



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)



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.





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



WOUND SIZE REDUCTION

54.0%

97mm (60-210mm) mean Spur-treated length (range)

VESSEL RECOIL

Defined as lumen compromise ≥10% at 15 minutes post Spur treatment

RUTHERFORD SCORE IMPROVEMENT

68.2[%] subjects improved to Rutherford classification 0



FREEDOM FROM OCCURRENCE OF VESSEL RECOIL

SPUR CASE EXPERIENCE



Images courtesy of Prof. Marianne Brodmann, MD



REFLOW Spur™

3.5 - 4.52.5 - 3.5Reference Vessel Diameter (mm) BSPUR460135CE Model BSPUR365135CE Device Diameter (mm) 3.0 4.0 65 Device Length (mm) 60 Catheter Effective Length (cm) 135 135 .074/5.6/1.88 Catheter OD (in/F/mm) .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 pats 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 as listed in the section below. Failure to do so could result in inadequate device performance or 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; 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; (RBP); Use only the recommended contrast medium to inflate the balloon to ensure adequate deliver; 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 beccome bent or kinked. Instead prepare a new catheter; During the procedure appropriate anticoagulant therapy must be provided to the patient as nee

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