



Michigan Vascular Center (MVC) - Mission Statement

MVC exists to improve the quality of life for patients by providing the most comprehensive, innovative and best possible vascular care based on sound principles of treatment.

MVC exists to render that care with compassion, respect, & integrity; exercising the best possible thought and judgment for the patient's benefit.

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Michigan Vascular Selected To Participate In Terumo Cardiovascular Systems' Endovascular Stent Graft IDE Study

For every dark cloud there is the proverbial silver lining and so it is in Michigan. While we have spent many anxious moments fretting over the economic storm that has caused the loss of many manufacturing jobs, we are also learning about the silver lining - the new, high-tech firms which are quietly moving into the state to diversify our economy and provide the base for tomorrow's job growth. With this in mind, we are happy to announce our association with Terumo Cardiovascular Systems, a Michigan medical device firm dedicated to cardiac and vascular surgery.

Terumo CVS has grown in Ann Arbor since 1999 and now employs about 500 people. It is a subsidiary of Terumo Corporation, a global medical device manufacturer focused on cardiac and vascular specialties with 13,000 associates and 17 production facilities around the world. Terumo CVS is the exclusive distributor of Vascutek® vascular grafts in the U.S. Their abdominal aortic endograft, *Anaconda*, is presently in clinical study in the United States. We at the Michigan Vascular Center are privileged to be an investigational site.

Please read the specifics on the *Anaconda* AAA Stent Graft System and the study in the following pages. We at the Michigan Vascular Center are glad that Terumo CVS is located in Michigan and we look forward to a long association. We are not alone in the belief that the engineering expertise of our state and region will become a magnet for other firms in the medical device field and we look forward to partnering with them as well.

Michigan Vascular Center is now enrolling patients in the *Anaconda* AAA Stent Graft System Phase II IDE Study and would welcome your patient referrals.

In closing, I would remind all that September is *Vascular Awareness Month*. As such, I leave you with this thought—SAAAVE a life, find an aneurysm!



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Anaconda™ AAA Stent Graft System

Disease State*

Abdominal aortic aneurysms (AAA) afflict 200,000 patients in the United States every year. The treatment of this disease is based upon the concept of aneurysm repair prior to the presentation of symptoms or rupture. Thus aneurysm repair can be viewed as a prophylactic procedure embarked upon to prevent the disastrous complications of a ruptured aneurysm. The decision to treat an aneurysm electively is based upon a risk to benefit ratio.

Treatment Options Include:

- Medical management of co-morbidities (hypertension, pulmonary disease, etc.) with observation of the aneurysm
- Open surgical aneurysm repair through a transabdominal or retroperitoneal approach
- Endovascular aneurysm repair

The decision to intervene is based upon physician judgment.

Endovascular repair has several beneficial characteristics in comparison to an open surgical approach. They include the potential for less blood transfusions, shorter ICU and total hospital stays, and less intraoperative intubation, to name a few. However, the procedure requires adequate imaging prior to graft placement and during follow-up, in addition to the availability of a trained team to ensure proper device placement.

Anaconda™ AAA Stent Graft System

Manufactured by Scotland-based Terumo subsidiary Vascutek Ltd., the Anaconda system is a modular component system designed for the endovascular repair of infrarenal AAA.

Some Characteristics Include:



- The various sizes of bifurcate bodies, legs and cuffs are made of woven polyester fabric.
- Independent, multiple-turn nitinol (NiTi) support rings on the legs and body of the graft are attached to the fabric.
- Body component can be repositioned during the procedure.
- The system utilizes active fixation by anchoring eight hooks (four pairs) into the infrarenal aorta.
- Guidewire with integrated magnet technology is used during the contralateral cannulation.

The Anaconda AAA Stent Graft System received CE Mark in Europe in April 2005. Outside of the United States, it has been successfully implanted in over 7,000 cases.

About Terumo

Who is Terumo Cardiovascular Systems?

Headquartered in Ann Arbor, Terumo Cardiovascular Systems is the sponsor of the Anaconda Stent Graft System Phase II IDE Study. Terumo CVS also develops, manufactures and distributes medical devices for cardiac and vascular surgery with an emphasis on cardiopulmonary bypass, intra-operative monitoring and vascular grafting. For more information, visit www.terumo-cvs.com.

Who is Vascutek Ltd.?

A sister company to Terumo CVS headquartered in Glasgow, Scotland, Vascutek is the manufacturer of the Anaconda AAA Stent Graft System. In addition to the Anaconda system, Vascutek manufactures a comprehensive line of thoracic, abdominal, and peripheral prosthetic grafts for vascular surgery and vascular access.

Our Parent Company

Terumo Corporation is a premier global medical device company with annual sales of more than three billion dollars for the year ending March 31, 2010. Founded in 1921, the company develops, manufactures and distributes world-class medical devices for use in cardiothoracic surgery, interventional procedures, transfusion medicine, and needle and syringe products. For more information, visit www.terumo.co.jp/English/index.html.

