DEEPER REVEAL: the Bare Temporary Spur Stent System for the Treatment of Critical Limb Ischemia

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SUMMARY

The DEEPER REVEAL clinical trial evaluates the safety and efficacy of the Bare Temporary Spur Stent System as a primary treatment for infrapopliteal lesions in patients with critical limb ischemia (CLI).

The Bare Temporary Spur Stent System is for investigational use only.

PREVIOUS/ONGOING TRIALS

	DEEPER (completed 2019)	DEEPER OUS (Enrollment complete April 2022)	DEEPER LIMUS (ongoing, initiated 2020)
Status	Completed [N=23 (ITT)] [N=17 (PP)]	N = 107 Follow up to 5 years	Enrollment ongoing Current N: 26
Study Design	Prospective, single center, single arm feasibility study: (Spur*+ Lutonix DCB).	Prospective, multicenter (Europe/New Zealand): Spur* + PTx-coated balloon	Prospective, single-center (Graz, Austria): Spur* + LIMUS-coated DCB
Endpoints	**Primary Efficacy:** Primary patency at 6 months (DUS): 88.9% (PP)	**Primary Efficacy:** Primary patency at 6 months (DUS) Interim Analysis: **37/46 (80.4%)**	**Primary Safety Endpoint:** 6-month composite of All-Cause Mortality, Major Amputation and CD-TLR **13.6% (3/22)**
	Primary Safety: Freedom from device and procedure-related death through 30 days: **100% (PP)** Freedom from target limb major amputation and CD-TLR through 6 months: **94.1% (PP)**	**Primary Safety:** Freedom from 30-day perioperative mortality Interim Analysis: **46/46 (100%)** **Vessel Recoil Sub-study:** Vessel recoil post Spur treatment (N=38): **Recoil reduced by more than 50%**	**Important Secondary Results** **Secondary Endpoints:** 1.LLL at 6 months by QVA 2.Primary patency at 6 months by QVA 3.Freedom from MALE and POD at 30 days 4.Freedom from MALE at 6 and 12 months

The acute procedural results of the DEEPER OUS trial led to the breakthrough application for the Bare Temporary Spur Stent System:

- Reduction in vessel recoil compared to previously published data.*
- Average residual stenosis post Spur <30% by angiography.**
- Dissections incurred during predilation decreased post-Spur.**

*Baumann, et al, 2014
**Core lab adjudicated (Syntropic, Columbus, OH)

TRIAL OVERVIEW

Trial Name	A Prospective Single-Arm Multicenter StuDy to Evaluate the Performance of the BarE TEmporary SPur StEnt System foR the tREatment of Vascular lesions located in the infrapoplitEal Arteries beLow the knee (DEEPER REVEAL)
Trial Design	Prospective, Non-Randomized, Multi-Center Clinical Trial evaluated against performance goal
Purpose	Compare safety and efficacy of Bare Temporary Spur Stent System in patients with CLI to a pre-established performance goal based on literature review.
Number of Sites	Up to 50
Number of Subjects	130
Principal Investigators	Dr. Jihad Mustapha, Dr. Jay Mathews, Dr. Mahmood Razavi

MATERIALS AND METHODS

Enrollment in the trial began in October, 2022. Patient follow up is at 1, 3, 6, and 12 months post-procedure with in person evaluations including ankle-brachial and toe-brachial indices (ABI and TBI), Duplex ultrasound (DUS)*, wound evaluation, adverse event monitoring, and Rutherford class score. Quality of life questionnaires are performed at baseline, 6, and 12 month visits. The primary endpoints are:

Primary Efficacy Endpoint
Technical success, defined as <30% residual stenosis within the treated lesion area by visual estimate on completion angiography.

Co-Primary Safety Endpoint
Freedom from the occurrence of major adverse limb events (MALE) [evaluated at 30 days post procedure] and peri-operative death (POD) [defined as all-cause mortality within 30 days post procedure].

A **secondary powered efficacy endpoint** will evaluate limb salvage and primary patency, defined as:

- Clinically-driven target lesion revascularization
- Above the ankle amputation in the index limb
- 100% total occlusion of target lesion

*Angiograms and ultrasounds are adjudicated by independent core labs (Syntropic, Columbus, OH, and Vascore, Boston, MA, respectively).

