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ENROUTE™
Transcarotid Neuroprotection System

TCAR Patient Resource Guide

A **less invasive approach** to treat carotid artery disease and reduce the risk of stroke.

Carotid artery disease is usually silent.

Know your risk factors.

Early detection may **save your life.**

Bob was diagnosed with carotid artery disease. His risk factors included high blood pressure, high cholesterol, and a family history.

You may not show symptoms of carotid artery disease, but if you have a family history of these risk factors, you may be more at risk. For many patients, medical management is one way to treat your disease. As your disease progresses, a procedure may be your best option.

RISK FACTORS

High Blood Pressure

Diabetes

Lack of Exercise

Age

High Cholesterol

Obesity

Smoking

Family History

Clogged Arteries

Having **one or more** of these risk factors increases your risk of developing carotid artery disease.[2]

Talk to your doctor about screening, it can be as simple as an ultrasound.

Don’t be slow to recognize stroke symptoms, **BE FAST**.

SIGNS OF STROKE

Don’t ignore even the smallest of stroke symptoms as effects could last from minutes to several years.[5]

Balance
Watch for sudden loss of balance.

Eyes
Check for vision loss.

Face
Look for an uneven smile.

Arms
Check if one arm is weak.

Speech
Listen for slurred speech.

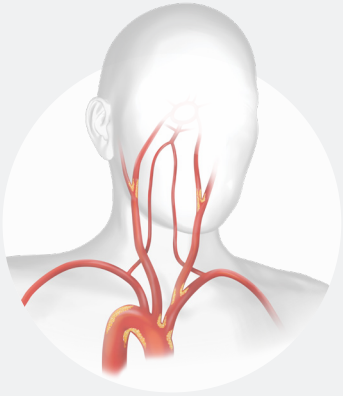
Time
Call 911 right away!

You've been diagnosed with

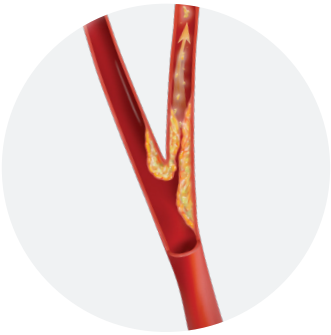
carotid artery disease...

What does this mean?

Carotid artery disease occurs when there is a buildup of cholesterol plaque or fatty deposits in the blood vessels known as the carotid arteries. The carotid arteries deliver blood to your brain and head. This buildup of plaque or narrowing of the blood vessels increases your risk of stroke.



One in three strokes are caused by carotid artery disease.[4]



A **stroke** happens when oxygen from your blood does not reach your brain. A stroke can lead to paralysis, speech problems, memory loss, and even death.

There is hope! **80% of strokes are preventable.**[3]

