

Dilation using Temporary Retrievable Intraluminal Device

Reflow Spur™

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ICD-10 Coordination and Maintenance Committee Update

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Endovascular Therapy

Chronic Limb Threatening Ischemia (CLTI) is associated with a high risk for cardiovascular events and mortality and accounts for approximately 90% of major amputations performed worldwide^{1,2}.

To avoid amputations, patients with blockage from below the knee (BTK) disease from CLTI may be treated with:

- Vein grafts/ peripheral bypass to reroute blood flow around blockage
- Catheter based endovascular techniques to optimize lumen and restore blood flow
 - Vessel pre-treatment
 - Balloon angioplasty to dilate the vessel
 - Atherectomy to remove plaque
 - Intravascular lithotripsy (IVL) to break up plaque and calcium
 - Balloon angioplasty to dilate the vessel (including cutting and/or scoring balloons)
 - Stenting/ device placement (*none currently FDA approved*) Permanent (Bare metal, drug-eluting)
 - Temporary (Drug-eluting resorbable scaffold or DRS)
- *To date, drug coated balloons (DCB's) have not shown to be effective for BTK (none currently FDA approved)*

1 - Uccioli L, Meloni M, Izzo V, et al. Critical limb ischemia: current challenges and future prospects. Vasc Health Risk Manag 2018;14:63–74.

2 - Karnabatidis D, Spiliopoulos S, Katsanos K, Siablis D. Below-the-knee drug-eluting stents and drug-coated balloons. Expert Rev Med Devices 2012;9:85–94.

Spur™ is a Peripheral Retrievable Stent

Retrievable

Self-expanding nitinol stent with integrated balloon catheter on an over the wire (OTW) system:

- Ease of use enabled by familiar pin-and-pull Spur™ deployment system
- Allows blood flow during treatment
- Recapture Spur™ with integrated balloon and remove

Stent

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

Radially expandable Spur™ spikes create channels that are designed to:

- Penetrate the lesion in a controlled fashion
- Provides temporary supportive structure
- Increase acute luminal diameter
- Modify the lesion morphology to change vessel compliance and reduce recoil

- Adverse events and complications are comparable or less than other endovascular therapies; i.e., balloon angioplasty, cutting or scoring balloons.
- Spur™ is contraindicated for use in patients with known intolerance to nitinol.

CLTI BTK Endovascular Treatment Challenges

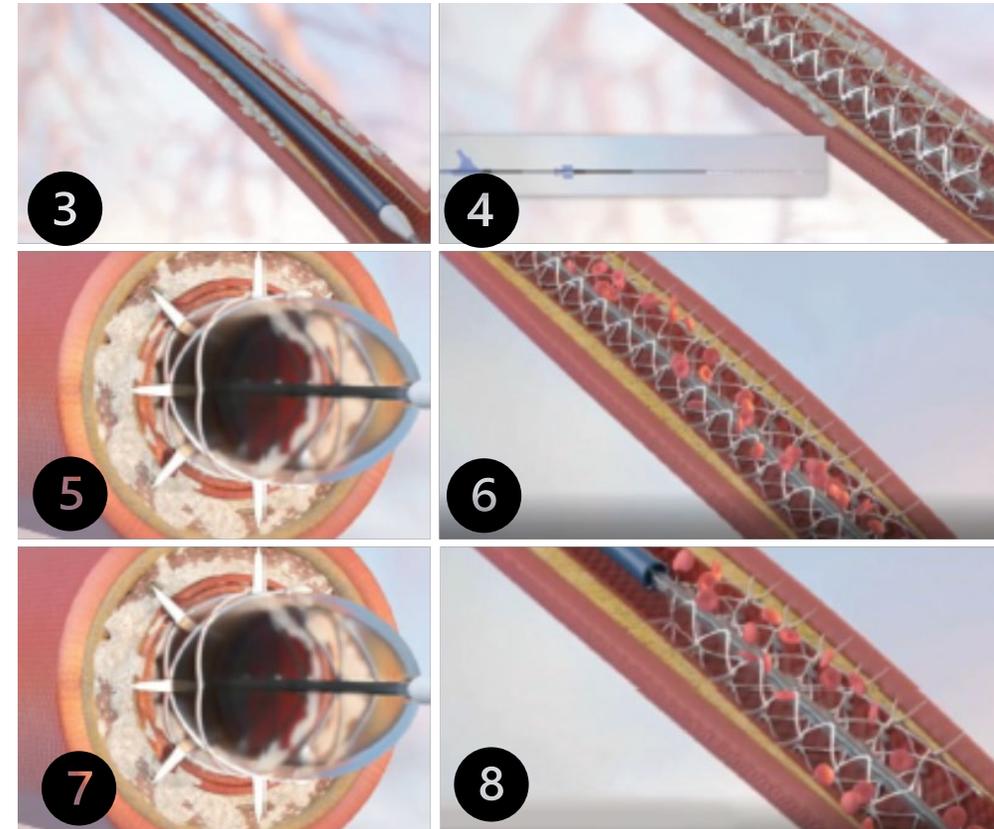
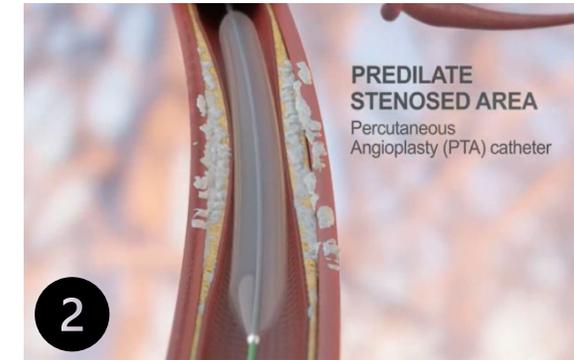
The Spur™ Peripheral Retrievable Stent System is placed in the infrapopliteal arteries to alleviate/treat the following CLTI treatment challenges:

<u>Challenge</u>	<u>Spur Attribute</u>
Calcification	Spur™ spikes create channels through controlled penetration that modifies lesion morphology and changes vessel compliance
Elastic Recoil	Spur™ spikes create channels through controlled penetration that minimizes recoil
Lesion Length and Tortuosity	Spur™ may be used to treat lesions up to 210 mm
Leave Nothing Behind	Spur™ is removed during the procedure to enable future treatment options

Dilation using Spur™ Device

Procedural Highlights:

1. Vessel selection
2. **BTK vessel pre-dilation**
3. **Track Spur to lesion site**
4. **Deploy Spur™**
5. **Inflate balloon**
6. **Deflate balloon with Spur™ stent expanded in artery allowing blood flow during treatment**
7. **Reinflate balloon**
8. **Recapture the Spur™**
9. Resheath and reposition for longer lesions or remove if lesion length <55 mm
 - Spur™ may be placed up to 4 times to treat long lesions (up to 210 mm)
10. Close vessel per standard of care



Spur™ Regulatory Status

- De Novo Classification Request Grant is expected by May 1, 2025
- Spur™ was granted breakthrough device designation August 23, 2021
 - Reflow Medical has applied for FY 2026 NTAP

Medical record of procedure/technology

- Documentation of the Spur™ Peripheral Retrievable Stent System procedure will be included in the operative report

Terms for procedure/technology

- Spur™ Retrievable Stent
- Spur™ Stent
- Temporary Retrievable Stent
- BTK Temporary Retrievable Stent
- BTK Retrievable Stent
- Stent
- Spur™
- (Spur™) Scaffold
- Retrievable scaffold

Open Discussion

Thank you for your time