MATERIALS AND METHODS

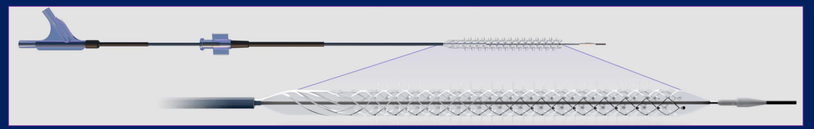
Secondary endpoints include clinical outcomes of change in Rutherford class and change in wound size evaluated by standardized software and core lab adjudicated*, safety outcomes including limb salvage and all cause mortality, and acute success endpoints including device and procedure success. Key eligibility criteria are listed below:

Key Inclusion Criteria	Key Exclusion Criteria
• Rutherford category 4 or 5 • Denovo or restenotic infrapopliteal lesion (popliteal excluded) • Target lesion •TV between 2.0 to 4.5 mm in dm •Reconstitutes at or above the ankle •Lesion length **up to 210 mm**	• Osteomyelitis proximal to phalanges (permitted in digits of target foot) • Planned target limb major amputation • Target lesion •Stents within target vessel/lesion •Angiographic evidence of thrombus in the target limb

THE BARE TEMPORARY SPUR STENT SYSTEM (SPUR)

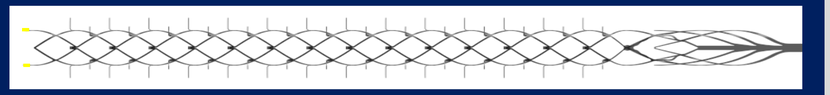
The Bare Temporary Spur Stent System was granted breakthrough designation by the FDA for the treatment of CLI in 2020.
The device has a novel, yet simple design, which delivers a temporary self-expanding stent to the peripheral vasculature via a sheathed delivery system. The intent of the device is to:

- Minimize recoil
- Minimize dissection through controlled dilatation
- Increase acute lumen gain
- Leave no implant behind, preserving future treatment options



Bare Temporary Spur Stent System

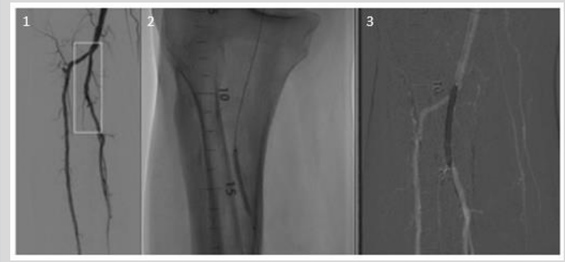
The stent component of the device is a self-expanding nitinol stent, which is re-capturable and able to be used up to 4 times sequentially to treat lesions up to 210 mm in length. Gold radiopaque markers on the stent and balloon components aid in visualization. Two sizes are available: 3.0x65 mm, and 4.0x60 mm.



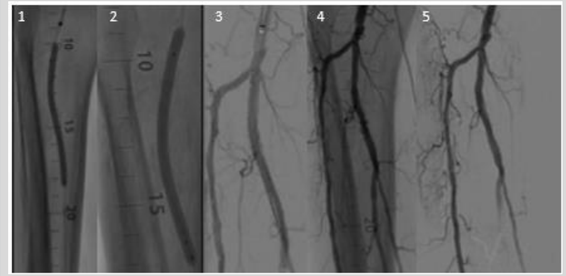
Stent Component

PATIENT CASE

87 y.o male, PMH of Type 2 DM, CAD, CHF, HLD, target lesion 70 mm proximal peroneal artery, 4.0 mm dm.



1. Target lesion; 2. Predilation inflation #1; 3. Predilation inflation #2



1. Spur deployment #1; 2. Spur resheathed and repositioned for deployment #2; 3. Flow through deployed Spur stent; 4. Post Spur image; 5. Final imaging

CONCLUSIONS

The Bare Temporary Spur Stent System is a novel device with a familiar and simple design to address challenges of infrapopliteal arterial disease treatment. The DEEPER REVEAL trial is the first US-based trial examining the safety and efficacy of this device for the treatment of patients with CLI. The trial is actively recruiting patients at up to 50 sites. The trial is expected to complete enrollment by Q4 2023, with analysis of the primary endpoints expected by Q1, 2024.

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