



Transcarotid Neuroprotection System

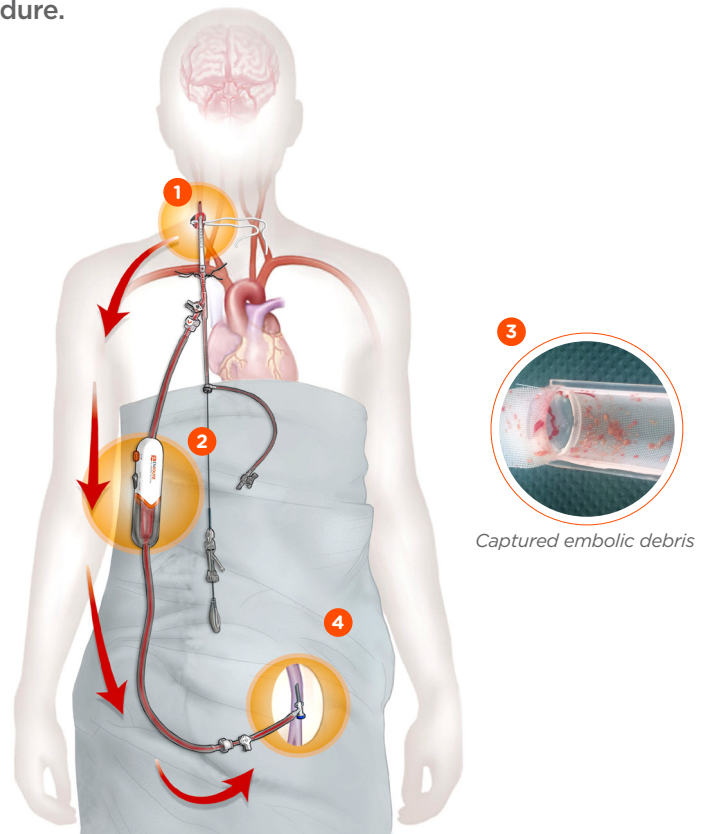


Reverse Flow Neuroprotection

The ENROUTE® Transcarotid Neuroprotection System features reverse flow technology to reduce intraprocedural stroke risk by capturing and filtering any debris that may become dislodged from the lesion during the procedure.

How does it work?

1. **Direct transcarotid approach** with a surgical cutdown **eliminates aortic arch crossing** and **minimizes scarring**.
2. **Temporary flow reversal** establishes **neuroprotection before the lesion is crossed** with the formation of a pressure gradient between the high-pressure arterial system and the low-pressure venous system.
3. **Embolitic debris is captured and filtered**, reducing intraprocedural stroke risk.
4. **Filtered blood is returned** via the femoral vein



Compared to CEA:

98.6%

Freedom from Stroke
for High Surgical Risk¹
and Standard Surgical Risk^{*2}

85-89%

Less Risk of
Cranial Nerve Injury (CNI)^{1,3}

47%

Less Risk of In-hospital
Myocardial Infarction (MI)
for High Surgical Risk¹

Purpose Built for Minimally Invasive Stroke Prevention

1 Transcarotid Arterial Sheath System designed for direct carotid access

- Uber Flex sheath tip with 15° anterior bias and gradual transition for smooth sheath insertion
- Depth markers to aid in arterial sheath insertion and limit fluoroscopy time
- Removable sheath stopper

