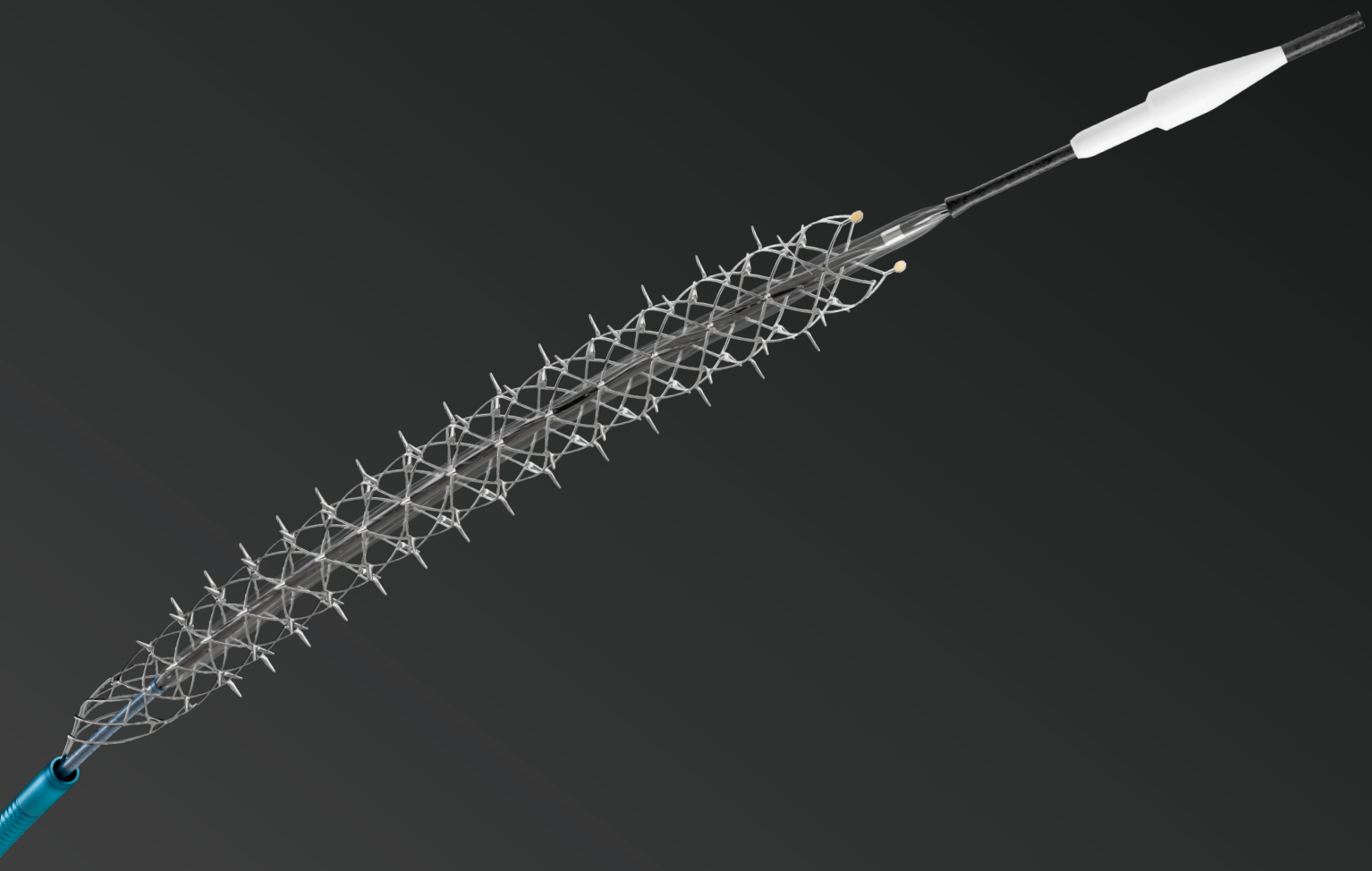
REFLOW spur®

PERIPHERAL RETRIEVABLE STENT SYSTEM

RETRIEVABLE RST SCAFFOLD THERAPY

SPUR RESOURCE GUIDE



REFLOW MEDICAL®

THE PULSE OF MEDICAL INGENUITY

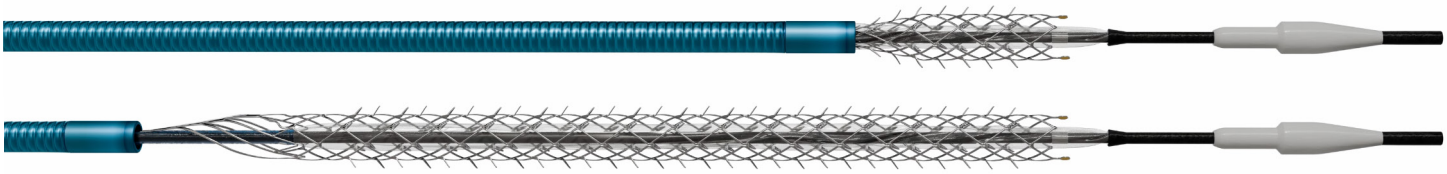
Table of Contents

Spur—Overview

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.

TECHNICAL FEATURES AND BENEFITS

- 6 F sheath compatible/.014" guidewire compatibility
- Integrated dilatation semi-compliant balloon
- Features a familiar pin-and-pull deployment system
- 3.0 mm and 4.0 mm device diameters conforming to vessel anatomy—2.5 mm to 4.5 mm
- Radiopaque markers for visibility
- Spikes optimized for controlled penetration and lesion treatment



Reference Vessel Diameter (mm)	**2.5–3.49**	**3.25–4.5**
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

INDICATIONS FOR USE

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

DEEPER REVEAL CLINICAL TRIAL

A Prospective Single-Arm Multicenter StuDy of the BarE TEmporary SPur StEnt System foR the tREatment of Vascular Lesions Located in the infrapoplitEal Arteries beLow the Knee (NCT05358353).

Prospective, single-arm, multicenter study designed to evaluate the safety and efficacy of the Spur Peripheral Retrievable Stent System.

Study Summary

PRIMARY OBJECTIVE

The primary objective of the DEEPER REVEAL IDE study was to compare the safety and efficacy of the Spur Peripheral Retrievable Stent System in subjects with infrapopliteal critical limb ischemia (CLI) to a pre-defined performance goal (PG) based on standard percutaneous transluminal balloon angioplasty (PTA).

POPULATION

130 patients in 49 clinical centers in the U.S.

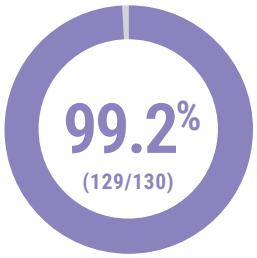
PRIMARY ENDPOINTS

