Initial Experience with the Temporary Spur Stent System to Enhance Drug Delivery to the Vessel Wall

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Disclosures

Speaker Name:

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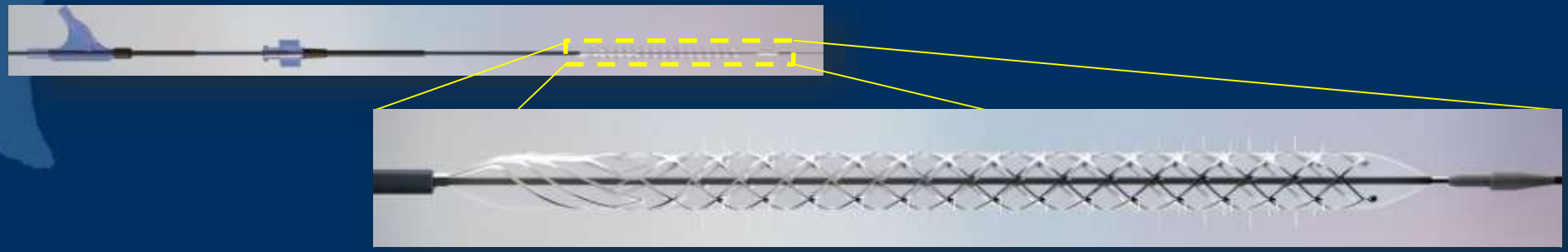
I have the following potential conflicts of interest to report:

- ☐ Consulting
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☒ Other(s) – Clinical Investigator for Reflow Medical

- ☐ I do not have any potential conflict of interest

Temporary SPUR Stent System* – Reflow Medical

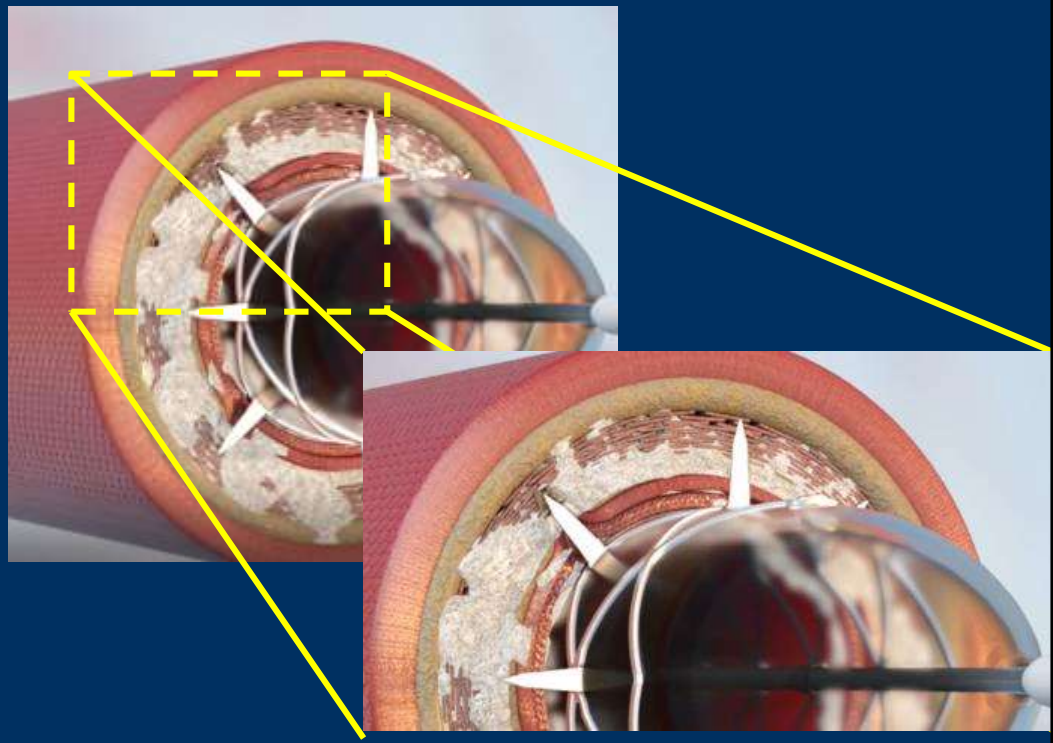
- Self Expanding nitinol frame – **Temporary (retrievable) stent**
- Used with a Drug coated balloon: DEEPER OUS Study
- 6F compatible sheath
- Hydrophilic coated balloon catheter



