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SPUR® PERIPHERAL RETRIEVABLE STENT SYSTEM

Instructions for Use

Description

The Spur® Peripheral Retrievable Stent System (Spur Stent System) is an over-the-wire percutaneous catheter available with a 135 cm working length that is compatible with 0.014" guidewires. The Spur Stent System consists of a temporary self-expanding nitinol stent (Spur Stent) that is attached to a balloon catheter shaft and collapsed on the balloon within a 5.6Fr outer shaft (see Figure 1). The delivery catheter is comprised of an outer shaft and balloon catheter. The balloon and outer shaft are fabricated from well-known materials including, metals, polycarbonate, nylon, polyurethane and high-density polyethylene. The system is intended to track over a guidewire, under fluoroscopy, to the intended site and be deployed within the target lesion. After deployment, the balloon catheter is inflated to fully expand the Spur Stent, deflated, then re-captured into the outer shaft for removal from the vasculature.

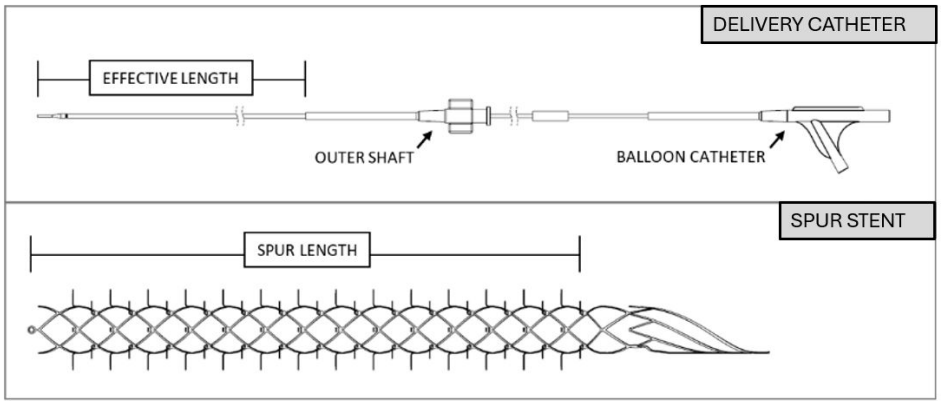

Figure 1. Spur® Peripheral Retrievable Stent System (Spur Stent System)

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 Stent System 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.

How Supplied

- The Spur Stent System is supplied sterile via ethylene oxide (EO) sterilization and is intended for single use (one patient) only. Do not resterilize as this could damage the device and could lead to patient injury. Do not reuse the device as this could result in cross-contamination that could result in patient injury.
- Carefully inspect all packaging for damage or defects prior to use. Do not use the device if there is any sign of breach of sterile barrier, as this would indicate loss of sterility that could result in patient injury.
- Store the Spur Stent System in a dry, dark place. Storage of the device in extreme conditions may damage the device and/or affect device performance that could lead to patient injury.

Devices Required but Not Supplied By Reflow Medical, Inc.

- 0.014" (0.36mm) Guidewire
- Introducer Sheath (minimum 6F (2mm))
- Predilatation PTA catheter
- Indeflator
- Luer lock syringe

Procedural Steps

Caution: Refer to the instructions for use for all equipment/devices to be used with the Spur Stent System and procedure.