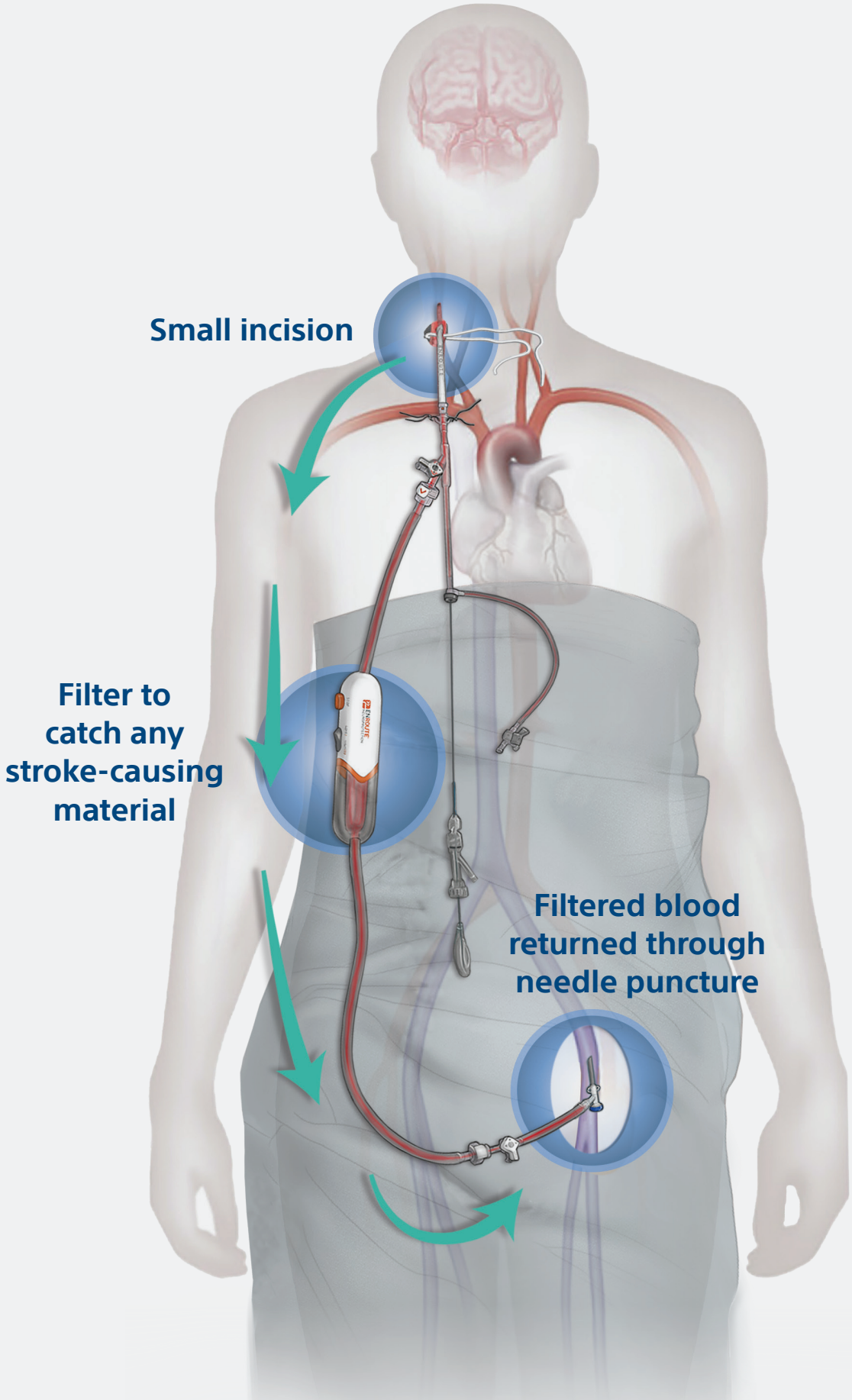
There are ways to manage your carotid artery disease through lifestyle modification, medication, or a procedure.

TCAR PROCEDURE

TransCarotid Artery Revascularization (TCAR) is a less invasive, clinically proven treatment option for carotid artery disease. The procedure begins with a small incision just above the collarbone. A temporary sheath (short hollow tube) is placed directly into the carotid artery in an area away from the diseased area (plaque). The sheath connects to a filter outside of the body.

The filter connects to another small sheath and, through a needle puncture in the groin, is placed directly into the vein, similar to an IV. The difference in pressure causes the blood to flow in reverse from the artery (high flow), through the filter, and into the vein (low flow), away from the brain. This establishes a circuit outside of the body.

A stent (an expandable mesh tube) is then inserted through the arterial sheath to open the blocked artery. Because of the blood flow reversal, any debris that might break loose during stent placement won't travel up to the brain, but rather, it travels downward, gets trapped in the filter, and the filtered blood returns to the vein.


Small incision
Filter to catch any stroke-causing material
Filtered blood returned through needle puncture

TCAR Benefits

Comparing TCAR to Other Procedures

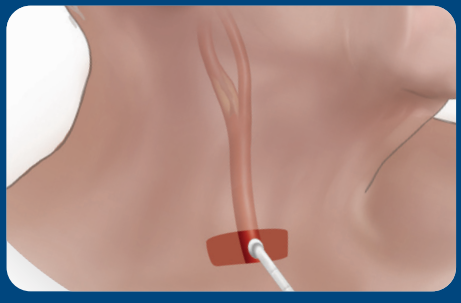
TCAR is a **direct access** procedure.

In a procedure called **transfemoral carotid artery stenting (TF-CAS)**, a wire enters the body through a needle puncture in the groin. The wire is moved through a large blood vessel from the groin to the neck. When the physician is steering the wires and catheters through the diseased blood vessels, debris could be knocked loose, increasing your chance of complications.