* For clinical investigational use only

Temporary SPUR Stent System* – Reflow Medical

- Nitinol Frame
  - Balloon expandable
  - Retrievable (< 2 min)
- Treat long lesions (multiple uses)
- Calcification penetration
  - Drug delivery: Deeper into the vessel wall
- Minimize vessel recoil



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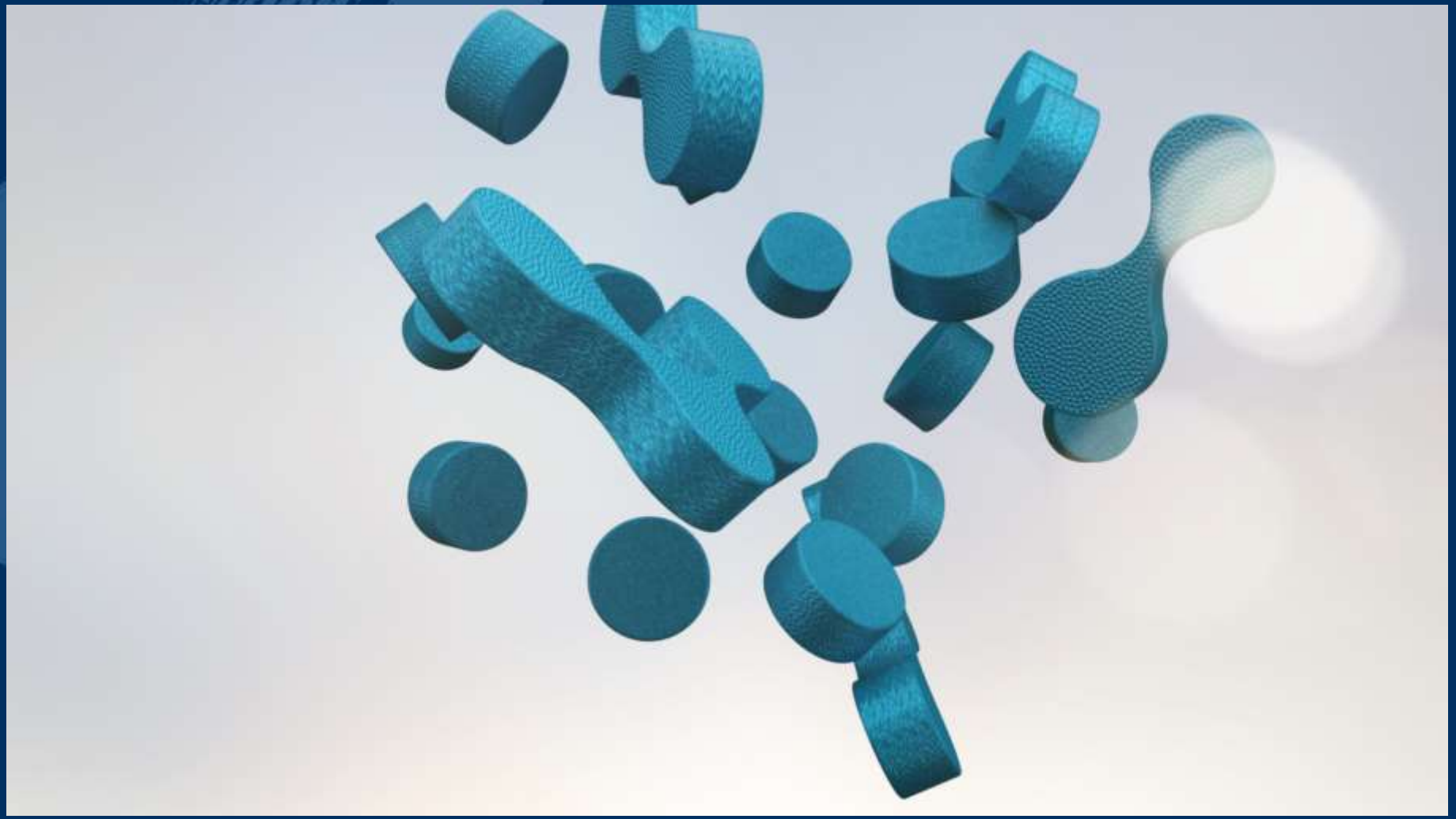
Temporary SPUR Stent System Animation



Clinical Trials

DEEPER FIH: Completed

(Patients: 17, per protocol group)

A Non-Randomize**D** F**E**asibility Trial of the Spur Syst**E**m for the Treatment of Lesions in the Infra**P**oplit**E**al Arte**R**y