1. Predilation of the target lesion with a PTA catheter is required prior to treatment with the Spur Stent System to ensure successful delivery of the device.
2. Spur Stent System Preparation for Use
   a. Select a Spur Stent System size 1:1 based on the reference vessel diameter as indicated in the Specification table.
   b. Using sterile technique, remove the Spur Stent System from the packaging and transfer it to the sterile field.
   c. Remove the delivery catheter from the packaging card and inspect for any bends or kinks. Remove the stylet from the tip of the device.
   d. Fill a sterile standard luer-lock syringe with sterile heparinized saline and flush the central lumen.
   e. Purge the air in the balloon catheter. Fill approximately one quarter of a 20mL indeflator with appropriate balloon inflation medium (e.g. 50:50 contrast-to-saline solution) and connect the indeflator to the inflation port of the balloon catheter. Hold the indeflator with the nozzle pointing downward and apply a vacuum. Repeat aspiration two times or until bubbles no longer appear during aspiration. Once completed, evacuate all air from the indeflator.
3. Prior to use, wet the distal 30cm of the delivery catheter with heparinized saline solution to activate the hydrophilic coating.
4. Through a previously inserted, appropriately sized introducer sheath, introduce the distal end of delivery catheter over a pre-positioned guidewire (see specifications) using standard technique.
5. Advancement / Spur Stent Deployment
   a. Under fluoroscopic guidance, advance the delivery catheter to the desired location within the vasculature. The radiopaque marker band of the outer shaft should be approximately 5 mm distal to the target vessel segment.
   b. To begin to deploy the Spur Stent, pin the outer shaft hub and advance the balloon catheter until the distal end of the Spur Stent is released from the outer shaft. The radiopaque Spur Stent markers should be just past the marker band at the distal tip of the outer shaft.
   c. To deploy the rest of the Spur Stent, pin the balloon catheter and pull the outer shaft hub proximally. The outer shaft will stop once the Spur Stent is fully exposed.
   d. Adjustment of the balloon catheter position may be needed to accurately position the Spur Stent in the target site. If repositioning is required after the Spur Stent has already been exposed, recapture the Spur Stent as detailed in #7 prior to repositioning it.
6. Spur Stent Expansion
   a. Slowly inflate the balloon (refer to balloon compliance chart) using the indeflator to fully expand the Spur Stent.
   b. Deflate the balloon until contrast solution is no longer visible under fluoroscopy. The Spur Stent will remain in an expanded state.
   c. The balloon may be reinflated to nominal pressure using the indeflator to fully expand the Spur Stent.
7. Repositioning / Removal (maximum 4 times)
   a. To re-sheath the Spur Stent, pin the balloon catheter and advance the outer shaft while maintaining the catheter in a straight configuration. The distal end of the outer shaft should be advanced until the outer shaft marker band is past the radiopaque Spur Stent markers. The balloon catheter can also be retracted to enable full re-sheathing of the Spur Stent.
   b. If required for longer lesions or geographic miss, reposition the device and repeat steps 5 &6. The recommended device overlap for overlapping inflations is at least 5 mm to avoid geographic miss.
   c. Remove delivery catheter from vasculature while leaving guidewire in place.
8. Remove all equipment from the body and close access site per standard clinical practice.
9. Inspect the device after use. If a device malfunction occurs or any defects are noted on the inspection, flush the guidewire lumen and clean the outer surface of the device with saline, store the device in a sealed biohazard plastic bag, and contact Reflow Medical, Inc. at complaints@reflowmedical.com for further instructions.
10. After use this product may be a potential biohazard. Handle and dispose of in accordance with acceptable medical practices, applicable laws and regulations.

If any portion of the Spur Stent System fails prior to or during a procedure, discontinue use and contact your local representative and/or Reflow Medical, Inc. at complaints@reflowmedical.com.

Caution: Federal law (U.S.) restricts this device to sale by or on the order of a physician.

Patents: This product is covered by U.S. Patent No. No. 10,172,729: 10,258,487; 11,253,379; 11,648,139); EPO 3362006, other pending applications, and foreign patents.

An electronic version of this instructions for use is available at: www.reflowmedical.com.

Warranty: Manufacturer warrants that the Spur Stent System is free from defects in material and workmanship when used by the stated Use By date and when package is unopened and undamaged immediately before use. Manufacturer's liability under this warranty is limited to replacement or refund of the purchase price of any defective Spur Stent System. Damage to the Spur Stent System caused by misuse, alteration, improper storage or handling, or any other failure to follow these Instructions for Use will void this limited warranty. THIS LIMITED WARRANTY IS EXPRESSLY IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING THE IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. No person or entity, including any authorized representative or reseller of the Manufacturer, has the authority to extend or expand this limited warranty and any purported attempt to do so will not be enforceable against the Manufacturer.

Specifications

Model (Ref.)	Sheath Compatibility	Guidewire Compatibility	Catheter Effective Length	Catheter OD	Vessel Diameter (mm)	Spur Stent Length	Spur Stent ID/OD	Spur Stent Percent Surface Area	Spur Stent Foreshortening
BSPUR365135US	MIN 6F (2mm)	.014" (.36 mm)	135cm	.074" (1.88mm / 5.6F)	2.5 to 3.49	65mm	2.7mm / 3.0mm	24%	9%
BSPUR460135US					3..25 to 4.5	60mm	3.7mm / 4.0mm	20%	18%

Compliance Chart

Pressure (Atm)	Nominal Balloon Diameter (mm)	
	3x65	4x60
4	2.95	3.94
6 (NP)	3.00	4.02
8	3.11	4.10
10	3.12	4.14
12 (RBP)	3.20	4.23

Adverse Effects
Vascular catheterization and/or vascular intervention may result in adverse effects including but not limited to those listed in Table 1.