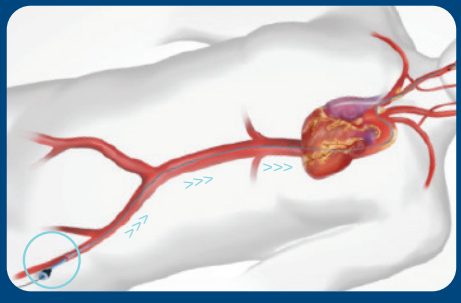
Additionally, with TF-CAS, a protection filter (like a small umbrella) needs to be moved across the diseased area of the carotid artery, before placing the stent to catch debris, which could also break loose, causing a stroke.

TCAR avoids this by directly accessing the carotid artery in a healthier area of the artery away from the disease. With TCAR, you are protected with the blood flow reversal before the wire goes near the “stroke-causing” plaque.

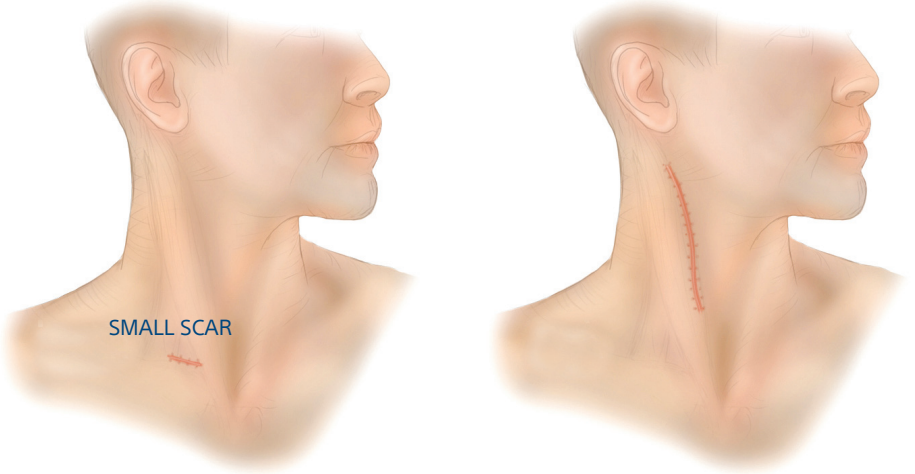
TCAR



TF-CAS



Direct access
Avoids touching the disease unprotected and provides less risk of having a stroke.



TCAR **CEA**

TCAR is a **less invasive** procedure.

Prior to TCAR, **carotid endarterectomy (CEA)** was the traditional way to treat carotid artery disease surgically. This surgery involves making a vertical incision on your neck to access the carotid artery and surgically removing the disease from the carotid artery. TCAR patients usually recover quickly with less pain and smaller scars.

When compared to CEA, **TCAR** has[6]:

Equivalent Stroke Prevention

Less Risk of Heart Attack

Shorter Procedure Time

Less Risk of Nerve Injury

Before Your Surgery

Not following these instructions could lead to a postponed procedure! **Call your TCAR physician with any questions.**

You will have **pre-admission testing** before your procedure.

It is critical to **follow your TCAR physician's instructions** for medications before and after this procedure.

Drink plenty of water before midnight on the day before your procedure.

Why is it important to adhere to the medication guidelines both before and after the procedure?

The stent being placed in the carotid artery takes approximately one month to incorporate itself fully into the carotid vessel wall. Until this happens, the stents are prone to platelets, which are found naturally in the bloodstream, sticking to the stent and potentially causing blood clots and stroke. However, following your physician's guidelines on prescribed medications both before and after your TCAR procedure serves as a protective measure.

It is critical to **follow your TCAR physician's instructions** for medications before this procedure.[9]

It's important to remember to take your medication the **day of your surgery.**

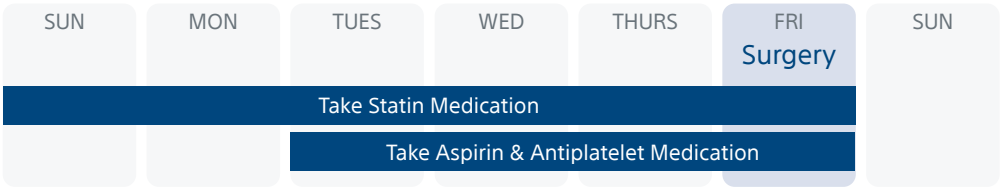
Take this daily at least 5 days prior AND the day of the surgery

Statin

Take this daily at least 3 days prior AND the day of the surgery

Aspirin **AND** **Antiplatelet Medication:** Plavix® (clopidogrel), or Brilinta® (ticagrelor), or Effient® (prasugrel)

Example medicine schedule below



Additional Notes

After Your Surgery

Most patients are able to **go home** the day after the procedure.

