First-in-man experience with the MOTIV Bioresorbable scaffold in below-the-knee arteries

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Disclosure

Speaker name: Michel Bosiers

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®

Sirolimus-Eluting Bioresorbable Vascular Scaffold System

Description	Bioresorbable BTK scaffold
Scaffold material	Tyrocore™
Coating material	Tyrocore
Drug	Sirolimus
Drug dose	1.97 µg/mm
Shortening	1% (lengthening)

Maximum expansion diameter	Size (mm)	Max Expansion (mm)
	2.5	3.25
	3.0	3.75
	3.5	4.0

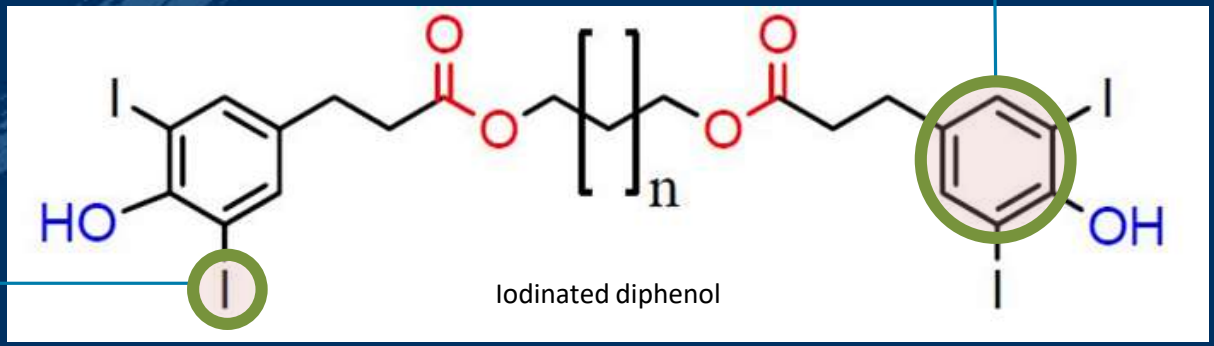
Catheter type	Rapid exchange
Guide catheter compatibility	6F
Working catheter length	139 cm
Scaffold lengths	12, 18, 24 mm
Nominal pressure	7 atm
Rated burst pressure	18 atm
Balloon material	Nylon

REVA

Tyrocore is Strong at its Core

Tyrocore gets its strength from its molecular structure

Phenyl ring structure of Tyrocore polymer is inherently strong



Iodinated diphenol

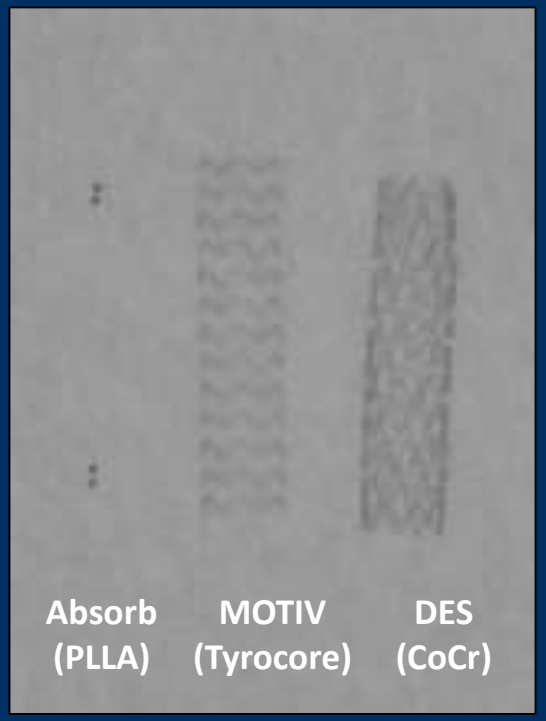
Covalently bound iodine for radiopacity

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[1]	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

