ENROUTE®

Transcarotid Stent and Neuroprotection Systems

SILKROAD MEDICAL®

This guidebook...

This guidebook is provided as a courtesy from Silk Road Medical intended to help you learn more about carotid artery disease.

For your convenience, a glossary of medical terms is included at the end of this booklet. You will find many words that are in bold throughout the text are defined in the glossary.

This booklet is only a guideline. It provides basic information about carotid artery disease and its treatment with the **ENROUTE® Transcarotid Stent System** and the **ENROUTE® Transcarotid Neuroprotection System**. It is not intended to diagnose a medical condition. The treatment of carotid artery disease may vary according to each individual's unique needs and doctor assessments. As with any medical procedure, the best source for information and advice is your doctor.

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Introduction

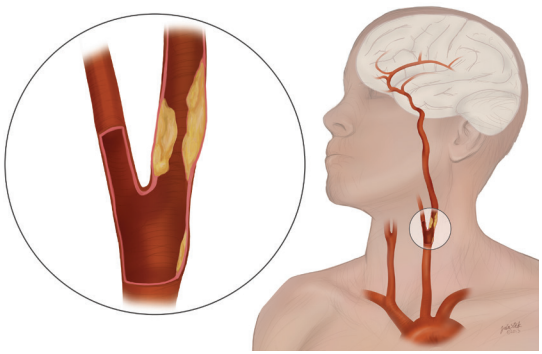
This guidebook is designed to help you and your family understand vascular disease of the **carotid arteries** of your neck and transcarotid treatment with a vascular **stent**. If you have any questions as you read, please write them down and discuss them with your doctor or nurse.

Vascular disease in the carotid arteries of the neck

Vascular disease is caused by the build-up of fatty substances that collect and stick to the linings of your arteries, in a process known as **atherosclerosis**. You may also hear the terms **"plaque"**, "blockage", **"lesion"**, or **"stenosis"**. As the **plaque** build-up continues, the internal lining of your artery thickens which causes the artery to narrow and limit blood flow to vital tissues and organs. Some of the more commonly affected arteries are those located in the heart, legs, arms, neck, and kidneys. The symptoms from these blockages depend on what artery is affected and the severity of the blockage causing limited blood flow. This guidebook describes peripheral vascular disease of the arteries in your neck, which are called **carotid arteries**.

The carotid arteries

Function - Arteries are vessels that carry blood away from the heart. The carotid arteries extend from the main artery (aortic arch) coming directly from your heart and supply oxygen-rich blood to the brain.



Carotid Artery Narrowing (stenosis) - When **plaque** builds up in the **carotid arteries**, they begin to narrow and slow down blood flow to the brain. This is called carotid artery **stenosis**. Severe carotid artery **stenosis** can be a major cause of stroke.

The carotid arteries

Diagnosis - You should be screened for carotid artery stenosis if you have:

- Weakness, numbness, tingling or paralysis of the arm, leg, or face on one side of your body
- Trouble swallowing
- Loss of eyesight or blurry eyesight in one eye
- Dizziness, confusion, fainting, or coma
- Unexplained slurred or garbled speech

Sometimes, patients are screened for carotid artery **stenosis** if the doctor knows the patient has vascular disease elsewhere in the body. Blockages can also be found when your physician hears a sound through a stethoscope placed on the neck. The sound is caused by blood flowing past the blockage.

The carotid arteries (continued)

The following tests may be performed if carotid artery disease is suspected.

Carotid artery ultrasound: This test uses sound waves that produce an image of the **carotid arteries** on a TV screen, and can be helpful in identifying narrowing in the **carotid arteries**. This test is painless and does not require the use of needles, dye, or x-rays.

Angiography: An **angiogram** uses x-rays to take a picture of your carotid artery. In order for the x-ray to "see" your arteries, a dye is injected through a small tube **(catheter)** inserted into an artery in the groin or arm. This procedure will determine exactly where the narrowing is located and will help to guide further treatments. You will be awake for the test, although you will be given a light sedative to relax you. The injection of dye may cause a warm sensation. After the test is complete, you will need to lie flat for 5-6 hours to allow the puncture site in your groin or arm to heal.