- ***Primary Efficacy Endpoint:***
  - Binary arterial flow of treated lesion sites by continuous wave doppler through 6 months
- ***Primary Safety:***
  - Freedom from device and procedure-related death through 30 days post-procedure
  - Freedom from target limb major amputation and clinically driven target lesion revascularization through 12 months post procedure.
- Conducted in the Dominican Republic, Santo Domingo (Dr. Ammar Ibrahim): Oct 2017 – May 2018
- Principal Investigator: Dr. Jihad Mustapha

DEEPER OUS: Ongoing

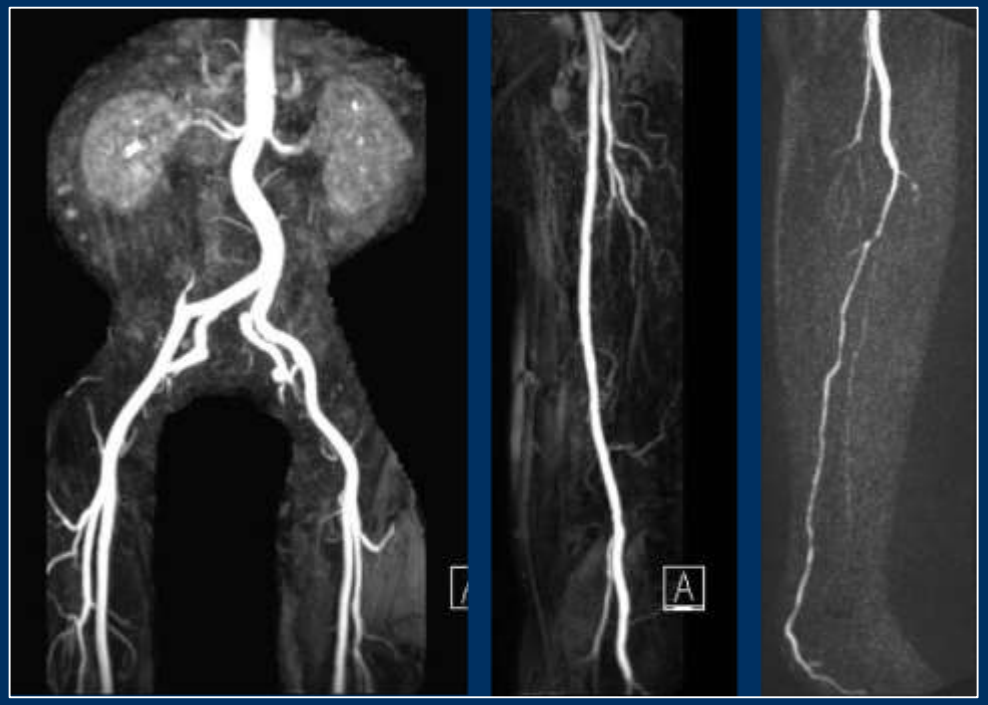
(Patients: 12/100)

A Non-Ran**D**omized Trial of the T**E**mporary Spur St**E**nt System for the Treatment of Lesions located in the Infra**P**oplitEal A**R**teries **O**utside of the **U**nited **S**tates

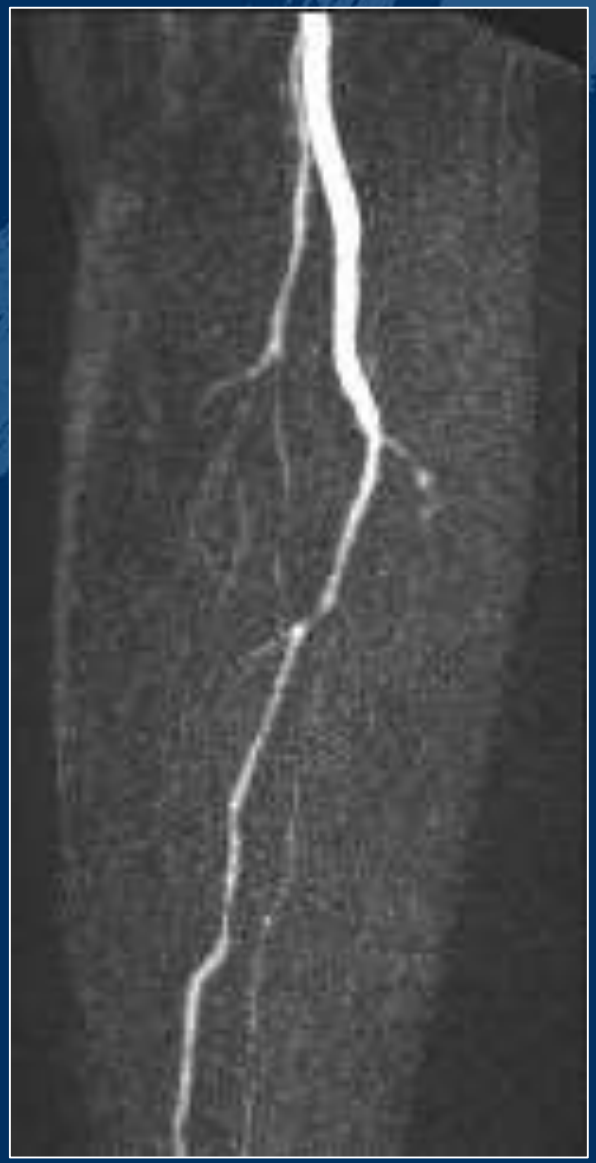
- ***Primary Efficacy Endpoint:***
  - Primary patency of treated lesion sites by duplex ultrasound in subjects who are free from clinically driven TLR
- Primary Safety:
  - Freedom from device and procedure-related death through 30 days post-procedure
- Sites: 4 Active, 2 pending
- Investigators:
  - Dr. Andrew Holden
  - Prof Dierk Scheinert
  - Prof Thomas Zeller
  - Prof Jos van den Berg
  - Prof Michael Lichtenberg (Pending)
  - Prof Gunnar Tepe (Pending)