- **Efficacy:** Technical success, defined as <30% residual stenosis within the treated lesion area by visual estimate on completion angiography.
- **Safety:** Freedom from the occurrence of major adverse limb events (MALE) [evaluated at 30 days post procedure] and perioperative death (POD) [defined as all-cause mortality within 30 days post procedure].

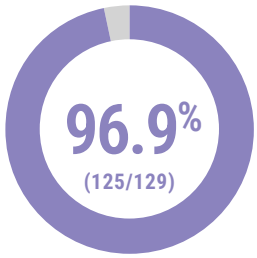
SAFETY AND EFFICACY RESULTS

Both co-primary endpoints were met with statistical significance in comparison to the performance goals.

DEEPER REVEAL[1] Prospective, multicenter, single-arm, performance goal comparator



Technical Success[2] **(<30% residual stenosis)**



Freedom from MALE and POD at 30 days[3]

STUDY DEVICE
Spur® Peripheral Retrievable 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

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).

Reimbursement Information

Traditional Medicare provides implicit coverage of lower extremity endovascular procedures without requiring prior authorization. Commercial payers manage Medicare Advantage plans and may require prior authorization. Prior authorization is also needed for many commercial plans. Contact your payers for information about any requirements.

The coding and reimbursement information below applies to lower extremity endovascular procedures in the tibial/peroneal arteries performed in these settings:

- Facility: Hospital Inpatient, Hospital Outpatient, and Ambulatory Surgical Center (ASC)
- Non-facility: Physician Office/Office-Based Lab (OBL)

The following tables represents codes for lower revascularization procedures in the tibial peroneal arteries as of 2026. The physician work of Spur Stent procedures is considered equivalent to stent placement.