If carotid disease is diagnosed during one of these tests, your doctor will discuss your treatment options with you.

Treatment options

There are four basic treatment options for patients with carotid artery stenosis. It is important to inform your doctor about your entire medical history. Be sure to ask your doctor to explain the risks and benefits of your treatment options and answer any questions you or your family may have.

Diet modification and exercise: Decreasing the amount of fat and **cholesterol** in your diet in combination with exercise (especially 30 minutes of walking) in your daily activities may be recommended. Your doctor will make specific dietary and exercise recommendations for you. Other lifestyle changes may also need to be made, including stopping smoking.

Medical Management: Your doctor may prescribe medicine to help thin your blood **(anticoagulants)**, which will improve blood flow and help prevent your blood from clotting. Additionally, medications that help to lower your **cholesterol** and fats may be prescribed. If you have diabetes, your physician may change your medications to help reduce your blood sugar levels.

Both of the above options do not require any physical intervention, but each of them may not be enough to manage your disease completely. If neither of the above options is sufficient to manage your disease, one of the following interventional options may be recommended.

Treatment options (continued)

Carotid Endarterectomy (open surgery): This surgical procedure removes **plaque** from inside of your carotid artery in order to restore normal blood flow to your brain. You are often put to sleep for this procedure using general anesthesia. The surgeon exposes your carotid artery through an incision (cut) in the side of the neck. The artery is clamped on both sides of the blockage and the artery is then opened. If the brain is not getting enough blood flow, a tube called a “shunt” may be placed around the blockage to keep blood flow during the procedure. The **plaque** inside of the artery is then removed and the artery is sewn back together. Sometimes, it is necessary to use a patch or graft when sewing the artery walls together to make the artery wider. Doctors have been successfully conducting the procedure for over 50 years. Be sure to ask your doctor about the risks associated with this surgical procedure.

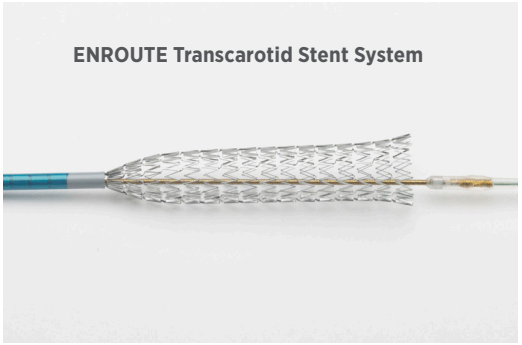
Treatment options (continued)

Transfemoral Carotid Artery Stenting is a procedure in which your physician inserts a slender, metal-mesh tube, called a stent, (introduced through your femoral artery) which expands inside your carotid artery to increase blood flow in areas blocked by plaque. This procedure has been performed safely for over 10 years.

Carotid Artery Stenting with the ENROUTE Transcarotid Stent and Neuroprotection Systems: This procedure is presently available to you only if you have other conditions that place you at a high risk for carotid endarterectomy (open surgery). The procedure involves placement of a **stent** into your carotid artery. The TCAR Procedure (TransCarotid Artery Revascularization) is performed through a small incision at your neckline just above your clavicle. The incision is smaller than a typical Carotid Artery Endarterectomy (CEA) incision. Your surgeon will temporarily place a tube directly into your carotid artery and connect it to a system that will temporarily direct blood flow away from your brain, to protect against particles that may come loose during the procedure. Your blood will flow through the system and very small particles may be captured in a filter. Your filtered blood will then be returned through a tube in your upper leg. While flow is reversed, a stent is placed at the area of your blockage. The stent holds the artery open to allow normal blood flow to the brain. The stent is approximately ¾ to 1½ inches in length and ¼ inch in diameter when expanded. You may remain awake during the stenting procedure. Please refer to “Stent implantation procedure” in this booklet for a more detailed description of the procedure. After the stent is placed successfully, flow reversal is turned off and blood flow resumes in its normal direction.

