

# TransCarotid Artery Revascularization (TCAR)

## *Frequently Asked Questions*

### **What is TransCarotid Artery Revascularization or TCAR?**

TCAR has been clinically proven as a less-invasive alternative to carotid endarterectomy, a traditional open surgery performed to treat carotid artery disease. What's unique about TCAR is it temporarily reverses the blood flow during the procedure, so that any small bits of plaque that may break off during the procedure are diverted away from the brain, preventing a stroke from happening. A stent is then placed inside the artery to stabilize the plaque, minimizing the risk of a future stroke.

### **How is TCAR better for patients?**

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

### **How safe is TCAR?**

Over 10,000 TCAR procedures have been performed worldwide through clinical trial and commercial use. TCAR has been studied extensively, and the clinical data have been excellent. In fact, the data are 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.

### **Who should be considered for the TCAR procedure?**

TCAR is recommended for patients who are considered high risk for traditional surgery due to age, anatomic issues and other medical conditions. A physician will determine if the TCAR procedure is right for a patient on a case-by-case basis based on his/her medical history and workup.

### **What happens during a TCAR procedure?**

A small incision is made at the base of the neck, just above the collarbone. A puncture is made into the carotid artery and a small tube is placed inside the artery, which is connected to the system that temporarily directs blood flow away from the brain and captures any dangerous debris that dislodges from the artery. The blood is then filtered and returned to a vein through a second tube placed in the groin. While the brain is protected during this temporary flow reversal, a stent is placed in the carotid artery to stabilize the plaque and is intended to help prevent against future stroke. The blood flow is then returned to normal and the system is removed.

The entire procedure usually takes less than an hour. Patients can be either asleep or awake during the TCAR procedure and patients are typically held overnight for observation.

### **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.

### **Who invented TCAR?**

Vascular surgeons Dr. David Chang and Dr. Enrique Criado came up with the idea separately, but around the same time in 2004. Silk Road Medical, Inc. based in California has worked over the past 10+ years with the vascular surgery community in refining the procedure, conducting clinical trials, and are now commercializing TCAR in the U.S.

For more information about the TCAR procedure and essential prescribing information, please visit <http://silkroadmed.com/ifus/>. For more information about carotid artery disease and the risks involved with any intervention (e.g. bleeding, death, myocardial infarction, restenosis, stroke, TIA, vessel dissection, vessel occlusion, etc.) please visit <http://silkroadmed.com/disease-and-treatment-options/>.