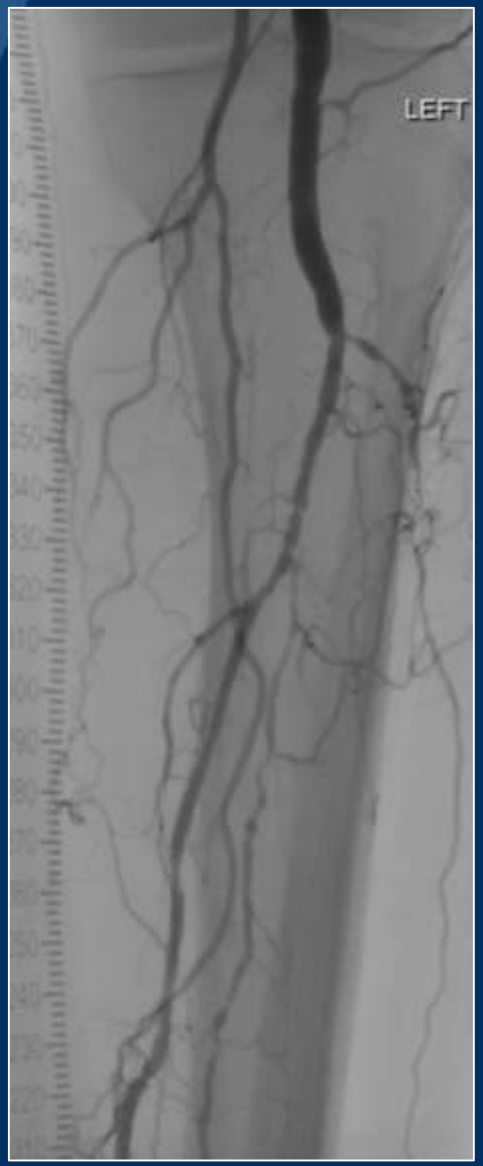
DEEPER OUS Case Presentation

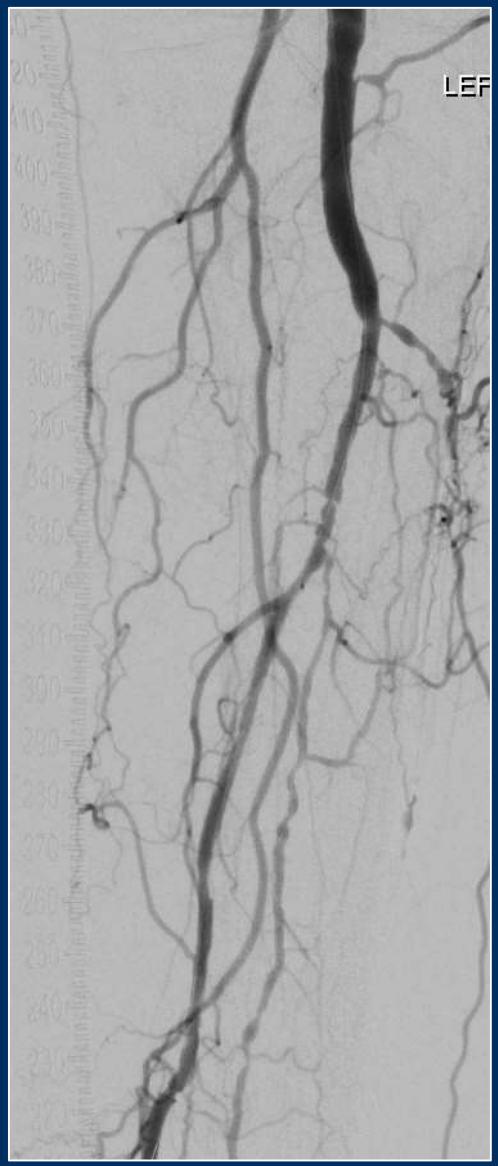
- Patient 001-001
- Male, Rutherford Class 5
- 64 years old
- IDDM
- Left foot rest pain and great toe ulceration
- Cerebrovascular Disease
- Hypertension
- Hyperlipidemia
- Claudication
- Peripheral Neuropathy



