

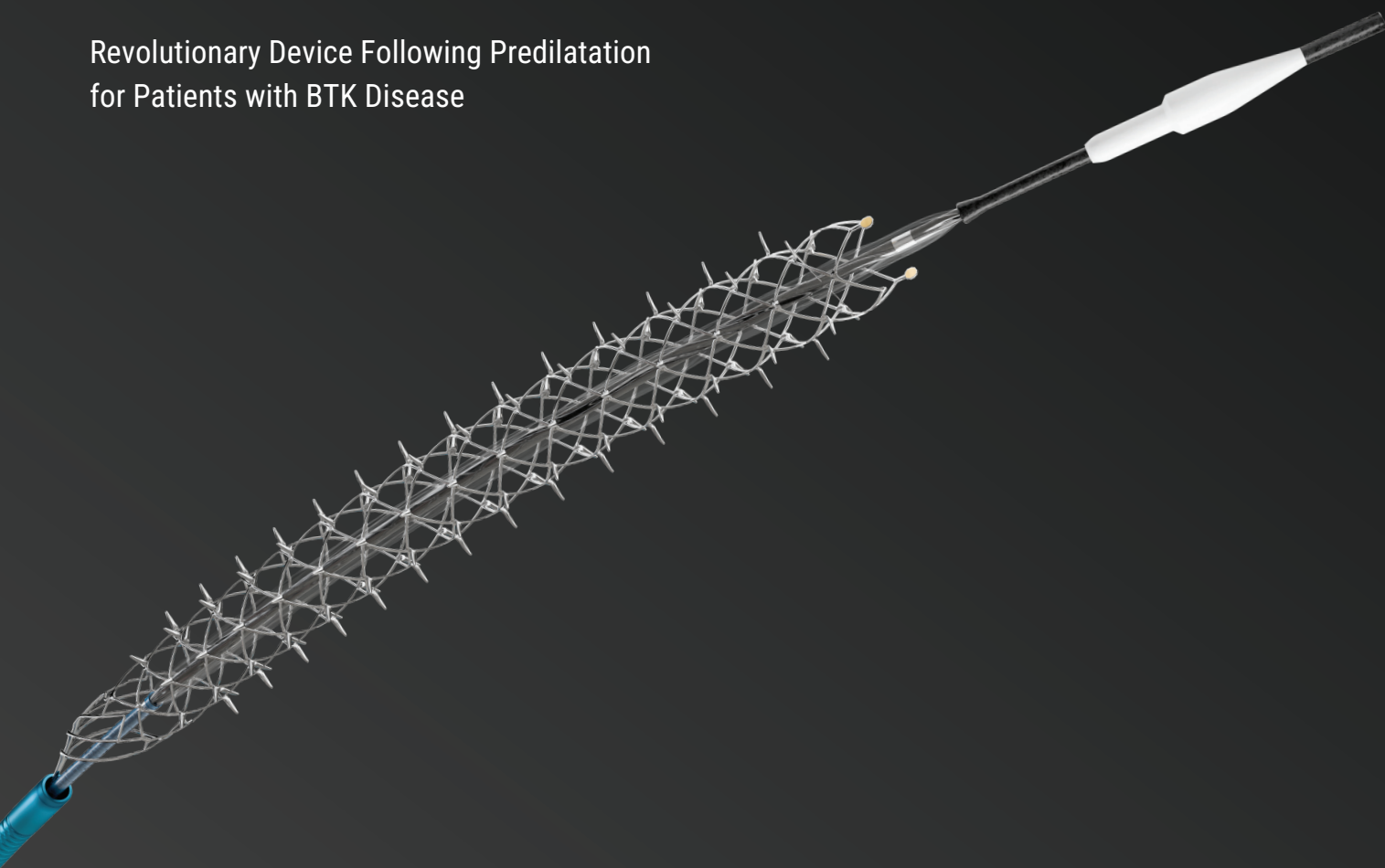


PERIPHERAL RETRIEVABLE STENT SYSTEM



SAFE AND EFFECTIVE OUTCOMES LEAVING NOTHING BEHIND¹

Revolutionary Device Following Predilatation
for Patients with BTK Disease

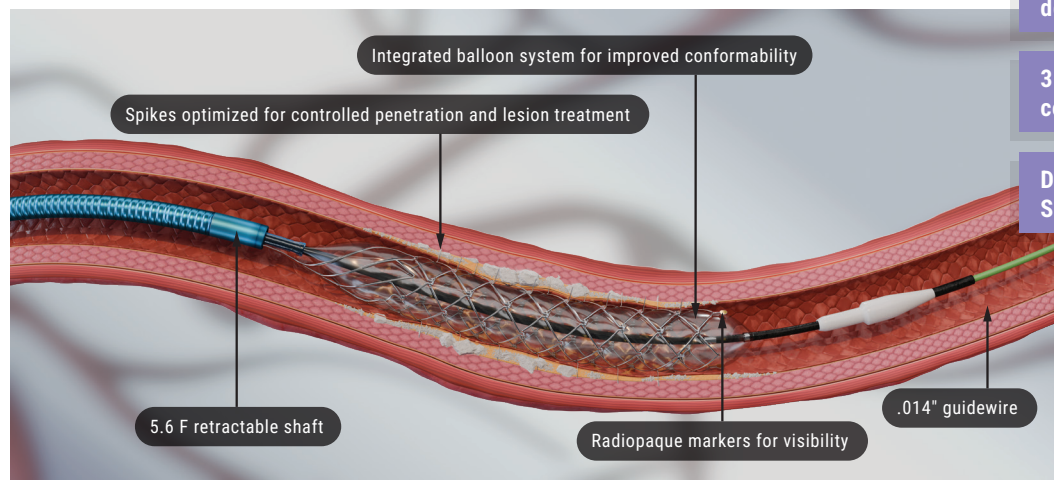


REFLOW MEDICAL
THE PULSE OF MEDICAL INGENUITY

Spur Retrieable Scaffold Therapy

A self-expanding stent with integrated dilation balloon catheter on an over-the-wire (OTW) system, designed for controlled penetration and lesion treatment after predilatation through a series of radially expandable spikes. Spur penetrates lesion to increase acute luminal diameter and modify the lesion morphology to change vessel compliance and reduce vessel recoil effect.

Ease of Use



Familiar pin-and-pull Spur deployment system

3.0 mm and 4.0 mm device diameters conform to vessel anatomy