Table 1. Potential Complications Related to Vascular Intervention

Additional intervention	Short term hemodynamic deterioration
Allergic reaction to drugs or contrast medium	Stroke Death
Aneurysm or pseudoaneurysm	Thrombosis
Hemorrhage, including bleeding at the puncture site	Vessel dissection, perforation, rupture, or spasm
Inflammation	Hematoma
Occlusion	Embolization
Pain or tenderness	Pneumothorax or hemothorax
Sepsis/Infection	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.	

Summary of Pivotal IDE Study (NCT05358353)

Primary Objective:
The primary objective of the DEEPER REVEAL IDE study was to compare the safety and efficacy of the Spur 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).

Study Design:
The DEEPER REVEAL clinical study is a prospective, multicenter, single arm study designed to evaluate the safety and efficacy of the Spur Stent System. The study enrolled 130 qualified subjects greater than 18 years of age with infrapopliteal critical limb ischemia, with clinical symptoms of Rutherford class 4-5 which were not amenable to conservative medical treatment in the opinion of the investigator. Other major eligibility criteria included de novo or restenotic lesions less than or equal to 210 mm in length in the infrapopliteal arteries, able to be crossed by a guidewire in the true lumen, with reconstitution at or above the level of the ankle, and a reference vessel diameter between 2.5 to 4.5 mm. One limb with one contiguous vessel segment was permitted to be enrolled per subject, with retrograde crossing permitted; however, deployment of the study device was required to be of an antegrade fashion after successful predilatation. Dual antiplatelet therapy was recommended through one month.

The primary efficacy endpoint hypothesis was that technical success (defined as <30% residual stenosis in subjects treated with the Spur Stent System) met a performance goal (PG) of 87.6% based on historical technical success rates with percutaneous transluminal balloon angioplasty (PTA) for below-the-knee infrapopliteal artery disease.

The primary safety endpoint hypothesis was that the primary safety endpoint of freedom from composite of MALE and POD at 30 days in subjects treated with the Spur Stent System met a PG of 87.6% based on historical outcomes with PTA for below-the-knee infrapopliteal artery disease.

The following data summarizes the results of the DEEPER REVEAL study through one month. Unless otherwise noted, the data reported in this IFU are in the full analysis set (FAS) population, defined as all subjects enrolled in the study and treated with the study device.

Demographics, Medical History, and Lesion Characteristics:

Table 2 and Table 3 describe baseline demographics and medical history, and lesion characteristics, respectively. The mean age was 69.7 years old, with 26.9% females. The average lesion length was 96.38 mm, with approximately 78% of lesions reported as calcified, majority TASC B or C (52.4%). 142 lesions were reported in 130 subjects.

Table 2. Baseline Demographics and Medical History

	Statistic	Overall (N=130)
Age	Mean ± (StdDev)	69.7 ± (10.9)
	Median (Q1,Q3)	69.5 (62.0, 78.0)
	Min, Max	36.0, 93.0
	Mean ± (StdDev)	69.7 ± (10.9)
Sex		
Male	% (n/N)	73.1% (95/130)
Female	% (n/N)	26.9% (35/130)
Race		
American Indian or Alaska Native	% (n/N)	0.0% (0/130)
Asian	% (n/N)	0.8% (1/130)
Black or African American	% (n/N)	16.2% (21/130)
Native Hawaiian or Other Pacific Islander	% (n/N)	0.0% (0/130)
White	% (n/N)	78.5% (102/130)
Other	% (n/N)	4.6% (6/130)
Ethnicity		
Hispanic or Latino	% (n/N)	23.8% (31/130)
Not Hispanic or Latino	% (n/N)	74.6% (97/130)
Not Reported	% (n/N)	0.8% (1/130)
Unknown	% (n/N)	0.8% (1/130)
History of Myocardial Infarction	% (n/N)	16.9% (22/130)
History of Coronary Artery Disease	% (n/N)	47.7% (62/130)
History of Congestive Heart Failure	% (n/N)	18.5% (24/130)
History of Cerebrovascular Disease	% (n/N)	16.2% (21/130)
History of Diabetes Mellitus	% (n/N)	74.6% (97/130)
Type I	% (n/N)	3.1% (3/97)
Type II	% (n/N)	96.9% (94/97)
History of Chronic Kidney Disease	% (n/N)	14.6% (19/130)
History of Hypertension	% (n/N)	92.3% (120/130)
History of Hyperlipidemia	% (n/N)	83.1% (108/130)
History of Tobacco Use	% (n/N)	52.3% (68/130)
Current Osteomyelitis of the target foot	% (n/N)	7.7% (10/130)
Previous Amputation of Index Limb or Toes	% (n/N)	22.3% (29/130)
Planned Amputation of Index Limb or Toes	% (n/N)	4.6% (6/130)

