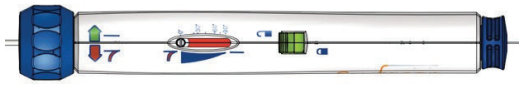
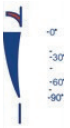
Bluegrass Vascular Technologies, Inc.
Surfacer® Inside-Out® Access Catheter System
INSTRUCTIONS FOR USE

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 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 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 and a catheter is in place, the Surfacer® System is 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.

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 to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body.

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.
4. Patients with severe anatomical tortuosity (scoliosis, lordosis, etc.) should be imaged before use or 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. The Workstation Sheath must be inserted to a stable position in the peripheral venous system.
7. 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.
8. The Needle Guide must be retracted (withdrawn into the Surfacer Device) before the device can be removed from the patient.
9. 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).
10. 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.

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, tamponade, 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
- 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.

Post-Procedure – Precautions

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

VIII. BASELINE PARAMETERS

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

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

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

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 Workstation Sheath provides a lumen for the Surfacer Device, preventing injury when it is advanced. Users have reported double sheathing or using reinforced introducer sheaths when necessary. Refer to Surfacer System Training Manual for further information.

Figure 1: Surfacer® Workstation Sheath

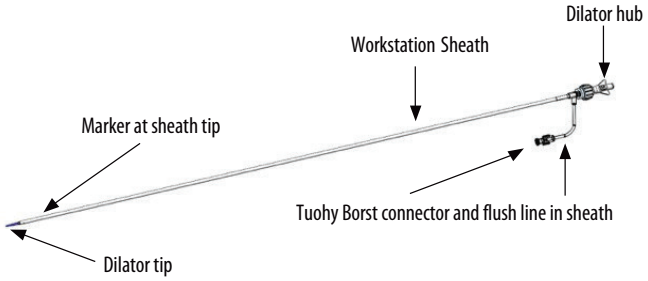
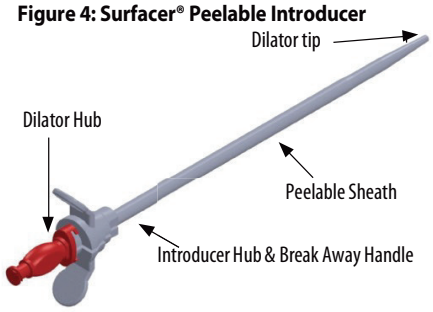


Figure 4: Surfacer® Peelable Introducer



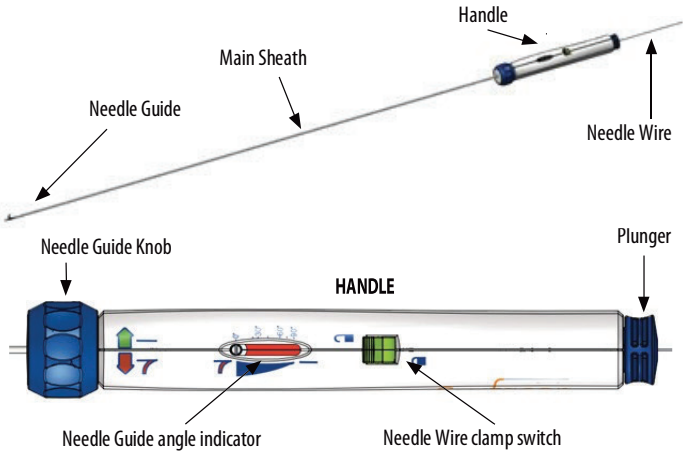
2. Surfacer Device - the Surfacer Device consists of a Main Sheath, Needle Guide, Needle Wire, and a Handle. **See Figure 2**.

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.

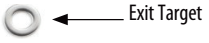
Figure 2: Surfacer® Device



3. Exit Target

The Exit Target is a radiopaque marker use 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 18F OD, 16 F ID and is 20 cm long. **See Figure 4**.

X. 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 Handle to reveal a maximum opening width.

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 recorded 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.

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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.
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 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.

XI. 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.

XII. 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.

XIII. STORAGE

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

XIV. 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		

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