



Surfacer®

Inside-Out® Access

Your bridge to improved
vascular access outcomes.

RESTORE ACCESS.
PRESERVE OPTIONS.®

The Surfacer® System enables
reliable & repeated **access to the
right internal jugular vein** and
avoids using other veins which
may compromise permanent
arteriovenous access.

Femoral
Venous Entry

BLUEGRASS
VASCULAR

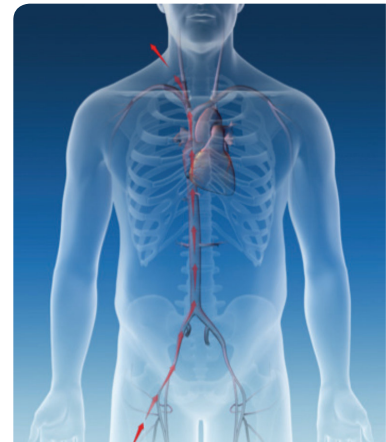
WHAT IS THE SURFACER SYSTEM?

The Surfacer® 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.



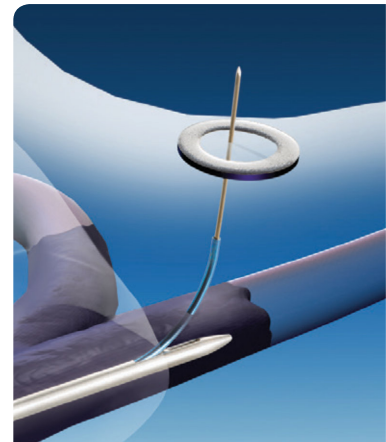
RESTORE ACCESS

- Achieves **reliable and repeatable central venous access** to the right internal jugular (RIJ) vein.¹
- Can be used for patients with **all types** of central venous occlusions.
- Applicable for patients utilizing **hemodialysis** catheters or those requiring central venous access for **nutritional support or chemotherapy**.



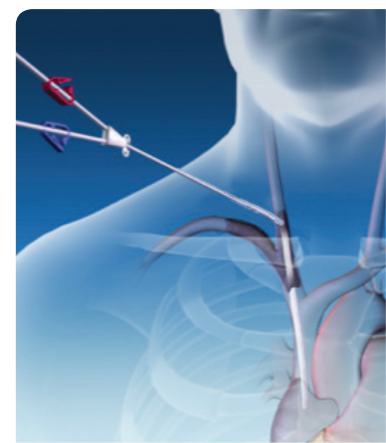
RELIABLE PROCEDURE¹⁻³

- **>95% success rate** with achieving central venous access placement.
- Three multi-center studies have reported on the **safety and efficacy** of the Surfacer System when used for the the inside-out procedure.
- **Shorter fluoroscopy and procedure time** and **less contrast** use compared to sharp recanalization.



REDUCE COMPLICATIONS

- **Preserves viability** of secondary central veins.
- Enables ability to avoid left-sided catheter placement in hemodialysis patients, improving the ability to create and/or mature arteriovenous (AV) access in the left arm, **reducing the need for long-term use of a catheter** and catheter-associated complications.
- **Facilitates removal of femoral catheters**, improving patient satisfaction and reducing risk of complications.^{4,5}



Surfacer®
Inside-Out® Access

A UNIQUE APPROACH

INSIDEOUT®

- The Surfacer® device works from the “Inside-Out®” making it safer to pass into or through the venous obstruction, facilitating placement of a central venous access device.
- The Surfacer System facilitates repeatable, right-sided catheter placement, the preferred insertion location for central venous access.¹
- A target is placed on the skin enabling you to see exactly where to point the device to exit the skin from the inside.

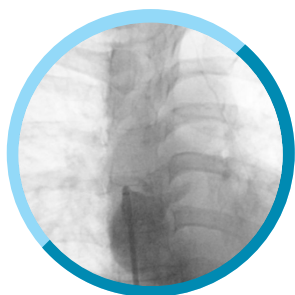


FIGURE 1:
Totally occluded
superior vena cava

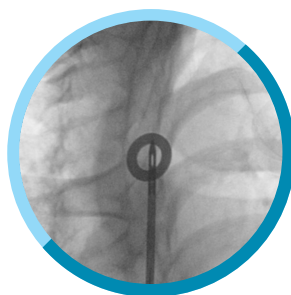


FIGURE 2:
Exit target provides a
zone to position the
Surfacer device to exit
the skin

