Surfacer® System (600200/A)
Technical Specification Sheet for U.S.

Product 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.

Classification/FDA Classification: DEN190038 granted Feb. 10, 2020
Trade/Device Name: Surfacer Inside-Out Access Catheter System
Regulation Number / Class: 21 CFR 870.1342 – Class II
Regulation Name / Product Code: Reverse central venous recanalization system - QJH

GMDN CODE 62045: A collection of sterile, invasive devices intended to enable introduction of a central venous catheter (CVC) into an occluded vein (e.g., subclavian) by creating a puncture site from the inside of the vein under fluoroscopic guidance. It typically includes: an introducer sheath, for initial vascular access via a secondary vein (e.g., femoral); a semi-rigid, noncoring, endovascular guide sheath assembly with a distal side-hole, intended to navigate into, and be stabilized by, the vascular occlusion; a percutaneous needle-wire, intended to puncture the vein/tissue to exit at the skin surface; and a sheath for introduction of a CVC; the catheter is not included. This is a single-use device and terminally sterilized via ethylene oxide.

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.

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.

Concept of Development: The Surfacer System has been developed and designed to satisfy an unmet lifesaving clinical need: facilitating central venous access in patients for whom access has been lost or diminished, due to obstruction of central veins. The Surfacer System is designed to safely overcome chronic, total occlusion of the superior vena cava (SVC) or both internal jugular and subclavian veins, as well as occlusions inaccessible by conventional methods.

Restoring CV access is necessary to provide life-saving therapies (dialysis, chemotherapy, pacing, nutrition), but it is also important to avoid risks such as post-thrombotic syndrome, pulmonary embolism, and catheter infections that are known to be associated with CV thrombosis.

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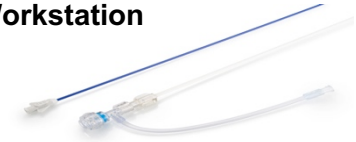
TECHNICAL INFORMATION

Component	Description	Specifications[1] English (in)	Metric (cm)	French
Workstation 	Shaft Diameter (OD)	0.137	0.348	10.4
	Shaft Diameter (ID)	0.096	0.244	7.3
	Usable Length	25.4	64.5	
Delivery Instrument (Surfacer Device) 	Shaft Diameter (OD)	0.095	0.241	7.2
	Usable Length	37.4	95.1	
	Needle Guide OD	0.041	0.104	3.1
	Needle Wire Size	0.024	0.06	1.8
	Needle Wire Usable Length	13.77 (minimum)	35 (minimum)	
Exit Target 	OD ID	0.63 0.335	1.6 0.85	48 25.5
Exit (Peelable) Introducer Sheath 	Shaft Diameter (OD)	0.241	0.612	18.4
	Shaft Diameter (ID)	0.214	0.544	16.3
	Usable Length	7.9	20	

[1] Dimensions are approximate

MATERIALS LIST[2]

Workstation Sheath		**Workstation Dilator**	
Sheath	Medical Grade Pebax	Dilator	High density polyethylene HDPE (20%) $BaSO_4$
Sheath Tip	Medical Grade Pebax (80% Tungsten)	Tuohy Borst	Polycarbonate (PC), Copolyester, Teflon, Silicone, and Polyvinyl chloride (PVC)
Female Luer	Polyvinyl chloride (PVC)	Dilator Luer	High density polyethylene (HDPE)
Adhesive	Medical Grade Dymax	Adhesive	Medical Grade UV-Cure Adhesive

Delivery Instrument (Surfacer Device)	
Shaft and shaft tip	Stainless Steel
Needle Guide	Super Elastic Nitinol
Needle Wire	Nickel Titanium
Handle	Acrylonitrile butadiene styrene (ABS), PC, PVC, Fluorinated ethylene propylene (FEP), Medical Grade UV-Cure Adhesive, Poly tetra fluoro ethylene(PTFE), Silicone, Stainless Steel, Steel, Nylon
Adhesive	Cyanoacrylate
Packaging Hoop	HDPE

Exit Target	Stainless Steel

Exit (Peelable) Introducer Sheath and Dilator			
Sheath	Teflon	Dilator	HDPE
Sheath Snap Hub and Snap Cap	ABS/Nylon	Valve	Silicone
Protector	PP		

[2] ***Materials subject to change without notice***

Packaging

- Components are packaged in a plastic tray and sealed in a Tyvek pouch, which is placed in a SBS carton.
- Overall package dimensions are 4.5 cm X 22.3 cm X 137.8cm
- Sterilization: ethylene oxide

Shelf Life: The shelf life of the Surfacer System is 36 months from the date of manufacture. The expiration date is clearly displaced on the carton label.

Dispose Condition: Device components and packaging are not considered hazardous material and can be discarded according the hospitals usual procedures for disposal of medical materials.

Cleaning and Sterilization Instructions: The contents of this package are designed for single use only. Do NOT resterilize. Do NOT use after expiration date. Do NOT use if package is damaged.

Special Handling Instructions: Do NOT expose to temperatures above 50°C.

Latex Free Denotation: As detailed above, the Surfacer System is primarily composed of stainless steel, Nitinol and Plastic and thus is free of latex parts. BVT recommends that all manufacturing/assembly be conducted using nitrile or similar latex-free gloves in order to prevent the accidental introduction of latex particles. Therefore, we herewith attest that all of these products are latex-free.

ORDERING INFORMATION:

Catalog/REF Number	Description	Quantity
600200/A	Surfacer® Inside-Out® Access Catheter System (single)	1

Each Surfacer® System contains:

Two (2) Exit Targets
One (1) Workstation Sheath
One (1) Surfacer Device
One (1) Peel-Away Sheath

Manufacturer

Bluegrass Vascular Technologies, Inc.
12500 Network Blvd, Suite 308
San Antonio, Texas 78249
Tel: 210.558.0819 Fax: 210.978.5469
Contact: Gabriele Niederauer, CEO & Pres.
Email: gniederauer@bluegrassvascular.com