PHYSICIAN

Effective 1/1/26 to 12/31/26

		Straightforward (Stenosis)				Complex (Occlusion)			
	Description	CPT® Code[1]	Work RVUs	2026 Medicare National Rate[2]		CPT® Code[1]	Work RVUs	2026 Medicare National Rate[2]	
				Facility	Non-facility/OBL			Facility	Non-facility/OBL
Tibial Peroneal Arteries	Angioplasty	37280	9.80	$448	$2,699	37282	12.31	$561	$6,103
	Angioplasty, additional vessel	+37281	3.00	$135	$737	+37283	4.26	$191	$863
	Stent placement, +/- angioplasty	37284	10.00	$461	$5,635	37286	13.46	$619	$10,375
	Stent placement, +/- angioplasty, additional vessel	+37285	3.34	$152	$2,791	+37287	5.00	$229	$4,944
	Atherectomy, +/- angioplasty	37288	13.50	$609	$7,802	37290	17.00	$767	$10,655
	Atherectomy, +/- angioplasty, additional vessel	+37289	4.75	$215	$922	+37291	6.50	$293	$1,076
	Stent placement and atherectomy, +/- angioplasty	37292	15.00	$679	$10,240	37294	18.00	$814	$15,211
	Stent placement and atherectomy, +/- angioplasty, additional vessel	+37293	6.50	$299	$3,512	+37295	8.16	$376	$6,006

Based on non qualifying APM Conversion factor of $33.40 x Total Non Facility RVUs
+ Indicates an add-on-code. List add-on-code(s) separately in addition to the primary procedure performed.

Reimbursement Information (continued)

HOSPITAL OUTPATIENT

HCPCS Level II C-codes are reported on claims submitted by hospital outpatient departments for CMS to track costs for devices. C1876 should be reported in addition to the appropriate procedural CPT® code on the hospital claim form. This information is used to for future OPPS rate setting for cost reporting purposes.

C-code	Description[3]
C1876	Stent, non-coated/non-covered, with delivery system

Effective 1/1/26 to 12/31/26

		Straightforward (Stenosis)			Complex (Occlusion)		
	Description	CPT® Code[1]	APC	2026 Medicare National Rate[4]	CPT® Code[1]	APC	2026 Medicare National Rate[4]
Tibial Peroneal Arteries	Angioplasty	37280	5193	$11,794	37282	5193	$11,794
	Angioplasty, additional vessel	+37281	—	No separate payment	+37283	—	No separate payment
	Stent placement, +/- angioplasty	37284	5194	$18,729	37286	5194	$18,729
	Stent placement, +/- angioplasty, additional vessel	+37285	—	No separate payment	+37287	—	No separate payment
	Atherectomy, +/- angioplasty	37288	5194	$18,729	37290	5194	$18,729
	Atherectomy, +/- angioplasty, additional vessel	+37289	—	No separate payment	+37291	—	No separate payment
	Stent placement and atherectomy, +/- angioplasty	37292	5194	$18,729	37294	5194	$18,729
	Stent placement and atherectomy, +/- angioplasty, additional vessel	+37293	—	No separate payment	+37295	—	No separate payment

APC 5193 = Level 3 Endovascular Procedures
APC 5194 = Level 4 Endovascular Procedures
+ Indicates an add-on-code. List add-on-code(s) separately in addition to the primary procedure performed.

AMBULATORY SURGICAL CENTER (ASC)

Effective 1/1/26 to 12/31/26

		Straightforward (Stenosis)		Complex (Occlusion)	
	Description	CPT® Code[1]	2026 Medicare National Rate[4]	CPT® Code[1]	2026 Medicare National Rate[4]
Tibial Peroneal Arteries	Angioplasty	37280	$7,078	37282	$7,078
	Angioplasty, additional vessel	+37281	No separate payment	+37283	No separate payment
	Stent placement, +/- angioplasty	37284	$12,207	37286	$12,207
	Stent placement, +/- angioplasty, additional vessel	+37285	No separate payment	+37287	No separate payment
	Atherectomy, +/- angioplasty	37288	12,373	37290	$12,373
	Atherectomy, +/- angioplasty, additional vessel	+37289	No separate payment	+37291	No separate payment
	Stent placement and atherectomy, +/- angioplasty	37292	$12,901	37294	$12,901
	Stent placement and atherectomy, +/- angioplasty, additional vessel	+37293	No separate payment	+37295	No separate payment

+ Indicates an add-on-code. List add-on-code(s) separately in addition to the primary procedure performed.