Device Description

ENROUTE Transcarotid Stent System: The ENROUTE Transcarotid Stent is made of a metal called nitinol. The **stent** is inside a tube (delivery system) for passage into the body to the **carotid arteries**, where it is released to hold open the blockage.



Device Description

ENROUTE Transcarotid Neuroprotection System: The ENROUTE Transcarotid Neuroprotection System draws upon proven surgical techniques to reduce the risk of stroke during carotid artery stenting. It allows physicians to deliver a stent directly from the neck, which is intended to avoid complications associated with starting from the femoral artery in the groin, which is typically used in carotid artery stenting procedures. To provide protection for the patient's brain during the entire procedure, the ENROUTE Transcarotid Neuroprotection System temporarily reverses blood flow in order to move any potential particles away from the brain.

Clinical Studies

The ENROUTE Transcarotid Stent System was approved via two clinical studies.

The ROADSTER study was a multi-center clinical study of the ENROUTE Transcarotid Neuroprotection System used together with any FDA-approved carotid artery stent used for treatment of carotid artery disease in patients who are at high risk for complications from carotid endarterectomy surgery. A sub-study of ROADSTER patients received the Cordis PRECISE stent, which is the same as the ENROUTE Transcarotid stent.

The ROADSTER sub-study demonstrated that the safety and effectiveness of the approved PRECISE stent system was not impacted when delivered through a transcarotid approach using the ENROUTE Transcarotid Neuroprotection System (i.e., via an incision in your neck instead of the typical femoral artery approach for carotid stenting, which involves an incision in your leg). One out of 52 patients in the sub-study experienced a minor stroke within 30 days following the procedure.

The Silk Road Medical Embolic Protection System: First In Man Study (PROOF) was a clinical study that collected short-term data from 75 patients in Germany using an early design of the ENROUTE Transcarotid Neuroprotection System. A subset of patients in the PROOF study (13 patients) was treated with a combination of the PRECISE Stent and the ENROUTE Transcarotid Neuroprotection System. None of the 13 patients experienced a major stroke, myocardial infarction, or death during the 30-day post-procedural period.

Clinical Studies

The ROADSTER 2 study evaluated usage of the ENROUTE® Transcarotid Stent System in conjunction with the ENROUTE® Transcarotid Neuroprotection System in high surgical risk patients with carotid artery stenosis. 692 patients were treated across 43 sites, with 81% of the physician enrollers being new TCAR operators. In the study, TCAR is demonstrated as a safe and effective procedure in a broad user base with varying TCAR experience levels. The per protocol results at 30 days from the study also demonstrate that low stroke (0.6%) and death (0.2%) rates are possible with TCAR, particularly when treatment protocols and society guidelines are followed (patient/lesion selection, drug regimen, procedure technique).

Potential Risks

Treatment with the ENROUTE Transcarotid Stent and Neuroprotection Systems may involve the following risks. Your doctor can help you understand these risks.

- Air embolism (air bubbles in arteries or veins)
- Allergic reaction to device materials
- Anemia (lack of healthy red blood cells)
- Aneurysm (weakened area of the artery)
- Angina/coronary ischemia (chest pain/reduced blood flow to heart tissue)
- Arrhythmia (irregular heart beat that may require medical correction)
- Arterial dissection (separation of the walls of the artery)
- Arterial occlusion/restenosis of the treated vessel (blockage of the artery or recurrence of blockage)
- Arterial occlusion/thrombus at puncture site (blockage at the puncture site or blood clot)
- Arterial occlusion/thrombus remotely (blockage or blood clot somewhere else in the body)
- Arteriovenous fistula (abnormal blood flow from an artery to a vein)
- Atelectasis (collapsed lung)
- Atrial Fibrillation (irregular heart rate)
- Bacteremia or septicemia (harmful bacteria in the blood)
- Cerebral edema (excess fluid in the brain)
- Congestive heart failure (poor functioning of the heart)
- Death
- Embolization, arterial (debris in the artery)
- Embolization, stent (debris in the stent)
- Emergent repeat hospital intervention
- Fever
- Gastrointestinal disorders (digestive system problems)
- GI bleeding from anticoagulation/antiplatelet medication (bleeding in the digestive system from medications)
- Hallucination (false sensations cause by the brain)
- Hematoma bleed, access site (abnormal collection of blood at the access site)
- Hematoma bleed, remote site (abnormal collection of blood away from the access site)
- Hemorrhage (bleeding from an artery or vein)
- Hyperperfusion syndrome (leaking of fluid from blood vessels that cause brain swelling or headache)
- Hypotension/hypertension (abnormally low or high blood pressure)

