MOTIV bioresorbable BTK scaffold pilot study

Preliminary results through 6 months

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Disclosure

Speaker name:

.....Thomas Rand.....

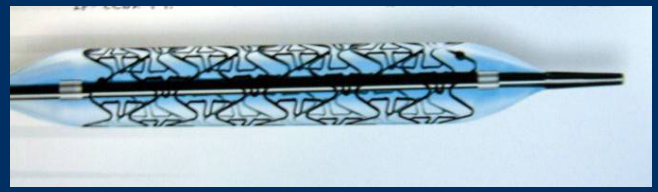
I have the following potential conflicts of interest to report:

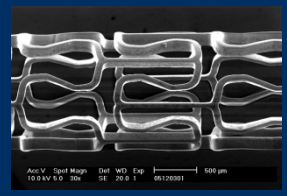
- ☐ Consulting
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s):

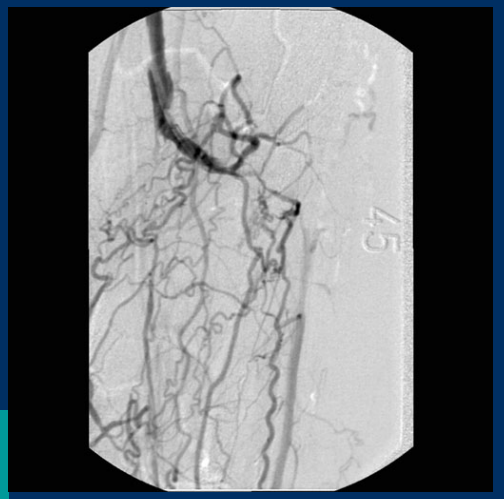
- ☒ I do not have any potential conflict of interest

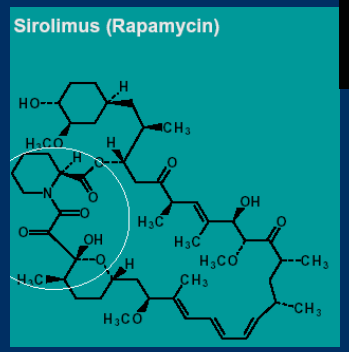
BTK Interventions in Critical Ischemia

- Bare metal stents (Feiring et al, ect.ect)
- Passive coating (InPeria I and II; Rand et al,ect..)
- Bioabsorbable Stents (AMS , Bosiers et al,ect-)
- Self expandible Stents (Abbott Xpert, Peregrin,ect-)
- Active coating (DES, Scheinert, Siablis et al,ect..)









MOTIV™ Bioresorbable Scaffold

Study Investigators

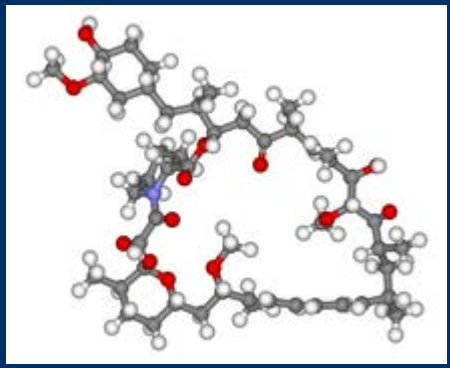
- **St. Franziskus Hospital**
  - **Dr. Bosiers**
- **Juedisches Krankenhaus Berlin**
  - **Dr. med. Schröder**
- **Katholisches Klinikum Mainz**
  - **Prof. Dr. med. Balzer**
- **Bad Oeynhausen**
  - **Dr. med. Willecke**
- **Klinikum Hochsauerland (Arnsberg)**
  - **Dr. Lichtenberg**
- **Klinik Floridsdorf**
  - **Prof. Dr. Rand**
- **Universitätsklinikum Münster**
  - **Dr. Malyar**
- **Universität Leipzig**
  - **Prof. Dr. med. Scheinert**
- **Klinikum Karlsruhe**
  - **Prof. Dr. med. Reimer**

