

SFA/PA 8F/6F

peroneal arteries 6/5/3F

plantar arch 3F

No relevant blood loss/  
procedure associated complications (dissection/perforation)

Hospitalisation 2 days

Re-thrombembolisation (30 d) 4%

Re-occlusion (12 months) 0%

# Conclusion

Preliminary results of Re-O<sup>2</sup> en Registry

*Indigo-system* in acute lower limb ischemia:

- easy-to-use
- safe
- efficient
- no need for lysis, blood transfusion





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