The Surfacer® System is intended to obtain central venous access to the right internal jugular (RIJ) vein. It 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.

### WHAT IS THE SURFACER SYSTEM?

- Achieves reliable and repeatable central venous access to the right internal jugular (RIJ) vein. It 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.
- 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 inside-out procedure.
- Shorter fluoroscopy and procedure time and less contrast use compared to sharp recanalization.
- 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.

### RESTORE ACCESS

- Achieves reliable and repeatable central venous access to the right internal jugular (RIJ) vein. It can be used for patients with all types of central venous occlusions.
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### 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.
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.

**WHAT IS THE SURFACER SYSTEM?**

- 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.

**RESTORE ACCESS**

- >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 inside-out procedure.
- Shorter fluoroscopy and procedure time and less contrast use compared to sharp recanalization.

**RELIABLE PROCEDURE**²³

- 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.⁴⁵

**REDUCE COMPLICATIONS**

- 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.
**A UNIQUE APPROACH**

- 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.
- A target is placed on the skin enabling you to see exactly where to point the device to exit the skin from the inside.

**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 Surfacer System.

**U.S. TEAC**
- **Trial design**: Prospective, 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
- **Results**: Patients referred for placement of a CVC with limited or diminishing upper body venous access or pathology impeding standard access methods
- **Number of study sites**: 7
- **Mean age, years ± SD**: 55 ± 12.9
- **Gender (male/female)**: 15/15
- **Access device**: Introducer sheath locked onto the Surfacer® device
- **Mean fluoroscopy time, minutes**: 36 ± 24.9
- **Mean procedure time, minutes**: 43 ± 29.7
- **Number of patients achieving successful catheter placement (%)**: 27/30 (90%)
- **Mean procedure time, minutes ± SD**: 20 ± 12.9
- **Mean contrast used, mL ± SD**: 6 ± 5.4
- **Device-related complications**: None
- **CVC = Central venous catheter, APC = American Society for Aesthetic Plastic Surgery, TEAC = Total Endovascular Access Center, SD = Standard deviation**

**INTERNATIONAL Registry**
- **Trial design**: Prospective, single-arm, multicenter study
- **Main inclusion criteria**: Patients referred for placement of a CVC with limited or diminishing upper body venous access or pathology impeding standard access methods
- **Results**: Patients referred for placement of a CVC with limited or diminishing upper body venous access or pathology impeding standard access methods
- **Number of study sites**: 5
- **Mean age, years ± SD**: 60 ± 12.8
- **Gender (male/female)**: 16/12
- **Access device**: Introducer sheath locked onto the Surfacer® device
- **Mean fluoroscopy time, minutes**: 62 ± 26.7
- **Mean procedure time, minutes**: 6 ± 2.6
- **Number of patients achieving successful catheter placement (%)**: 13/16 (81%)
- **Mean procedure time, minutes ± SD**: 16 ± 10.5
- **Mean contrast used, mL ± SD**: 6 ± 3.8
- **Device-related complications**: None
- **CVC = Central venous catheter, APC = American Society for Aesthetic Plastic Surgery, TEAC = Total Endovascular Access Center, SD = Standard deviation**

**MULTICENTER Registry**
- **Trial design**: Retrospective, single-arm, multicenter study
- **Main inclusion criteria**: Patients with central venous occlusion and successful use of the Surfacer System across a wide range of patient populations
- **Results**: Patients referred for placement of a CVC with central venous occlusion
- **Number of patients**: 29 (96.7%)
- **Mean age, years ± SD**: 59 ± 15
- **Gender (male/female)**: 60/25
- **Access device**: Introducer sheath locked onto the Surfacer® device
- **Mean fluoroscopy time, minutes**: 30 ± 12.8
- **Mean procedure time, minutes**: 14 ± 6.8
- **Number of patients achieving successful catheter placement (%)**: 11/12 (91%)
- **Mean procedure time, minutes ± SD**: 6 ± 2.4
- **Mean contrast used, mL ± SD**: 6 ± 2.3
- **Device-related complications**: None
- **CVC = Central venous catheter, APC = American Society for Aesthetic Plastic Surgery, TEAC = Total Endovascular Access Center, SD = Standard deviation**

**A NEWLY RECOGNIZED TREATMENT OPTION**

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 patient 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. 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, bruising, 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 other signs of neurologic injury, deep vein thrombosis.