MOTIV™ Bioresorbable Scaffold

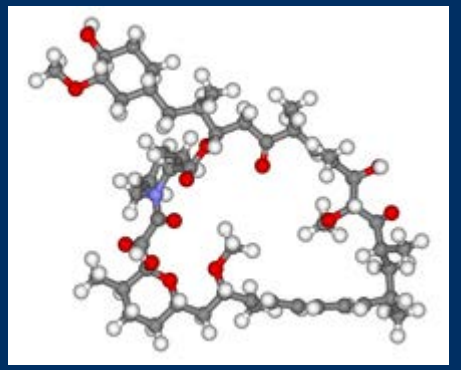
Sirolimus-Eluting + Bioresorbable Vascular Scaffold

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

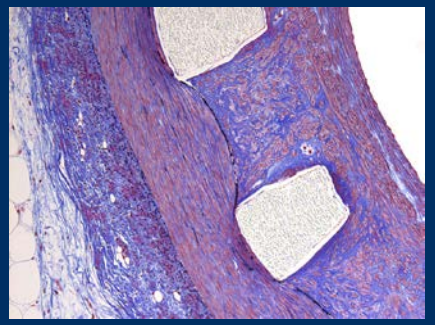
Maximum expansion diameter	Size (mm)	Max Expansion (mm)
	2.5	3.25
	3.0	3.75
	3.5	4.0



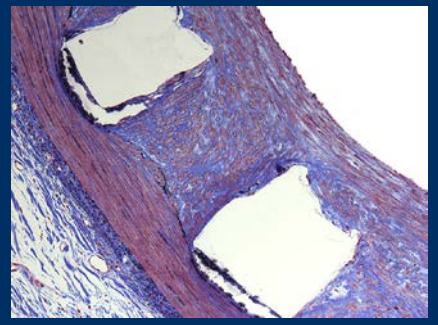
Absorbable Scaffold + Sirolimus



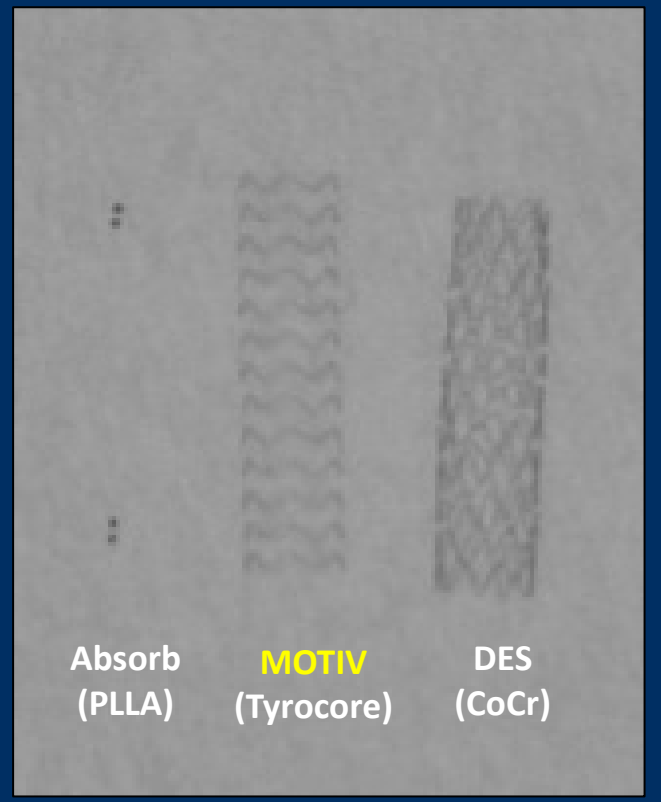
- Tyrocore: derived from the naturally occurring tyrosine amino acid
- Low inflammation, irritation, during degradation
- No formation of calcification