Reimbursement Information (continued)

ICD-10-PCS CODES FOR HOSPITAL INPATIENT

Effective 10/1/2025

CMS has issued the following New Technology ICD-10 PCS codes for the temporary intraluminal device in below-the-knee arteries, effective October 1, 2025. The new ICD-10 PCS codes are for use in the hospital inpatient setting for the Spur Stent[6].

ICD-10-PCS[6]	Description
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

The appropriate code from Table 047 should be assigned to report the angioplasty portion of the procedure[7]

Medical/Surgical/ Lower Arteries/Dilation	Body Part	Approach	Device	Qualifier
047	P Anterior Tibial Artery, Right Q Anterior Tibial Artery Left R Posterior Tibial Artery, Right S Posterior Tibial Artery, Left T Peroneal Artery, Right U Peroneal Artery, Left	3 Percutaneous	Z No Device	Z No Qualifier

HOSPITAL INPATIENT

Effective 10/1/2025 to 9/30/2026

The chart below shows the typical Medicare Severity Diagnosis Related Groups (MS-DRG) and other hospital reimbursements for patients undergoing procedures using the Spur Stent. Individual patient MS-DRG assignments may differ according to the clinical situation. The list does not include all possible MS-DRGs.

MS-DRG	Description	2026 Medicare National Rate[5]
252	Other vascular procedures with MCC	$25,384
253	Other vascular procedures with CC	$18,888
254	Other vascular procedures without CC/MCC	$12,965

CC = Complication or co-morbidity / MCC = Major complication or co-morbidity

The most common MS-DRG assignments for cases where the Spur System is used in conjunction with atherectomy or thrombectomy in the tibial/peroneal area are listed here:

MS-DRG	Description	2026 Medicare National Rate[5]
270	Other major cardiovascular services with MCC	$38,394
271	Other major cardiovascular services with CC	$25,878
272	Other major cardiovascular services without CC/MCC	$18,578

CC = Complication or co-morbidity / MCC = Major complication or co-morbidity

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

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August 29th, 2024

RE: Reflow Medical Devices

I hereby attest that the following Reflow Medical devices are not manufactured with natural rubber latex:

- Spur Peripheral Retrievable Stent System

Evidence of this is on file at Reflow Medical and available for review upon request.

Sincerely,

Isa

Name of Attesting Company Official: Isa Rizk
Job Title: CEO
Date: August 29th, 2024

Form **W-9**
(Rev. October 2018)
Department of the Treasury
Internal Revenue Service

Request for Taxpayer Identification Number and Certification

▶ **Go to *www.irs.gov/FormW9* for instructions and the latest information.**

Give Form to the requester. Do not send to the IRS.

Print or type. See **Specific Instructions** on page 3.

1 Name (as shown on your income tax return). Name is required on this line; do not leave this line blank.

Reflow Medical, Inc.

2 Business name/disregarded entity name, if different from above

3 Check appropriate box for federal tax classification of the person whose name is entered on line 1. Check only **one** of the following seven boxes.

☐ Individual/sole proprietor or single-member LLC ☑ C Corporation ☐ S Corporation ☐ Partnership ☐ Trust/estate

☐ Limited liability company. Enter the tax classification (C=C corporation, S=S corporation, P=Partnership) ▶ _____

Note: Check the appropriate box in the line above for the tax classification of the single-member owner. Do not check LLC if the LLC is classified as a single-member LLC that is disregarded from the owner unless the owner of the LLC is another LLC that is **not** disregarded from the owner for U.S. federal tax purposes. Otherwise, a single-member LLC that is disregarded from the owner should check the appropriate box for the tax classification of its owner.

☐ Other (see instructions) ▶

4 Exemptions (codes apply only to certain entities, not individuals; see instructions on page 3):

Exempt payee code (if any) _____

Exemption from FATCA reporting code (if any) _____

(Applies to accounts maintained outside the U.S.)

