



Dr. Michel Bosiers

**MOTIV BTK Pilot Study:**  
Initial Safety and Performance  
Study of the MOTIV Sirolimus-  
Eluting Bioresorbable Coronary  
Scaffold in Patients with CLTI and  
BTK lesions

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# Disclosure

Speaker name: Michel Bosiers

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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)
  
- I do not have any potential conflict of interest



# MOTIV Bioresorbable Scaffold

## Device Specifications Overview

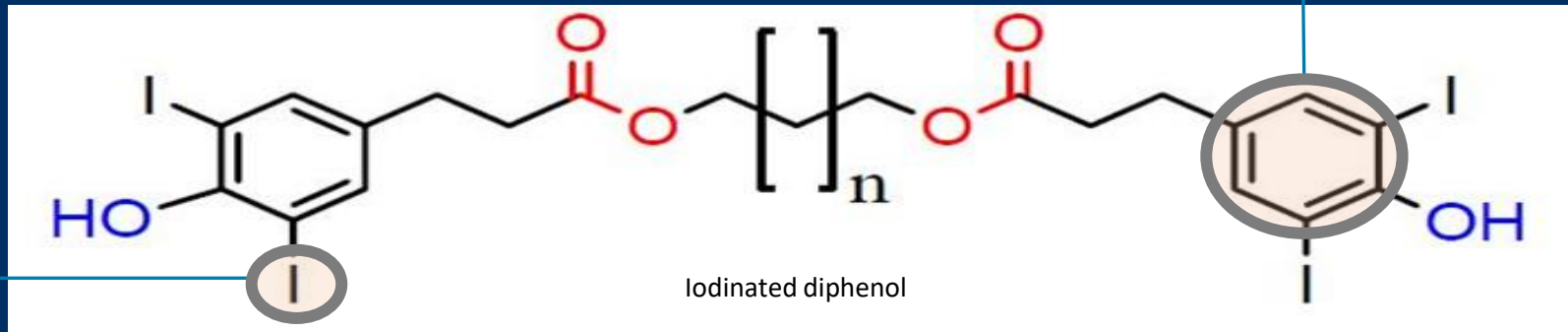


<b>Description</b>	Bioresorbable BTK scaffold	
<b>Scaffold material</b>	Tyrocore™	
<b>Coating material</b>	Tyrocore	
<b>Drug</b>	Sirolimus	
<b>Drug dose</b>	1.97 µg/mm	
<b>Shortening</b>	1% (lengthening)	
<b>Maximum expansion diameter</b>	<b>Size (mm)</b>	<b>Max Expansion (mm)</b>
	2.5	3.25
	3.0	3.75
	3.5	4.0

<b>Catheter type</b>	Rapid exchange
<b>Guide catheter compatibility</b>	6F
<b>Working catheter length</b>	139 cm
<b>Scaffold lengths</b>	12, 18, 24 mm 36 & 48mm
<b>Nominal pressure</b>	7 atm
<b>Rated burst pressure</b>	18 atm
<b>Balloon material</b>	Nylon