Tyrocore



PLLA



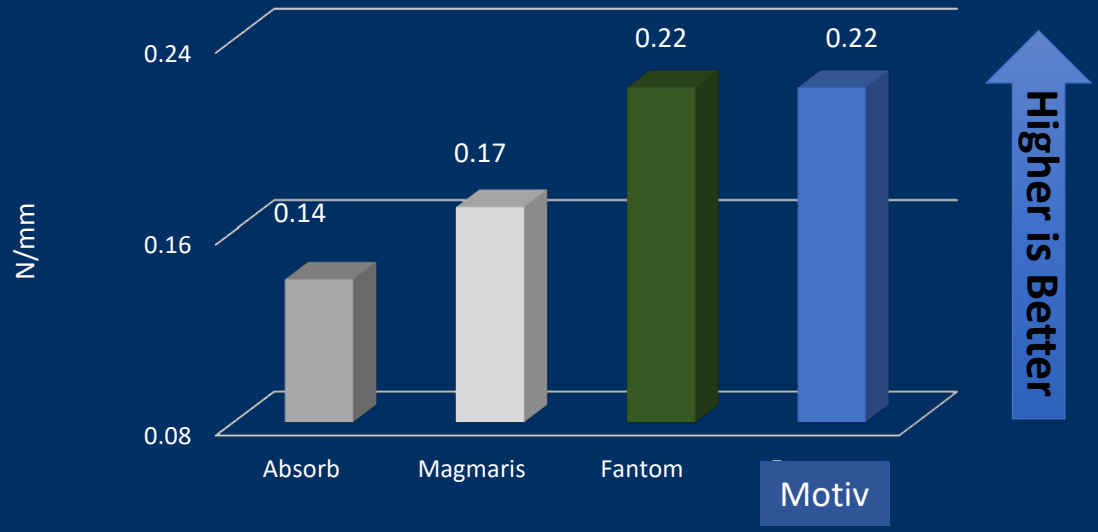
Thin Struts with Best-in-Class Radial Strength

MOTIV®
Sirolimus-Eluting Bioresorbable Vascular Scaffold System

Strut Thickness (µm)[1]

	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 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.

MOTIV™ Bioresorbable Scaffold

Study Design

- **Prospective, single-arm, multi-center study**
- Total of **58 patients; 60 study limbs, 76 MOTIV scaffolds**
- Follow-up period of 1, 6, 12, 24 and 36 months
- **Rutherford** classification score **4 to 5**
- **Primary De novo** lesion or **Restenotic** lesion after PTA in below the knee arteries or Residual **flow-limiting dissection** or restenosis of a longer lesion.
- Target vessel diameter ≥2.5mm and ≤3.50mm
- Total target lesion ≤ 100mm
- +/- contralateral treatment

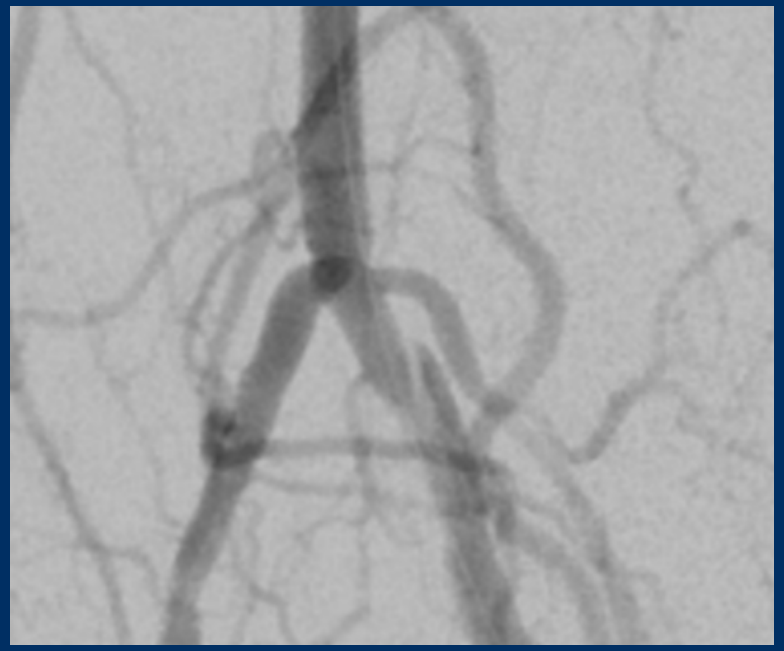
MOTIV™ Bioresorbable Scaffold
Lesion Characteristics

