

# G O R E P E R I P H E R A L VISION

PERFORMANCE through collaboration



## Physicians and Gore Reach Milestones Together

**SPECIAL  
edition  
2009**

This year at the AIM Symposium™ / VEITH Symposium™ in New York, Gore is recognizing the efforts of physicians around the globe for their advancement of patient care through the development and use of Gore products.

In the winter of 1970, before Gore had produced any medical products, Bill Gore was invited to speak at a cardiovascular conference in Denver, Colorado. During some downtime from the meeting, he hit the slopes and struck up a conversation with Ben Eisman, MD, a surgeon who was also an enthusiastic pioneer of new technologies.

### IN THIS ISSUE

Physicians and Gore Reach Milestones Together .....	1
First US and European Implants of Next Generation Conformable GORE TAG® Thoracic Endoprosthesis and Initiation of US Clinical Trial for Thoracic Aortic Aneurysms .....	3
Gore's Aortic Portfolio Balloons .....	3
GORE PROPATEN® Vascular Graft with Integrated Rings .....	4
Gore Reverses Thinking on Stroke Prevention .....	4



# M I L E S T O N E S I N T H E M A K I N G



As they rode up the chairlift, Bill and Doctor Eisman discussed the challenges faced with arterial reconstructions and the complications of harvesting veins. The two men came to a thought, “Wouldn’t a GORE-TEX® tube be a perfect substitute for human vein or artery?”

Early animal studies followed, and the first human implants of the GORE-TEX® Vascular Graft were performed in 1973 by Doctor Eisman. Jack Hoover sold the first graft commercially in 1975 and the rest, as they say, is history.

From that first conversation on the ski slopes of Colorado, Gore has been engaged with physicians. Together we are creating medical milestones by bringing world-class products to market and making a difference in the lives of patients.

Today, Gore has broadened its application of ePTFE and developed bioactive technologies that help improve care in many areas of medicine, but the milestones with the greatest impact have come in the vascular arena. From the aorta through the peripheral vascular system and into the carotids, physicians and Gore have engaged in a synergy that has grown as vascular therapies have grown. The relationship continues to produce improvements for patient care which positively impact the lives of millions of people around the world.

*Gore would like to thank all the physicians who have improved patient lives and contributed to the achievement of these vascular therapy milestones. Through Gore’s new product development, we ensure that there will be many more milestone solutions that continue to “do what we say they will do.”*

- 1973** — First human implant of a GORE-TEX® Vascular Graft
- 1980** — Bifurcated GORE-TEX® Vascular Graft introduced
- 1991** — Launch of the GORE-TEX® Stretch Vascular Graft
- 1996** — GORE HEMOBAHN® Endoprosthesis is introduced as the first stent-graft for vascular applications (now marketed as GORE VIABAHN® Endoprosthesis)
- 1997** — Implantation of the first GORE EXCLUDER® Device
- 1998** — Implantation of the first GORE TAG® Device
- 1999** — GORE PROPATEN® Vascular Graft – a surgical graft with a heparin-bonded surface – is introduced
- 2002** — GORE INTERING® Vascular Graft is launched
- 2004** — GORE VIATORR® Device is introduced for TIPS procedures and quickly becomes the market leader
- 2005** — GORE VIABAHN® Device becomes the first stent-graft in the US approved for the SFA
- GORE TAG® Device is the first thoracic stent-graft to market in the US
- US availability of the GORE Flow Reversal System for neuroprotection during CAS
- GORE VIABAHN® Device receives approval for iliac artery disease treatment in the US
- GORE EXCLUDER® Device is the single-most used AAA stent-graft in the US by a 2:1 margin over the next closest competitor<sup>1</sup>
- 40,000 patients treated with the GORE TAG® Device worldwide
- 2009** — 176,000 GORE VIABAHN® Endoprotheses sold worldwide
- First implants of the Conformable GORE TAG® Device in Europe and a US clinical study
- 100,000 patients treated with the GORE EXCLUDER® AAA Endoprosthesis
- More than 3.5 million implants of GORE-TEX® Vascular Grafts

<sup>1</sup> IMS Health® Q2 2009

## First US and European Implants of Next Generation Conformable GORE TAG® Thoracic Endoprosthesis and Initiation of US Clinical Trial for Thoracic Aortic Aneurysms



The first human implants of the next generation Conformable GORE TAG® Thoracic Endoprosthesis were performed recently in the US and in Europe.

First implants in the US were for the treatment of thoracic aortic aneurysms (TAAs) and were done

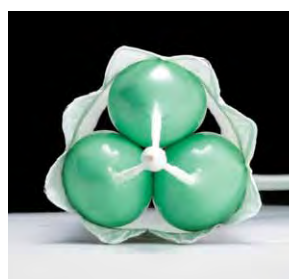
by Joshua Rovin, MD and Eugene Murphy, MD, at Bayfront Medical Center (St. Petersburg, Florida) and William McMillan, MD and Scott Schultz, MD, at North Memorial Medical Center (Minneapolis, Minnesota). “It is exciting to be part of the clinical trial for the next generation Conformable GORE TAG® Device,” said Doctor Joshua Rovin, a cardiovascular surgeon. Prof. Dittmar Böckler at the University of Heidelberg in Heidelberg, Germany and Doctor Thomas Larzon at the Örebro University Hospital in Örebro, Sweden were the first European physicians to implant the next generation Conformable GORE TAG® Device.

