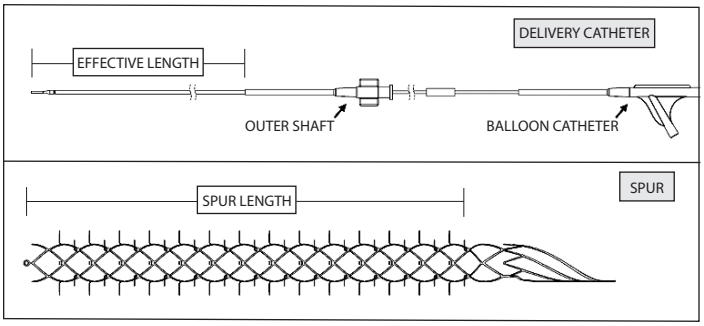
REFLOW MEDICAL

REFLOW MEDICAL BARE TEMPORARY SPUR™ STENT SYSTEM

Instructions for Use (IFU)

Device Description

The Bare Temporary Spur™ Stent System (Spur System) is an over-the-wire percutaneous catheter with a 135cm working length and is compatible with 0.014" guidewires. The Spur System consists of a self-expanding nitinol stent that is attached to a balloon catheter shaft and collapsed on the balloon within a 5.6Fr outer shaft. 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, deflated, then re-captured into the outer shaft for removal from the vasculature.



Indications for Use

The Bare Temporary Spur Stent System is indicated for treatment of de novo or restenotic infrapopliteal lesions, with reference vessel diameters ranging from 2.5 – 4.5mm, prior to treatment with a commercially available drug coated balloon.

Intended Use

The Bare Temporary Spur Stent System is intended to treat de novo or restenotic lesions in the infrapopliteal arteries to prepare the vessel for treatment with a commercially available drug coated balloon to enhance drug absorption.

Target Population

The Bare Temporary Spur Stent System is intended to treat patients ≥ 18 years of age, with symptomatic infrapopliteal disease.

Contraindications

The Bare Temporary 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.
- 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.
- Ensure the Bare Temporary 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 Bare Temporary 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.

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.

Expected Clinical Benefit

The clinical benefits of the Bare Temporary Spur Stent System when used as intended for treatment of infrapopliteal arteries prior to drug coated balloon treatment, include: 1) Reduction in clinically driven target lesion revascularization through 12 months post-procedure, 2) improvement in vessel patency through 1 year and 3) Improvement in Rutherford class score from baseline through 6 months, 4) improvement in WIfI risk score, and 5) improvement in hemodynamic measurements of ankle brachial index and/or toe brachial index (ABI and TBI). The Bare Temporary Spur Stent System may also reduce vessel recoil.

The prospective, single-arm multicenter clinical study (DEEPER OUS) of the Bare Spur Stent System was conducted to evaluate the safety and efficacy of the device to treat infrapopliteal lesions prior to treatment with a drug coated balloon (DCB). Between July 11, 2019, and April 28, 2022 a total of 107 patients were enrolled into the DEEPER OUS study at 10 sites in Europe (Germany, Switzerland) and New Zealand.

The mean age with the standard deviation of the 107 subjects in the ITT group was 76±8.8 years, ranging between 49 and 98 years; the majority of subjects were male (77.6%) and white (98.1%). The mean Spur treated length was 92.7±36.63 mm with a range of 60 – 240 mm. The mean DCB-treated length was 103.6±27.9 mm with a range of 60 – 150 mm. The Spur 3x60 mm device was used in the majority of cases (82.8%) while the median DCB diameter used was 3 mm (range 2 – 4 mm).

The primary safety endpoint for the DEEPER OUS study was freedom from device and procedure related death through 30 days post procedure. Secondary safety endpoints were 1) Freedom from target limb major adverse limb event (MALE) & all-cause perioperative death (POD) at 30 days; and 2) Freedom from major amputation of the target limb at 12 months. All adverse events were adjudicated by an independent Clinical Events Committee (CEC). Primary and secondary safety endpoints were met, see Table 1.

