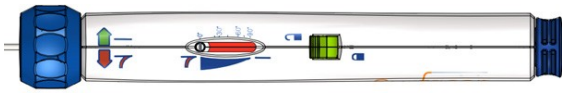
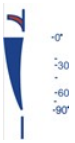
Bluegrass Vascular Technologies, Inc.
Surfacer® Inside-Out® Access Catheter System
INSTRUCTIONS FOR USE

℞ only

SURFACER DEVICE HANDLE

The table below defines symbols and wording on the Surfacer Device Handle.



Symbol	Image	Function
"Out" Arrow		Indicates direction to turn the Needle Guide Knob to deploy the Needle Guide. The "Out" arrow is colored red. The operator should exercise caution.
"In" Arrow		Indicates direction to turn the Needle Guide Knob to retract the Needle Guide. The "In" arrow is colored green. The Needle Guide must be fully retracted before the Delivery Instrument is removed from the patient.
Angle Indicator		The angle indicators (0, 30, 60, and 90) indicate the cranial angle in degrees (°) of the Needle Guide deployment. Angles are indicated down the right side. The left side provides a visual indicator of the corresponding Needle Guide deployment angulation.
"Unlock"		"Unlock" indicates the status of the Needle Wire. The Needle Wire must be unlocked to deploy the Needle Wire.
"Lock"		"Lock" indicates the status of the Needle Wire. The Needle Wire must be locked to pull in the Exit Introducer into the body.
Needle Guide Deployment Indicator (Inset)		As the Needle Guide is deployed the inset increasingly turns red. Red indicates that the Needle Guide is deployed and that the operator should exercise caution.

I. DEVICE DESCRIPTION

The Surfacer® Inside-Out® Access Catheter System (Surfacer® System) is designed to facilitate entry and placement of central venous access catheters and/or other devices including but not limited to: central lines, nutritional catheters, central venous outflow access devices, within the peripheral vasculature. The Surfacer® System is comprised of four components: a Workstation (Workstation Sheath) for percutaneous access to the femoral vein; a Delivery Instrument (Surfacer Device) which contains a Needle Wire and Needle Guide which is advanced to the supraclavicular space; an Exit Target which provides fluoroscopic guidance to mark the exit point; and an Exit (Peelable) Introducer which is introduced over the Needle Wire to access the central venous system. The Surfacer® System facilitates the entry and positioning of standard access catheters by establishing a transient passage across venous occlusions. Once the access is obtained, all Surfacer® components are removed.

II. CONTENTS

The Surfacer® System is comprised of the following components:

1) One (1) Workstation (Workstation Sheath)
2) One (1) Delivery Instrument (Surfacer Device) - (Sheath, Needle Guide, Needle Wire, and a Handle)
3) Two (2) Exit Targets
4) One (1) Exit (Peelable) Introducer

The Surfacer® System, once in place, facilitates stable upper body central venous access that is suitable for any conventional catheter.

III. INDICATIONS FOR USE

The Surfacer® Inside-Out® Access Catheter System is intended to obtain central venous access to facilitate catheter insertion into the central venous system for patients with upper body venous occlusions or other conditions that preclude central venous access by conventional methods.

IV. CONTRAINDICATIONS

The Surfacer® System is contraindicated for patients with an occlusion of the right femoral vein, right iliac vein or inferior vena cava, or acute thrombosis within any vessel to be crossed by the Surfacer® System. Special precautions may be required for patients with coagulation disorders or on anti-coagulation therapy.

The Surfacer® System is not intended for use in the coronary or cerebral vasculature.

This device is not to be used in the arterial system.

V. WARNINGS

1. Only physicians who have received appropriate training and are familiar with the principles, clinical applications, complications, side effects and hazards commonly associated with interventional procedures should use this device.
2. Appropriate institutional practices for prevention of infection during percutaneous procedures should be practiced.
3. This device should be used only in institutions where emergency surgery can be performed and where blood transfusions can be performed.
4. Patients with severe anatomical tortuosity (e.g. patients with scoliosis, lordosis) should be imaged before use, and if detected, do not use.
5. Once the patient is positioned flat on the table in a supine position, do not reposition or elevate the torso or head while the Surfacer System is in the body.
6. In the cases of Type III and Type IV lesions, the operator should be prepared for immediate treatment of emergencies such as venous tears, pericardial tamponade, and hemothorax, with appropriate equipment readily available.
7. The Workstation Sheath must be inserted to a stable position in the peripheral venous system.
8. The Surfacer Device should only be inserted through the recommended Workstation Sheath to avoid damage to the patient or to the device during its use.
9. The Needle Guide must be retracted (withdrawn into the Surfacer Device) before the device can be removed from the patient.
10. Orientation of the Needle Guide should be confirmed (under fluoroscopy) before it is advanced to avoid complications including vascular damage, or other serious injury to the patient (refer to section VI. Risks).
11. Peelable Introducer is not a hemostasis valve and is not intended to create a complete two-way seal. It is designed to reduce air intake and blood loss.
12. Angioplasty balloons should not be used to dilate new venous access tracts obtained with the Surfacer System.