Table 3. Summary of site-reported lesion characteristics

	Statistic	Overall (Number of Patients N=130, Number of Lesions m =142)
Target Vessel		
Anterior Tibial	% (n/N)	33.1% (47/142)
Posterior Tibial	% (n/N)	17.6% (25/142)
Peroneal	% (n/N)	19.0% (27/142)
TP Trunk	% (n/N)	4.2% (6/142)
Tibial Trunk/Peroneal	% (n/N)	19.0% (27/142)
Tibial Trunk/Posterior tibial	% (n/N)	7.0% (10/142)
Location Start		
Proximal	% (n/N)	55.6% (79/142)
Mid	% (n/N)	21.8% (31/142)
Distal	% (n/N)	22.5% (32/142)
Total Lesion Length (mm)	Mean ± (StdDev)	96.38 ± (59.25)
	Median (Q1,Q3)	80.00 (50.00, 150.00)
	Min, Max	10.00, 210.00
Spur-treated Length	Mean ± (StdDev)	110.40 ± (51.49)
	Median (Q1,Q3)	87.50 (70.00, 150.00)
	Min, Max	15.00, 230.00
RVD (mm)	Mean ± (StdDev)	3.10 ± (0.42)
	Median (Q1,Q3)	3.00 (3.00, 3.20)
	Min, Max	2.50, 4.50
Calcification	% (n/N)	78.2% (111/142)
Calcification severity score		
1	% (n/N)	21.6% (24/111)
2	% (n/N)	25.2% (28/111)
3	% (n/N)	35.1% (39/111)
4	% (n/N)	18.0% (20/111)
TASC Classification*		
A	% (n/N)	32.6% (46/141)
B	% (n/N)	26.2% (37/141)
C	% (n/N)	26.2% (37/141)
D	% (n/N)	14.9% (21/141)
Pre-stenosis		
70-90%	% (n/N)	52.1% (74/142)
91-99%	% (n/N)	21.1% (30/142)
100%	% (n/N)	26.8% (38/142)
Spur stent size		
3.0 x 65 mm	% (n/N)	81.7% (116/142)
4.0 x 60 mm	% (n/N)	19.0% (27/142)
Postdilation performed	% (n/N)	18.8% (24/128)

*TASC was not reported for one subject

Procedural Characteristics

Procedure characteristics are described in Table 4. The mean procedure duration was approximately 108 minutes. Approximately 50% of subjects had only 1 vessel runoff at the start of the procedure, with approximately 42% having 2 vessel runoff; only about 6% had 3 vessel runoff. The majority of subjects had 1 lesion treated (90.8%), and most subjects were treated with one Spur system, deployed an average of nearly 2 times per lesion.

Table 4 Procedural Characteristics (site-reported)

	Statistic	Overall (N=130)
Procedure Duration (minutes)	Mean ± (StdDev)	108.18 ± (51.91)
	Median (Q1,Q3)	95.50 (73.00, 130.00)
	Min, Max	34.00, 286.00
Number of Runoff Vessels at start of Procedure		
1	% (n/N)	51.5% (67/130)
2	% (n/N)	42.3% (55/130)
3	% (n/N)	6.2% (8/130)
Number of lesions treated		
1 Lesion	% (n/N)	91.5% (119/130)
2 Lesions	% (n/N)	7.7% (10/130)
3 Lesions	% (n/N)	0.8% (1/130)
>3 Lesions	% (n/N)	0.0% (0/130)
Predilatation performed	% (n/N)	100.0% (130/130)
Number of Spur Stent System used during procedure (per subject)		
1	% (n/N)	96.2% (125/130)
2	% (n/N)	3.8% (5/130)
3	% (n/N)	0.0% (0/130)
>3	% (n/N)	0.0% (0/130)
Number of Times Devices were Deployed	Mean ± (StdDev)	1.82 ± (0.91)
	Median (Q1,Q3)	2.00 (1.00, 2.00)
	Min, Max	1.00, 4.00

Study Results

Primary endpoint Analysis:

The primary efficacy endpoint was met, with 99.2% of subjects meeting technical success as described in Table 5. The lower bound interval of the 90% confidence interval was 96.4%, exceeding the performance goal of 87.6%.

Table 5. Primary Efficacy Endpoint Analysis

Endpoint	Statistic	Overall (N = 130)	Performance goal	Lower bound of the 90% exact Binomial confidence interval	P value[1]
Technical success: <30% residual stenosis by visual estimate within the treated lesion area on completion angiography.	% (n/N)	99.2% (129/130)	87.6%	96.4%	<.0001

Bail-out stenting procedure has been classified as a technical failure. If a subject has multiple lesions, technical success must be achieved in all lesions to declare an overall technical success.