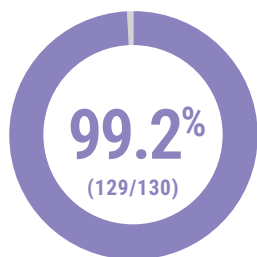
Designed to treat long lesions, Spur can be utilized up to 4 times

Clinically Proven

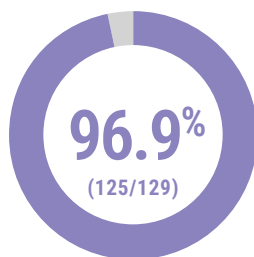
MAXIMIZING BTK* TREATMENT OUTCOMES WITHOUT COMPROMISING ON SAFETY

DEEPER REVEAL¹

Prospective, multicenter, single-arm, performance goal comparator



Technical Success²
(<30% Residual Stenosis)



Freedom from MALE and POD at 30 days³

STUDY DEVICE

Spur Peripheral Retrieable Stent System

STUDY SIZE

† 130 patients enrolled

🏢 49 centers (United States)

BASELINE CHARACTERISTICS

62.3% Rutherford class 5

37.7% Rutherford class 4

27% total occlusions

42% moderately/severely calcified lesions

96.4 mm mean lesion length

VESSEL RECOIL SUBSTUDY

Occurrence of vessel recoil is defined as lumen compromise $\geq 10\%$ at 15 minutes post Spur treatment