DEEPER OUS Case Presentation







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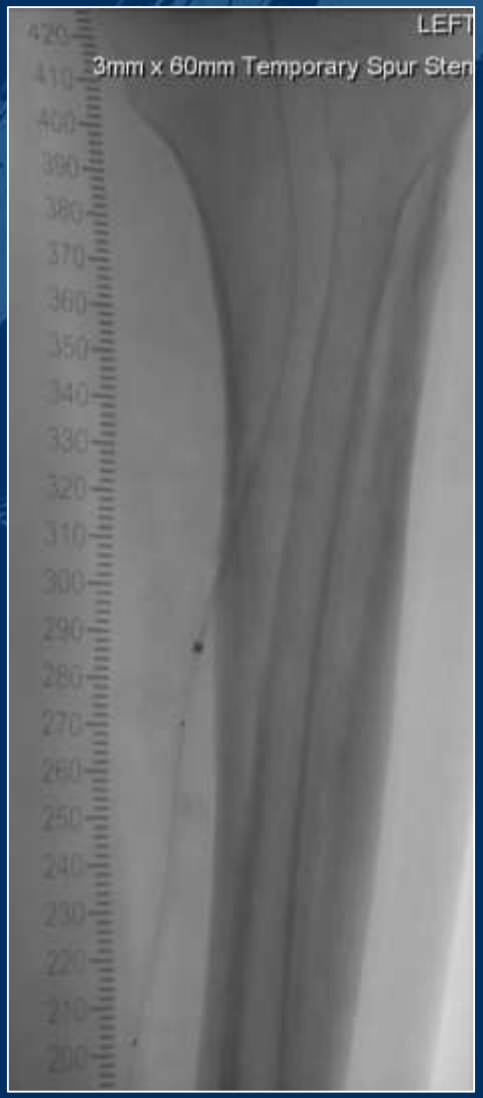