You may experience some pain after this procedure, but it should **be minimal.**

Follow all of your **TCAR physician's instructions** for taking care of your incision.

If you experience headaches, dizziness or other unusual symptoms, call your **TCAR physician immediately or dial 911!**

Do NOT discontinue these medications after your **TCAR procedure** until told by your physician[9]:

Aspirin
Plavix® (clopidogrel), or Brilinta® (ticagrelor), or Effient® (prasugrel)
Statin

Additional Notes

Please remember to **schedule** your follow-up appointment. This may include:

1st Follow-up | 2nd Follow-up | 1-Year Follow-up | Additional Screening

Need more information on the treatment options for **carotid artery disease?**

Additional resources:

To learn about other vascular conditions and treatments, visit the Society of Vascular Surgery: **www.vascular.org/patients.**

To learn about stroke, other conditions, and the vast network of support, please visit:

The American Stroke Association: **www.stroke.org**

The American Heart Association: **www.heart.org**

For information on caregiver support, visit:

Family Caregiver Alliance: **www.caregiver.org**

Frequently Asked Questions

What are the benefits of TCAR for patients?

TCAR has a very low procedural stroke rate. It is also less invasive than open surgery, so there's less chance of surgical complications like heart attacks, infection, and nerve injury.[6] TCAR patients also recover quickly and almost always go home the next day with less pain and smaller scars.[6]

How safe is TCAR?

Over 100,000 TCAR procedures have been performed worldwide inside and outside of clinical trials. TCAR has been studied extensively, and the clinical data have been excellent. In fact, the data is so compelling that the Society of Vascular Surgeons, Centers for Medicare and Medicaid Services (CMS), and the U.S. Food and Drug Administration (FDA) came together in September 2016 to create a program to support its reimbursement.

Is it ever a problem that the blood is being diverted away from the brain?

It's rarely a problem because the brain has multiple arteries that supply it with blood. In addition, the critical part of the procedure, when the blood flow is reversed, only lasts about 10 minutes.

Why is it important to follow up with my physician after the procedure?

After your TCAR procedure, it is essential to continue seeing your TCAR provider so they can examine your incision site and ultrasound scan your carotid artery to ensure the stent is working properly. You and your doctor have formed a team in an effort to reduce the risk of restenosis (re-occurring blockage) in the area of your stent. A big part of this includes following your physician's instructions on medications and going to any follow-up appointments. To help stay healthy in the future, you are encouraged to make important diet, exercise, and lifestyle changes. Some patients may need a few modifications, while others may need to make many changes.

Tips to prevent carotid artery disease after my surgery?

After your surgery, it is important to manage the risk factors that put you at risk of having a stroke. This includes smoking cessation, treatment of high blood pressure, and control of blood sugar levels if you have diabetes. Your physician may prescribe medication such as aspirin, warfarin, or ticlopidine to help prevent future blockages in your arteries.[8]

1. www.emro.who.int/health-topics/stroke-cerebrovascular-accident/index.html
2. www.nhlbi.nih.gov/health-topics/carotid-artery-disease
3. www.cdc.gov/stroke/facts.htm
4. Society of Vascular Surgery's Patient-Resources, for further information and disclaimer: vascular.org/patient-resources/vascular-conditions/carotid-artery-disease
5. www.stroke.org/en/help-and-support/for-family-caregivers/15-things-caregivers-should-know-after-a-loved-one-has-had-a-stroke
6. Stroke.2020; 51:2620-2629
7. JAMA. 2019 Dec 17;322(23):2313-2322
8. https://www.ninds.nih.gov/questions-and-answers-about-carotid-endarterectomy
9. rebrand.ly/TCARWhitePaper