Subjects with missing technical success data were excluded from the analysis.

1. Exact Binomial test with a 1-sided alpha of 0.05 was used to compare the observed primary efficacy events proportion with the PG of 87.6%.

One subject failed the technical success endpoint due to bail-out stent.

Technical success was also analyzed by the angiographic core lab. Residual stenosis discrepancies were observed due to the location of the calculated RVD's for each respective core lab. Core Lab 1 residual stenosis was calculated by finding the RVD within a treated segment. Core Lab 2 residual stenosis was calculated by finding the RVD outside of the treated segment.

Secondary Endpoint	Statistic	Core Lab 1	Core Lab 2
Angiographic core lab adjudicated technical success (defined as <30% residual stenosis within the treated lesion area on completion angiography).	% (n/N)	46.6% (54/116)	85.7% (120/140)

116 lesions were analyzable by Core Lab 1.

140 lesions were analyzable by Core Lab 2.

The primary safety endpoint was met with 97% freedom from the occurrence of MALE and POD at 1-month, exceeding the performance goal of 87.6%, with the lower bound confidence interval at 93%, as described in Table 6.

Table 6. Primary Safety Endpoint Analysis

Endpoint	Statistic	Overall (N = 130)	Performance goal	Lower bound of the 90% exact Binomial confidence interval	P value[1]
Freedom from composite of major adverse limb events (MALE) and peri-operative death (POD) at 30 days post procedure	% (n/N)	96.9% (125/129)	87.6%	93.0%	0.0007

Endpoint	Statistic	Overall (N = 130)	Performance goal	Lower bound of the 90% exact Binomial confidence interval	P value[1]

MALE is defined as: Above-the-ankle amputation of the index limb, Major reintervention (new bypass graft, jump/interposition graft revision, or thrombectomy/thrombolysis) of the index limb involving the infrapopliteal arteries
Only subjects with an appropriate 30-day follow-up (>=23 days post-procedure) or who experienced the relevant event by Day 30 were included in the analysis. Follow-up data for one subject is missing after the procedure and was not included in the primary safety analysis.
1. Exact Binomial test with a 1-sided alpha of 0.05 was used to compare the observed primary safety events proportion with the PG of 87.6%.
Three instances of POD within 30 days were reported.

DEEPER REVEAL Secondary Outcomes

Secondary performance endpoints with data available through 1-month are listed in Table 7. 140 lesions were identified by the Core Lab, as angiographic imaging data was unreadable for 2 subjects. Acute procedure success (technical success and the absence of MAEs within 72 hours of the index procedure) was high at 99.2%. Acute lumen gain was a mean of 1.52 mm, and the occurrence of bail-out stent was low, 0.7% (1/140), as adjudicated by the angiographic core lab. Core lab adjudicated technical success of <30% stenosis was 85.7% (120/140 lesions).

Site-reported device and procedure related adverse events (AEs) at procedure and one month show no increase in the occurrence of device-related AEs, with 3.1% occurrence rate at both timepoints. Procedure-related AEs were 7.7% and 10% at pre-procedure and one month, respectively. The majority of AEs were reported as mild in severity for both device and procedure related AEs. Core lab-reported procedural complications are described separately, in Table 10.

Table 7 Secondary performance endpoints through 30-days

Endpoint	Statistic	Overall (N = 130)
Acute procedure success defined as acute technical success and absence of major adverse events (MAE) defined as death, stroke, MI, acute onset of limb ischemia, index bypass graft or treated segment thrombosis, and/or need for urgent/emergent vascular surgery) within 72 hours of the index procedure [evaluated in-hospital] †	% (n/N)	99.2% (129/130)
Acute luminal gain (mm) post treatment by angiographic core lab*	N	140
	Mean ± (StdDev)	*1.52 ± (0.56)*
	Min, Max	*-0.01, 2.74*
The occurrence of bail-out stent and/or implantable dissection repair device.	% (n/N)	0.7% (1/140)
Angiographic core lab adjudicated technical success	% (n/N)	*85.7% (120/140)*

Endpoint	Statistic	Overall (N = 130)
Device related Adverse Event at index procedure (site-reported)	% (n/N)	3.1% (4/130)
Severity		
Mild	% (n/N)	2.3% (3/130)
Moderate	% (n/N)	0.8% (1/130)
Severe	% (n/N)	0.0% (0/130)
Procedure related Adverse Event at index procedure	% (n/N)	7.7% (10/130)
Severity		
Mild	% (n/N)	5.4% (7/130)
Moderate	% (n/N)	2.3% (3/130)
Severe	% (n/N)	0.8% (1/130)
Device related Adverse Event at 1 month	% (n/N)	3.1% (4/130)
Severity		
Mild	% (n/N)	2.3% (3/130)
Moderate	% (n/N)	0.8% (1/130)
Severe	% (n/N)	0.0% (0/130)
Procedure related Adverse Event at 1 month	% (n/N)	10.0% (13/130)
Severity		
Mild	% (n/N)	6.9% (9/130)
Moderate	% (n/N)	2.3% (3/130)
Severe	% (n/N)	1.5% (2/130)

*Lesion-Level Analysis. For the subject with a bailout stent, lumen gain was calculated prior to the stent.
†Site Reported Adverse Events within 72 hours of the Index Procedure were included.