# Tyrocore is Strong at its Core

Tyrocore gets its strength from its molecular structure



Phenyl ring structure of Tyrocore polymer is inherently strong



Covalently bound iodine for radiopacity

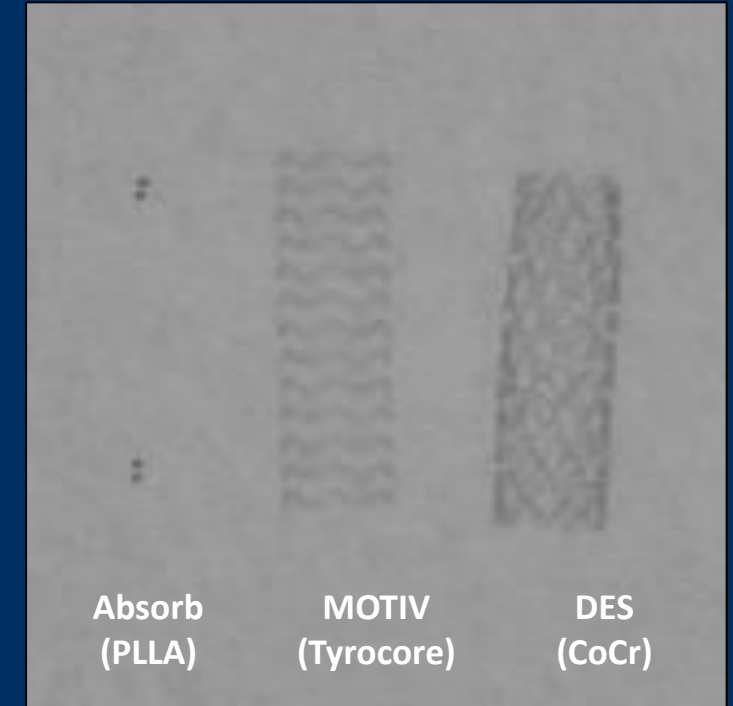


High molecular weight and composition provide ductility

# Tyrocore is Twice as Strong and 10 Times More Ductile than Poly-l-lactic acid (PLLA)

## Properties of Tyrocore versus PLLA

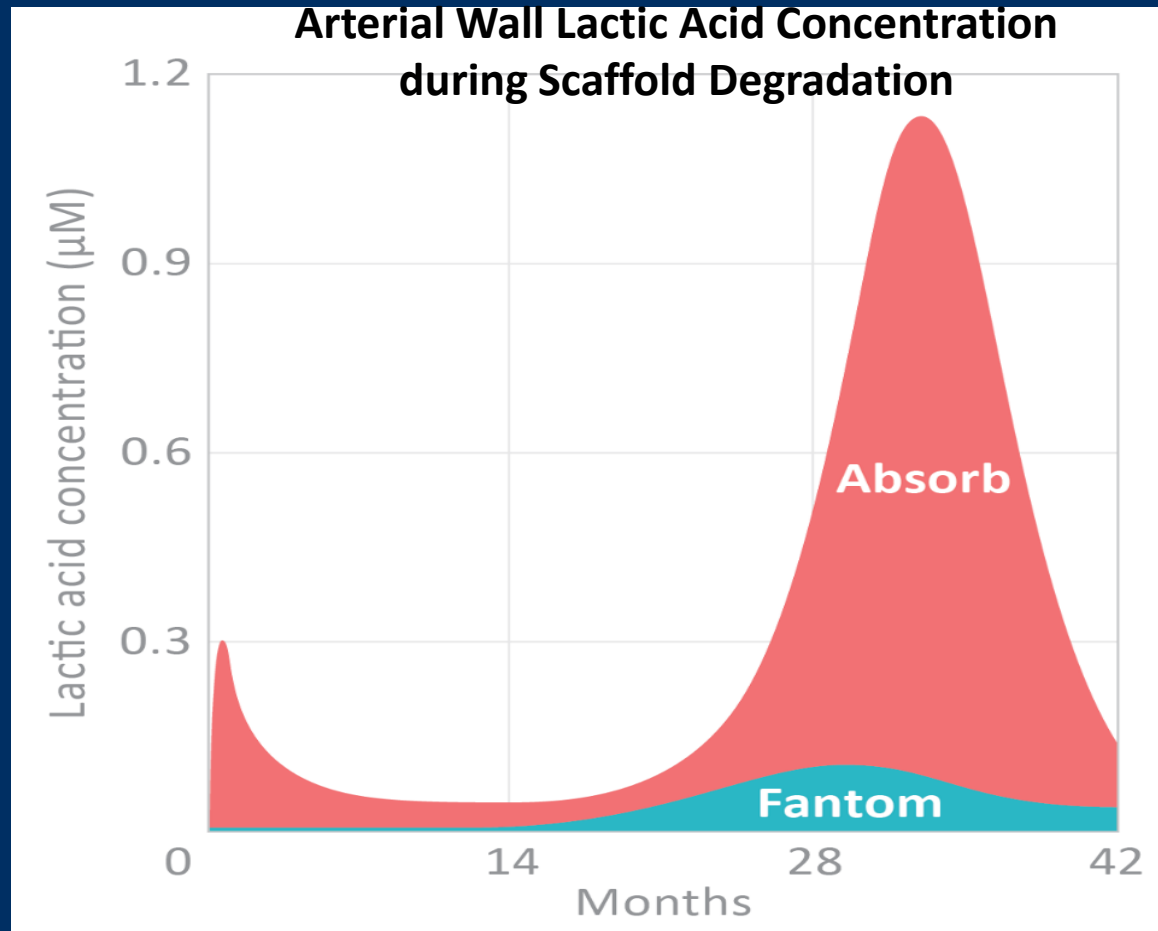
Attribute	Tyrocore	PLLA <sup>1</sup>	Benefit
Ultimate Tensile Strength	100-110 MPa	50-70 MPa	Thinner struts Radial strength
Elongation at Break (Ductility)	120-200%	2-10%	Single-step inflation Larger expansion range
X-Ray Visible	Yes	No	Accurate placement



A single MOTIV scaffold contains < 1% of the iodine found in 1 mL of contrast media

1) Poly(Lactic acid): Synthesis, Structure, Properties, and Applications. Edited by R.Auras, L-T.Lim, S.E.M.Selke, H.Tsuji. 2010 John Wiley & Sons, Inc.; p.141

