



PERIPHERAL RETRIEVABLE SCAFFOLD SYSTEM



DURABLE SAFETY AND EFFICACY OUTCOMES LEAVING NOTHING BEHIND^{1,2}

Revolutionary Below-the-Knee (BTK) Treatment
for Chronic Limb-Threatening Ischemia (CLTI) in
Conjunction with Drug-Coated Balloon (DCB)

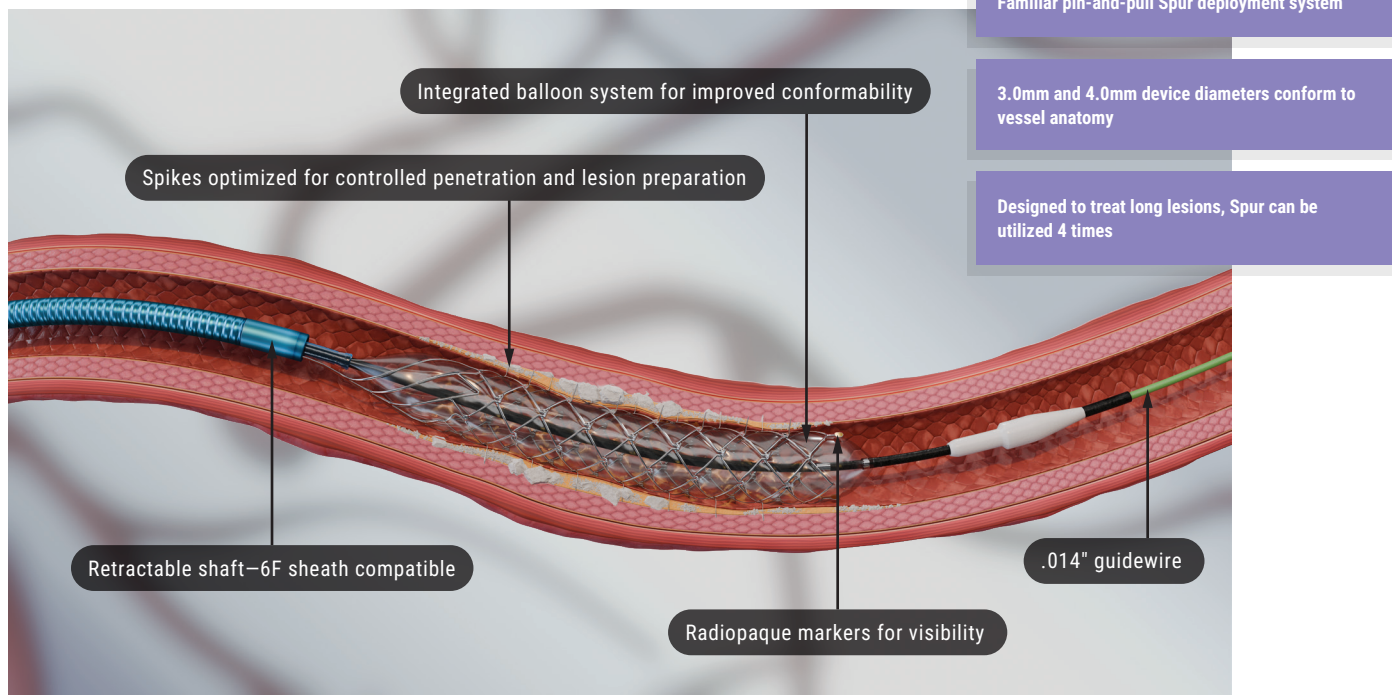


REFLOW MEDICAL
THE PULSE OF MEDICAL INGENUITY

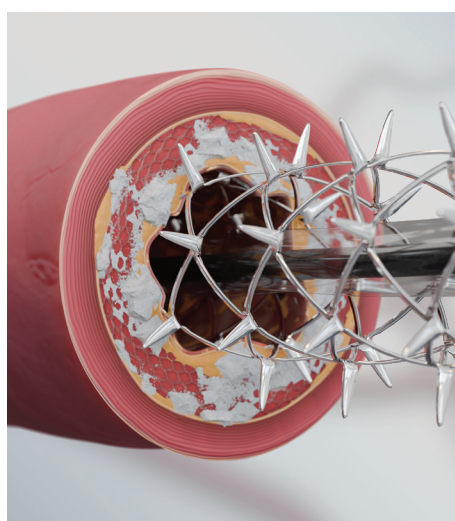
Spur Retrievable Scaffold Therapy

A self-expanding scaffold with integrated dilation balloon catheter designed for controlled penetration and lesion preparation through a series of radially expandable spikes. Spur creates channels that modify the lesion morphology, decreasing the recoil effect and changing vessel compliance. Channels optimize drug uptake in conjunction with DCB.

Ease of Use



RST Mechanism of Action



- Track Spur system to lesion site and deploy using pin-and-pull method.
- Inflate integrated balloon in a controlled fashion.

Radial spikes penetrate the vessel wall and create channels designed to:

- modify lesion morphology to change vessel compliance and reduce vessel recoil, and
- enhance drug absorption.

- Scaffold provides temporary supportive structure.
