

SPUR® REIMBURSEMENT FAQ – 2025

Product Description / FDA Clearance

1. What is Spur Peripheral Retrieable Stent System? And what is the FDA-cleared indication?

The Spur Stent System is a temporary, retrievable, self-expanding stent delivered via an over-the-wire (OTW) system. The Spur Stent provides scaffolding when placed and expanded in the vasculature, supporting the vessel wall and maintaining the vessel open to facilitate blood flow. Uniquely, the Spur Stent is designed for use during treatment and incorporates a series of radially expandable spikes that enable controlled lesion penetration. Following predilatation, Spur Stent treats the lesion to increase acute luminal diameter and modify the lesion morphology to change vessel compliance and reduce vessel recoil effect – while leaving nothing behind.

Indication for Use: The Spur Peripheral Retrieable 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.

2. How is the Spur Stent System classified by the FDA?

The Spur Peripheral Retrieable Stent System was FDA cleared via De Novo pathway on May 29, 2025. The FDA classified/defined Spur Stent System as a stent/scaffold.

Device Type	Peripheral Temporary and Retrieable Stent System
Regulation Number	870.5110
Product Code	SEU Peripheral Temporary and Retrieable Stent System
Definition	A peripheral temporary and retrievable stent system is a temporary scaffold placed into the peripheral vasculature via a delivery catheter system for treating stenotic lesions. The device is designed to be retrieved and removed following successful treatment.
Physical State	Stent-like scaffold deployed via a catheter system

Coding Spur Stent Procedures

CPT® Coding

3. How is the Spur Stent System categorized for reimbursement and coding purposes?

The Spur Peripheral Retrieable Stent System is classified by the FDA as a stent based on its design and function. When deployed, Spur Stent provides temporary scaffolding to support the vessel wall and maintain the vessel open, facilitating blood flow – core mechanical functions of a stent.

From a regulatory standpoint, Spur Stent System received FDA market authorization via the De Novo pathway, recognizing it as a novel stent for below-the-knee use. Clinical data, including findings from the DEEPER REVEAL study, supports its safety and effectiveness in infrapopliteal arteries.

For coding and reimbursement, Spur Stent System procedures fall under existing CPT® stent codes (37230, 37231, 37234, 37235), because these codes reflect the procedural intent and actions performed by the physician (i.e. vessel access, stent deployment, mechanical scaffolding, and lesion modification). Coding is based on the procedure performed (stent placement), making Spur Stent System fully aligned with stent procedure classification.

See question 6 for comparison of Spur Stent System procedural steps vs. peripheral intervention stenting.

4. What specific CPT code(s) should I use to report procedures utilizing the Spur Stent System?

The following CPT codes are applicable to the placement of the Spur Stent System:

- 37230 (Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed)
- 37231 (Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed)
- +37234 (Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, each additional vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed (List separately in addition to code for primary procedure)
- +37235 (Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, unilateral, each additional vessel; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed (List separately in addition to code for primary procedure)

Documentation and Procedure Details

5. For documentation and coding purposes, how should I refer to having used the Spur Peripheral Retrieable Stent System in a procedure?

Dictation is typically based on the procedure (stent placement) versus the use of trademark names but is ultimately the choice of the surgeon. Dictation should at minimum refer to a stent, Spur Stent or Spur Stent System.

6. Can you provide an overview of procedural elements for procedures utilizing the Spur Stent System and the comparison to code descriptor/stenting peripheral interventions?