Secondary Endpoints through 30-days:

Table 8 lists additional secondary safety and efficacy endpoints with data available at 30 days through 1 month. Clinically driven target lesion revascularization (CD-TLR) occurred in 2 (1.6%) subjects at 1 month. Approximately 18% of wounds reported at baseline were completely healed; 16% of subjects experienced a new wound. Rutherford class score improved by nearly 40% from baseline to 30 days. There was a slight improvement seen in the ankle brachial and toe brachial index ratio at 30 days, as well as some improvement in quality of life scores.

Table 8. Secondary Safety and Efficacy Endpoints through 30 days

Safety Endpoint	**Statistic**	**Overall**
Freedom from major adverse limb event (MALE) at one month	% (n/N)	99.2% (126/127)
Limb salvage, defined as preservation of the limb above the level of the ankle at one month	% (n/N)	100.0% (127/127)
The occurrence of all-cause mortality at one month	KM (%)	2.3% (3/130)
Occurrence of Clinically-Driven Target Lesion Revascularization at 1 month	% (n/N)	1.6% (2)
Efficacy Endpoint		
Change in wound size, wound healing, and time to wound healing for subjects with Rutherford class 5 at one month:		
30-day Qualitative (Full) Wound Healing[1]	% (n/N)	17.7% (11/62)
30-day Change in Mean Wound Area	Mean ± (StdDev)	-0.06 ± (0.60)
The occurrence of new wounds in the index limb at one month[2]	% (n/N)	12.3% (16/130)
Change in Rutherford class score at 1 month[3]	% (n/N)	38.8% (45/116)
Change in Ankle-Brachial Index and Toe Brachial Index at one month:		
30-day Change in Ankle-Brachial Index	Mean ± (StdDev)	0.17 ± (0.34)
30-day Change in Toe-Brachial Index	Mean ± (StdDev)	0.11 ± (0.29)
Change in VascuQOL-25 and EQ-5D scores at one month:		
30-day Change in VascuQOL-25 score, change from baseline	Mean ± (StdDev)	30.96 ± (33.96)
30-day Change in EQ-5D score, change from baseline	Mean ± (StdDev)	0.09 ± (0.26)

[1] 48 subjects with 62 wounds had wounds evaluable by the core lab both at baseline and at 1 month.

[2] 19 new wounds occurred in 16 subjects at 1 month. 1 new wound was due to a minor amputation.

[3] 116 subjects had Rutherford class score recorded at 1 month

Observed Adverse Events

CEC-adjudicated adverse events at 6 months are summarized in Table 9. One subject may experience multiple events. Events are listed by subject in the primary event category (in bold), and by event in the subcategory. 28 subjects, 21.5% of the treated population, experienced a major event. Some subjects experienced the same event multiple times, and some experienced an event meeting multiple different criteria (for example, occlusions which were treated with CDTLR) which were identified as separate events.

Table 9. CEC Adjudicated and Site-reported Endpoint-related Adverse Events Through 6 Months

Event type (N=130 subjects)	**72 hours**	**30 days**	**90 days**	**180 days**
Death	0 (0.0%)	3 (2.3%)	5 (3.8%)	6 (4.6%)
Loss of primary patency	**1 (0.8%)**	**4 (3.1%)**	**13 (10%)**	**20 (15.38%)**
CDTLR	1 (0.8%)[2]	4[1, 2] (3.1%)	10 (7.7%)[1, 2]	17 (13.1%)[1, 2, 3]
100% total occlusion in the target lesion associated with worsening symptoms	1 (0.8%)	2 (1.5%)	9 (6.9%)[1]	12 (9.2%)[1]
Above the ankle amputation in the presence of totally occluded vessel[4]	0 (0.0%)	0 (0.0%)	0 (0.0%)	1(0.8%)
Major Adverse Limb Event	**0 (0.0%)**	**1 (0.8%)**	5 (3.8%)[1]	**7 (5.4%)**
Above the ankle amputation	0 (0.0%)	0 (0.0%)	1 (.8%)	4 (3.1%)
Major reintervention of the index limb	0 (0.0%)	1 (0.8%)	4 (3.1%)[1]	4 (3.1%)
Index Bypass graft or treated segment thrombosis	**0 (0.0%)**	**0 (0.0%)**	**1 (0.8%)[1]**	**1 (0.8%)[1]**
Surgical bypass around index target lesion	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Thrombolysis or thrombectomy of the target lesion thrombus	0 (0.0%)	0 (0.0%)	1 (0.8%)[1]	1 (0.8%)[1]

One adverse event may be classified under multiple endpoints; table is displayed per subject.