- Deflate the balloon and recapture the Spur system.
- Treat lesion with any commercially available DCB.
- Durable safety and efficacy outcomes leaving nothing behind.

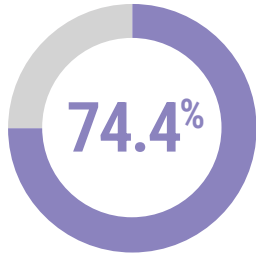
Clinically Proven

MAXIMIZING BTK TREATMENT OUTCOMES WITHOUT COMPROMISING ON SAFETY

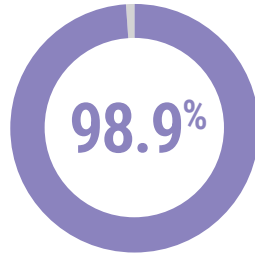
DEEPER OUS

Prospective, multicenter, single-arm, performance goal comparator

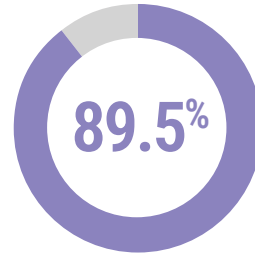
12-MONTH RESULTS¹



Patency of lesions (DUS)



Freedom from MALE



Freedom from CD-TLR

RUTHERFORD SCORE IMPROVEMENT

58.4% improvement in mean Rutherford score from the baseline

WOUND SIZE REDUCTION

63.1% ↓

STUDY DEVICES

Spur + paclitaxel-coated DCB*

STUDY SIZE

† 107 patients enrolled

🏢 10 centers (EU + NZ)

BASELINE LESION CHARACTERISTICS

21% total occlusions

21% moderately/severely calcified lesions

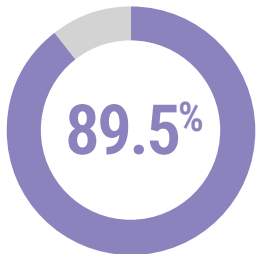
92.7mm (60-240mm)

mean Spur-treated length (range)

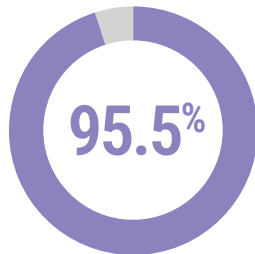
DEEPER LIMUS

Prospective, single-center, pilot, single arm

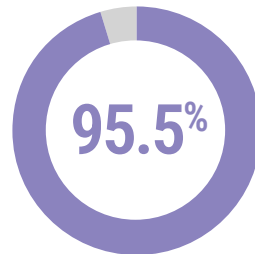
12-MONTH RESULTS²



Patency of lesions (DUS)