# Low Lactic Acid to Support Full Vessel Recovery

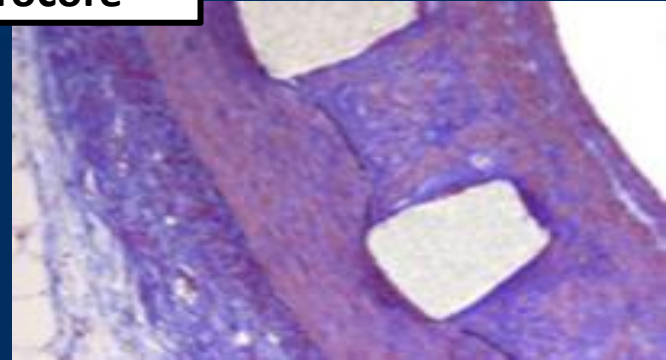


**10 Times Lower  
Lactic Acid Release  
with Tyrocore**

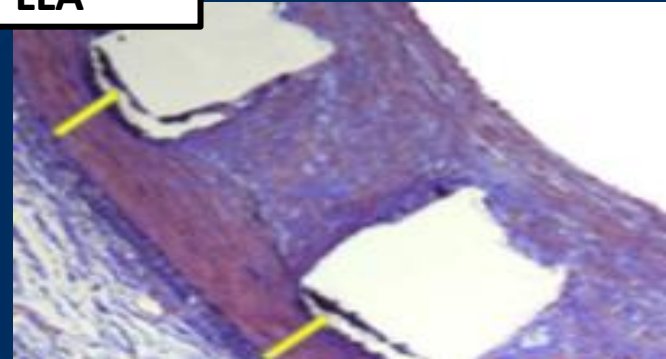
# Tyrocore Excellent Vessel Healing

- Tyrocore is derived from the naturally occurring tyrosine amino acid
- Low inflammation, irritation, during degradation
- No formation of calcification during degradation as seen in PLLA

Tyrocore



PLLA

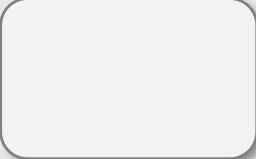




6-month degradation in porcine artery

# Tyrocore enables MOTIV to be the *World's Thinnest BRS*

**95  $\mu\text{m}$  Strut Thickness is Thinnest Strut of any CE Mark BRS**

**Strut Profiles of 2.5 mm BRS**

Absorb <sup>1</sup>	Magmaris <sup>2</sup>	Fantom	MOTIV
	2.5 mm not available		
157 $\mu\text{m}$	n/a	125 $\mu\text{m}$	95 $\mu\text{m}$

1) Ormiston, J. New BRS Platforms. Presented EBC Rotterdam 2016.; Foin, N. Biomechanical Assessment of Bioresorbable Devices. Presented CRT 2017. 2) Manufacturer reported data on file at REVA Medical.

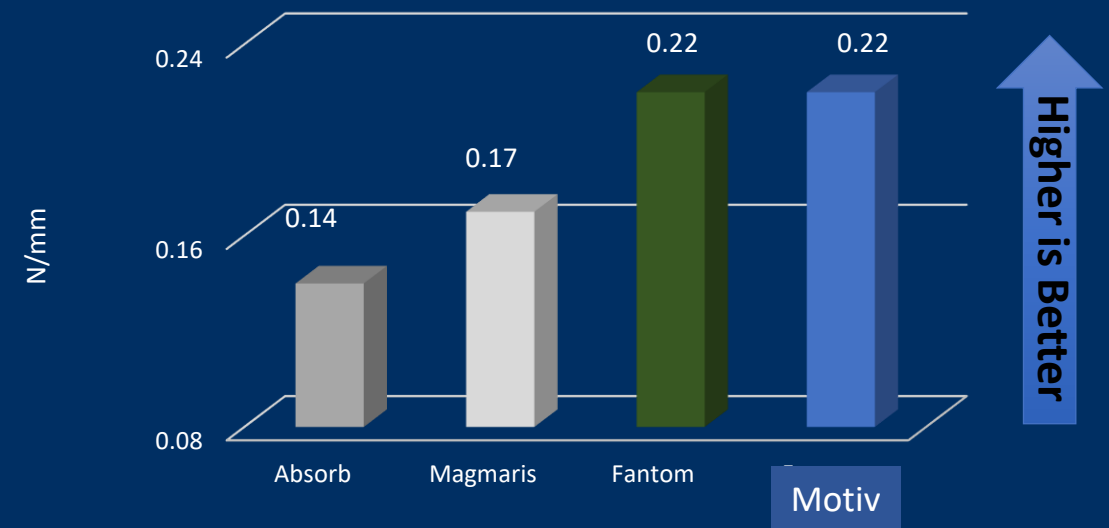


# Thin Struts with Best-in-Class Radial Strength

Strut Thickness ( $\mu\text{m}$ )<sup>1</sup>

	Absorb <sup>1</sup>	Magmaris <sup>1</sup>	Fantom	MOTIV
2.5 mm	157	n/a	125	95
3.0 mm	157	166	125	105
3.5 mm	157	166	125	115