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Pre-implant



**Post-implant
with Anaconda
Stent Graft in
place**

* Excerpted from www.clinicaltrials.gov

Anaconda™ AAA Stent Graft System Phase II IDE Study

About the Study

The primary objective of the study is to assess the safety and effectiveness of the Anaconda Stent Graft System in subjects presenting with an infrarenal abdominal aortic aneurysm (AAA) compared to historical open surgical repair. The secondary objective is to assess the clinical outcomes of the Anaconda AAA Stent Graft System associated with treatment of an infrarenal AAA.

Currently 27 sites in the United States and Canada participate in the study with an enrollment goal of 180 patients. See the map below for current site locations.

More detailed information is available at www.clinicaltrials.gov. Reference trial identifier NCT00612924.

Patients and their families can stay informed and organized by reading Terumo's patient support materials specific to this study. These materials address many frequently asked questions and concerns associated with AAA and repair. They are available to all prospective study participants through Michigan Vascular Center.

Basic Inclusion Criteria:

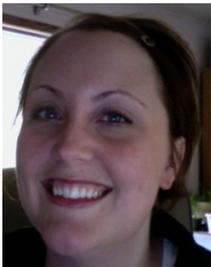
- Males with infrarenal AAA ≥ 4.5 cm in diameter, or AAA growth ≥ 1.0 cm/yr
- Females with infrarenal AAA ≥ 4.0 cm in diameter, or AAA growth ≥ 1.0 cm/yr
- Male or female ≥ 18 and ≤ 85 years of age
- Willing and able to comply with the 5 year follow-up period
- Femoral/Iliac artery access vessels, size and morphology compatible with appropriate introducer sheath (18F, 20F or 23F)
- Only proximal, non-aneurysmal aortic neck lengths of 15mm or greater and neck angulations of 60 degrees or less

Thank You

Terumo Cardiovascular Systems would like to thank Michigan Vascular Center for allowing them to reach its newsletter readers and let them know about the Anaconda AAA Stent Graft System Phase II IDE Study. As a Michigan company, Terumo CVS welcomes the opportunity to help Michigan patients through the study program.

As Dr. Dall'Olmo mentioned, Michigan Vascular Center is an experienced clinical site currently participating, and actively enrolling, in the Anaconda Phase II IDE Clinical Study.

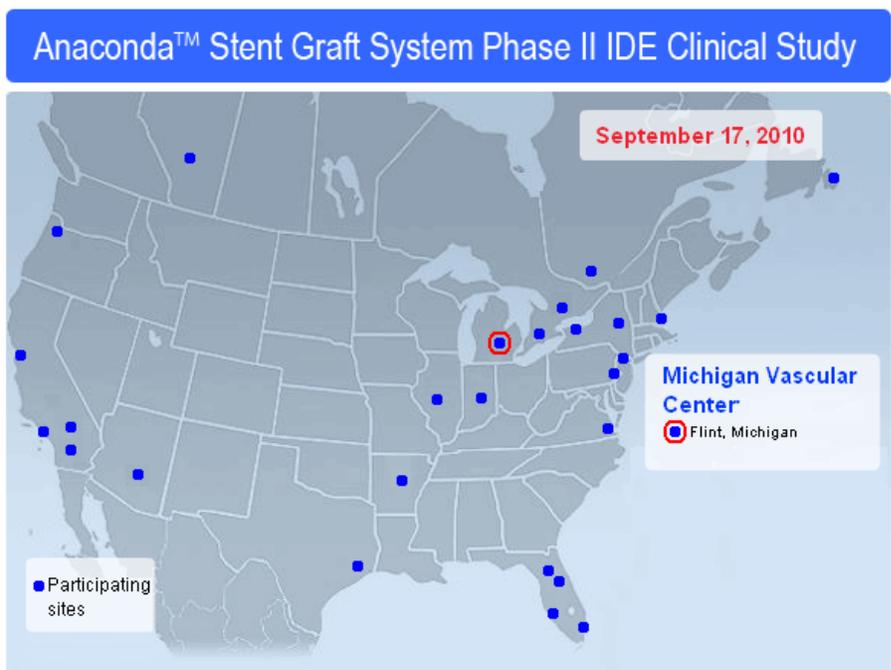
For More Information



For more information about the study in Michigan, and to find out how your patients can enroll in the Anaconda AAA Stent Graft Clinical Study, contact Jill George, Research Coordinator, Michigan Vascular

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Michigan Vascular Center
Serving the Community since 1963

MVC Core Values

- We are a professional organization –a team– working equally in a common cause: To provide the best possible vascular care for the physicians, patients, and institutions of our community.
- We share a commitment to excellence in the vascular care of patients through the pursuit of knowledge, communication, innovation, and research.
- We value our employees and incorporate them into our team.
- We commit to each other to honor & pursue these values.

VISIT US ON THE WEB

WWW.MICHIGANVASCULAR.COM