There are uncommon but potentially serious complications of combined blunt and sharp recanalization through extra-anatomic spaces in the mediastinum and supraclavicular region.

- When making treatment recommendations, and as part of the informed consent process, consider that serious complications may include bleeding from perforation of the right atrium and superior vena cava, and damage to the subclavian artery and its branches. These can potentially lead to cardiac tamponade, hemothorax, or life- threatening bleeding.
- In discussing treatment options, physicians should discuss the risks and benefits of all available central venous access options and explore their patients' expectations, concerns, and treatment preferences.

VI. RISKS

Risks associated with using the Surfacer® System include risks associated with routine interventional procedures and risks associated with the underlying patient condition.

The potential risks include, but are not limited to:

- Pain
- Infection
- Bleeding
- Adverse tissue reaction; allergic reaction
- Cardiovascular sequelae including: perforation of the right atrium, superior vena cava, subclavian artery or arterial branches, cardiac tamponade, hemothorax, spasm or effusion
- Lymphatic system sequelae
- Pulmonary sequelae including: pneumothorax, pulmonary embolism
- Vascular sequelae including vasospasm, vessel perforation, dissection, or aneurysm
- Unintended embolization or thrombosis
- Arrhythmias
- Neurologic sequelae including stroke; transient ischemic attack; nerve injury
- Arteriovenous Fistula
- Death
- Surfacer® System component failure or malfunction

VII. PRECAUTIONS

General – Precautions

The Surfacer® System should only be used by physicians experienced with interventional procedures. Prior to use, operators must review the Instructions for Use and be familiar with techniques associated with the use of the device.

Surfacer® System Handling – Precautions

- Store all Surfacer® System components in a location that is cool and dry.
- Inspect package prior to use. Do not use if the peel pouch is damaged or opened or if the contents appear to be damaged.
- **For SINGLE USE ONLY**. Do not re-sterilize or reuse. Re-sterilization or cleaning may damage the device and impair the performance of the Surfacer® System.
- Use the product prior to the "Use By" date.
- Use sterile techniques at all times when handling the Surfacer® System.

Use in Specific Patient Populations – Precautions

Do not use the Surfacer® System in patients for whom this procedure is contraindicated. Certain conditions may require special consideration when using this product. These may be, but are not limited to hemodynamic instability, hyponatremia, hypotension.

Post-Procedure – Precautions

Employ proper access site management per institutional protocol post-procedure and post hospital discharge to maintain patency and prevent infection.

Potential Complications

Perforation of the right atrium, pericardial tamponade, hemothorax, tears of the superior vena cava, lacerations of the main subclavian artery and its branches, and hematoma are known complications that may occur during or after use of the device.

VIII. BASELINE PARAMETERS

Perform baseline venography or optional venous duplex of the upper body veins (superior vena cava (SVC), jugular, inferior vena cava (IVC), brachiocephalic and subclavian).

Perform baseline anterior posterior (AP) and lateral chest x-ray with contrast or cine fluoroscopy with contrast to define the pattern of occlusions and to rule out acute thrombus.

Perform CT venography or MR venography.

Evaluate pre-procedural screening diagnostics and confirm supraclavicular exit location.

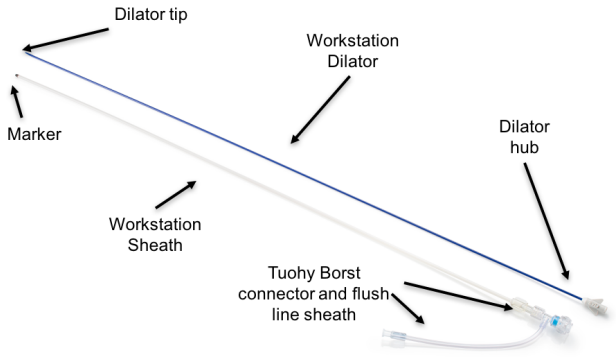
Use of color doppler ultrasound can aid in evaluating the supraclavicular space for intervening arteries prior to and after advancement of the sharp needle wire through the soft tissues of the supraclavicular space and neck.

IX. COMPONENTS

The specific components of the Surfacer® System are described as follows:

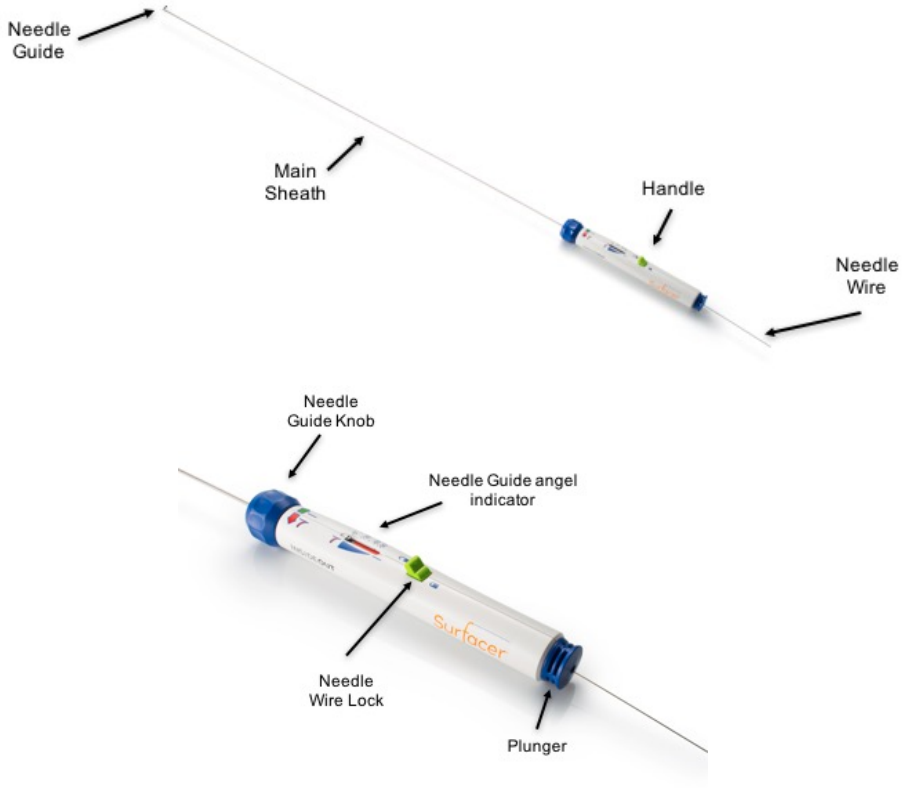
1. **Workstation Sheath -** the Workstation Sheath provides access to the peripheral venous system via the right femoral vein. The length of the Workstation Sheath is 65 cm, with an ID of 7.3 Fr and OD of 10.4 Fr. The Workstation Sheath provides a lumen for the Surfacer Device, preventing injury when it is advanced (**See Figure 1**). Users have reported double sheathing or using reinforced introducer sheaths when necessary. For example, users have reported using shorter, large bore (12 Fr, 45 cm long) braided or reinforced introducer sheaths to get past the iliac-inferior vena cava angulation, and then passing the Workstation sheath through this introducer sheath and advancing it to the site of the central venous occlusion.

Figure 1: Surfacer® Workstation Sheath



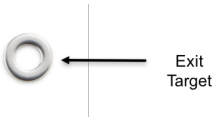
2. **Surfacer Device -** the Surfacer Device consists of a Main Sheath, Needle Guide, Needle Wire, and a Handle. **See Figure 2**.
The Main Sheath is 7F and has a 95 cm effective length. The Main Sheath provides access to the peripheral venous system via the right femoral vein. The Main Sheath has a lumen for the Needle Guide.
Needle Guide - The Needle Guide is 3F and extends 10 mm from the main sheath. The Needle Guide provides access to the peripheral venous system via the right femoral vein. It has a lumen for the Needle Wire. The Needle Guide passes though the Main Sheath.
Needle Wire - The Needle Wire is 2F and 180 cm long. The Needle Wire is advanced through the Needle Guide to the percutaneous exit location at the supraclavicular space.
Handle - The Handle incorporates a rotating Needle Guide Knob to move the Needle Guide in and out. A gauge indicates the position of the Needle Guide in degrees in the cranial direction. A switch actuates a clamp in the Handle to grip the Needle Wire when it is in the "LOCK" position and allows the Needle Wire to move in or out when in the "UNLOCK" position. The plunger at the proximal end of the Handle advances the wire as it is pushed in and slides over the Needle Wire as it pulled out. The exit for the Needle Guide at the distal end of the Surfacer Device is aligned with the top of the Handle.

Figure 2: Surfacer® Device



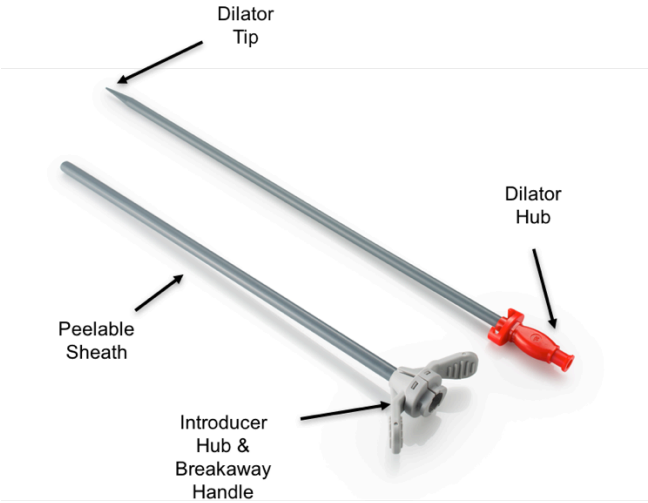
3. **Exit Target**
The Exit Target is a radiopaque marker used to locate the desired Needle Wire exit location (the supraclavicular space) using fluoroscopic imaging. **See Figure 3**.

Figure 3: Surfacer® Exit Target



4. **Peelable Introducer**
The Peelable Introducer provides percutaneous access to the venous system and permits insertion of the CVA catheter. The Peelable Introducer has a peelable sheath, valve and dilator. The Peelable Introducer has an 18 F OD, 16 F ID and is 20 cm long. **See Figure 4**.