Table 1: Primary and Secondary Safety Endpoint Results

Visit	Endpoint	Result (N=107)
30 days	Freedom from device and procedure-related death	102/102 (100.0%)
	Freedom from MALE[1]	102/102 (100.0%)
	Freedom from all cause POD	102/102 (100.0%)
12 months	Freedom from MALE	92/93 (98.9%)2

[1]Note: MALE is defined as Major (above the knee) Amputation

[2] At 12 months, one subject had undergone a major amputation of target limb, resulting in a freedom from MALE rate of 98.9%

The primary efficacy endpoint for the DEEPER OUS study was primary patency of the treated lesion by duplex ultrasound (DUS) in subjects that were free from clinically driven TLR at 6 months post-procedure. Secondary effectiveness endpoints were 1) Freedom from clinically driven TLR through 6 months post-procedure; 2) Improvement in Rutherford class score at 3, 6, and 12 months; and 3) Wound healing score for subjects with Rutherford class 5 and 6 at 12 months, as assessed by the investigator using the Wound, Ischemia, foot Infection (WIfI) score. The Primary Effectiveness endpoint met the performance goal, results are presented in Table 2.

Table 2: Primary Efficacy Endpoint (Primary Patency)

Visit	Primary Patency*
6 months	72/84 (85.7%)
12 months	61/82 (74.4%)

**Patency analysis performed on subjects with evaluable data (either a diagnostic duplex ultrasound per the core lab, or a CD-TLR)*

Secondary efficacy endpoint results for the MITT populations for freedom from CD-TLR and Rutherford category changed from baseline are shown in Table 3 and Table 4, respectively.

Table 3: Secondary Efficacy Endpoint Analysis (CD-TLR)

Visit	Cumulative Freedom From CD-TLR*
6 months	88/95 (92.6%)
12 months	85/95 (89.5%)

**CD-TLR analysis performed on subjects with available data at the 6- or 12-month visit*

Table 4: Secondary Efficacy Endpoint Analysis (Rutherford Score)

Variable	Statistics	Baseline	6 months	12 months
	N (number of patients)	107	90	91
Rutherford [Scale (1-6)]	Mean Rutherford Score	4.5	2.1	1.9
	P Value when compared to baseline	NA	<.0001	<.0001

**Rutherford class analysis performed on subjects with available data at the 6- or 12-month visit*

Additionally, there was a significant improvement for wound and ischemia score at 30-days and 3 months ($p<0.05$) and significant improvement for infection score at 30-days 3 months and 6 months [($p<0.001$) MITT]. ABI and TBI were found to be statistically significantly reduced at 12 months compared to baseline [($p<.001$) MITT].

In the DEEPER OUS Vessel Recoil substudy, conducted on a subset of 38 subjects with 40 lesions, 17/40 lesions (42.5%) had vessel recoil, defined as ≥ 10% decrease in lumen diameter after 15 minutes post treatment with the Bare Temporary Spur Stent System. These results demonstrate that the Bare Temporary Spur Stent System reduces the occurrence of vessel recoil by more than 50%, compared to previously reported rates with balloon angioplasty.

Adverse Events

A summary of the adverse events observed in the DEEPER OUS clinical study as adjudicated by the Clinical Events Committee (CEC) are shown in Table 5.

Table 5: Summary of Procedure Related Adverse Events Identified by the CEC (12 Months) - MITT Population

		CEC	
	Event Type	Patients (%)[1,2]	Events (E/pt)[3]
All Adverse Events		39 (36.45%)	62 (0.58)
Procedure Related		27 (25.23%)	33
	Anemia	1 (0.93%)	1
	Edema	1 (0.93%)	1
	Hematoma	1 (0.93%)	1
	Peripheral arterial reocclusion	2 (1.87%)	2
	Peripheral artery dissection	11 (10.28%)	11
	Peripheral artery recoil	1 (0.93%)	1
	Pseudoaneurysm	1 (0.93%)	1
	Radiocontrast nephropathy	1 (0.93%)	1
	Vascular access site pseudoaneurysm	1 (0.93%)	1
	Vasospasm	12 (11.21%)	12
	Vessel perforation	1 (0.93%)	1
[1]Note: Denominator of percentage (%) is the number of treated patients.			
[2]Patient can have more than one procedure related event.			
[3]Event Per Patient.			