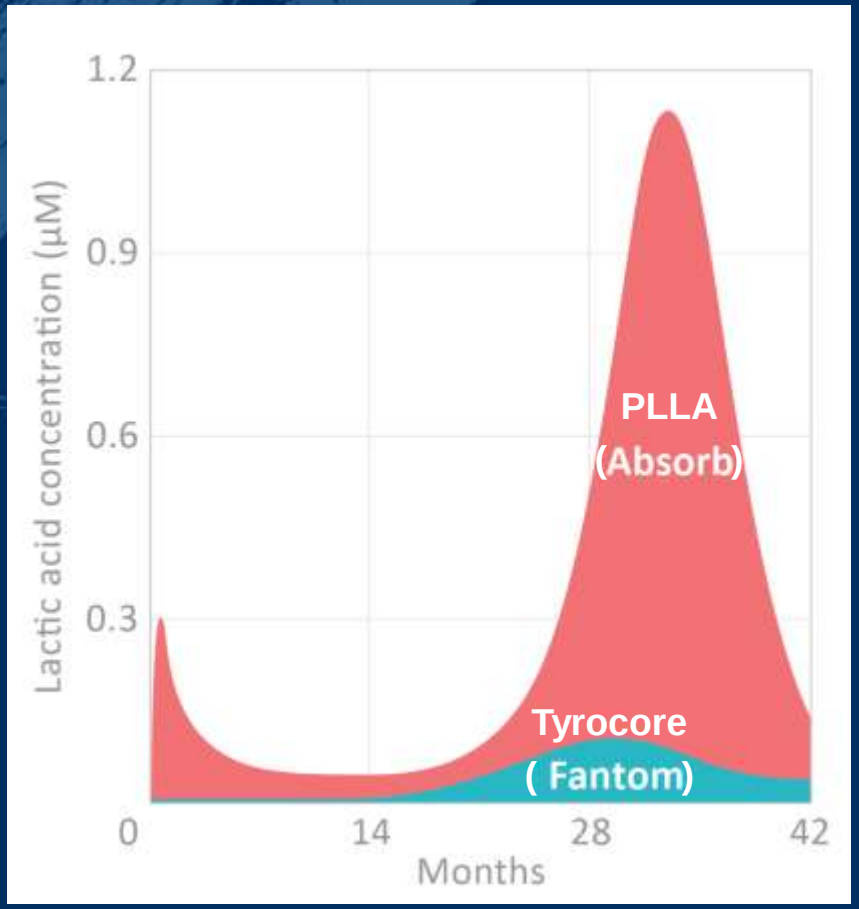


A single MOTIV scaffold contains < 1% of the iodine found in 1 mL of contrast media

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

Arterial Wall Lactic Acid Concentration during Scaffold Degradation

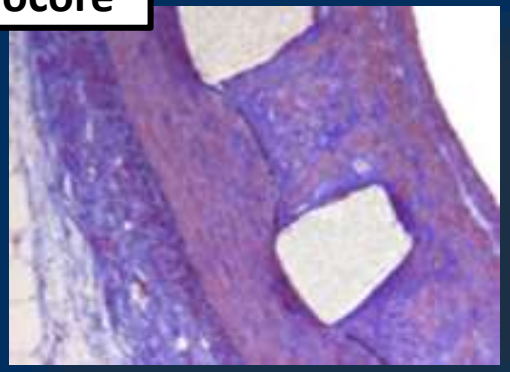


10 Times Lower Lactic Acid Release with Tyrocore

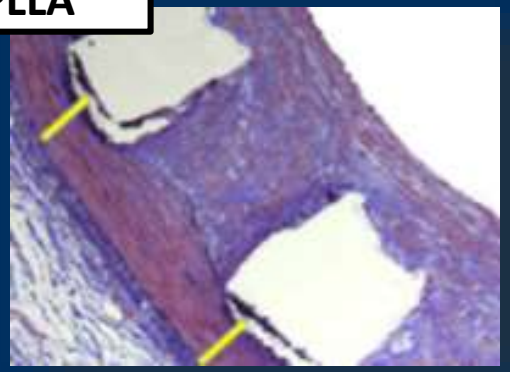
Tyrocore Excellent Vessel Healing

- 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

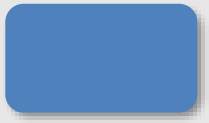


6-month degradation in porcine artery

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

95 µm Strut Thickness is Thinnest Strut of any CE Mark BRS

Strut Profiles of 2.5 mm BRS

Absorb[1]	Magmaris[2]	Fantom	MOTIV
	2.5 mm not available		
157 µm	n/a	125 µm	95 µm