Radial Strength<sup>2</sup>



- Thinner struts achieved without compromising radial strength through manufacturing process improvements of the Tyrocore polymer

# Study design

- **Study Objective:**  
To evaluate the immediate and long-term (up to 36 months) outcome of the MOTIV™ Bioresorbable Scaffold (Reva Medical) in a controlled prospective investigation for the treatment of patients with rest pain or minor tissue loss (CLI) due to the presence of lesions of max **100mm in length** at the level of the below-the-knee arteries.
- **Primary Endpoint:**  
**Primary Patency at 12 months**, defined as no evidence of at least 50% restenosis or reocclusion within the originally treated lesion based on color-flow duplex ultrasound (CFDU) measuring a peak systolic velocity ratio  $\leq 2.5$ .

# Participating centers

- **Pilot study (15 Pts.) at St. Franziskus-Hospital Münster**

- **Protocol Amendment 06/2020:**

➤ Prospective, single-arm, multi-center study

➤ Total of 50 patients

➤ Follow-up period of 36 months

➤ Lesion length up to 100mm

## Participating centers

- Dr. Michel Bosiers – St. Franziskus-Hospital Münster, Münster, Germany
- Dr. Michael Lichtenberg – Klinikum Hochsauerland KarolinenHospital Hüsten, Arnsberg, Germany
- Dr. Nasser Malyar – Universitätsklinikum Münster (UKM), Münster, Germany
- PD Dr. Hendrik Schroeder – Jüdisches Krankenhaus, Berlin, Germany (*Maxis Medical*)
- Prof. Dr. Med Jörn Balzer – Katholisches Klinikum, Mainz, Germany (*Maxis Medical*)
- Dr. Florian Willecke – Herz-und Diabeteszentrum, Bad Oeynhausen, Germany (*Maxis Medical*)
- Prof. Thomas Rand - Klinik Floridsdorf, Wien, Austria (*Maxis Medical*)
- Prof. Dierk Scheinert/PD Dr. Andrej Schmidt – Universitätsklinikum Leipzig, Leipzig, Germany (*Maxis Medical*)

# Main inclusion criteria

- **Rutherford** classification from **4 to 5**
- Patient has a projected **life-expectancy of at least 24-months**
- De novo lesion or Restenotic lesion after PTA in the infrapopliteal arteries, suitable for endovascular therapy
- Target vessel diameter visually estimated to be  **$\geq 2.5\text{mm}$  and  $\leq 3.50\text{mm}$**
- Guidewire and delivery system successfully traversed the lesion
- Total target lesion is maximally **100mm**
- Definition of **Target Lesion** is
  - a) **de novo or Restenotic lesion after PTA**
  - or
  - b) **a residual flow-limiting dissection or restenosis after PTA of a longer lesion**

# Study overview



	pre-procedure	procedure	discharge	1MFU	6MFU	1, 2 & 3 YFU
Patient informed consent	■					
Inclusion/ Exclusion Criteria Check	■					
Medical / Clinical History	■					
Laboratory Test	■					
Medication	■		■	■	■	■
Physical Examination	■		■	■	■	■
Rutherford Classification	■		■	■	■	■
ABI	■		■	■	■	■
Color Flow Duplex	■	■		■	■	■
Wound Imaging (as needed)	■		■	■	■	■
Angiography	■	■				■*

\* 12MFU: Angiography / CT Angiography / MR Angiography control at the discretion of the investigator

# Patient Demographics – Preliminary Data (first 18Pts.)

Demographics	Mean or % (n/N)
Male (%)	90 (17/18)
Age (min – max)	73 (54 – 87) years
Comorbid Conditions	% (n/N)
<b>Smoking</b>	
<i>Past</i>	22,22% (4/18)
<i>Current</i>	16,66% (3/18)
<b>Vascular</b>	
<i>Hypertension</i>	66,66% (12/18)
- <i>medicated</i>	55,55% (10/18)
<i>Previous Peripheral vascular intervention</i>	44,44% (8/18)
<i>Previous coronary intervention</i>	38,88% (7/18)
<i>Previous cerebrovascular intervention</i>	5,55% (1/18)

Comorbid Conditions (cont.)	% (n/N)
<b>Endocrine</b>	
<i>Diabetes Type I</i>	22,22% (4/18)
<i>Diabetes Type II</i>	67% { 44,44% (8/18)
<b>Renal</b>	
<i>Renal insufficiency</i>	44,44% (8/18)
<i>Dialysis</i>	11,11% (2/18)
<b>Obesity</b>	16,66% (3/18)
<i>BMI (average; min - max)</i>	27.47 (21.16 - 37.58)
<i>Hypercholesterolemia</i>	38,88% (7/18)