	Average or %, n/N (min – max)
Lesion length	29.46 (5.00 – 100.00) mm
Ref Vessel Diameter	3.00 (2.50 – 3.50) mm
Total Scaffolds Implanted	76
More than 1 MOTIV stent implanted	21.67% (13/60)
Pre-dilatation *(obligatory)*	100% (60/60)
Post-dilatation *(obligatory)*	100% (60/60)

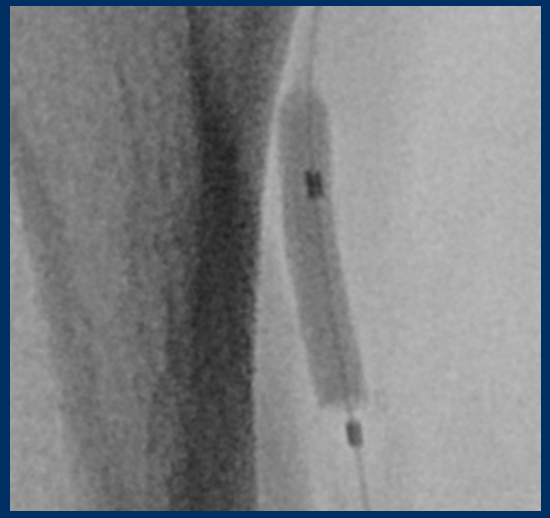
	Average or %, n/N (min – max)
Target lesion definition	
De novo lesion or restenotic lesion after PTA	61.67% (37/60)
Residual flow-limiting dissection or restenosis after PTA of a longer lesion	38.33% (23/60)
Target lesion pre-conditions	
Ulceration	11.67% (7/60)
Calcified lesion	46.67% (28/60)
Thrombus	30.00% (18/60)
Dissection	21.67% (13/60)
None of the above	13.33% (8/60)

MOTIV™ Bioresorbable Scaffold
Procedural Characteristics

	Average or %, n/N (min – max)
Procedure time	76.41 (29-180) minutes
Fluoroscopy time	17.16 (4.0 – 56.0) minutes
Amount of contrast	86.73 (20 – 350) mL
Cross-over performed	55% : 45%
Artery treated:	25% : 75%
Anterior Tibial Artery (ATA)	36.67% (22/60)
Posterior Tibial Artery (PTA)	11.67% (7/60)
Fibular artery (FbA)	21.67% (13/60)
Truncus Tibiofibularis (TT)	20.00% (12/60)
ATA + TT	1.67% (1/60)
PTA + TT	1.67% (1/60)
FbA + TT	6.67% (4/60)
Inflow Lesion Treated (%)	26.67% (16/60)
Additional Lesions Treated (%)	43.33% (26/60)