Gore received approval of an investigational device exemption (IDE) from the US Food and Drug Administration (FDA) to investigate the use of the next generation Conformable GORE TAG® Thoracic Endoprosthesis in thoracic aortic aneurysms. In addition to TAAs, the next generation Conformable GORE TAG® Device has been approved to investigate endovascular repair of other etiologies including traumatic aortic transection and aortic dissection. William Jordan, MD from the University of Alabama, Birmingham will serve as the national principle investigator (PI) in the Conformable GORE TAG® Device in Thoracic Aortic Aneurysm Trial (GORE TAG 08-03). Richard Cambria, MD, Massachusetts General (Boston, Massachusetts) is the PI for the Dissection Trial (08-01) with Mark Farber, MD serving as the PI for the TAG 08-02 study in trauma patients.

**CAUTION** – Investigational Device Limited by United States Law to Investigational Use.

## Gore’s Aortic Portfolio Balloons

We are proud to announce the addition of two new balloon catheters to our portfolio of aortic products. They are the new Enhanced Design GORE Tri-Lobe Balloon Catheter and the Q50 Stent Graft Balloon Catheter distributed exclusively in the US by Gore.



The new Enhanced Design GORE Tri-Lobe Balloon Catheter allows for continuous blood flow around the inflated lobes of the balloon catheter while decreasing the hemodynamic pressure on the inflated balloons. The three compliant polyurethane balloons inflate and deflate rapidly in a

uniform and simultaneous manner. This balloon catheter is available in two 18 Fr introducer sheath compatible sizes that can be utilized in vessel diameters from 16 – 42 mm. Gore has received FDA clearance and CE Mark on the new GORE Tri-Lobe Balloon Catheter and it is now available in the United States and the European Union.



The Q50 Stent Graft Balloon Catheter is a full occlusion balloon catheter that can treat vessel diameters from 10 – 50 mm. The 12 Fr introducer sheath compatible balloon catheter offers a compliant polyurethane balloon that inflates and deflates rapidly and a short flexible tip that increases trackability. The Q50 Stent Graft Balloon Catheter has received FDA clearance and is now available in the United States.

## GORE PROPATEN® Vascular Graft with Integrated Rings *Now Available!*



With the GORE PROPATEN® Vascular Graft, Gore was the first company to introduce a new category in vascular bypass built on proven elements that can be trusted — a combination of innovation and a history of clinical success. To date, more than 30,000 GORE PROPATEN® Vascular Grafts have been successfully implanted worldwide. The success of the GORE PROPATEN® Vascular Graft is further evidenced by our market leadership in vascular grafts for more than 30 years.

This month, Gore will expand the line of GORE PROPATEN® Vascular Grafts to include configurations having a unique, all ePTFE radial support. These new configurations will feature the same proprietary end-point covalently bonded heparin bioactive surface in addition to integrated ePTFE radial support that resists kinking and compression. The GORE PROPATEN® Vascular Graft with Integrated Rings has longitudinal extensibility inherent to GORE-TEX® Stretch Vascular Grafts and can provide up to a 24% reduction in profile compared to an externally ringed or spiral graft. We are committed to improvement in vascular surgery and, with the current release of GORE PROPATEN® Vascular Graft with Integrated Rings, we have added more than 30 additional catalogue numbers to the original family of GORE PROPATEN® Vascular Grafts.



**W. L. GORE & ASSOCIATES, INC.**  
Flagstaff, AZ 86004

+65.67332882 (Asia Pacific)  
00800.6334.4673 (Europe)  
800.437.8181 (United States)  
928.779.2771 (United States)

[goremedical.com](http://goremedical.com)

 Consult Instructions for Use

**\* CAUTION — Investigational device. Limited by United States law to investigational use.**

**INDICATIONS FOR USE IN THE US:** The GORE TAG® Thoracic Endoprosthesis is intended for endovascular repair of aneurysms of the descending thoracic aorta in patients who have appropriate anatomy, including: Adequate iliac / femoral access; Aortic inner diameter in the range of 23-37 mm;  $\geq 2$  cm non-aneurysmal aorta proximal and distal to the aneurysm. **CONTRAINDICATIONS:** Patients with known sensitivities or allergies to the device materials. Patients with a systemic infection who may be at risk of endovascular graft infection. Refer to *Instructions for Use* at [goremedical.com](http://goremedical.com) for a complete description of all warnings, precautions and adverse events. **Rx Only**