57.5%

DEEPER OUS
Substudy⁴
N=40

POBA⁵
N=30

3%

FREEDOM FROM OCCURRENCE OF VESSEL RECOIL

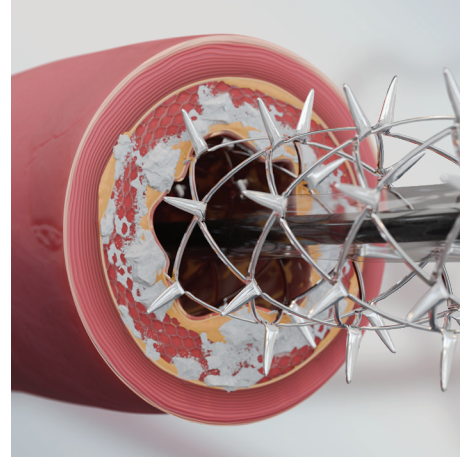
RST Mechanism of Action⁶

- 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 are designed to:

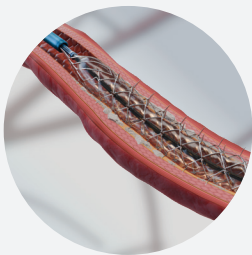
- increase acute luminal diameter
- modify lesion morphology to change vessel compliance and reduce recoil

- Stent provides temporary supportive structure.
- Deflate balloon and reinflate balloon to fully expand the Spur.
- Recapture the Spur system.



SPUR STENT

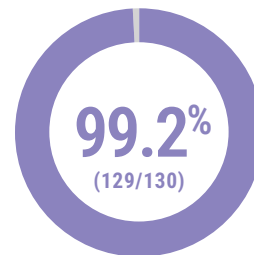
PROVIDES SUPPORTIVE STRUCTURE



The self-expanding nitinol stent provides temporary support through controlled expansion.



INCREASE ACUTE LUMINAL DIAMETER

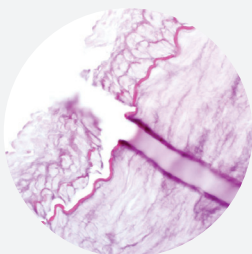


RST increases acute luminal diameter, achieves a very low residual stenosis rate, while leaving nothing behind.

<30% Residual Stenosis²

SPUR SPIKES

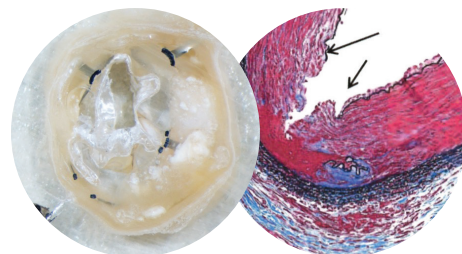
PENETRATE LESION



The spikes penetrate lesion in a controlled manner.