Figure 4: Surfacer® Peelable Introducer



X. CLINICAL DATA

Summary of Clinical Information

The primary clinical data provided to support the De Novo request was the United States SAVE-US IDE Study. Additional clinical data was provided from the International Post Market SAVE Registry. Details of the design of these studies and selected clinical results are provided below.

United States SAVE-US IDE Study

Purpose: To assess the safety and effectiveness of the Surfacer Inside-Out Access Catheter System used to facilitate upper body central venous access.

Design: The SAVE-US Study was a prospective, single-arm, multi-center study using the Surfacer Inside-Out Access Catheter System in subjects who require central venous access. A total of thirty (30) subjects at seven (7) centers in the United States were treated. Subjects who required central venous access and met the study inclusion/exclusion criteria were enrolled and treated with the Surfacer Inside-Out Access Catheter System.

An Independent Data Safety and Monitoring Board (DSMB) was created to monitor the study. Proctors representing Bluegrass Vascular Technologies, Inc. were present for 29/30 cases.

Primary Endpoints:

1) Safety: The primary safety endpoint was acute device safety, defined as the absence of procedural complications (hemopericardium, hemothorax, pneumothorax, blood transfusion, resuscitation, emergency post-procedural intervention, transfer to an intensive care unit, and death) at discharge and 7 days post-procedure. Overall device and procedure related anticipated adverse events were compared to historical safety data from central vein placement procedures.

2) Effectiveness: The primary effectiveness endpoint was the rate of safe insertion and patency of central venous catheters (CVCs) created across venous occlusions.

Secondary Endpoints: Secondary endpoints consisted of the following:

1) Safety: The rate of conversion to alternative central vein placement techniques.

2) Effectiveness: Surfacer System clinical utility assessed by the ability of the Surfacer System to facilitate central venous access placement.

Eligibility Criteria Summary: The study population consisted of male and female subjects, between 18 - 80 years of age.

Key inclusion criteria included the following:

- Subjects have been referred for placement of central venous access catheter.
- Subjects have limited or diminishing upper body venous access or pathology impeding standard access methods.

Key exclusion criteria included the following:

- Subjects were contraindicated for Surfacer System use if one of the following are found (per the IFU):
  - Occlusion of the right femoral vein;
  - Occlusion of the iliac vein;
  - Occlusion of the inferior vena cava.
- Subject with acute thrombosis within any vessel (Superior Vena Cava (SVC), jugular, inferior vena cava (IVC), brachiocephalic and subclavian) planned to be crossed by Surfacer System.
- Subjects with tortuous anatomy which precludes a straight line from femoral venous entry to subclavian exit.

Accountability: Subjects were exited from the study upon completing the final protocol required 7-day follow-up visit. In three cases, subjects prematurely exited or withdrew from the study because the subject was determined to be ineligible during procedural imaging, in which anatomical tortuosity or inability of the system to be safely advanced was ascertained.

Patients were followed per the following scheduled assessments:

Table 1: Scheduled Assessments

Assessments/Interval	Screening	Baseline	Intra-Procedural	Hospital Discharge	7 Days (+7) Post Procedure
Informed Consent	X				
Study Eligibility	X				
Medical History/Demographics	X				
Physical Exam including Vital Signs		X		X	X
TCVO Lesion Type Classification		X			
Procedural Complication Assessment			X	X	X
Study Device Performance			X		
Medications (Antithrombotic & Cardiovascular)		X		X	X
Clinical Laboratory Tests					
Pregnancy Test	X				
Creatinine		X			
Coagulation Profile (APTT/PT/INR)		X		X	
CRP		X		X	
LDH/ASAT/ALAT		X		X	
Fibrinogen/D-dimer		X		X	
Exams and Tests					
AP and LAT Chest X-Ray or cine-fluoroscopy		X	X	X	
Ultrasound or Venous Duplex Venography		X			
ECG 12-lead		X			
TTE			Only If Cardiac Events	Only If Cardiac Events	
Contrast Angiography			X		
Fluoroscopy			X		
Cone Beam CT/cardiac echo/advanced imaging modalities			X		
Adverse Events			X	X	X
Protocol Deviations		X	X	X	X

Demographics: The total population consisted of 30 subjects. Demographic information on the subjects is provided in Table 2 below.