# Procedural characteristics – Preliminary Data (first 18 Pts.)

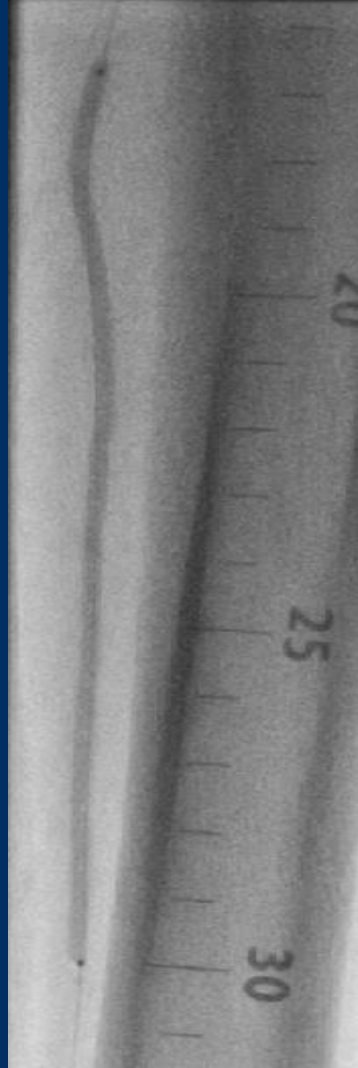
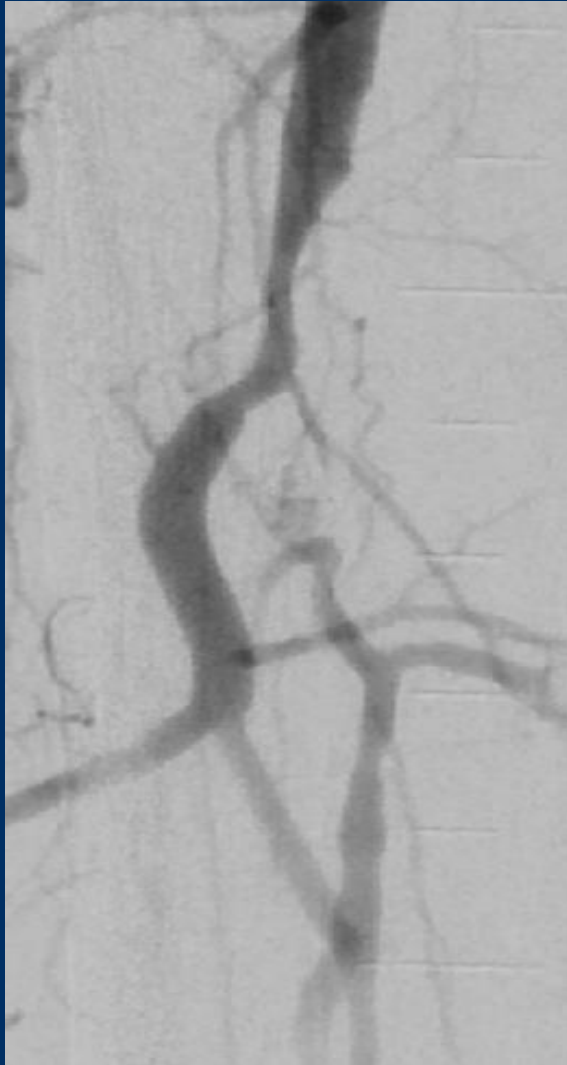
	Average or %, n/N (min – max)
Procedure time	65,77 (17-180) minutes
Fluoroscopy time	18,21 (4.0 – 56.0) minutes
Amount of contrast	96,94 (28 – 350) mL
Cross-over performed	0% (0/18)
Artery treated:	
Anterior Tibial Artery	27,77% (5/18)
Posterior Tibial Artery	16,66% (3/18)
Fibular artery	38,88% (7/18)
Truncus Tibiofibularis	38,88% (7/18)
Inflow Lesion (%)	33,33% (6/18)
Outflow lesion (%)	50,00% (9/18)