Freedom from MALE



Freedom from CD-TLR

RUTHERFORD SCORE IMPROVEMENT

68.2% subjects improved to Rutherford classification 0

WOUND SIZE REDUCTION

54.0% ↓

STUDY DEVICES

Spur + sirolimus-coated DCB**

STUDY SIZE

† 26 patients enrolled

🏢 1 center (Austria)

BASELINE LESION CHARACTERISTICS

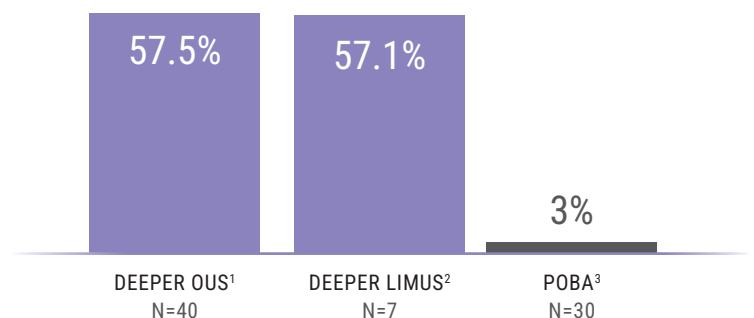
37% total occlusions

97mm (60-210mm)

mean Spur-treated length (range)

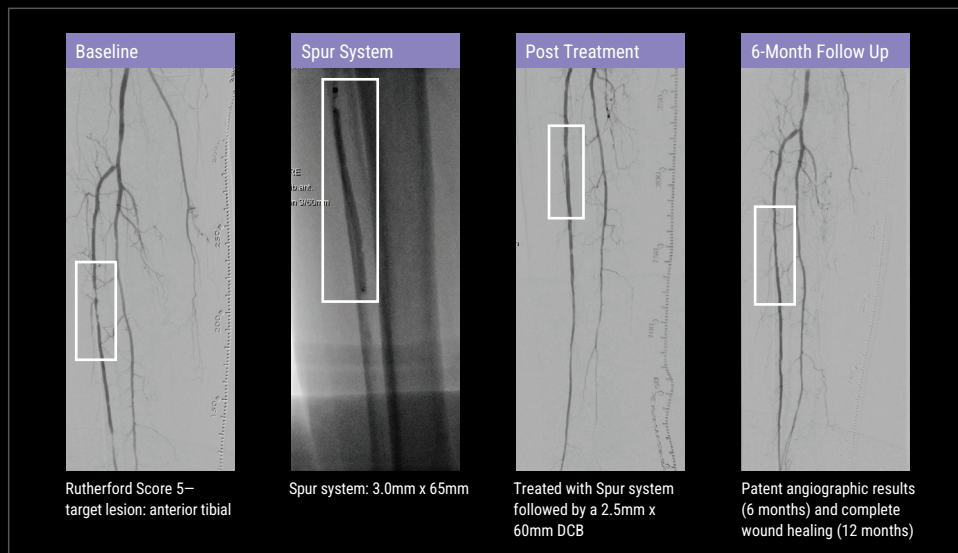
VESSEL RECOIL

Defined as lumen compromise $\geq 10\%$ at 15 minutes post Spur treatment

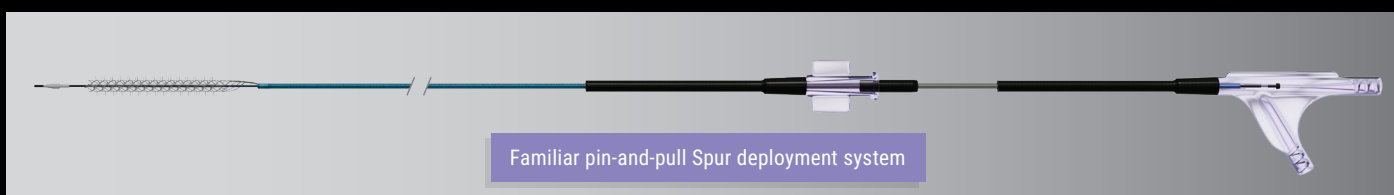


FREEDOM FROM OCCURRENCE OF VESSEL RECOIL

SPUR CASE EXPERIENCE



Images courtesy of Prof. Marianne Brodmann, MD



Reference Vessel Diameter (mm)