5 Address (number, street, and apt. or suite no.) See instructions.

208 Avenida Fabricante Suite 100

Requester's name and address (optional)

6 City, state, and ZIP code

San Clemente, CA 92672

7 List account number(s) here (optional)

Part I Taxpayer Identification Number (TIN)

Enter your TIN in the appropriate box. The TIN provided must match the name given on line 1 to avoid backup withholding. For individuals, this is generally your social security number (SSN). However, for a resident alien, sole proprietor, or disregarded entity, see the instructions for Part I, later. For other entities, it is your employer identification number (EIN). If you do not have a number, see *How to get a TIN,* later.

Note: If the account is in more than one name, see the instructions for line 1. Also see *What Name and Number To Give the Requester* for guidelines on whose number to enter.

Social security number

			–		–				

or

Employer identification number

2	6	–	4	6	7	0	0	9	1

Part II Certification

Under penalties of perjury, I certify that:

1. The number shown on this form is my correct taxpayer identification number (or I am waiting for a number to be issued to me); and
2. I am not subject to backup withholding because: (a) I am exempt from backup withholding, or (b) I have not been notified by the Internal Revenue Service (IRS) that I am subject to backup withholding as a result of a failure to report all interest or dividends, or (c) the IRS has notified me that I am no longer subject to backup withholding; and
3. I am a U.S. citizen or other U.S. person (defined below); and
4. The FATCA code(s) entered on this form (if any) indicating that I am exempt from FATCA reporting is correct.

Certification instructions. You must cross out item 2 above if you have been notified by the IRS that you are currently subject to backup withholding because you have failed to report all interest and dividends on your tax return. For real estate transactions, item 2 does not apply. For mortgage interest paid, acquisition or abandonment of secured property, cancellation of debt, contributions to an individual retirement arrangement (IRA), and generally, payments other than interest and dividends, you are not required to sign the certification, but you must provide your correct TIN. See the instructions for Part II, later.

Sign Here | **Signature of U.S. person** ▶ Chad Hollister | **Date** ▶ 3/3/2025

General Instructions

Section references are to the Internal Revenue Code unless otherwise noted.

Future developments. For the latest information about developments related to Form W-9 and its instructions, such as legislation enacted after they were published, go to *www.irs.gov/FormW9.*

Purpose of Form

An individual or entity (Form W-9 requester) who is required to file an information return with the IRS must obtain your correct taxpayer identification number (TIN) which may be your social security number (SSN), individual taxpayer identification number (ITIN), adoption taxpayer identification number (ATIN), or employer identification number (EIN), to report on an information return the amount paid to you, or other amount reportable on an information return. Examples of information returns include, but are not limited to, the following.

- Form 1099-INT (interest earned or paid)
- Form 1099-DIV (dividends, including those from stocks or mutual funds)
- Form 1099-MISC (various types of income, prizes, awards, or gross proceeds)
- Form 1099-B (stock or mutual fund sales and certain other transactions by brokers)
- Form 1099-S (proceeds from real estate transactions)
- Form 1099-K (merchant card and third party network transactions)
- Form 1098 (home mortgage interest), 1098-E (student loan interest), 1098-T (tuition)
- Form 1099-C (canceled debt)
- Form 1099-A (acquisition or abandonment of secured property)

Use Form W-9 only if you are a U.S. person (including a resident alien), to provide your correct TIN.

If you do not return Form W-9 to the requester with a TIN, you might be subject to backup withholding. See What is backup withholding, *later.*

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COMPANY INFORMATION

Shipping Address…….	**Reflow Medical, Inc.** 208 Avenida Fabricante, #100 San Clemente, CA 92672
Customer Service Telephone…….	949.481.0399, Select Option #1
Customer Service Email……..	**salesorders@reflowmedical.com**
Main Office Telephone…….	949.481.0399

FINANCE INFORMATION

Remit/ Billing Address……..	**Reflow Medical, Inc.** 208 Avenida Fabricante, #100 San Clemente, CA 92672
Bank Address…….	JPMorgan Chase Bank, N.A. Irvine Plaza 3 Park Plaza, 8th Floor Irvine, CA 92614
Federal Tax ID#.....	26-4670091
Payment Terms……	Net 30 Days
FOB……	Origin