# Lesion Characteristics – Preliminary Data (first 18 Pts.)

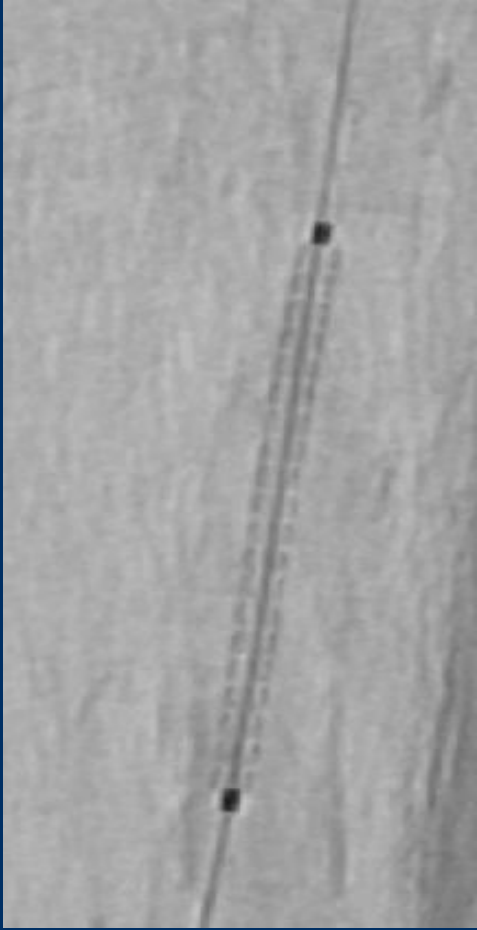
	Average or %, n/N (min – max)		Average or %, n/N (min – max)
Lesion length	36,08 (10,00 – 69,00) mm	<b>Target lesion definition</b>	
Ref Vessel Diameter	3,12 (2.50 – 3.50) mm	<i>short de novo or restenotic lesion after PTA</i>	44,44% (8/18)
Pre-dilatation (obligatory)	100% (18/18)	<i>short residual flow-limiting dissection or restenosis after PTA of a longer lesion</i>	55,55% (10/18)
More than 1 MOTIV stent implanted	27,77% (5/18)	<b>Target lesion pre-conditions</b>	
Post-dilatation (obligatory)	100% (18/18)	<i>Ulceration</i>	5,5% (1/18)
		<i>Calcified lesion</i>	72,22% (13/18)
		<i>Thrombus</i>	11,11% (2/18)
		<i>Dissection</i>	22,22% (4/18)
		<i>None of the above</i>	16,66% (3/18)



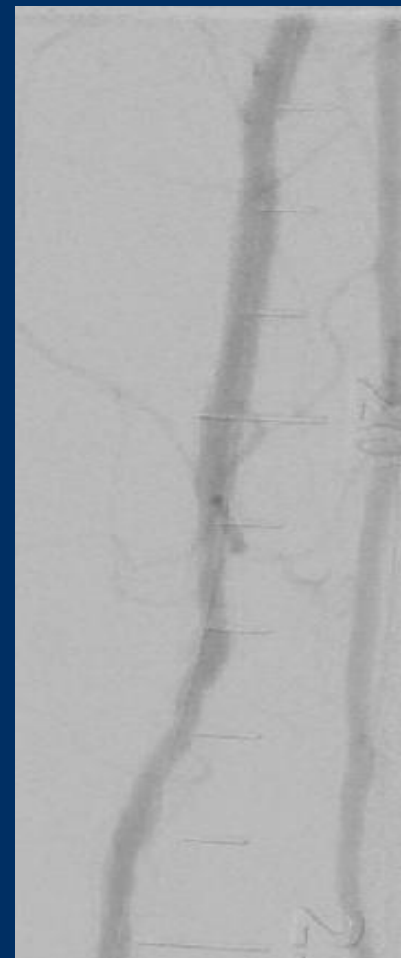
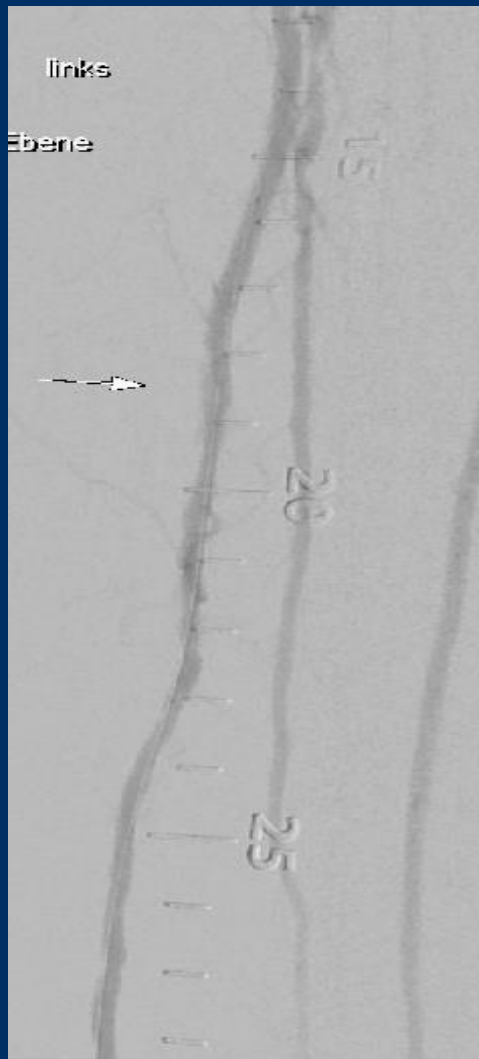
# Example 1