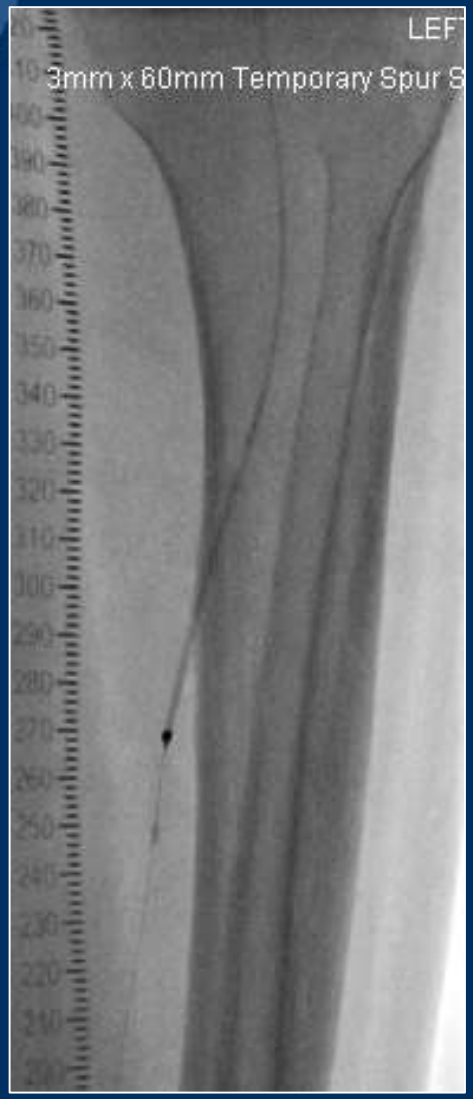

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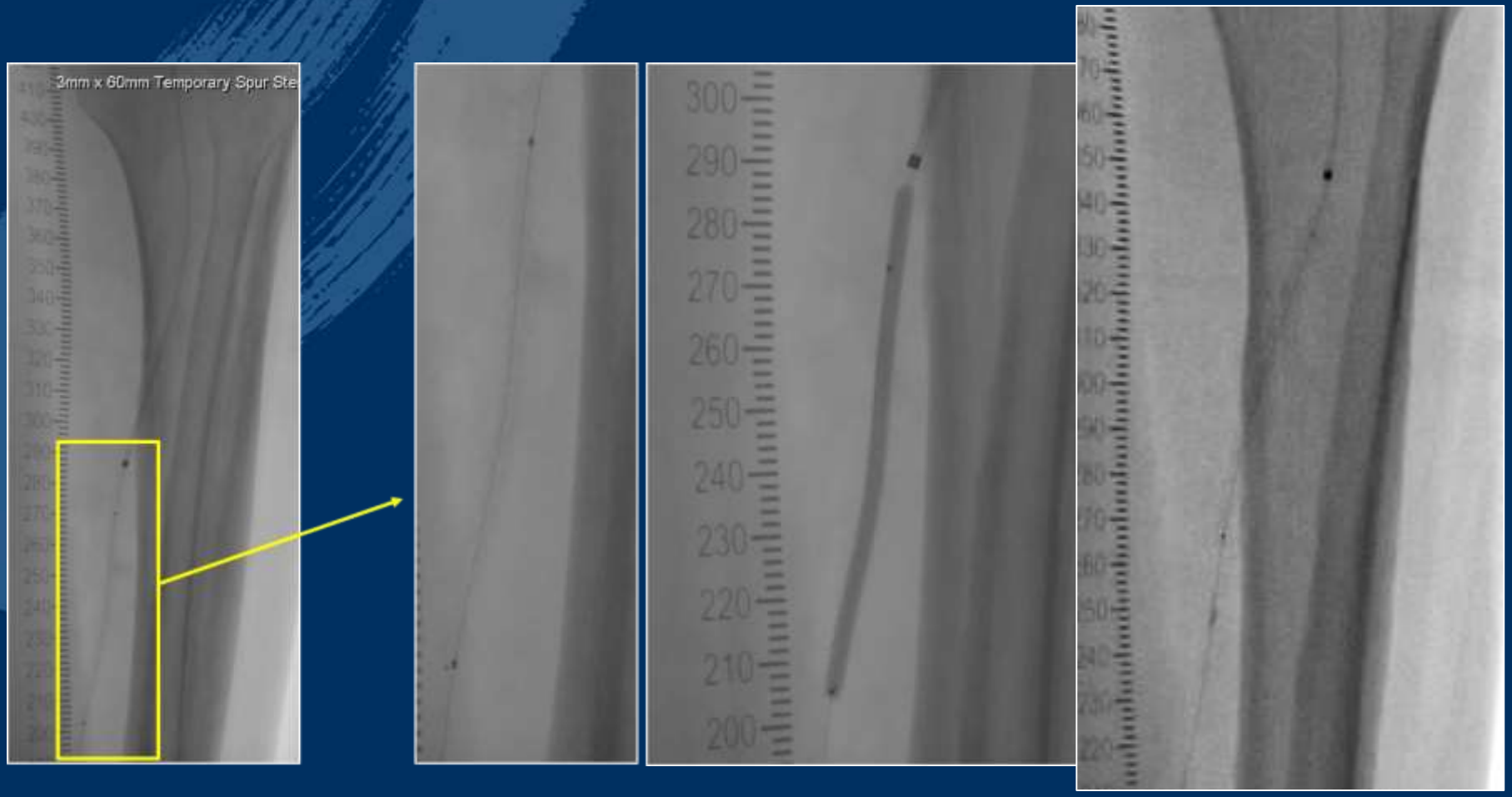