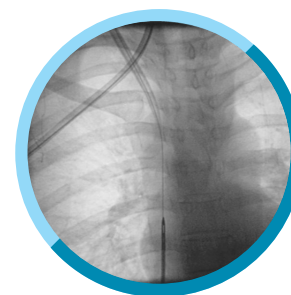
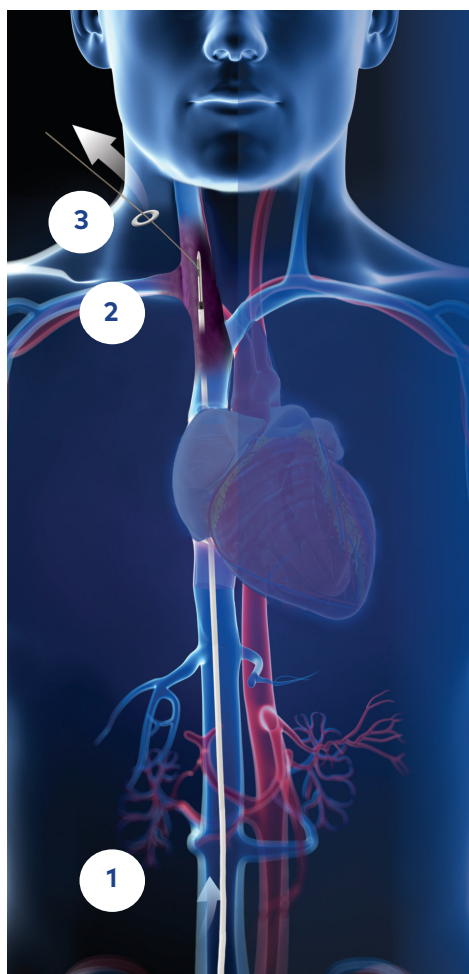


FIGURE 3:
Introducer sheath locked onto
needle wire and pulled into
right atrium



Step 3. A needle is extended from the device through a target on the skin and the catheter is inserted.



Step 2. The Surfacer device is passed through the venous occlusion.



Step 1. The Surfacer device is inserted into a vein in the groin (the femoral vein).

Go to bit.ly/surfacer-video to view a video which shows how the Surfacer System works.

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DEMONSTRATED CLINICAL RESULTS

Results from 3 multicenter studies demonstrate the ability to **safely and efficiently** achieve central venous access in over 95% of procedures with the Surfacor System.

	U.S. IDE Study ²	International Registry ³	Multicenter Study ¹
Trial design	Prospective, single-arm, multicenter study	Prospective, single-arm, multicenter study	Retrospective, single-arm, multicenter study
Main inclusion criteria	Patients referred for placement of CVC with limited or diminishing upper body venous access or pathology impeding standard access methods	Patients referred for placement of a CVC with limited or diminishing upper body venous access pathology impeding standard access methods	Patients with bilateral TCVO requiring urgent vascular access and patients with right-sided TCVO requiring a CVC
Number of study sites	7	5	3
Study site locations	USA	Austria, Germany, Italy and Paraguay	Austria, Germany, and United Kingdom
Number of patients	30	30	32*
Mean age, years \pm SD,	55.5 \pm 12.9	60.1 \pm 12.8	59 ^d
Gender (males/females)	15/15	18/12	6/26
% requiring venous access for hemodialysis	28 (93.3%)	29 (96.7%)	100%
TVCO type ⁶ (%)			
Type 1	7 (23.3%)	8 (26.7%)	3 (8%)
Type 2	6 (20.0%)	5 (16.7%)	27 (75%)
Type 3	16 (53.3%)	8 (26.7%)	3 (8%)
Type 4	1 (3.3%)	9 (30.0%)	3 (8%)
Number of patients obtaining successful catheter placement (%)	27/30 (90%)	29 (96.7%)	38 (97.4%)
Mean procedure time, minutes \pm SD	19.1 \pm 25.1 ^a	24 \pm 14.9 ^a	43 ^{b,c}
Mean fluoroscopy time, minutes \pm SD	11.2 \pm 9.72	6.8 \pm 4.5	6 ^c
Mean contrast used, mL \pm SD	95.4 \pm 107.3	29.7 \pm 22.2	15 ^c
Device-related complications	None	None	None

CVC = Central venous catheter, SD = Standard deviation, TCVO = Thoracic central venous obstruction

*7 patients repeated the procedure during the study period but more than 3 months following initial procedure in order to replace a malfunctioning catheter

^a from initial device insertion to removal of the workstation sheath

^b initial femoral access to end of central venous catheter implantation

^c Standard deviation not reported

A NEWLY RECOGNIZED TREATMENT OPTION



25% to 40% of patients with catheters develop central venous occlusions. The Surfacer System can help you achieve and maintain venous access for your patients.