Potential Risks (continued)

- Hypomagnesaemia (abnormal magnesium levels in the blood)
- Hypophosphatemia (abnormal levels of phosphate in the blood)
- Infection
- Intimal injury/dissection (injury to the walls of an artery)
- Ischemia/infarction of tissue/organ (lack of blood flow to tissue or organ/permanent damage to tissue or organ)
- Local infection and pain at insertion site
- Malposition (failure to deliver the stent to the intended site)
- Myocardial infarction or cardiac enzyme increase (heart attack or abnormal increase in heart muscle proteins that could signify heart muscle damage)
- Nausea
- Oxygen saturation decrease (decreased concentration of oxygen in the blood)
- Pain
- Pseudoaneurysm (injured blood vessel causing blood to leak)
- Rales (clicking or bubbling sounds in the lungs)
- Renal failure (kidney failure)
- Respiratory Infection (lung infection)
- Restenosis of the vessel (> 50% obstruction) (re-blockage of the vessel)
- Rhinorrhea (runny nose)
- Seizure
- Severe unilateral headache
- Stent migration
- Stent thrombosis (blood clots in the stent)
- Stroke
- Transient ischemic attack (mini-stroke lasting a short time)
- Transient intolerance to reverse flow (temporary loss of consciousness or reduced consciousness)
- Urinary tract infection
- Vasospasm (abnormal constriction of a blood vessel)
- Venous occlusion/thrombosis, at puncture site (blockage or blood clots in a vein used for access)
- Venous occlusion/thrombosis, remote from puncture site (blockage or blood clots in a vein not used for access)
- Vessel rupture, dissection, perforation (burst or damaged artery or vein)
- Vomiting (throwing up)
- Wheezing (difficulty breathing)

Potential Risks (continued)

Contraindications:

If you cannot take antiplatelet medication and/or anticoagulation therapy medications, if you have a bleeding problem, or if you have a known allergy to nickel or Nitinol, then this procedure is not suitable for you.

Preparing for your procedure

When **plaque** builds up in your **carotid arteries**, they begin to narrow and slow down blood flow to your brain. This is called carotid artery stenosis. Severe carotid artery stenosis is a major cause of stroke. The benefit of having **carotid artery** stenting is to reduce carotid artery stenosis.

As with any intervention, the stenting procedure involves some risks. These risks include, but are not limited to:

- Stroke, heart attack, allergic reaction to the dye, slow heartbeat which requires treatment, or death
- Rupture or damage to your carotid artery, excessive bleeding, infection/fever
- Bleeding, bruising or swelling at the access site in your neck
- Failure to deliver the stent to the site of your blockage (treatment failure)

Be sure that your doctor has discussed the procedure and the possible benefits and risks with you and that any questions you have are answered.

Suggested Medication
- Start Aspirin ≥ 3 days prior
- Start Plavix (P2Y12 inhib) ≥ 3 days prior
- Start Statin > 5 days prior

Preparing for your procedure (continued)

Upon admission to the hospital, you will have had tests such as carotid artery ultrasound, angiography and routine blood tests. Be sure to tell your doctor what medications you are currently taking and any allergies you might have. You will probably be asked not to eat or drink anything after midnight on the night before your procedure. You will be asked to take aspirin for one to two days before the procedure and your doctor may ask you to change other medications.

Do NOT discontinue these medications on the day of the TCAR procedure:
- Aspirin
- Plavix
- Statin

The procedure will be performed in a catheterization laboratory or an operating room. You will lie on a table, and an x-ray camera will pass over your neck during the procedure. Your heart and blood pressure will be monitored during the course of the procedure.
The procedure will involve little to moderate pain and you will experience mild to moderate discomfort during the first few hours following the procedure. Dye injected through catheters will allow the doctor to see the area of blockage in your vessels. Although rare, dye may produce an allergic reaction causing low blood pressure and breathing difficulties.