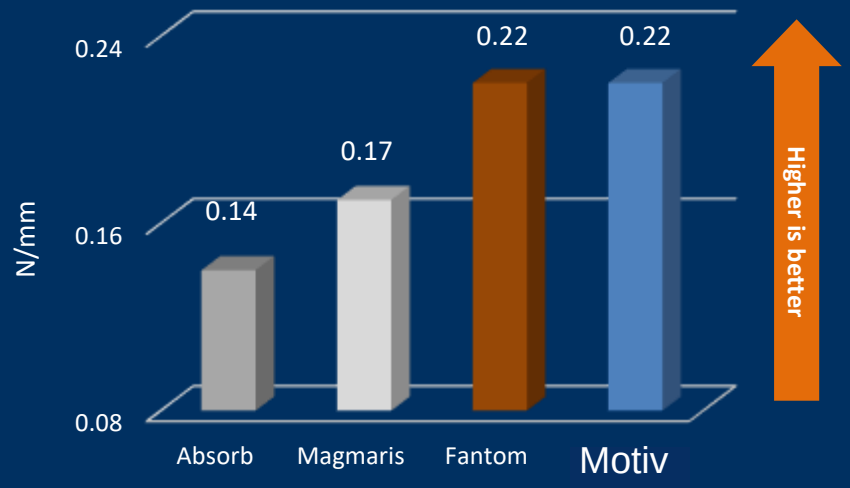
1) Ormiston, J. New BRS Platforms. Presented EBC Rotterdam 2016.; Foin, N. Biomechanical Assessment of Bioresorbable Devices. Presented CRT 2017. 2) Manufacturer reported data on file at REVA Medical.

Thin Struts with Best-in-Class Radial Strength

Strut Thickness (µm)

	Absorb[1]	Magmaris[1]	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[2]



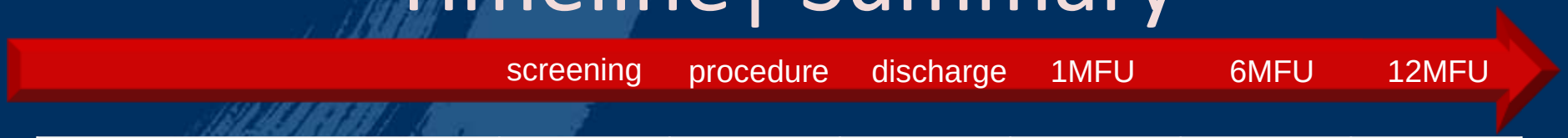
- Thinner struts achieved without compromising radial strength through manufacturing process improvements of the Tyrocore polymer

1) Ormiston, J. New BRS Platforms. Presented EBC Rotterdam 2016.; Foin, N. Biomechanical Assessment of Bioresorbable Devices. Presented CRT 2017. 2) Bench testing on 3.0 mm scaffolds in water at 37°C. Radial strength measured at 15% compression. Tests performed by and data on file at REVA Medical.

Physician-Initiated Trial investigating the ***MOTIV™ Bioresorbable Scaffold*** (Reva Medical) for the Treatment of ***Below-The-Knee artery disease***

- **Prospective, single-arm, single-center study**
- Total of **15 patients**
- Follow-up period of 12 months
- **Rutherford** classification score from **4 to 5**
- **De novo** lesion or **Restenotic** lesion after PTA BTK
- Target vessel diameter ≥2.5mm and ≤3.50mm
- Total target lesion is ≤ 40mm

Timeline| Summary



	screening	procedure	discharge	1MFU	6MFU	12MFU
Patient informed consent	■					
In- / Exclusion Criteria Check	■					
Medical / Clinical History	■					
Laboratory Test	■					
Medication	■	■	■	■	■	■
Physical Examination	■	■	■	■	■	■
Rutherford	■		■	■	■	■
ABI	■	■	■	■	■	■
Color Flow Duplex				■	■	■
Angiography		■				*

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

Primary Endpoint

- ***Efficacy Endpoint***
  Primary patency rate at 12-months, (PSVR ≤2.5, and/or angiography) without target lesion revascularization (TLR) within 12 months.