2 Flow controller with filter provides neuroprotection

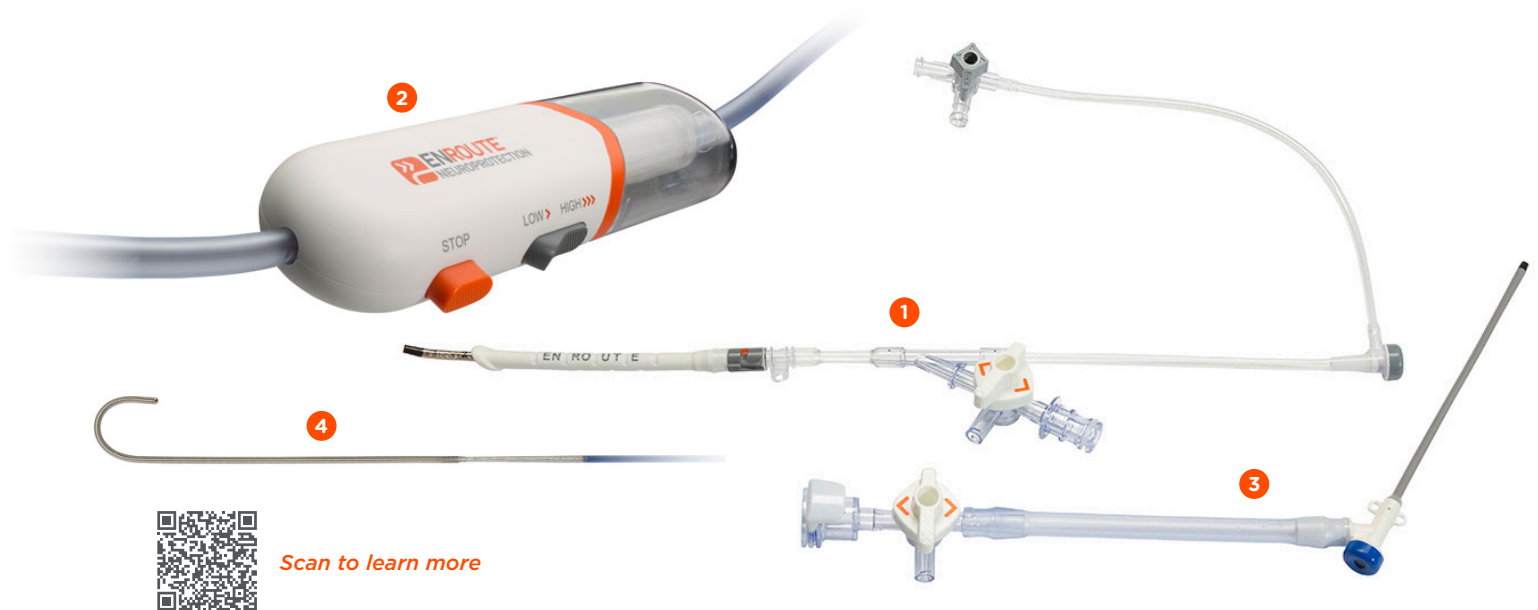
- 200µ filter designed to capture micro and macro emboli during TCAR device delivery and deployment

3 Venous Sheath System returns filtered blood back to the body

- 4mm radiopaque tip for visibility

4 0.035" Extra Support - J-Tip Guidewire

- Short length designed for TCAR: 90cm
- Nitinol core, teflon coated



Ordering Information: ENROUTE® Transcarotid Neuroprotection System

Catalog Number	Product Description	Components	Shipped
SR-250-NPS	ENROUTE® Transcarotid Neuroprotection System PLUS	<ul style="list-style-type: none"> - Transcarotid Arterial Sheath with Arterial Dilator - Venous Return Sheath with Venous Dilator - Flow Controller with Filter - 0.035" Extra Support, J-Tip Guidewire 	1 Each
SR-200-NPS <i>(Retiring Soon)</i>	ENROUTE® Transcarotid Neuroprotection System	<ul style="list-style-type: none"> - Transcarotid Arterial Sheath with Arterial Dilator - Venous Return Sheath with Venous Dilator - Flow Controller with Filter - 0.035" Extra Support, J-Tip Guidewire 	1 Each

References

* at 30 days

† in-hospital

1. Malas MB, Dakour-Arifi H, Kashyap VS, et al. TransCarotid Revascularization With Dynamic Flow Reversal Versus Carotid Endarterectomy in the Vascular Quality Initiative Surveillance Project. Ann Surg. 2022 Aug 1; 276(2):398-403. doi: 10.1097/SLA.0000000000004496.

2. Liang P, Cronenwett J, Secemsky E, et al. Expansion of transcarotid artery revascularization to standard risk patients for treatment of carotid artery stenosis. J Vasc Surg. 2021;74:e27-8. doi: 10.1016/j.jvs.2021.06.048

3. Liang P, et al. Expansion of Transcarotid Artery Revascularization to Standard Risk Patients for Treatment of Carotid Artery Stenosis. Oral presentation at the Vascular Annual Meeting; August, 2021; San Diego, CA.

Indications for Use: The ENROUTE® Transcarotid Neuroprotection System is intended to provide transcarotid vascular access, introduction of diagnostic agents and therapeutic devices, and embolic protection during carotid artery angioplasty and stenting procedures for patients diagnosed with carotid artery stenosis and who have the appropriate anatomy described below:

- Adequate femoral venous access
- Common carotid artery reference diameter of at least 6mm
- Carotid bifurcation is a minimum of 5 cm above the clavicle as measured by duplex Doppler ultrasound (DUS) or computerized axial tomography (CT) angiography or magnetic resonance (MR) angiography

Please refer to Instructions for Use for indications, contraindications, warnings, and precautions.

Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician.



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