Table 2: Subject Demographics

Characteristic	**Enrolled (ITT) (N=30) n, %**	**Treated (PP) (N=27) n, %**
Respiratory diseases	14, 46.7%	12, 44.4%
Asthma	7, 23.3%	7, 25.9%
Chronic obstructive pulmonary disease (COPD)	6, 20.0%	4, 14.8%
Pulmonary hypertension	2, 6.7%	2, 7.4%
Allergy or intolerance to anticoagulation or antiplatelet therapy that cannot be pre-treated.	0, 0.0%	0, 0.0%
Angina	3, 10.0%	3, 11.1%
Bleeding diatheses or coagulopathy	1, 3.3%	1, 3.7%
Carotid Stenosis	4, 13.3%	4, 14.8%
Coronary Artery Disease	11, 36.7%	10, 37.0%
Previous CAD interventional procedures	6, 20.0%	5, 18.5%
Previous Stroke	6, 20.0%	6, 22.2%
Previous Transient Ischemic Attack (TIA)	5, 16.7%	5, 18.5%
Diabetes	14, 46.7%	12, 44.4%
Type 1 Type 2	2, 6.7% 12, 40.0 %	2, 7.4% 10, 37.0%
Controlled by diet	7, 23.3%	6, 22.2%
Controlled by medication	8, 26.7%	7, 25.9%
Dyslipidemia	6, 20.0%	4, 14.8%
Active Endocarditis	0, 0.0%	0, 0.0%
Hypertension	21, 70.0%	18, 66.7%
Hyperlipidemia	15, 50.0%	12, 44.4%
Previous Myocardial Infarction	5, 16.7%	5, 18.5%
Active Pericarditis	0, 0.0%	0, 0.0%
Peripheral Vascular Disease (PVD)	10, 33.3%	9, 33.3%
Chronic Kidney Disease (CKD)	28, 93.3%	25, 92.6%
Dialysis	28, 93.3%	25, 92.6%
Renal Dysfunction	24, 80.0%	22, 81.5%
Smoking status (current or Ex-)	11, 36.7%	10, 37.0%
Pneumothorax	0, 0.0%	0, 0.0%
Hemothorax	1, 3.3%	1, 3.7%
Prior CVA (central venous access)	19, 63.3%	18, 66.7%
Other Relevant Procedures (hysterectomy, ileostomy, colectomy, heart transplant, bilateral mastectomy, kidney transplant, testicular surgery, sympathectomy, renal transplant Hero graft placement).	11, 36.7%	10, 37.0%
Other Relevant History (chronic AF, CHF, Quadriplegia, Lymphoma, Peripheral Neuropathy, Sickle Cell Anemia, Prostate Cancer)	13, 43.3%	12, 44.4%

Adverse Events: The adverse events presented in Table 3 were observed in SAVE-US. A total of ten (10) adverse events (AEs) were reported in seven (7) subjects at five sites. Five (5) adverse events in four subjects were reported as a serious adverse event (SAE).

Table 3: Adverse Event Classification, Severity and Device/Procedure Relatedness

AE Term N=30 pts	AE # Subjects (%*) [#Events]	SAE #Subjects[1] (%*) [#Events]	Device Related # Subjects[1] (%*) [#Events]	Procedure Related AEs # Subjects[1] (%*) [#Events]
Experienced at least one AE	7 (23.3%) [10]	4 (13.3%) [5]	0 (0%) [0]	5 (16.7%) [6]
Bleeding	2 (6.7%) [2]	2 (6.7%) [2]	0 (0%) [0]	2 (6.7%) [2]
Adverse tissue reaction	1 (3.3%) [1]	0 (0%) [0]	0 (0%) [0]	1 (3.3%) [1]
Allergic reaction	1 (3.3%) [1]	0 (0%) [0]	0 (0%) [0]	0 (0%) [0]
Unintended embolization	1 (3.3%) [1]	1 (3.3%) [1]	0 (0%) [0]	1 (3.3%) [1]
Other events	3 (10.0%) [5]	2 (6.7%) [2]	0 (0%) [0]	2 (6.7%) [2]

* Calculated as (n/N) 100%, where n = number of subjects experiencing AE, N = total number of enrolled subjects.
[1] One subject experienced more than one AE/SAE from different category.

Results:

Primary Safety Endpoint: The primary safety endpoint was analyzed in all enrolled subjects based on acute device safety, defined as the absence of procedural complications at discharge and 7 days post procedure. Specifically, procedure-related adverse events were observed in 4/30 subjects (13.3%) through the 7-day follow-up period. The four (4) subjects whom the analysis classified as not having met the primary safety endpoint included: unintended embolization; hemodynamic instability; bleeding; and hypotension and bleeding. No anticipated (ADE) or unanticipated device (UADE) related adverse events were reported. Absence of device-related adverse events in 100% of treated subjects was evaluated and monitored by the DSMB.

Table 4: Primary Safety Outcome ITT

		95% CI[1]	
Characteristic	**%(n/N)**	**Lower Confidence Limit**	**Upper Confidence Limit**
% subjects without serious procedural complications at discharge and 7 days post procedure	86.7% (26/30)	69.3%	96.2%

[1] *Exact Binomial CI*
[2] *where n = number of subjects with serious procedural complication, N = total number of enrolled subjects*