- ***Safety Endpoint***
  Proportion of subjects who experience **serious device-related adverse events within 30 days post-procedure**.

Secondary endpoints

- **Technical success**

  cross & dilate the lesion to achieve <30% residual stenosis
- Primary Patency Rate at 1 & 6-month follow-up
- **Clinically-driven TLR** , defined as a repeat intervention to maintain or re-establish patency within the region of the treated arterial vessel plus 5mm proximal and distal to the device/PTA edge.
- **Limb salvage rate ,** defined as absence of major amputation (above the ankle)
- **Clinical success** at follow-up (improvement of Rutherford classification)
- **Serious Adverse Events** as defined per ISO 14155:2011.

Remarks

- **Contralateral treatment** is allowed

- Inflow:
  All **inflow-limiting lesions have to be treated prior** to treating the study lesion

- *Antiaggregants:*
  - **Clopidogrel : 75mg QD for at least 3-4 months**
  - **Aspirin : 75-300mg QD lifelong**

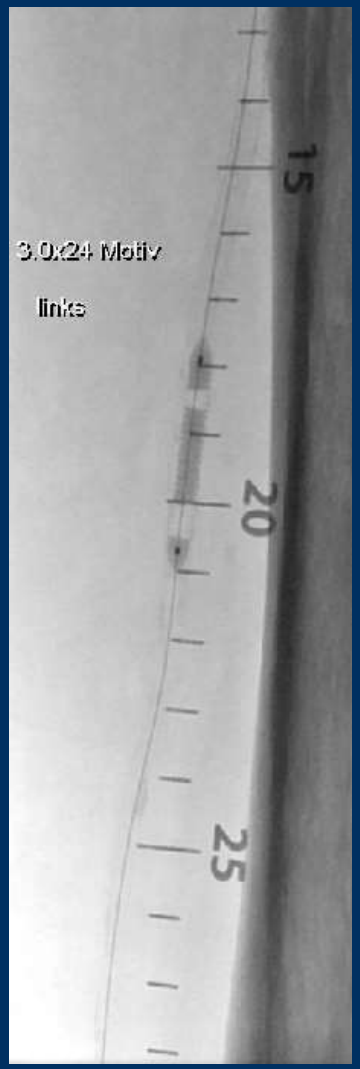
Example 1

Example 1

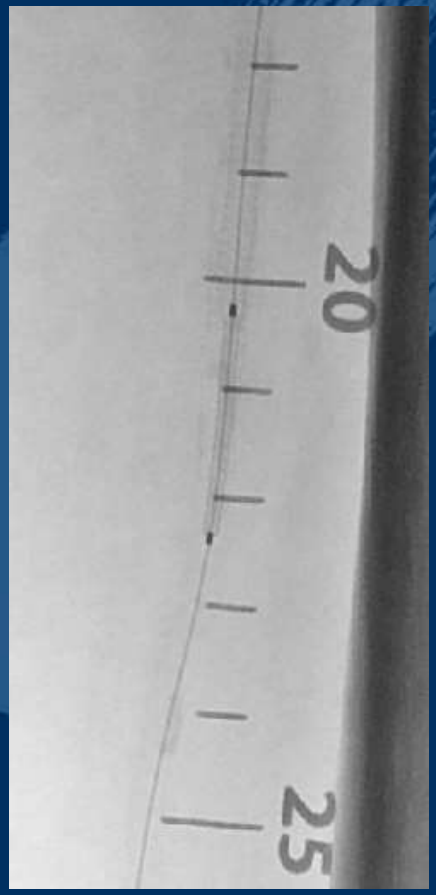
Example 2


15
20
3x120 PTA li

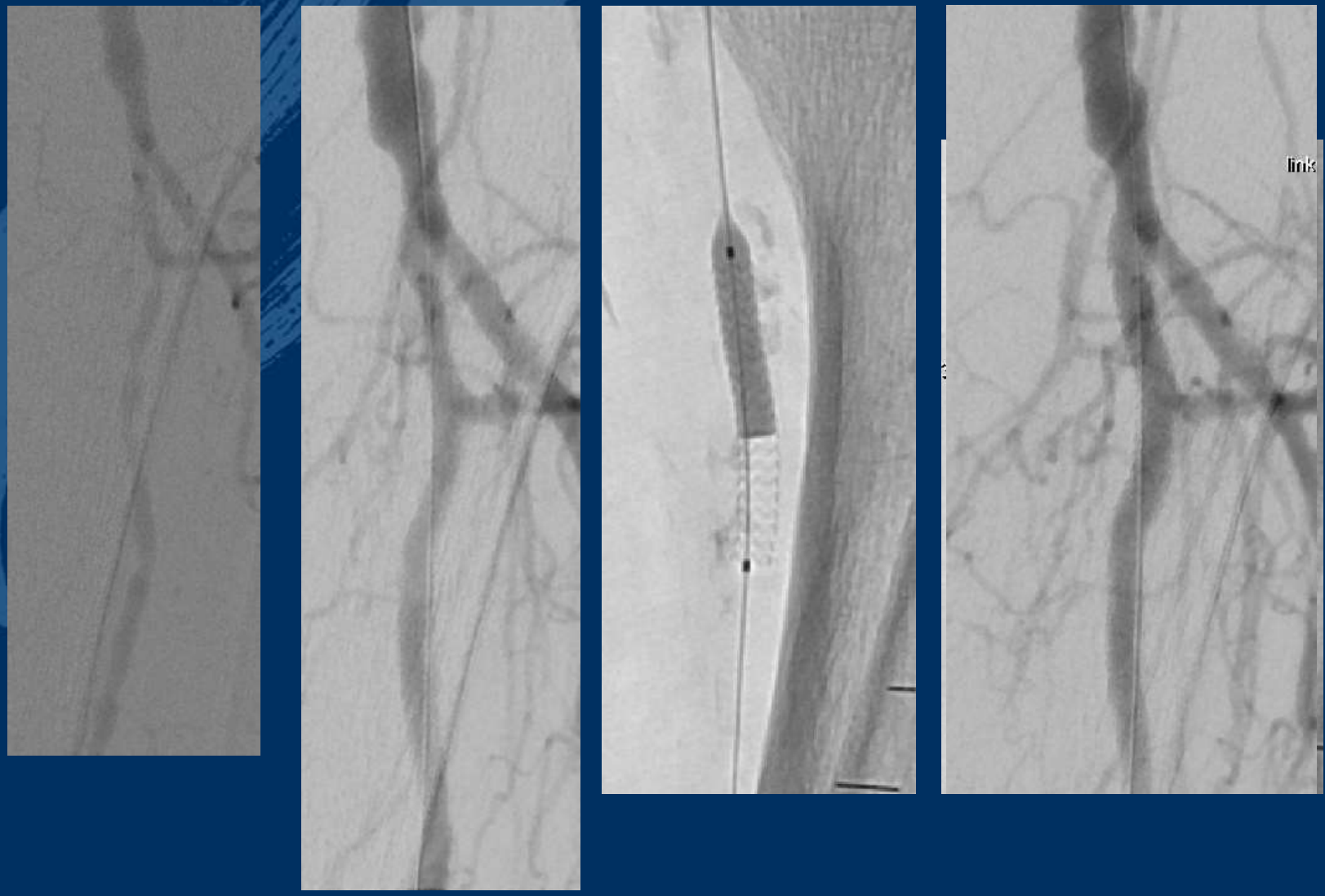

links
Ebene
15
20
25


3.0x24 Motiv
links
15
20
25

Example 2



Example 3



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 (serious) adverse events

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