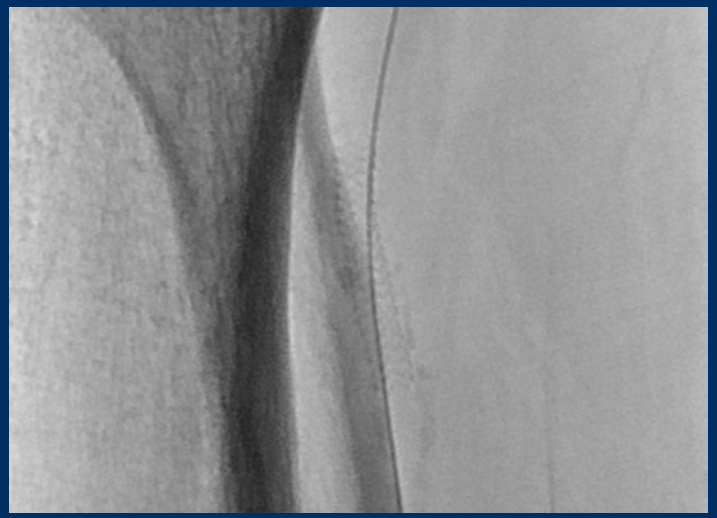


Dissection + High Grade Stenosis

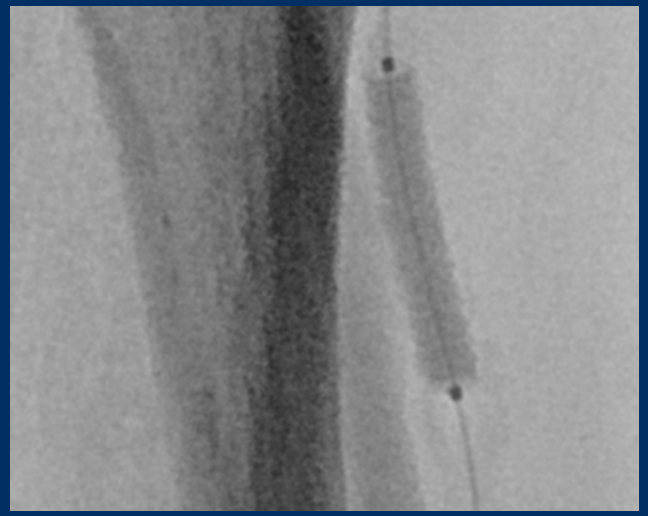


Predilatation 3x20mm

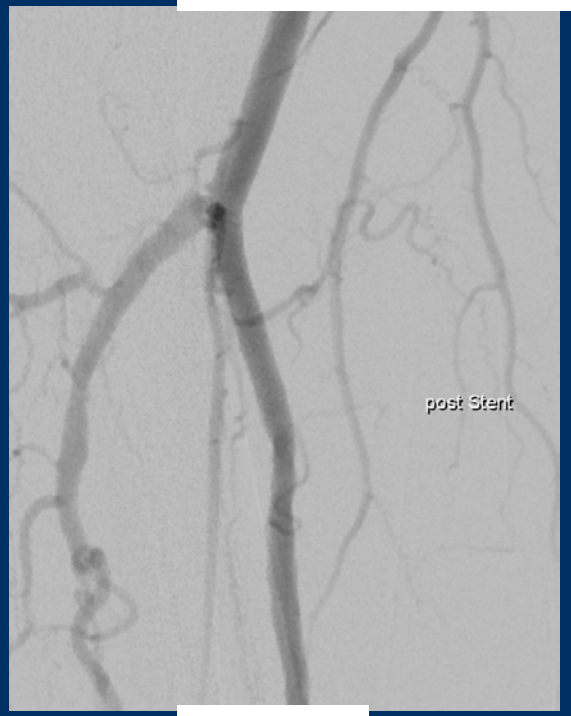
STENT: MOTIV 3x18



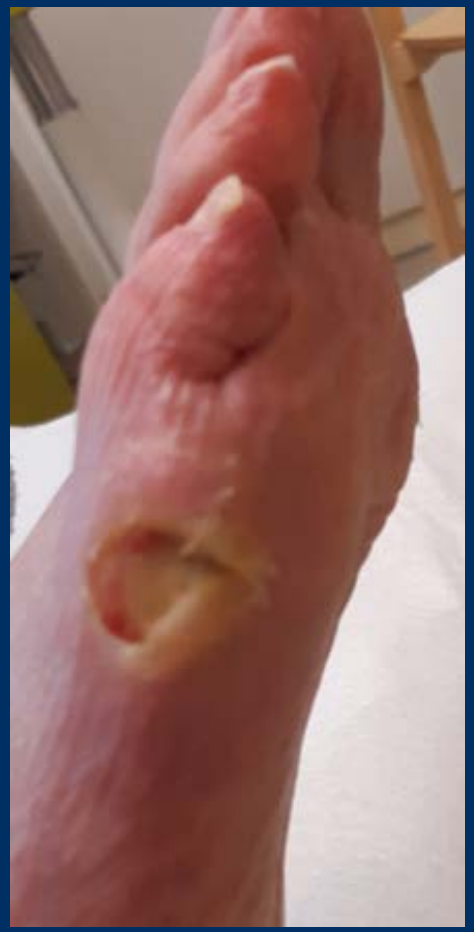
STENT: MOTIV 3x18

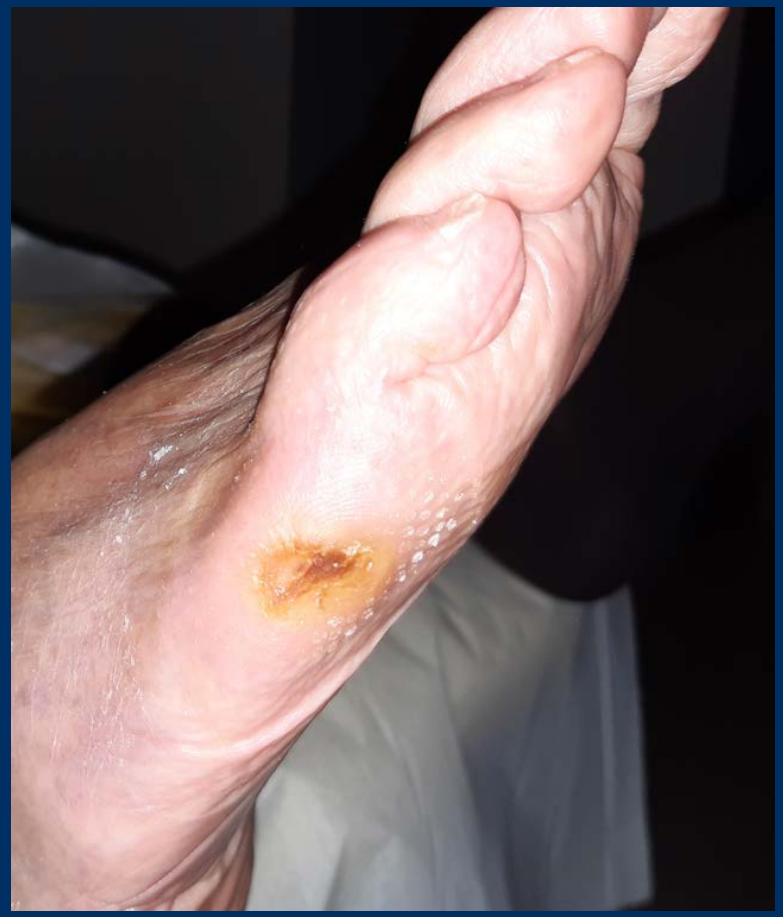


Post Dilatation 3x20mm



Result





Rutherford	Number of patients	6 Months FU
RF4	15	5
RF5	45	15

MOTIV™ Bioresorbable Scaffold
Preliminary Study Outcomes

- 99% Technical Success in all patients (71/72 Scaffolds)
- Primary Patency
  - **6-month final result: 90% Patency** *(N=47 patients/48 limbs)*[1]
- Clinically Driven TLR rate: 3% *(two events across all study patients)*
- Limb Salvage Rate: 97% *(across all study patients)*
  - *One patient had a lower leg amputation at ~1-month due to wound healing disorder; reported as unrelated to the MOTIV scaffold*
  - *One patient had an amputation of study limb at ~4 months due to a septic wound infection; reported as unrelated to the MOTIV scaffold*
- *8 deaths (14% of patients)*
  - *All deaths outside of 30d and **not device or procedure related***
  - *Heart & Respirtory Failure = 1, Septic Shock/Renal Failure = 4, Multi-Organ Failure = 3*

1. PSVR data for 40 patients (36/40 patent); 7 patients completed 6-month visit; no device related adverse events; PSVR not recorded
2. 29 patients have completed the 12-month follow up as of 20APR2022

MOTIV™ Bioresorbable Scaffold
Conclusion

- Excellent tracking and visibility, problem free delivery
- Easy to use, due to thin struts (Tyrocore polymer)
- 90% Vessel Patency - Demonstrated in patients through 6 months
- Demonstrated improvement in Rutherford Classification and wound healing
- Patency remained stable in patients between 6 & 12 Months *(In 29 patients that have reached 12M)*