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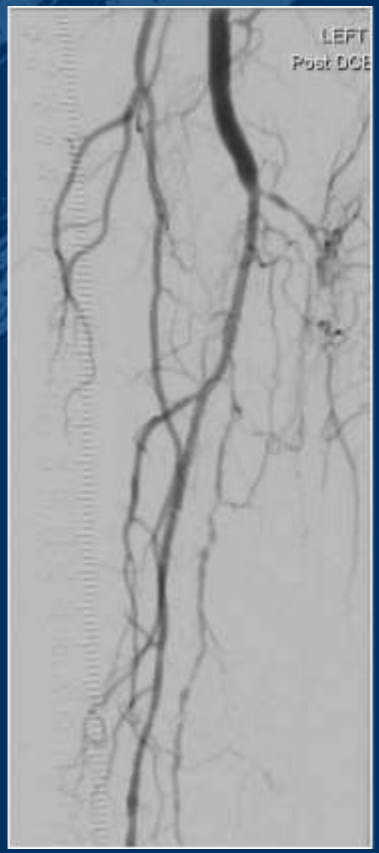
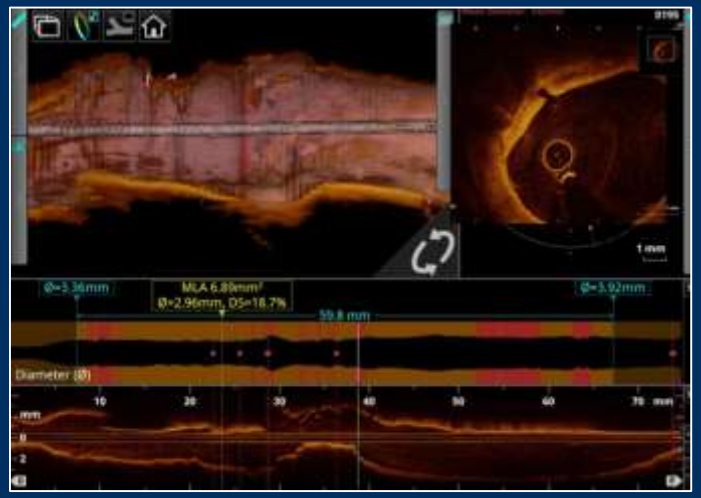
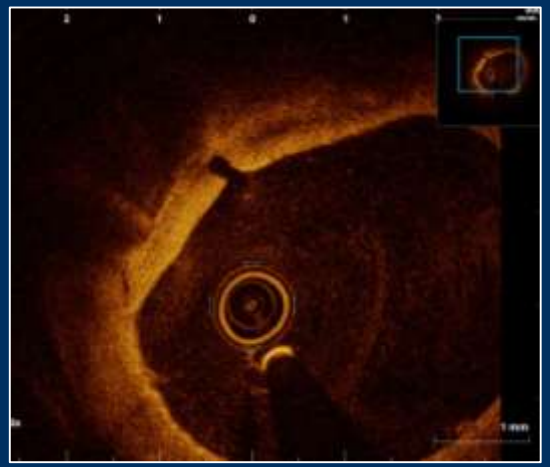
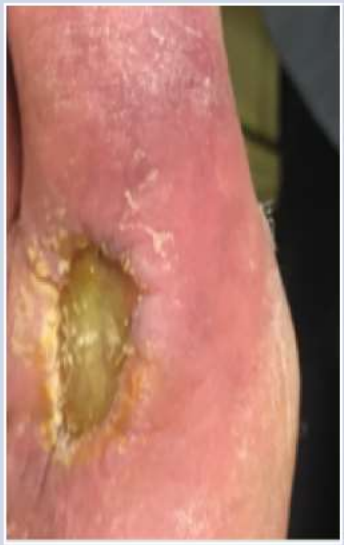
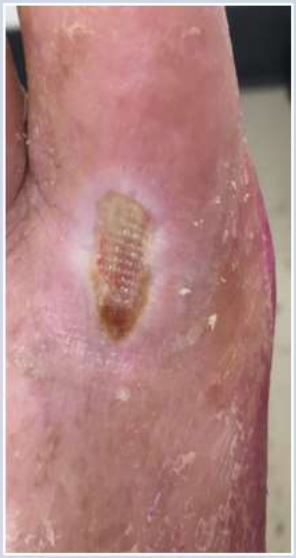
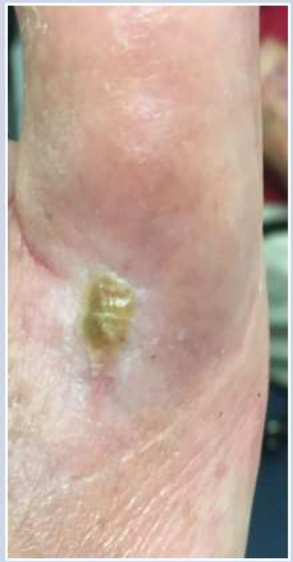






Rest Pain Resolved and Wound Healing

DEEPER OUS Wound Healing Baseline	30 days	3 months
		

DEEPER OUS Demographics and Clinical Characteristics (n=12 pts)

DEEPER OUS demographics and clinical characteristics	N=12
Variable	Value
Age, yr	71 (55, 86)
Female sex	16.7% (2/12)
Type 2 Diabetes	75% (9/12)
Hypertension:	100% (12/12)
Tobacco abuse	58.3% (5/12)
Hyperlipidemia (HLD)	100% (12/12)
Chronic Kidney Disease (CKD)	41.6% (5/12)
Rutherford class	
3	25% (3/12)
4	8% (1/12)
5	66% (8/12)