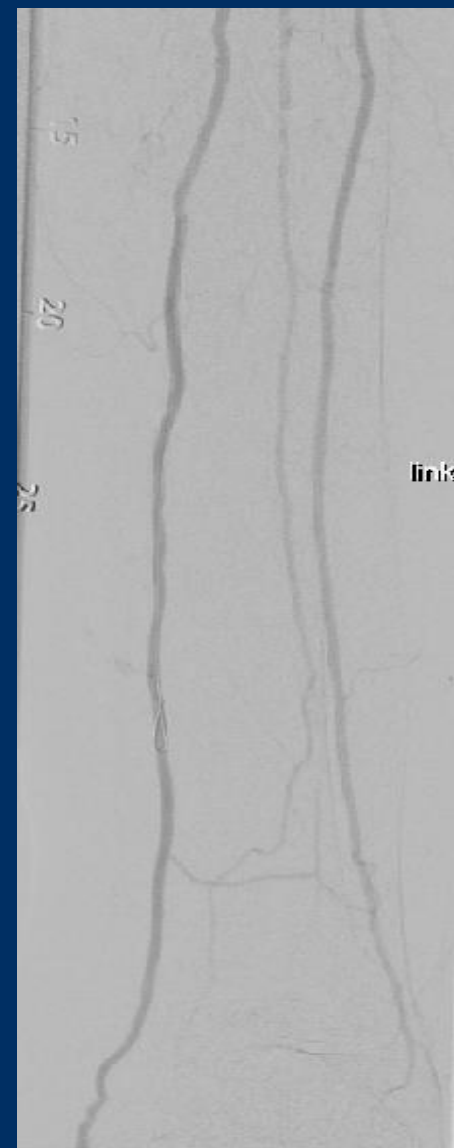
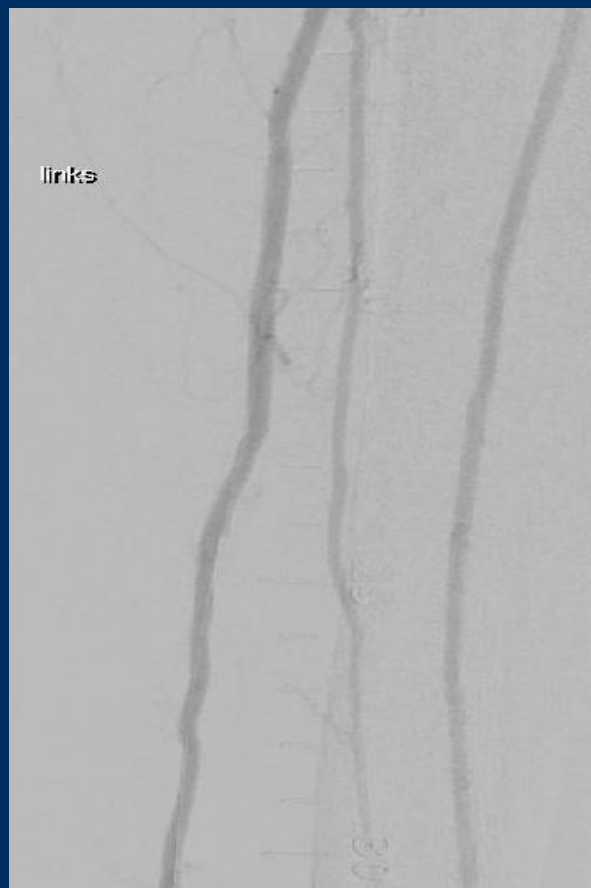
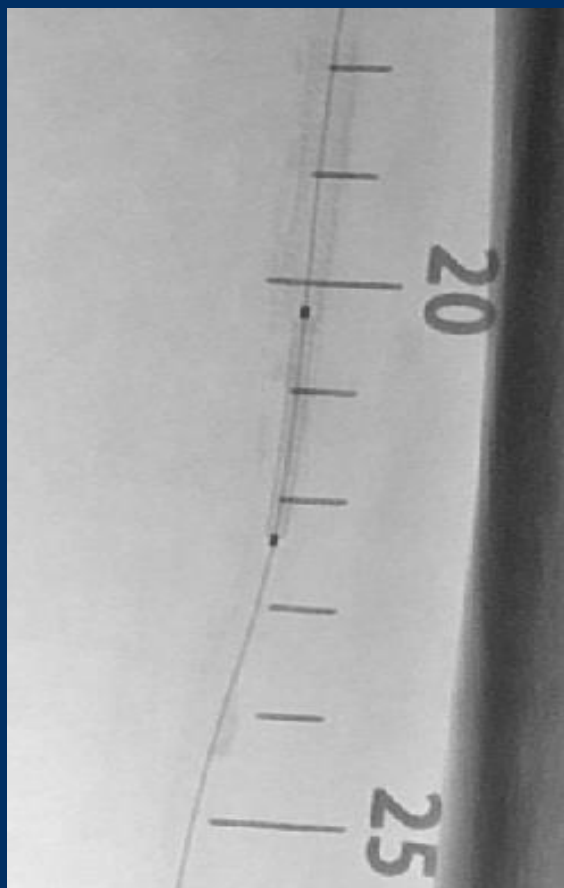
# Example 1