[1]010-009 experienced an event on April 1, 2024, at 31 days, which was adjudicated as treated segment thrombus, but not as MALE, CDTLR, or total occlusion. The event will be sent for re-adjudication at a later date to add the MALE, occlusion, and CDTLR events, and to confirm date to event.

[2]020-001 experienced an event on July 13, 2023, within 72 hours, which was adjudicated as an occlusion, but not a CDTLR. This event will be sent for re-adjudication at a later date to add the CDTLR event.

[3]004-006 experienced a CDTLR event on January 16, 2024 (6 months), which was incorrectly adjudicated for the date of October 23, 2023 (3 months). The event will be sent for re-adjudication at a later date to correct the date, and is included in the 6 month events in this table.

[4]047-003 was adjudicated as having a totally occluded vessel, concurrent with the adverse event for the amputation. Additional subjects with above the ankle amputations had occlusions reported at different timepoints, and thus are included as occluded in the patency data.

Table 10 provides a summary of core lab reported adverse events. Perforations were all Type 1 of 3, the lowest grade (extraluminal crater); perforation after the use of the Spur Stent was 2.1% without bailout stent. Dissection rates post Spur Stent were 6.4% in total, without flow limiting dissections; one bailout stent was used for a Type B dissection. TIMI 0 flow post Spur was demonstrated in 3 subjects and resolved with post-dilation (2.1%). Vasospasm was reported in 6.4% of subjects post Spur Stent. Aneurysm was reported in 1 vessel (.7%) post Spur Stent; the initial aneurysm was visualized post-wire, but it did not reach a resolution until final imaging. Arteriovenous (AV) fistula was reported in 2.9% of subjects post Spur Stent. There were no reports of distal embolization.

Table 10 Core lab reported procedural adverse events

	Angiographic Core lab Procedural Adverse Events: Core Lab 2 (N=140 lesions)					
	Guide wire	**Predilation balloon**	**Spur Stent**	**Cumulative procedural adverse events***	**Post dilation balloon**	**Bailout stent**
Perforation (Type 1)	4/140 (2.9%)	3/140 (2.1%)	3/140 (2.1%)	10/140 (7.1%)	1/30 (3.3%)	0/1 (0.0%)
Dissection	**Guide wire**	**Predilation balloon**	**Spur Stent**	**Cumulative procedural adverse events***	**Post dilation balloon**	**Bailout stent**
A	0/140 (0.0%)	0/140 (0.0%)	0/140 (0.0%)	0/140 (0.0%)	0/30 (0.0%)	0/1 (0.0%)
B	1/140 (0.7%)	13/140 (9.3%)	5/140 (3.6%)	19/140 (13.6%)	0/30 (0.0%)	0/1 (0.0%)
C	1/140 (0.7%)	5/140 (3.6%)	3/140 (2.1%)	9/140 (6.4%)	0/30 (0.0%)	0/1 (0.0%)
D	2/140 (1.4%)	5/140 (3.6%)	1/140 (0.7%)	8/140 (5.7%)	0/30 (0.0%)	0/1 (0.0%)
Total	4/140 (2.9%)	23/140 (16.4%)	9/140 (6.4%)	36/140 (25.7%)	0/30 (0.0%)	0/1 (0/0%)
TIMI 0 (no flow)	12/140 (8.6%)	1/140 (0.7%)	3/140 (2.1%)	16/140 (11.4%)	0/27 (0.0%)	0/1 (0.0%)
Vasospasm	1/140 (0.7%)	4/140 (2.9%)	9/140 (6.4%)	14/140 (10.0%)	0/30 (0.00%)	0/1 (0.00%)
Aneurysm	1/140[6] (0.7%)	1/140[6] (0.7%)	1/140 (0.7%)	3/140 (2.1%)	0/30 (0.0%)	0/1 (0.0%)

Arteriovenous Fistula	2/140 (1.4%)	3/140 (2.1%)	4/140 (2.9%)	9/140 (6.4%)	0/30 (0.00%)	0/1 (0.00%)
Distal Embolization	0/140 (0.00%)	0/140 (0.00%)	0/140 (0.00%)	0/140 (0.0%)	0/29 (0.00%)	0/1 (0.00%)

[4] Cumulative occurring prior to Post dilation/Bailout, or Procedure End. One bailout stent was placed for a Type B dissection.