Table 5: Adverse Event Classification for IDE study

Category	Overall Event Rate ITT Population (N= 30) N (%) 95% CI[1]	Overall Event Rate PP Population (N= 27) N (%) 95% CI[1]
Device / Procedure Related		
Hemopericardium	0 (0.0%) 0.0%, 11.6%	0 (0.0%) 0.0%, 12.7%
Blood Transfusion	2 (6.7%) 0.1%, 22.1%	2 (7.4%) 0.1%, 24.3%
Pneumothorax	0 (0.0%) 0.0%, 11.6%	0 (0.0%) 0.0%, 12.7%
Hemothorax	0 (0.0%) 0.0%, 11.6%	0 (0.0%) 0.0%, 12.7%
Resuscitation	0 (0.0%) 0.0%, 11.6%	0 (0.0%) 0.0%, 12.7%
Emergency Post Intervention	0 (0.0%) 0.0%, 11.6%	0 (0.0%) 0.0%, 12.7%
ICU Transfer	0 (0.0%) 0.0%, 11.6%	0 (0.0%) 0.0%, 12.7%
Death	0 (0.0%) 0.0%, 11.6%	0 (0.0%) 0.0%, 12.7%
Bleeding (SAE)	2 (6.7%) 0.1%, 22.1%	2 (7.4%) 0.1%, 24.3%
Unintended embolization or thrombosis (SAE)	1 (3.3%) 0.1%,17.2%	1 (3.7%) 0.1%,19.0%
Other SAE Events: (1) hemodynamic instability requiring prolonged hospitalization and one (1) hypotension	2 (6.7%) 0.1%, 22.1%	2 (7.4%) 0.1%, 24.3%
Composite SAE rate (# Subjects) as described in the study protocol	**4 (13.3%) 3.8%, 30.7%**	**4 (14.8%) 4.2%, 33.7%**

Primary Effectiveness Endpoint: Primary efficacy endpoints were analyzed based on rate of safe insertion and patency created across venous occlusions. In the PP population the analysis of both the primary and secondary efficacy endpoints resulted in a 100% success rate (27/27). In the ITT population, 27/30 subjects (90%) obtained central venous access (CVA) using the Surfacer System with a confidence interval (CI) of 73.5%, 97.9%. Three (3) subjects did not receive access via the Surfacer System due to extreme vessel tortuosity. In these cases, imaging during intra-procedural venography revealed the inability to safely exit due to tortuosity of upper vasculature anterior, posterior, right and left.

Table 6: Primary Efficacy Endpoint: Rate of safe insertion and patency of CVCs created across venous occlusions.

Characteristic	N		
Total # of insertion attempts	30		
		95% CI[1]	
	% (n/N)	Lower Confidence Limit	Upper Confidence Limit
% safe insertion and patency of CVCs created across venous occlusions	90.0% (27/30)	73.5%	97.9%

[1] *Exact Binomial CI*
[2] *where n = number of subjects with safe insertion and patency, N = total number of enrolled subjects.*

Secondary Safety Endpoint: Secondary safety outcome was evaluated as technique conversion rate and is presented in Table 7 below. Distorted anatomy was reported as main reason for conversion. In total, three (3) subjects or (10%) failed the primary and secondary efficacy endpoints.

Table 7: Safety Endpoint: Technique Conversion rate and causes

Characteristic	%(n/N)[2]	95% CI[1]	
		Lower Confidence Limit	Upper Confidence Limit
% subjects with conversion	10.0% (3/30)	2.1%	26.5%
Reason for conversion (N=3)			
Reason: subjects' distorted anatomy presented higher risk for placement	100.0% (3/3)		

[1] *Exact Binomial CI*
[2] *where n = number of subjects with a conversion, N= total number of enrolled subjects.*

Secondary Effectiveness Endpoints: The Surfacer System was advanced from entry in the femoral vein to supraclavicular exit in 27/27 or 100% of PP treated subjects.

Conclusions: The SAVE-US trial support the safety and effectiveness of the Surfacer Inside-Out Access Catheter System to facilitate upper body central venous access. Surfacer System deployment was successfully achieved in 90.0% of subjects in the ITT population and 100% in the PP population. The primary safety endpoint success rate, absence of procedural complications, was 86.7% in the ITT population (26/30) and 85.2% in the PP population (23/27). Four of 30 subjects (13.3%) did not meet the safety endpoint of the study.

International Post Market SAVE Registry

Purpose: The Surfacer System to Facilitate Access in Venous Occlusions (SAVE) Registry (ClinicalTrials.gov Identifier: NCT02875899) was established to assess the standard of care and clinical outcomes of the Surfacer Inside-Out Access Catheter System used in routine clinical practice outside the United States.

Design: The International SAVE Registry was a prospective, single-arm, post market, multicenter, international registry of the Surfacer System for the treatment of subjects with limited or diminishing upper body venous access or pathology impeding standard access methods. A total of thirty (30) subjects at five (5) centers in Germany, Italy, Austria and Paraguay were enrolled. Following ethics committee approvals, subject demographics, medical history and type of occlusion were documented at enrollment.

Primary Endpoints:

1) Safety: The primary safety endpoint was a safety evaluation at end of procedure and at discharge. Acute device safety was also assessed, defined as the absence of device related SAEs.

2) Performance: The primary performance endpoint was an evaluation of the success rate defined as the ability to facilitate placement of CVCs using the Surfacer System to establish a transient passage across venous occlusions.

Secondary Endpoints: Secondary endpoints consisted of the following:

1) Safety: The rate of technique conversion and causes. CV Access catheter malposition.
2) Performance: Assessment of the ability of the Surfacer System to be advanced from the femoral vein to subclavicular exit to facilitate CVC placement.