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 8/29/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
Marsh & McLennan Agency LLC
Marsh & McLennan Ins. Agency LLC
1 Polaris Way #300
Aliso Viejo CA 92656

License#: 0H18131

CONTACT NAME:
PHONE (A/C, No, Ext): **FAX (A/C, No):**
E-MAIL ADDRESS: occerts@marshmma.com

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : Atlantic Specialty Insurance Company	27154
INSURER B : OBI National Insurance Company	14190
INSURER C : Homeland Insurance Company of New York	34452
INSURER D :	
INSURER E :	
INSURER F :	

INSURED
Reflow Medical, Inc.
208 Avenida Fabricante Unit A
San Clemente CA 92672

REFLOMEDIC

COVERAGES **CERTIFICATE NUMBER:** 1324159304 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X **COMMERCIAL GENERAL LIABILITY** CLAIMS-MADE X OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: POLICY PRO-JECT X LOC OTHER:			7110182760002	9/1/2025	9/1/2026	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$ 1,000,000 $ 1,000,000 $ 15,000 $ 1,000,000 $ 2,000,000 $ EXCLUDED
A	**AUTOMOBILE LIABILITY** X ANY AUTO OWNED AUTOS ONLY / SCHEDULED AUTOS X HIRED AUTOS ONLY / X NON-OWNED AUTOS ONLY			7110182760002	9/1/2025	9/1/2026	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$ 1,000,000 $ $ $
A	X **UMBRELLA LIAB** X OCCUR **EXCESS LIAB** CLAIMS-MADE DED RETENTION $			7110182760002	9/1/2025	9/1/2026	EACH OCCURRENCE AGGREGATE	$ 5,000,000 $ 5,000,000
B	**WORKERS COMPENSATION AND EMPLOYERS' LIABILITY** Y / N ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? N / A **(Mandatory in NH)** If yes, describe under DESCRIPTION OF OPERATIONS below	N / A		4060494360002	9/1/2025	9/1/2026	X PER STATUTE / OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	 $ 1,000,000 $ 1,000,000 $ 1,000,000
C	PRODUCTS LIABILITY RETRO: 11/30/2010			8500002180002	9/1/2025	9/1/2026	$10,000,000 LIMIT EACH CLAIM/AGGREGATE $50,000 RETENTION	

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
Umbrella policy excludes Products/Completed Operations

CERTIFICATE HOLDER

Evidence of Coverage

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE
Monica Fisk

May 29, 2025

Reflow Medical, Inc.
Lori Grace
Sr. Director, Regulatory Affairs
208 Avenida Fabricante, Suite 100
San Clemente, California 92672

Re: DEN240048
Trade/Device Name: Spur Peripheral Retrievable Stent System
Regulation Number: 21 CFR 21 CFR 870.5110
Regulation Name: Peripheral temporary and retrievable stent system
Regulatory Class: Class II
Product Code: SEU
Dated: September 19, 2024
Received: September 20, 2024

Dear Lori Grace:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the Spur Peripheral Retrievable Stent System, a prescription device under 21 CFR Part 801.109 with the following 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.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Spur Peripheral Retrievable Stent System, and substantially equivalent devices of this generic type, into Class II under the generic name peripheral temporary and retrievable stent system.

FDA identifies this generic type of device as:

> **Peripheral temporary and retrievable stent system**. 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.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may

request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On September 20, 2024, FDA received your De Novo requesting classification of the Spur Peripheral Retrievable Stent System. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Spur Peripheral Retrievable Stent System into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the Spur Peripheral Retrievable Stent System can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Table 1 – Identified Risks to Health and Mitigation Measures

Risks to Health	**Mitigation Measures**
Infection	Sterilization validation Shelf life testing Pyrogenicity testing Labeling
Adverse tissue reaction	Biocompatibility evaluation Pyrogenicity testing
Device misuse, damage, and/or malfunction, resulting in intra-procedural complications, including: • Vascular injury (e.g. perforation, dissection, aneurysm, fistula) • Embolic events • Vessel spasm • Hemodynamic instability • Prolonged procedure time	Clinical performance testing Animal performance testing Non-clinical performance testing Labeling
Post-procedural events (short- or long-term), including: • Additional intervention/surgery • Thromboembolic episodes • Restenosis	Clinical performance testing Animal performance testing Biocompatibility evaluation Labeling

In combination with the general controls of the FD&C Act, the Peripheral temporary and retrievable stent system is subject to the following special controls:

(1) Clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. Testing must include:
   (i) Analysis of all adverse events, including serious and non-serious complications; and
   (ii) Clinically meaningful endpoints that assess device performance and clinical benefit.