Flow reversal and stent implantation procedure

Your procedure will be performed in a room equipped with special instruments and x-ray equipment. Once you enter this room, you will be moved onto an x-ray table. You will be covered with sterile sheets and the areas where the incision will be made and the **catheters** will be inserted (groin & neck) will be shaved and washed with an antiseptic solution to prevent infection.

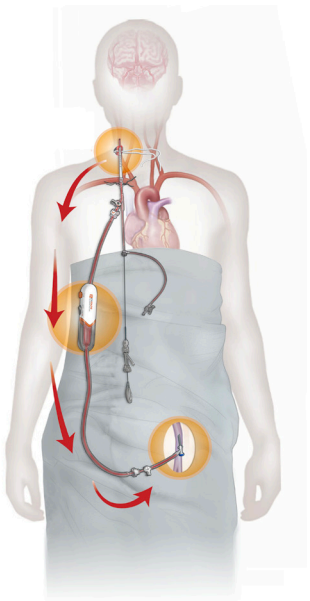
You may be awake during your procedure. Your doctor or a hospital member may give you instructions. It is important to listen for these instructions and do what is asked.

A numbing medication **(local anesthetic)** will be used at the sites where the **catheter** is inserted and where the incision will be made. You may feel a stinging sensation when this medication is given. After the medication takes effect, you should only feel dull pressure where the doctor is working with the **catheters**. Where the neck is cut, a small tube called a sheath will be inserted into your carotid artery. The sheath provides a passageway through which the doctor can insert the ENROUTE Transcarotid Neuroprotection System, the ENROUTE Transcarotid Stent System, and other potential catheters.

Flow reversal and stent implantation procedure (continued)

Dye injected through the **catheters** will allow the doctor to see the area of blockage in your arteries. An x-ray machine with a TV screen allows the doctor to see your arteries and any **catheters** that are moved in your arteries. Once your doctor has taken pictures of the blockage, the ENROUTE Transcarotid Neuroprotection System is activated and flow reversal begins. Your filtered blood will then be returned through a tube in your upper leg.

The ENROUTE Transcarotid **Stent** is then put into the **carotid artery** on a delivery system and moved to stabilize the blocked area of the artery. The **stent** will open to fit the artery when it is released. One or more **stents** may be implanted. After the **stent** is placed, the delivery system is taken out. The **stent** stays in place permanently, holding the artery open. After **stent** placement is completed, the ENROUTE Transcarotid Neuroprotection System is turned off and taken out of the body. The small incision in your neck is then sutured closed. Your procedure will take approximately 60-90 minutes.



After your procedure

The sheath that was put in your leg at the beginning of the procedure is removed at the end of the procedure and handheld pressure will be administered to stop the bleeding. After the procedure, you will be moved to a special care unit where you will be closely monitored by the hospital staff. Your blood pressure and heart rhythm will be monitored continuously.

While you are in the hospital, notify your doctor if you feel lightheaded or dizzy, have trouble swallowing, have trouble seeing, or have blurry eyesight in one eye. Also notify them if you have weakness, numbness, or tingling or can't move your arm, leg, or face on one side of your body, or have unexplained slurred or garbled speech, or if you notice any bleeding, swelling, or discomfort from where your neck was cut or where the sheath was placed in your leg.

Your recovery

Before you leave the hospital, your doctor will give you advice for activity, diet and medications. You will be asked to avoid hard activities like lifting for at least a week. You will be told when you can resume normal activity and return to work. Your doctor will prescribe medications for you to take to prevent blood clots from forming in your newly opened artery. Please notify your doctor if these medications cause unpleasant reactions. Do not stop taking them unless your doctor tells you to do so. Different medications may be prescribed that suit you better.

Patients who undergo carotid **stent** implantation are usually discharged from the hospital the next day. You should arrange to have someone take you home rather than driving yourself. After you leave the hospital, it is important to keep all of your scheduled appointments so that your progress can continue to be monitored.