1. For each complication, the N is for a new complication (indicating relationship to the device).
2. N is displayed as 140 for complications related to wire, predilatation, and Spur Stent, to display the rate of complication per device for all subjects/lesions in whom these devices were used. N is displayed only for available images/lesions for post-post dilatation and post-bailout, as only a small group of subjects/lesions received these treatments.
3. Total percentage is based on events/ 140

Site reported Serious Adverse Events (SAEs)

Table 11 provides a list of MEDRA-coded site-reported SAEs at 30 days.

Table 11 MEDRA-coded site-reported SAEs at 30 days

SOC PT	Statistic	Overall (N=130)
Any Serious Adverse Event	% (n/N)	23.1% (30/130)
Blood and lymphatic system disorders	% (n/N)	0.8% (1/130)
Anaemia	% (n/N)	0.8% (1/130)
Cardiac disorders	% (n/N)	5.4% (7/130)
Cardiac arrest	% (n/N)	1.5% (2/130)
Acute myocardial infarction	% (n/N)	0.8% (1/130)
Atrial fibrillation	% (n/N)	0.8% (1/130)
Cardiac failure acute	% (n/N)	0.8% (1/130)
Cardiac failure congestive	% (n/N)	0.8% (1/130)
Peripheral swelling	% (n/N)	0.8% (1/130)
Ventricular tachycardia	% (n/N)	0.8% (1/130)
Endocrine disorders	% (n/N)	0.8% (1/130)
Hyperglycaemia	% (n/N)	0.8% (1/130)
Gastrointestinal disorders	% (n/N)	0.8% (1/130)
Nausea	% (n/N)	0.8% (1/130)
Infections and infestations	% (n/N)	3.8% (5/130)
Gangrene	% (n/N)	1.5% (2/130)
Osteomyelitis	% (n/N)	1.5% (2/130)
Sepsis	% (n/N)	0.8% (1/130)
Injury, poisoning and procedural complications	% (n/N)	1.5% (2/130)
Fall	% (n/N)	0.8% (1/130)
Skin laceration	% (n/N)	0.8% (1/130)
Musculoskeletal and connective tissue disorders	% (n/N)	1.5% (2/130)
Lumbar spinal stenosis	% (n/N)	0.8% (1/130)
Pain in extremity	% (n/N)	0.8% (1/130)
Nervous system disorders	% (n/N)	0.8% (1/130)
Encephalopathy	% (n/N)	0.8% (1/130)
Respiratory, thoracic and mediastinal disorders	% (n/N)	1.5% (2/130)
Respiratory, thoracic and mediastinal disorders (cont)		
Bronchitis	% (n/N)	0.8% (1/130)
Hypoxia	% (n/N)	0.8% (1/130)
Skin and subcutaneous tissue disorders	% (n/N)	0.8% (1/130)
Gangrene	% (n/N)	0.8% (1/130)
Surgical and medical procedures	% (n/N)	3.1% (4/130)
Foot amputation	% (n/N)	1.5% (2/130)
Toe amputation	% (n/N)	1.5% (2/130)
Peripheral revascularisation	% (n/N)	0.8% (1/130)
Vascular disorders	% (n/N)	9.2% (12/130)
Peripheral artery occlusion	% (n/N)	3.1% (4/130)
Arterial occlusive disease	% (n/N)	1.5% (2/130)
Artery dissection	% (n/N)	0.8% (1/130)
Carotid artery stenosis	% (n/N)	0.8% (1/130)
Epistaxis	% (n/N)	0.8% (1/130)
Extremity necrosis	% (n/N)	0.8% (1/130)
Hypertensive crisis	% (n/N)	0.8% (1/130)
Peripheral arterial occlusive disease	% (n/N)	0.8% (1/130)
Peripheral ischaemia	% (n/N)	0.8% (1/130)

SOC = System organ class PT = Preferred term

Symbols:

	Batch code		Do not re-sterilize
	Catalogue number		Do not re-use
	Use by date		Do not use if package is damaged and consult instructions for use
	Manufacturer		Keep dry
	Consult instructions for use		Keep away from sunlight
Rx	Prescription Use Only		Medical device
	Non-pyrogenic		Rated burst pressure
	Sterilized using ethylene oxide gas		

Reflow Medical, Inc.
208 Avenida Fabricante, Suite 100
San Clemente, CA 92672
USA