The Surfacer System has been used to place catheters in **over 700 patients worldwide** and has received **authorization from the FDA** for use in the U.S.



Multiple peer-reviewed publications demonstrating the safety and successful use of the Surfacer System across a wide range of patients populations.



Medicare has created a **new HCPCS code** for the Surfacer System procedure (C9780) and has assigned the code to **New Technology APC 1534** with a national average hospital outpatient payment rate of \$8,250.



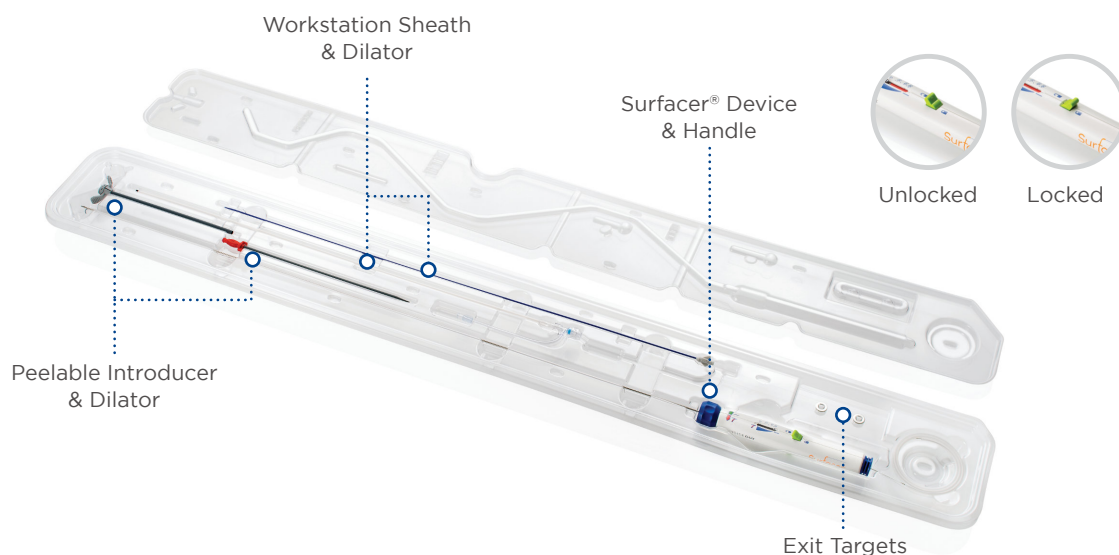
Total procedure time is typically less than 1 hour with the Surfacer System portion of the procedure usually taking **less than 20 minutes**.² Reduced procedure & fluoroscopy time and improved efficiency and workflow compared to sharp recanalization.

There are potential complications associated with Surfacer System procedure. These risks are similar to those associated with other procedures used to obtain central venous access. While rare, possible risks include pain, infection, bleeding, tissue or allergic reaction, pneumothorax, pulmonary embolism, vessel vasospasm, vessel perforation, dissection, or aneurysm, embolization or thrombosis, arrhythmias, stroke, transient ischemic attack or nerve injury, development of arteriovenous fistula, or death.

References

1. Reindl-Schwaighofer R, et al. A novel inside-out access approach for hemodialysis catheter placement in patients with thoracic central venous occlusion. Am J Kidney Dis. 2020 Apr;75(4):480-487.
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3. Gallieni M, et al. Multicenter Experience with the Surfacer Inside-Out Access Catheter System in patients with thoracic venous obstruction: Results from the SAVE Registry. J Vasc Interv Radiol. 2020 Oct;31(10):1654-1660.e1.
4. Huang C, Smeds MR. Use of the Surfacer® Inside-Out® access catheter system to place permanent dialysis access via hemodialysis reliable outflow (HeRO) graft. Annals of Vascular Surgery - Brief Reports and Innovations, 2021, 1(2):100026.
5. Maya ID, Allon M. Outcomes of tunneled femoral hemodialysis catheters: comparison with internal jugular vein catheters. Kidney Int. 2005 Dec;68(6):2886-9.
6. Dolmatch BL, et al; Central Vein Work Group; Technology Assessment Committee. Society of Interventional Radiology Reporting Standards for Thoracic Central Vein Obstruction. J Vasc Interv Radiol. 2018 Apr;29(4):454-460.e3.

SURFACER® SYSTEM COMPONENTS



ORDERING INFORMATION

Order Number	Description	Quantity
600200/A	Surfacер® Inside-Out® Access Catheter System (single)	1

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VASCULAR

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Now available for sale in the United States.
Also CE Mark Approved and available for sale in Europe.
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