If you have any pain, discomfort or bleeding from where your neck was cut or where the sheath was placed in your leg, call your doctor immediately. Also call your doctor immediately if you are lightheaded or dizzy, have trouble swallowing, have trouble seeing, or have blurry eyesight in one eye. Also notify your doctor if you have weakness, numbness, tingling or can't move your arm, leg, or face on one side of your body, or have unexplained slurred or garbled speech. If your doctor can not be reached immediately, call 911 to be taken to the nearest hospital emergency room.

After **stent** placement, you will be followed closely to monitor your recovery. An **ultrasound** will be performed at a later date to determine if any narrowing has occurred in the treated artery.

Lifestyle changes

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**.

To help stay healthy in the future, you are encouraged to make important diet, exercise, and lifestyle changes. Some patients may need few modifications while others may need to make many changes. It is extremely important to avoid smoking. If you need help quitting, please notify your healthcare provider.

Stent implant card

Be sure your doctor gives you a completed "Stent implant card" that you can keep as a record of your procedure. Carry the card with you at all times and show it to any doctors or healthcare workers who may be treating you. The card will have the date of the **stent** procedure, location of the **stent** in your body, the name of the doctor who performed the procedure, and other important information.

If you require magnetic resonance imaging (MRI) after carotid artery stenting

If you require **MRI** after carotid artery stenting, tell your healthcare providers that you have a stent and show them your stent implant card, which will advise them to refer to the ENROUTE Transcarotid Stent System Instructions for Use or to call 408-720-9002 for more information about **MRI** compatibility of the ENROUTE Transcarotid Stent System.

Conclusion

You have a very important role to play in order to ensure that your stent implantation is successful. It is essential that you cooperate with your doctor and follow through with your responsibilities as part of the patient/doctor medical team. Keep your appointments, live a healthy lifestyle, and continue to follow your doctor's advice with respect to any other medical conditions that you are being treated for. If you have any questions or concerns, please contact your doctor to discuss them. It is important that you get the most benefit from your treatment and join the thousands of people with vascular disease who are leading healthy, productive lives.

Glossary

Angiogram: A procedure in which contrast dye is injected into the arteries to diagnose a narrowing or blockage of an artery.

Anticoagulant: A medicine that slows or prevents the clotting of blood.

Atherosclerosis: The process of fatty deposits and/or calcium buildup (plaque) on the inside of the arteries.

Carotid Arteries: Arteries are vessels that carry blood away from the heart. The carotid arteries extend from the main artery (aortic arch) coming directly from the heart and supply oxygen rich blood to the brain.

Catheter: A long hollow tube used to introduce a device, drug, or dye into a blood vessel,

Catheterization: A procedure that involves passing a tube (catheter) through blood vessels and injecting dye to detect blockages.

Cholesterol: A substance that circulates in the blood and when deposited in the artery, plays a role in the formation of blockages. Cholesterol originates in foods that are rich in animal fat.

Lesion: A blockage in a blood vessel. Also known as plaque or stenosis.

Local Anesthetic: A substance used to numb the area to which it is applied.

MRI (Magnetic Resonance Imaging): A diagnostic test that uses magnetic waves to obtain images of the inside of your body.

Plaque: An accumulation or build-up of fatty deposits, calcium, and/or cell debris in an artery that leads to narrowing of the artery.

Restenosis: The recurrence of a narrowing of blockage in an artery after treatment.

Stent: An expandable, metallic tubular shaped device that provides structural support for a vessel.

Stenosis: A narrowing in your arteries caused by plaque build-up, which restricts blood flow.

Ultrasound: A non-invasive test using sound waves to determine the presence of arterial narrowing.

Contact Information:
Your doctor or nurse will review this material with you. We encourage you to ask them any questions regarding your treatment and recovery.

Additionally, your doctor may recommend that you join a support group to speak with others who have undergone similar procedures. Ask your doctor for contact information about these groups and possible web site addresses.

For more information, please visit
www.silkroadmed.com

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