# Example 2



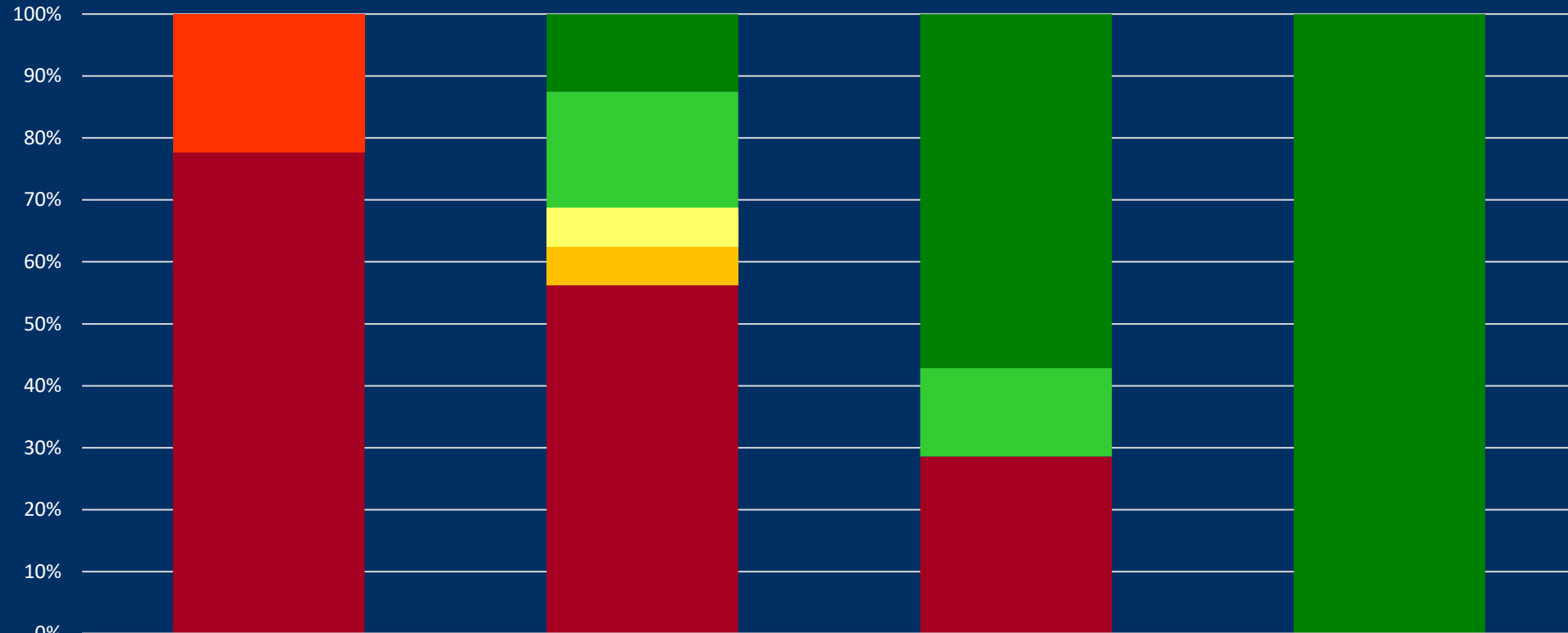
# Example 2



# Preliminary Outcomes (enrollment and FU visits still ongoing)

- **100% primary patency** (according to peak systolic velocity ratio)
- **100% freedom of TLR**
- 12 SAEs – not device related
  - 3 Patients died
    - not device-, study procedure- or study lesion-related (*multi-organ failure due to Urosepsis, heart & respiratory failure, septic shock and endocarditis*)
  - 8 non-vascular
  - 1 study-lesion/in-/outflow related (*Prolongation of existing hospitalization due to wound treatment and prostavasin therapy*)
- 2 AEs - vascular, unrelated (*oedema in legs; iron deficiency anemia*)

# Rutherford evolution



	Before procedure (18 Pts.)	M1FU (16 Pts.)	M6FU (7 Pts.)	M12FU (2 Pts.)
RF 0	0	2	4	2
RF 1	0	3	1	0
RF 2	0	1	0	0
RF 3	0	1	0	0
RF 4	4	0	0	0
RF 5	14	9	2	0

# Conclusion

- Excellent tracking and visibility, therefor problem free delivery
- Easy to use, due to thin struts (Tyrocore polymer)
- Without losing radial force
- So far excellent patency and no related (serious) adverse events