Eligibility Criteria Summary: The study population consisted of male and female subjects, at least 18 years of age.

Key inclusion criteria included the following:

- Subjects have been referred for placement of central venous access catheter.
- Subjects have limited or diminishing upper body venous access or pathology impeding standard access methods.

Key exclusion criteria included the following:

- Subjects were contraindicated for Surfacer System use if one of the following are found (per the IFU):
  - Occlusion of the right femoral vein;
  - Occlusion of the iliac vein;
  - Occlusion of the inferior vena cava.
- Subject with acute thrombosis within any vessel (superior vena cava (SVC), jugular, inferior vena cava (IVC), brachiocephalic and subclavian) planned to be crossed by Surfacer System.

Demographics: The mean age of subjects enrolled in the registry was 60.1 years. This included eighteen (18) males and twelve (12) females in whom the Surfacer System was used to establish central venous access. Of the 30 subjects enrolled 17 had TYPE 3 or TYPE 4 occlusions (three or more upper body veins) and 13 had Type 1 or 2 occlusion.

Table 8: Subject demographics (n=30)

VARIABLE	Mean ± SD	Range
Age (years)	60.1 ±12.8	38-80
Weight (kg)	68.0 ±11.5	48-91
Height (cm)	160.4 ±17.9	96-178

Adverse Events: Safety was defined as the rate of serious device-related adverse events (SADEs) that occurred during the first 48 hours to hospital discharge. No SADEs were reported to date. No Procedure related adverse events were reported.

Results:

The results of primary safety and performance endpoint evaluations are summarized in Table 9. Device performance and adverse events were collected during the procedure and upon hospital discharge. Of the thirty (30) enrolled subjects, twenty-nine (29) (96.7%) subjects received placement of central venous catheter.

Evaluation of the secondary performance endpoint, including visualization of the needle guide and needle wire exit under fluoroscopy, placement of patent central venous catheter (CVC) using the exit introducer, was confirmed in the 29 treated subjects.

The study's secondary safety endpoints confirmed successful central venous access in 29 subjects of 30 subjects. One (1) conversion to alternative access methods was observed due to significant vascular anatomical tortuosity.

Table 9: Endpoints Evaluation

Primary Endpoints	**Outcome # Subjects (%)**
Performance (N=30)	
Implementation of success rate: ability to facilitate placement of CVC's using the Surfacer to establish a transient passage across venous occlusions.	29 (96.7%)
Safety (N=29*)	
Safety evaluation at end of procedure and at discharge. Complications free.	29 (100%)
Acute device safety, defined as the absence of device related SAEs.	29 (100%)
SECONDARY Endpoints	
Performance (N=30)	
Surfacer advancement from femoral vein to sub-clavicular exit to facilitate CVC placement assessed by:	29 (96.7%)
Ability of Needle Guide and Needle Wire entry to exit superior vena cava as visualized fluoroscopically	
Ability of exit introducer to facilitate placement of CVC	29 (96.7%)
Safety (N=30)	
Technique Conversion rate	1 (3.3%)
CV Access catheter malposition	0 (0%)

*Includes subjects with Surfacer System only

Conclusions:
The results obtained for subjects enrolled in the SAVE Registry support the safety and efficacy of the Surfacer Inside-Out procedure when used for restoring a right-sided central venous access in subjects with central venous occlusions.

EU Vigilance Reports
Since receipt of CE Mark, four (4) European vigilance reports were filed with events such as bleeding, blood vessel/vein damage; and arterial damage. Two events resulted in patient death. One subject tolerated access of the central venous system with the Surfacer device, but died of acute bleeding into the pleural space after the tract was dilated with an angioplasty balloon to insert a HeRO catheter. None of the vigilance reports were related to device malfunction. Bleeding is a known and anticipated risk of Surfacer System use. Users should follow the instructions/warnings provided in the labeling.

XI. DIRECTIONS FOR USE

DO NOT use any component of the Surfacer® System if there is any visible loss of package integrity.

A. Patient Preparation

1. Prepare the right femoral and right supraclavicular area for sterile percutaneous access and exit. Administer conscious sedation and local anesthesia according to hospital protocols.

B. Femoral Access

1. Access the right femoral vein and insert a 0.035" exchange guidewire and advance to the venous occlusion.

C. Workstation Sheath Insertion

1. Remove the Workstation Sheath and Dilator from the sterile package, inspect for damage, and flush.
2. Insert Workstation Sheath dilator into Workstation Sheath, and close Tuohy Borst valve around the dilator.
3. Advance the Workstation Sheath and dilator over the exchange wire to the venous occlusion.
4. Remove the exchange wire and the dilator and close the Tuohy Borst valve
5. Attach a syringe and inject contrast to confirm location of Workstation Sheath at the venous occlusion (as previously defined by angiography).

D. Exit Target Placement

1. Remove the Exit Target from package.
2. Place the Exit Target on the desired point of exit in the supraclavicular exit area.

