



Cardiothoracic and
Vascular Surgeons

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**CARDIOTHORACIC & VASCULAR SURGEONS THE
FIRST IN TEXAS TO ENROLL IN GLOBAL CLINICAL TRIAL FOR
NEW CAROTID ARTERY TREATMENT**

New Procedure Designed to Help Safely Open Blocked Carotid Arteries Less Invasively

September 17, 2013 – Austin, Texas – Cardiothoracic and Vascular Surgeons is the first in Texas to enroll patients in the ROADSTER Study, a global, multicenter clinical trial evaluating the safety and efficacy of the Silk Road™ System for the treatment of carotid artery disease. Dr. Mazin Foteh and Dr. Jeffrey Apple, board-certified vascular surgeons, performed the procedure on two patients.

Every year, more than 300,000 people in the United States are diagnosed with blockages, or plaques, in their carotid artery. If left untreated, these blockages can slow or even stop blood flow to the brain, causing a potentially disabling stroke, also known as a “brain attack.”

Current treatment options include an open surgery known as carotid endarterectomy (CEA) and a minimally invasive alternative known as carotid artery stenting (CAS). Both procedures have been shown to effectively treat the blockage and reduce a patient’s risk of stroke. However, each option has limitations for patients. CEA involves a large incision along the neck and carries a risk of surgical complications. CAS is less invasive, but in some studies, has not been as effective in preventing strokes as CEA.

The ROADSTER trial is investigating a new system designed to combine the advantages of both CEA and CAS in a procedure called Transcarotid Stenting with Dynamic Flow Reversal, also known as the Silk Road procedure. This procedure incorporates proven surgical techniques to protect the brain from stroke risk during carotid stenting. It allows physicians to deliver a stent directly from the neck, potentially offering a safer delivery route than the groin, which is typically used in CAS procedures. Another unique aspect of the system is the ability to temporarily reduce blood flow during the procedure which is intended to continuously protect the brain during the intervention. The Silk Road procedure is minimally invasive and can be performed using local anesthesia.

Cardiothoracic and Vascular Surgeons was selected as one of 25 centers around the world participating in the trial, which is expected to enroll 140 patients. The trial is intended to support FDA clearance of the Silk Road System in the United States.

“The potential to treat carotid disease with a less invasive method that potentially offers the same safety profile as traditional surgery is exciting. Our goal is to treat the blockage with as little procedural risk as possible so that our patients can return to full and productive lives,” Dr. Apple said.

In a European study (PROOF) performed last year, the Silk Road procedure demonstrated very encouraging results. In a population of 75 patients, the results closely matched the outcomes demonstrated in numerous CEA studies and were better than the stroke outcomes reported in several CAS studies.

The PROOF study also used a sensitive imaging test to determine how well the Silk Road System protected the brain from tiny plaque debris that can be displaced during CEA and CAS treatment and lodge in the brain. . The imaging analysis indicated that the Silk Road system provided impressive protection with a very low rate of localized brain injury.

“This procedure is first-of-its-kind in combining the safety advantages of traditional surgery with the more patient-friendly advantages of stenting,” said Dr. Foteh, ROADSTER investigator with Cardiothoracic and Vascular Surgeons. “We are proud to contribute to this important research and potentially find a new treatment alternative.”

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About Cardiothoracic and Vascular Surgeons

For over five decades, Cardiothoracic and Vascular Surgeons (CTVS) has been proud to offer Central Texas the most specialized and innovative cardiothoracic, vascular, and pediatric surgical care available. The most sophisticated diagnostic and surgical techniques are provided by 22 CTVS surgeons from offices in Central Austin, Williamson County, Hays County, and all area hospitals. Individually and collectively, CTVS surgeons have amassed a record of medical “firsts” in Central Texas, including performing the first heart and kidney transplants in the area. Since 1958, the surgeons along with the clinical team of physician assistants, nurses, and technicians, have shared a commitment to patients, their health and the community. To learn more about Cardiothoracic and Vascular Surgeons, please call 512-459-8753 or visit us online at www.ctvstexas.com.

About the Silk Road System

The Silk Road procedure includes a combination direct carotid access sheath and dynamic flow reversal circuit (the Silk Road System) and a carotid stent. After a tiny incision is made at the neckline, the physician inserts a small tube, called a sheath, into the carotid artery. The sheath is connected to a device that temporarily re-directs blood flow away from the brain. Reversing the blood flow allows a physician to place a stent inside the blockage without risk of plaque breaking off and traveling up toward the brain. After the stent is placed successfully, flow reversal is turned off and blood flow resumes in its normal direction. Typically, the Silk Road procedure is performed under local anesthesia and can significantly minimize recovery time and scarring for the patient. Silk Road Medical is a private company based in Sunnyvale, California.

Caution: Investigational device. Limited by federal (USA) law to investigational use.