ENROUTE™ Transcarotid Neuroprotection System
CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions. **INTENDED USE/ INDICATIONS FOR USE:** The ENROUTE Transcarotid Neuroprotection System (ENROUTE Transcarotid NPS) 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 appropriate anatomy described following: Adequate femoral venous access • Common carotid artery reference diameter of at least 6 mm • 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.
CONTRAINDICATIONS: The ENROUTE Transcarotid NPS is contraindicated for use in patients exhibiting the following conditions: Patients in whom antiplatelet and/or anticoagulation therapy is contraindicated • Patients with unresolved bleeding disorders • Patients with severe disease of the ipsilateral common carotid artery • Uncontrollable intolerance to flow reversal (i.e. pre-conditioning does not result in in tolerance to vessel occlusion/flow reversal) **WARNINGS:** Only physicians who have received appropriate training and are familiar with the principles, clinical applications, complications, side effects and hazards commonly associated with carotid interventional procedures should use this device. • Do not advance any part of the ENROUTE Transcarotid NPS if resistance is felt. Stop and assess the cause of resistance. Failure to do so may cause vessel or product component damage. • If excess resistance is encountered during flushing, preparation, or injection of fluids into any of the ENROUTE Transcarotid NPS system components, stop and assess cause of resistance. Failure to do so may result in damage to the product or harm to the patient.
• The safety and efficacy of the ENROUTE Transcarotid Neuroprotection System has not been demonstrated with carotid stent systems other than Precise® ProRx Carotid Stent, Acculink® Carotid Stent, Xact® Carotid Stent, PROTÉGÉ® Carotid Stent, Carotid WALLSTENT™ Endoprosthesis and ENROUTE® Transcarotid Stent. • Consider severe disease of the contralateral arteries and ipsilateral posterior arteries which may affect adequate cerebral blood flow during flow reversal. • Systemic antiplatelet and anticoagulation therapy should be used before, during and after the procedure based on hospital and physician preferred protocol. **PRECAUTIONS:** Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions. Failure to do so may result in complications. • Refer to Instructions for Use supplied with other interventional devices to be used in conjunction with the ENROUTE Transcarotid NPS for their intended uses, contraindications and potential complications. • The ENROUTE Transcarotid NPS is not recommended in patients who cannot tolerate contrast agents necessary for intra-operative imaging. • Common carotid artery and femoral vein size and morphology should be compatible at the respective access site with the 8 Fr. Transcarotid Arterial and Venous Return Sheaths using standard vascular access techniques. • Proper placement of the ENROUTE Transcarotid NPS Sheaths should be monitored and confirmed fluoroscopically. • Monitoring of patients' neurological status during carotid artery stenting procedure is recommended. • The J-tipped wire provided is not intended to be rotated or torqued during use. • Do not withdraw or manipulate the coated wire in a metal cannula or sharp-edged object. • Avoid wiping the wire with dry gauze as this may damage the wire coating. • Avoid using alcohol, antiseptic solutions or other solvents to pre-treat the guidewire as this may cause unpredictable changes in the coating which can affect the wire safety and performance. • Always inspect the guidewire carefully for bends, kinks or other damage prior to insertion or re-insertion. Do not use damaged guidewires. **POTENTIAL PROCEDURE AND / OR DEVICE RELATED ADVERSE EVENTS:** Complications and adverse events can occur when using any embolic protection device in carotid artery stenting procedures. These complications include, but are not limited to: abrupt vessel closure • allergic reactions • aneurysm • angina / coronary ischemia • arteriovenous fistula • bacteremia or septicemia • bleeding from anticoagulant or antiplatelet medications • bradycardia / arrhythmia and other conduction disturbances • cerebral edema • cerebral hemorrhage • component damage • congestive heart failure • cranial nerve injury (CNI) • death • deployment and retrieval failure • distal embolization • drug reactions • embolism (which includes thrombus, plaque, air, device and / or component) • emergent / urgent endarterectomy • fever • fluid overload • groin hematoma • headache • hemorrhage / hematoma • hemorrhagic stroke • hyperperfusion syndrome • hypertension / hypotension • infection / sepsis • ischemia / infarction of tissue / organ • ischemic stroke • intolerance to vessel occlusion and / or flow reversal • myocardial infarction • pain and tenderness • pseudoaneurysm • reduced blood flow • renal failure / insufficiency • restenosis of the stented artery • seizure • stent deformation • stroke or other neurological complications (e.g., paralysis, paraplegia or aphasia) • surgery required due to device failure • temporary or total occlusion of the artery • thromboembolic episodes • thrombophlebitis • transient ischemic attacks (TIAs) • vascular access complications (e.g., bleeding, vessel damage, pseudoaneurysm and infection) • ventricular fibrillation • vessel spasm, dissection, rupture, or perforation • vessel thrombosis (partial blockage) • unstable angina pectoris. There may be other potential adverse events that are unforeseen at this time. PI-2027808-AA

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