E. Surfacer Device Insertion

1. Remove the Surfacer Device from the sterile package and inspect for damage.
2. Retract the Needle Guide completely by turning Needle Guide Knob all the way to the right. Confirm guide is fully retracted.
3. Insert the Surfacer Device through the Workstation Sheath and advance the tip of the Surfacer Device to the venous occlusion under fluoroscopic guidance. The Surfacer Device should be advanced under fluoroscopy into the occlusion until the tip overlies the right clavicle in the Anterior-Posterior projection
4. Without moving the Surfacer Device, reposition the image intensifier or fluoroscopy system, until the opening in the tip of the Surfacer Device visibly overlays the Exit Target. Record this degree of cranial angulation to input into the Surfacer Device Handle in step 6.
5. Maintaining this fluoroscopic position, rotate the Surfacer Device Handle until the opening in the tip is visible. Optimum orientation is achieved by rotating the Surfacer Device

Warning! DO NOT Advance the Needle Guide or Needle Wire with the topside of the device (i.e. the side with the controls) facing the patient.

6. Advance the Needle Guide from the tip of the Surfacer Device by rotating the Needle Guide Knob to the left on the Surfacer Device Handle. The Surfacer Device Handle indicator should match the degree of cranial angulation at step 4.
7. Select "Unlock" on the Surfacer Device Handle and advance the Needle Wire by pumping the Surfacer Device Handle plunger. Advance the Needle Wire until it arrives to the skin. "Tenting" of the skin may be seen. Remove the Exit Target and continue to advance the Needle Wire through the skin. A #11 scalpel blade may facilitate complete penetration of the skin if necessary.
8. Advance sufficient length of the Needle Wire to allow the Peelable Introducer with Dilator to be loaded on to the exposed wire.
9. **Fully retract the Needle Guide** into the Surfacer Device by turning the Needle Guide Knob to the right.'

CAUTION: Distal tip of needle wire is sharp, handle with care to prevent needle stick.

F. Peelable Introducer Attachment

1. Remove the Peelable Introducer component from the sterile package and insert the Peelable Introducer dilator into the Peelable Introducer sheath.
2. Verify the exit target has been removed and load the Peelable Introducer onto the exposed Needle Wire.
3. Attach a hemostat or clamp onto the distal end of the exposed Needle Wire just above the Peelable Introducer.

WARNING - Needle Guide must be fully retracted into the Surfacer Device before attempting to draw the Peelable Introducer into the body.

4. After verifying under fluoroscopy the Needle Guide is fully retracted into the Surfacer Device, select the "Lock" position on the Surfacer Device Handle. (Locks the Needle Wire into place).
5. Pull the Surfacer Device Handle to draw the Peelable Introducer and dilator into the body. The Workstation Sheath may be partially withdrawn with the Surfacer Device.
6. Remove hemostat from Needle Wire. Remove the Peelable Introducer dilator from the Peelable Introducer.
7. Select the "Unlock" position on the Surfacer Device handle; pull the Plunger back (Proximally) and pull the Needle Wire back into the Needle Guide.
8. Withdraw the Surfacer Device into the Workstation Sheath.

CAUTION: To avoid air entry, the dilator must be removed BEFORE the Needle Wire is withdrawn into the Workstation Sheath.

CAUTION: The Surfacer Device and Needle Wire should be withdrawn in a continuous motion until the tip of the Needle Wire is within the Workstation Sheath.

9. Remove the Surfacer Device, leaving the Workstation Sheath in place.
10. Insert central venous catheter or access device through the Peelable Introducer.
11. Crack the plastic hub of the Peelable Introducer to split and remove the sheath.
12. Adjust the final position of the central venous catheter under fluoroscopic guidance. The catheter tip is typically positioned at the SVC-RA junction.

CAUTION: The central venous catheter must be positioned BELOW the point of occlusion. If necessary, perform contrast injections through the catheter to confirm a satisfactory tip location.

13. Confirm proper function of the central venous catheter. The catheter must aspirate and flush freely.
14. The catheter may be secured or tunneled to complete the procedure.
15. Aspirate, flush and remove the Workstation Sheath.
16. Post procedure dressing per hospital standard of care.

XII. HOW SUPPLIED

The Surfacer® System is supplied sterile. The Workstation Sheath, Surfacer Device, Exit Target and the Peelable Introducer are packaged together in a plastic tray contained in the sterilized pouch.

XIII. STERILIZATION

The Surfacer® System is sterilized using Ethylene Oxide. The Surfacer® System is supplied sterile and is for SINGLE USE ONLY.

DO NOT clean, re-sterilize, or reuse as this may damage or compromise performance of the Surfacer® System and may expose patient to risk of transmitting infectious disease.

XIV. STORAGE

Do not store at temperatures >50°C (122°F). Avoid prolonged exposure to elevated temperatures.

XV. DEFINITIONS

The symbol definitions used in the product labeling are listed below:

LOT	Batch Code	STERILE EO	Sterilized using ethylene oxide
	Use by date		Consult instructions for use
	Manufacturer		Keep dry
	Date of Manufacture	50 °C	Store up to 50 degrees C
Rx only	Prescription use only		Do not use if package is damaged
	Do not resterilize		Do not re-use
	Caution	REF	Catalog Number

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Patents: www.bluegrassvascular.com/patents

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REF: 600200/A
IFU0002-US-02