(2) Animal performance testing must evaluate the device's performance in a physiological environment, including assessing vascular compatibility, deployment and retrieval behavior, and acute and subacute adverse effects (e.g. dissection, perforation, spasm, hemorrhage, thrombosis, stenosis). Evaluations must include:
   (i) Post-procedural examination of the catheter for thrombus or damage;
   (ii) In-life clinical observations of the test animals;
   (iii) Clinical pathology assessment;
   (iv) Imaging to assess vascular response and patency;
   (v) Complete gross necropsy;
   (vi) Examination of downstream tissue beds for particulate or thromboembolic events; and
   (vii) Comprehensive target tissue histopathology and histomorphometry evaluation.

(3) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following characteristics must be evaluated:
   (i) Dimensional verification testing, including compatibility of the device with the intended anatomy and all labeled accessories;
   (ii) Mechanical integrity and bond strength testing of the entire device, including all joints and component interfaces, under tensile and torsional forces expected during challenging clinical use conditions;
   (iii) Simulated use testing, including insertion, tracking, activation, and removal without device damage, to demonstrate that the device is able to function as intended under challenging clinical use conditions;
   (iv) Device visibility testing under standard imaging modalities;
   (v) Kink resistance when subjected to clinically relevant tortuosity;
   (vi) Delivery catheter functional testing. If the delivery catheter utilizes a balloon component the following must be demonstrated:
      (A) Balloon inflates and deflates within clinically relevant timeframes;
      (B) Balloon withstands rated burst pressure without failure;
      (C) Balloon withstands repeated inflation/deflation cycles without degradation; and
      (D) Balloon inflates uniformly, meeting labeled diameter and compliance specifications for stent deployment;
   (vii) Durability testing under clinically relevant mechanical stresses over time;
   (viii) Coating integrity and particulate testing of any coatings on the delivery catheter or stent; and
   (ix) Material stability testing, including *in situ* stability and resistance to degradation (e.g. corrosion, wear, delamination) of all device materials.

(4) All patient-contacting components of the device must be demonstrated to be biocompatible.

(5) All patient-contacting components of the device provided sterile must be demonstrated to be sterile and non-pyrogenic.

(6) Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the established shelf life.

(7) Labeling must include:
   (i) A detailed summary of the device's technical parameters and materials;
   (ii) A summary of expected complications associated with the device; and
   (iii) A summary of the clinical performance testing conducted with the device, including device- and procedure-related adverse events.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the peripheral temporary and retrievable stent system they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD&C Act; 21 CFR 1000-1050).

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System Rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

If you have any questions concerning the contents of the letter, please contact Luis Guardia at (240) 402-2912.

Sincerely,

for Bram Zuckerman, M.D.
Director
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Product Ordering Information

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 6 atm (mm)	3.00	4.02
Balloon Diameter @ RBP 12 atm (mm)	3.20	4.23
Hydrophilic Coating—Distal (cm)	30	30
	(01)00850025525169	(01)00850025525176
List Price	$3,995.00	$3,995.00

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

REFERENCES

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[3] CMS, 2026 Alpha-Numeric Index HPCPS file: https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system/quarterly-update

[4] Hospital Outpatient Prospective Payment and Ambulatory Surgical Payment Systems-Notice of Final Rulemaking with Comment Period for CY 2026, CMS-1834-FC: https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices/cms-1834-fc

[5] Hospital Inpatient Prospective Payment—Final Rule FY2026, CMS-1833-F: https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/fy-2026-ipps-final-rule-home-page

[6] 2026 ICD-10 PCS. Centers for Medicare and Medicaid Services. https://www.cms.gov/files/document/2026-official-icd-10-pcs-coding-guidelines.pdf

[7] AHA Coding Clinic. ICD-10-CM and ICD-10-PCS. Fourth Quarter Volume 12 No 4 2025.

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.