## Key Statistics

Silk Road Statement	Reference statement	URL
Every year, 15 million people worldwide suffer a stroke, also known as a brain attack	Annually, 15 million people worldwide suffer a stroke. Of these, 5 million die and another 5 million are left permanently disabled, placing a burden on family and community.	<a href="http://www.emro.who.int/health-topics/stroke-cerebrovascular-accident/index.html">http://www.emro.who.int/health-topics/stroke-cerebrovascular-accident/index.html</a>
Every year, about as many Americans have a stroke as a heart attack	Each year, about as many Americans have a stroke as a heart attack	<a href="http://www.strokeassociation.org/STROKEORG/AboutStroke/AmericanStrokeMonth/American-Stroke-Month_UCM_459942_SubHomePage.jsp">http://www.strokeassociation.org/STROKEORG/AboutStroke/AmericanStrokeMonth/American-Stroke-Month_UCM_459942_SubHomePage.jsp</a>
Often called the silent killer, the first symptom of a patient at risk for stroke is a stroke itself	Nearly 800,000 (approximately 795,000) people in the United States have a stroke every year, with about three in four being first time strokes.  Stroke is the No. 5 cause of death in the United States, killing 130,000 people a year.	<a href="https://www.strokeassociation.org/STROKEORG/AboutStroke/Impact-of-Stroke-Stroke-statistics_UCM_310728_Article.jsp">https://www.strokeassociation.org/STROKEORG/AboutStroke/Impact-of-Stroke-Stroke-statistics_UCM_310728_Article.jsp</a>
Every year, stroke kills 6 million and another 5 million are permanently disabled	An estimated 17.7 million people died from CVDs in 2015, representing 31% of all global deaths. Of these deaths, an estimated 7.4 million were due to coronary heart disease and 6.7 million were due to stroke.	<a href="http://www.who.int/mediacentre/factsheets/fs317/en/">http://www.who.int/mediacentre/factsheets/fs317/en/</a>
87% of strokes are caused by blocked arteries	Ischemic stroke accounts for about 87 percent of all cases.	<a href="http://www.strokeassociation.org/STROKEORG/AboutStroke/TypesofStroke/IschemicClots/Ischemic-Stroke-Clots_UCM_310939_Article.jsp">http://www.strokeassociation.org/STROKEORG/AboutStroke/TypesofStroke/IschemicClots/Ischemic-Stroke-Clots_UCM_310939_Article.jsp</a>
80% of strokes are preventable	80% of strokes are preventable	<a href="http://www.strokeassociation.org/STROKEORG/AboutStroke/AmericanStrokeMonth/American-Stroke-Month_UCM_459942_SubHomePage.jsp">http://www.strokeassociation.org/STROKEORG/AboutStroke/AmericanStrokeMonth/American-Stroke-Month_UCM_459942_SubHomePage.jsp</a>
Up to 1/3 of strokes are caused by carotid artery disease	Carotid stenosis is responsible for up to one-third of all strokes	<a href="https://vascular.org/patient-resources/vascular-conditions/carotid-artery-disease">https://vascular.org/patient-resources/vascular-conditions/carotid-artery-disease</a>
About 1 in 3 people who have a transient ischemic attack (TIA) will have a stroke	About 1 in 3 people who have a transient ischemic attack will eventually have a stroke, with about half occurring within a year after the transient ischemic attack.	<a href="https://www.mayoclinic.org/diseases-conditions/transient-ischemic-attack/symptoms-causes/syc-20355679">https://www.mayoclinic.org/diseases-conditions/transient-ischemic-attack/symptoms-causes/syc-20355679</a>

<p>People with diabetes are 2-4 times more likely to have a stroke</p>	<p>High blood sugar can make you 2-4 times more likely to have a stroke.</p> <p>People with diabetes are up to four times more likely to have a stroke than people who don't.</p>	<p><a href="https://www.webmd.com/stroke/guide/understanding-stroke-prevention#2">https://www.webmd.com/stroke/guide/understanding-stroke-prevention#2</a></p> <p><a href="http://www.stroke.org/understand-stroke/preventing-stroke/medical-risk-factors">http://www.stroke.org/understand-stroke/preventing-stroke/medical-risk-factors</a></p>
<p>About 1 in 5 people who suffer a stroke have A-fib</p>	<p>And an irregular atrial heart rhythm — a condition called atrial fibrillation — is present in about one out of five strokes.</p>	<p><a href="http://www.heart.org/HEARTORG/Conditions/Arrhythmia/AboutArrhythmia/High-Blood-Pressure-AFib-and-Your-Risk-of-Stroke_UCM_443852_Article.jsp#.Wox7Gqjwbb0">http://www.heart.org/HEARTORG/Conditions/Arrhythmia/AboutArrhythmia/High-Blood-Pressure-AFib-and-Your-Risk-of-Stroke_UCM_443852_Article.jsp#.Wox7Gqjwbb0</a></p>
<p>In people having a stroke for the first time, 3/4 have high blood pressure</p>	<p>About three out of four people who have a stroke for the first time have high blood pressure.</p>	<p><a href="http://www.heart.org/HEARTORG/Conditions/Arrhythmia/AboutArrhythmia/High-Blood-Pressure-AFib-and-Your-Risk-of-Stroke_UCM_443852_Article.jsp#.Wox7jqjwbb0">http://www.heart.org/HEARTORG/Conditions/Arrhythmia/AboutArrhythmia/High-Blood-Pressure-AFib-and-Your-Risk-of-Stroke_UCM_443852_Article.jsp#.Wox7jqjwbb0</a></p>

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