References
A UNIQUE APPROACH

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.

A target is placed on the skin enabling you to see exactly where to point the device to exit the skin from the inside.

INSIDEOUT

DISTRIBUTED 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 Surfacer System.

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.

MEDICARE

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.

DEMONSTRATED CLINICAL RESULTS

<table>
<thead>
<tr>
<th>Study site locations</th>
<th>Number of sites</th>
<th>Number of patients</th>
<th>Mean age, yrs</th>
<th>Gender (males/females)</th>
<th>Time to achieving successful catheter placement, minutes</th>
<th>Time to fluoroscopy, minutes</th>
<th>Time to successful CVC placement, minutes</th>
<th>CVC = Central venous catheter, SD = Standard deviation, TCVO = Thoracic central venous obstruction</th>
</tr>
</thead>
<tbody>
<tr>
<td>USA</td>
<td>7</td>
<td>51</td>
<td>60.1 ± 9.72</td>
<td>55.5 (12.9)</td>
<td>27.30 (90.6)</td>
<td>23.4 ± 14.9</td>
<td>19.1 ± 25.1</td>
<td>Mean procedure time, minutes ±SD</td>
</tr>
</tbody>
</table>


c | b | c | d

References


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

● Patients receiving the procedure during 1 calendar year were enrolled and followed for a minimum 1-month period to ensure a successful femoral catheter was placed with a national average hospital outpatient payment rate of $8,250.

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 aneurism, embolization or thrombosis, arrhythmias, stroke, transient ischemic attack or demise, development of enteric fistula, iatrogenic perforation.

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

Step 1. A needle is advanced from the device through a target on the skin and the catheter is inserted.

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

Step 3. The Surfacer device is inserted into the vein in the groin (the femoral vein).

Step 4. To go to Surfacer videos to view videos on how the Surfacer System works.

Step 5. The Surfacer device is passed from the “Inside-Out®” making it safer to pass into or through the venous obstruction, facilitating placement of a central venous access device.

Step 6. The Surfacer System facilitates repeatable, right-sided catheter placement, the preferred insertion location for central venous access.

Step 7. A target is placed on the skin enabling you to see exactly where to point the device to exit the skin from the inside.

Step 8. To exit target provides a zone to position the Surfacer device through a needle wire and pulled into right atrium.

Step 9. Introduction sheath locked onto device to exit the skin from the inside.

Step 10. Exit the skin from the inside.
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 Surfacer System.

<table>
<thead>
<tr>
<th>Study site locations</th>
<th>Number of patients</th>
<th>Mean age, years ±SD</th>
<th>Gender (males/females)</th>
<th>Number of patients requiring vascular access for hemodialysis</th>
<th>VHD type (%)</th>
<th>Number of patients obtaining successful catheter placement (%)</th>
<th>Mean procedure time, minutes ±SD</th>
<th>Mean fluoroscopy time, minutes ±SD</th>
<th>Mean contrast used, mL ±SD</th>
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<tbody>
<tr>
<td>USA</td>
<td>100</td>
<td>73.1 ± 12.9</td>
<td>60/14 ± 12.8</td>
<td>70/30</td>
<td>64%</td>
<td>93 (96.8)</td>
<td>19 ± 4.9</td>
<td>12 ± 4.5</td>
<td>107.3 ± 22.2</td>
</tr>
<tr>
<td>Austria, Germany, Italy and Paraguay</td>
<td>22</td>
<td>71.6 ± 12.6</td>
<td>16/6 (53.3%)</td>
<td>38/8 (97.4%)</td>
<td>33%</td>
<td>29 (96.6%)</td>
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</tbody>
</table>


cVCI = Cerebral venous collateral, SD = Standard deviation, VHD = Venous head defect

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References

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**

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**ORDERING INFORMATION**

<table>
<thead>
<tr>
<th>Order Number</th>
<th>Description</th>
<th>Quantity</th>
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<tbody>
<tr>
<td>600200/A</td>
<td>Surfacer® Inside-Out® Access Catheter System (single)</td>
<td>1</td>
</tr>
</tbody>
</table>

**RESTORE ACCESS. PRESERVE OPTIONS.**

Your bridge to improved vascular access outcomes.

**BLUEGRASS VASCULAR**

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