The following events are potential adverse effects associated with standard catheter-based peripheral interventions which were not observed in the DEEPER OUS clinical study:

- Occlusion
- Sepsis/Infection
- Additional intervention
- Short term hemodynamic deterioration
- Stroke
- Death
- Heart attack
- Vessel rupture
- Hemorrhage
- Pain or tenderness
- Embolization
- Arrhythmia
- Shock

How Supplied

- The Bare Temporary 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 Bare Temporary 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.

Required Devices for the Bare Spur Stent Procedure

Contents: Bare Spur Stent System (1)

Devices Required but Not Supplied By Reflow Medical, Inc.

- 0.014" (0.36mm) Guidewire
- Introducer Sheath (minimum 6F (2mm))
- Predilatation PTA catheter
- Indeflator
- Commercially available drug coated balloon
- Heparinized Saline
- Contrast
- Luer lock syringe

Specifications

Model	Catheter Effective Length	Catheter OD	Spur Length	Spur ID/OD	Stent Percent Surface Area	Stent Foreshortening
BSPUR365CE	135cm	.074" (1.88mm / 5.6F)	65mm	2.7mm / 3.0mm	24%	9%
BSPUR460CE			60mm	3.7mm / 4.0mm	20%	18%
BSPUR365150CE	150cm		65mm	2.7mm / 3.0mm	24%	9%
BSPUR460150CE			60mm	3.7mm / 4.0mm	20%	18%

Compliance Chart

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

Procedural Steps

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

1. Predilation of the target lesion with a PTA catheter is required prior to treatment with the Spur to ensure successful delivery of the device.
2. Spur System Preparation for Use
   a. Select a Spur System size 1:1 based on the reference vessel diameter.
   b. Using sterile technique, remove the Spur 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.
   d. Remove the stylet from the tip of the device.
   e. Fill a sterile standard luer-lock syringe with sterile heparinized saline and flush the central lumen.
   f. 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 in deflator 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.
7. Repositioning / Removal (maximum 4 times)
   a. To re-sheath the Spur, 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 markers. The Balloon Catheter may need to be retracted slightly to enable full re-sheathing of the Spur.
   b. If required for longer lesions or geographic miss, reposition the device and repeat steps 3 & 4. The recommended balloon 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. Treat the Spur-treated segment with a commercially available drug coated balloon.
9. Remove all equipment from the body and close access site per standard clinical practice.
10. 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 (+1) 949-481-0399 for further instructions.
11. After use this product may be a potential biohazard. Handle and dispose of in accordance with acceptable medical practices applicable laws and regulation.

Patient Information

Physicians should instruct patients to seek medical attention immediately for signs and symptoms of bleeding, pain in the treated leg or the groin site, loss of sensation, or cold extremities, chest pain, shortness of breath, nausea, vomiting, signs or symptoms of a stroke, and signs or symptoms of infection. Patients should be instructed to comply with the medication regimen as prescribed by their physician.

Device Feedback and Return of Devices

If any portion of the Bare Spur Stent System fails prior to or during a procedure, discontinue use and contact your local representative and/or Reflow Medical, Inc. (001) 949-481-0399 or www.reflowmedical.com).

For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation 2017/745/EU on Medical Devices): if, during the use of this devices or as a result of its use, a serious incident has occurred, this must be reported to the EU member state.

Warranty: Manufacturer warrants that the Spur Temporary 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 Temporary Stent System. Damage to the Spur Temporary 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.

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

Basic UDI-DI:
850025525BSPUR

Electronic IFU: www.reflowmedical.com

Symbols:

Standard Symbol Legend					
LOT	Batch Code		Contains 1 unit (Contents:1)		Manufacturer
	Do not reuse	REF	Catalogue Number		Keep dry
UDI	Indicates a carrier that contains Unique Device Identifier information		Do not resterilize		Importer
	Date of Manufacture		Non-pyrogenic	MD	Medical Device
EC REP	Authorized representative in the European Community		Consult instructions for use		Keep away from sunlight
	Distributor	CE	Conformité Européenne		Single sterile barrier system
RBP	Rated burst pressure		Do not use if package is damaged		
	Use By Date	STERILE EO	Single sterile barrier system with protective packaging outside. Sterilized using Ethylene oxide.		

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