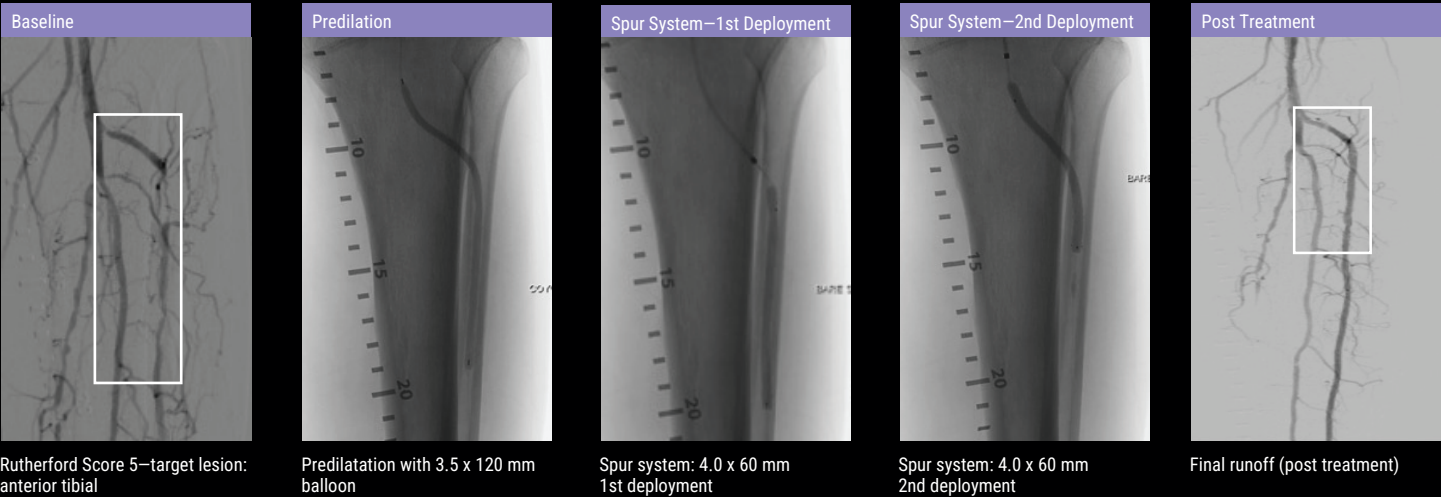


MODIFY CALCIFICATION & DISRUPT LAMINA



The spikes modify lesion morphology to change vessel compliance and reduce recoil.

Spur Case Experience



Reference Vessel Diameter (mm)	2.50–3.49	3.25–4.50
Model	BSPUR365135US	BSPUR460135US
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: *Below the knee; 1. Data on file for DEEPER REVEAL clinical trial (NCT05358353); 2. Primary endpoint defined as Technical success: <30% residual stenosis by visual estimate within the treated lesion area on completion angiography. Core lab adjudicated technical success of <30% stenosis was 85.7% (120/140 lesions); 3. MALE defined as: above-the-ankle amputation of the index limb, OR major reintervention of the index limb involving the infrapopliteal arteries; Peri-operative death (POD); 4. Zeller et al. Early Tibial Vessel Recoil Following Treatment With the Bare Temporary Spur Stent System: Results from the DEEPER OUS Vessel Recoil Substudy. Journal of Endovascular Therapy. 2024;0(0). doi:10.1177/15266028241280685; 5. 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; 6. Reflow Medical data on file.

Indications for Use: The Spur Peripheral Retrievable Stent System is intended as an adjunct to percutaneous transluminal angioplasty (PTA) to dilate stenoses in infrapopliteal arteries ranging in diameter from 2.5 mm to 4.5 mm.

Contraindications: The Spur is not intended for use in coronary and cerebral vasculature.

Warnings: Do not use the device past the expiration date on the label. Use of expired products may result in patient injury; Do not treat the target vessel more than four times with the same device. Do not deploy the Spur Stent System more than two times within the same vessel segment; 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; Use with caution in patients with a history of severe bleeding or coagulopathy; Ensure the Spur Stent System 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 Stent System 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; This device contains nitinol, an alloy of nickel and titanium. Persons with allergic reactions to these materials may suffer an allergic reaction to this device. Prior to use, patients should be counseled on the materials contained in the device, as well as potential for allergy/hypersensitivity to these materials.

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; Ensure that predilatation achieves a lumen diameter greater than the outer diameter of the device catheter (approximately 2 mm) in order to advance the catheter.

Adverse Events: Additional intervention; Allergic reaction to drugs or contrast medium; Aneurysm or pseudoaneurysm; Hemorrhage, including bleeding at the puncture site; Inflammation; Occlusion; Pain or tenderness; Sepsis/Infection; Short term hemodynamic deterioration; Stroke; Death; Thrombosis; Vessel dissection, perforation, rupture, or spasm; Hematoma; Embolization; Pneumothorax or hemothorax; Shock; If the system is damaged, this product may perforate or dissect a blood vessel wall. Extreme caution needs to be taken when removing a damaged device. In the case of complications resulting from the removal of the entire system, stop procedure immediately, and perform appropriate treatment at the discretion of the physician.

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