2.5–3.5

3.5–4.5

Model	BSPUR365135CE	BSPUR460135CE
Device Diameter (mm)	3.0	4.0
Device Length (mm)	65	60
Catheter Effective Length (cm)	135	135
Catheter OD (in/F/mm)	.074/5.6/1.88	.074/5.6/1.88
Guidewire Compatibility (in)	.014	.014
Sheath Compatibility (F/mm)	6/2.0	6/2.0
Balloon Diameter @ NP 6atm (mm)	3.00	4.02
Balloon Diameter @ RBP 12atm (mm)	3.20	4.23
Hydrophilic Coating—Distal (cm)	30	30

References: 1. Data on file for DEEPER OUS clinical trial (NCT03807531); 2. Data on file for DEEPER LIMUS clinical trial (NCT04162418); 3. Baumann et al. (2014). Early recoil after balloon angioplasty of tibial artery obstructions in patients with critical limb ischemia. *Journal of Endovascular Therapy*, 2014(21): 44–51; * any commercially available DCB; ** Concept Medical™ MagicTouch™ PTA. **Intended Use:** The Spur is intended to treat de novo or restenotic lesions in the infrapopliteal arteries to prepare the vessel for treatment with a commercially available drug coated balloon to enhance drug absorption. **Warnings:** Do not use the device past the expiration date on the label. Use of expired products may result in patient injury; Inspect the device packaging prior to use. Do not use the device if the device packaging has been damaged or if sterility has been compromised. Damaged product could result in patient injury; Ensure the Spur is used with appropriately sized ancillary devices as listed in the section below. Failure to do so could result in inadequate device performance or patient injury; Remove excess slack from the catheter (outside of the patient) to ensure the Spur is recaptured appropriately; If an inability to inflate or maintain balloon pressure occurs, remove the device and use a new one; Do not use excessive force or torque (more than 1 full turn) on the catheter as this could result in damage to the device and result in patient injury. **Precautions:** This device should only be used by physicians experienced in interventional vascular procedures; The system is intended for single (one) use only. DO NOT re-sterilize and/or reuse; Inflate the balloon according to the balloon compliance chart. Balloon pressure should not exceed the rated burst pressure (RBP); Use only the recommended contrast medium to inflate the balloon to ensure adequate delivery; Perform all device manipulations under adequate fluoroscopy; Do not advance or retract the catheter unless the balloon is fully deflated under vacuum. If resistance is met, determine the cause of the resistance before proceeding; Do not attempt to straighten a catheter if the shaft has become bent or kinked. Instead prepare a new catheter; During the procedure appropriate anticoagulant therapy must be provided to the patient as needed. Antiplatelet therapy should be prescribed post procedure in accordance with the treating physicians routine practice for endovascular procedures; Precautions should be taken when handling the device after exposure to patient, e.g. contact with blood. Used products are considered biohazardous material and should be disposed of properly as per hospital procedure. **Adverse Events:** The following events are potential adverse effects associated with standard catheter-based peripheral interventions: Anemia; Edema; Hematoma; Peripheral arterial reocclusion; Peripheral artery dissection; Peripheral artery recoil; Pseudoaneurysm; Radioccontrast nephropathy; Vascular access site pseudoaneurysm; Vasospasm; Vessel perforation; Occlusion; Sepsis/Infection; Additional intervention; Short term hemodynamic deterioration; Stroke; Death; Heart attack; Vessel rupture; Hemorrhage; Pain or tenderness; Embolization; Arrhythmia; Shock.

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