According to the SCAI "Coding Guidelines for Peripheral Interventions", stent placement includes:

- Balloon angioplasty in treated vessel
- Post-dilation following stent placement
- Treatment of another lesion in the same vessel (when appropriate)
- Use of different size balloon to achieve therapeutic result
- Radiological supervision and interpretation directly related to intervention
- Closure of arteriotomy
- Imaging to document completion of intervention

The table below outlines the comparison of the steps between a standard lower extremity revascularization (LER) and a LER with the Spur Stent System:

Procedural Step	CPT 37230 (LER)	Spur Peripheral Retrieable Stent System
Access	Catheter and guidewire access. Roadmapping for vessel sizing.	Catheter and guidewire access. Roadmapping for vessel sizing.
Pre-Dilatation	Pre-dilate target lesion initially with balloon angioplasty	Pre-dilate target lesion initially with balloon angioplasty
Target Lesion	Cross any stenosis/occlusion and advance the Delivery Catheter to the desired location within the vasculature	Cross any stenosis/occlusion and advance the Delivery Catheter to the desired location within the vasculature
Stent Deployment and Stenting	Deploy the stent either by placement of a self-expanding stent or balloon-expandable stent. Seat the stent or fully open with additional ballooning.	Deploy the self-expanding Spur Stent for placement. Post dilate to further expand the Spur stent.
Device Removal and Closure	Deflate the balloon and remove stent delivery system. Perform completion angiography and closure.	Deflate balloon and recapture Spur Stent to remove Delivery Catheter. Perform completion angiography and closure.

FDA classification confirmed that Spur Stent System is a stent (even if temporary and retrievable); the CPT codes do not specify permanence of the implant, only the stent placement procedure itself.

Therefore, CPT codes for peripheral stenting remain appropriate because the device and procedure are categorized and defined as stenting under regulatory and clinical guidelines. This matches how the procedure was coded in Reflow Medical's DEEPER REVEAL trial and has been utilized in commercial use to date.

7. What is the HCPCS/C-code for Spur Stent System?

Hospitals may report C1876 (Stent, non-coated/non-covered, with delivery system) for cost reporting purposes for the Spur Stent System.

8. How do sites code for more than one treated vessel using the same Spur Stent System?

If two vessels are treated in the tibial/peroneal territory, the first vessel is reported using either 37230 or 37231, depending on whether atherectomy is used or not, with the second vessel reported with either 37234 or 37235.

9. Has Spur Stent System received New Technology Add-On Payment (NTAP)?

Spur does not currently have a NTAP. However, CMS created new ICD-10-PCS¹ codes to report procedures utilizing Spur Stent System (Effective Oct. 1, 2025) in the hospital inpatient setting:

X2HP38B	Insertion of Temporary Intraluminal Device into Right Anterior Tibial Artery, Percutaneous Approach, New Technology Group 11
X2HQ38B	Insertion of Temporary Intraluminal Device into Left Anterior Tibial Artery, Percutaneous Approach, New Technology Group 11
X2HR38B	Insertion of Temporary Intraluminal Device into Right Posterior Tibial Artery, Percutaneous Approach, New Technology Group 11
X2HS38B	Insertion of Temporary Intraluminal Device into Left Posterior Tibial Artery, Percutaneous Approach, New Technology Group 11
X2HT38B	Insertion of Temporary Intraluminal Device into Right Peroneal Artery, Percutaneous Approach, New Technology Group 11
X2HU38B	Insertion of Temporary Intraluminal Device into Left Peroneal Artery, Percutaneous Approach, New Technology Group 11

Additional Reimbursement Resources

For more information or answers to questions about your reimbursement options, please email reimbursement-reflowmedical@jdlaccess.com or call +1 (866) 786-2180.

Reference: 1. 2026 ICD-10 PCS. Centers for Medicare and Medicaid Services: <https://www.cms.gov/files/document/2026-official-icd-10-pcs-coding-guidelines.pdf>

Disclaimer: The information contained in this guide is provided to assist you in understanding the reimbursement process. It is intended to assist providers in accurately obtaining reimbursement for health care services. It is not intended to increase or maximize reimbursement by any payer. We strongly suggest that you consult your payer organization with regard to local reimbursement policies. The information contained in this document is provided for information purposes only and represents no statement, promise or guarantee by Reflow Medical, Inc. concerning levels of reimbursement, payment or charge. Similarly, all CPT & HCPCS codes are supplied for information purposes only and represent no statement, promise or guarantee by Reflow Medical, Inc. that these codes will be appropriate or that reimbursement will be made.

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www.reflowmedical.com | info@reflowmedical.com | 949-481-0399