DEEPER OUS: Lesion Characteristics

DEEPER OUS Lesion Characteristics N=12	
Target artery	**Results [mean (n/N)]**
Anterior tibial	8.3% (1/12)
Posterior tibial	25% (3/12)
Tibioperoneal trunk	41.7% (5/12)
Peroneal	25% (3/12)
Diameter stenosis, % [mean (range)]	94% (90-100%)
Spur-treated length mm [mean (range)]	96 mm (60-160)

DEEPER OUS Lesion Characteristics N=12	
TASC Classification	**Results [mean (n/N)]**
A	41.6% (5/12)
B	16.7% (2/12)
C	33.4% (4/12)
D	8.3% (1/12)
Calcification (PARC 1-4)	
1	16.7% (2/4)
2	33.4% (4/12)
3	33.4% (4/12)
4	8.3% (1/12)

Clinical Data To Date

DEEPER FIH: Completed

Primary Efficacy Endpoint: (PP Analysis)	N= 18 arteries [n/N (%)]
Binary arterial flow via ultrasound at 6 months	**16/18 (88.9%)*** *core lab adjudicated: Vascore

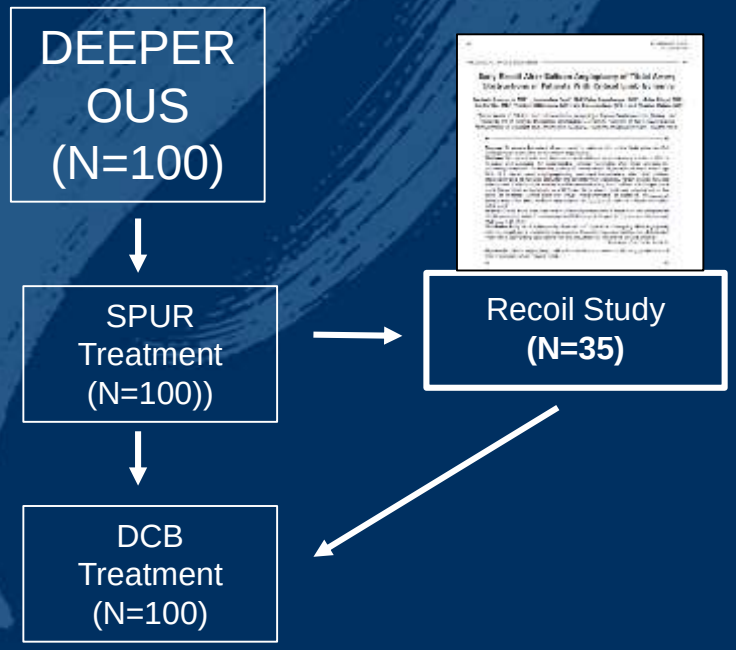
Primary Safety Endpoints: Spur + DCB (PP Analysis)	N= 17 subjects [n/N (%)]
Freedom from device and procedure-related death through 30 days post-procedure	**17/17 (100%)**
Freedom from target limb major amputation and CD-TLR through 12 months post procedure	**16/17 (94.1%)**

DEEPER OUS: Ongoing

Primary Efficacy Endpoint	One month (N=12)	6 months (N=3)
Patency by ultrasound	**100% (12/12)*** *Core Lab adjudicated: (Vascore)	**100% (3/3)*** *Site reported

Safety Endpoint		One month (N=12)
Primary	Freedom From Device and procedure related death through 30 days post procedure	**100% (12/12)**
Secondary	Freedom from target limb MALE & all cause POS at 30 days	**100% (12/12)**

DEEPER OUS: Clinical Trial– Recoil Sub-Study



Recoil SUB-Study	Results (n=9 patients)
Minimal Luminal Gain Post SPUR	1.5mm (-.9mm, 2.9mm)
Elastic Recoil* Defined as lumen compromise ≥ 10% Post 15 min of SPUR treatment	**22%** (2/9) vs Baumann paper: **97%** (29/30)
* Corelab adjudication: Syntropic	

First 10 patients at each site part of recoil sub-study until goal met, until 30 patients have been included

Conclusions

- Temporary Drug Coated Spur Stent System is a novel technology to treat Cardiovascular Disease
- Provides Localized Drug Delivery (agnostic to drug choices)
- Encouraging and Positive Data:
  - DEEPER FIM
  - DEEPER OUS
- LEAVES NOTHING BEHIND: **Preserves future treatment options**

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