**INDICATIONS FOR USE:** Trunk-Ipsilateral Leg Endoprosthesis and Contralateral Leg Endoprosthesis Components. The GORE EXCLUDER® AAA Endoprosthesis is intended to exclude the aneurysm from the blood circulation in patients diagnosed with infrarenal abdominal aortic aneurysm (AAA) disease and who have appropriate anatomy as described below: Adequate iliac / femoral access; Infrarenal aortic neck treatment diameter range of 19 – 29 mm and a minimum aortic neck length of 15 mm; Proximal aortic neck angulation  $\leq 60^\circ$ ; Iliac artery treatment diameter range of 8 – 18.5 mm and iliac distal vessel seal zone length of at least 10 mm. **Aortic Extender Endoprosthesis and Iliac Extender Endoprosthesis Components.** The Aortic and Iliac Extender Endoprostheses are intended to be used after deployment of the GORE EXCLUDER® AAA Endoprosthesis. These extensions are intended to be used when additional length and / or sealing for aneurysmal exclusion is desired. **CONTRAINDICATIONS:** There are no known contraindications for these devices. Refer to *Instructions for Use* at [goremedical.com](http://goremedical.com) for a complete description of all warnings, precautions and adverse events. **Rx Only**

**INDICATIONS FOR USE IN THE US:** The GORE VIABAHN® Endoprosthesis is indicated for improving blood flow in patients with symptomatic peripheral arterial disease in superficial femoral artery lesions with reference vessel diameters ranging from 4.0 – 7.5 mm. The GORE VIABAHN® Endoprosthesis is indicated for improving blood flow in patients with symptomatic peripheral arterial disease in iliac artery lesions with reference vessel diameters ranging from 4.0 – 12 mm. **CONTRAINDICATIONS:** The GORE VIABAHN® Endoprosthesis is contraindicated for non-compliant lesions where full expansion of an angioplasty balloon catheter was not achieved during pre-dilatation, or where lesions cannot be dilated sufficiently to allow passage of the delivery system. Do not use the GORE VIABAHN® Endoprosthesis with Heparin Bioactive Surface in patients with known hypersensitivity to heparin, including those patients who have had a previous incidence of Heparin-Induced Thrombocytopenia (HIT) type II. Refer to *Instructions for Use* at [goremedical.com](http://goremedical.com) for a complete description of all warnings, precautions and adverse events. **Rx Only**

**INDICATIONS FOR USE:** The GORE Flow Reversal System is intended to provide embolic protection during carotid artery angioplasty and stenting for patients diagnosed with carotid artery stenosis and who have appropriate anatomy as described in the Instructions for Use. Refer to the Instructions for Use at [goremedical.com](http://goremedical.com) for contraindications, warnings and precautions. **Rx Only**

Products listed may not be available in all markets. Q50 is a trademark of QX Medical, LLC. GORE, GORE-TEX®, ACUSEAL®, EXCLUDER®, HEMOBahn®, INTERING®, PERIPHERAL VISION, PERFORMANCE THROUGH COLLABORATION, PROPATEN®, TAG®, VIABAHN®, VIATORR®, and designs are trademarks of W. L. Gore & Associates. © 2009 W. L. Gore & Associates, Inc. AN0996-EN1 NOVEMBER 2009

## Gore Reverses Thinking on Stroke Prevention

Gore's commitment to stroke prevention began in the 1980s with the offering of two ePTFE patches, GORE-TEX® Cardiovascular Patch (1981) and GORE ACUSEAL Cardiovascular Patch (1999) for use during carotid endarterectomy (CEA). Gore has continued its commitment to the prevention of stroke with a focus on interventional therapies for carotid artery disease, beginning with the development of a neuroprotection platform for use during carotid artery stenting.

The GORE Flow Reversal System is a unique neuroprotection system that operates on the principle of reversing the flow of blood at the treatment site. With flow reversal established, the GORE Flow Reversal System continuously directs both macro and micro emboli away from the brain, minimizing the risk of emboli reaching the brain during critical stages of carotid artery stenting (CAS). Because the system is positioned proximal to the target lesion, protection is established before interaction with the target lesion occurs, minimizing the risk of emboli while establishing protection.

The Gore EMPiRE Clinical Trial, designed to assess the safety and efficacy of the GORE Flow Reversal System, is one of the first carotid artery stenting studies that has reported rates that are within the American Heart Association guidelines for CEA of < 3% death / stroke for asymptomatic patients and < 6% death / stroke for symptomatic patients.

In addition to the GORE Flow Reversal System, Gore has developed a distal filter that is designed to limit the escape of debris between the filter and the vessel wall, with enhanced vessel wall apposition. The GORE Embolic Filter\* is currently part of a clinical study (Gore EMBOLDEN Clinical Study) in the US.

Gore has shown a continuing commitment to providing physicians with tools that improve patient outcomes. With promising data from the Gore EMPiRE Clinical Study and initiation of a study evaluating the GORE Embolic Filter, Gore is committed to raising the bar for embolic protection during CAS.

For further discussions regarding Carotid Artery Stenting, please see the November issue and supplement of *Endovascular Today*.

**Have a story idea or case study to share?**

Send your suggestions to [peripheralvision@wlgore.com](mailto:peripheralvision@wlgore.com)

Please visit [goremedical.com](http://goremedical.com) to subscribe to an online version of *Gore Peripheral Vision*, or contact your local Gore Sales Associate to be added to the distribution list.