

GORE PERIPHERAL

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GORE RECEIVES FDA APPROVAL FOR LARGER DIAMETER, SMALL PROFILE AAA ENDOPROSTHESIS

Unique device design allows physicians to deliver safe, effective and proven treatment to broader patient population

W. L. Gore & Associates (Gore) announced the availability of the 31 mm diameter version of the GORE EXCLUDER® AAA Endoprosthesis. The device provides physicians with a safe and effective endovascular option to treat abdominal aortic aneurysms (AAAs) in patients with aortic inner neck diameters from 27 to 29 mm. Other important enhancements include a flat-top design that enables greater production efficiency, an additional pair of proximal anchors to help ensure excellent fixation, and a lengthening of the trunk from 7 to 8 cm to accommodate larger anatomies.

Jon Matsumura, MD, National Principal Investigator, stated, “The availability of the larger aortic diameter GORE EXCLUDER® Devices will certainly broaden the range of American patients that can have their aneurysms treated with endovascular repair. This less invasive option has clear benefits of more rapid recovery and lower postoperative risk of fatal complications compared to open surgical repair.”

More than 87,000 GORE EXCLUDER® Devices have been implanted in patients worldwide, making it a widely accepted, minimally invasive treatment option for individuals with AAA. In March 2009, the US Food and Drug Administration (FDA) approved the 31 mm diameter version. It has been available outside of the US since 2004 and has been implanted in more than 3,300 patients. The 31 mm device has been available in the US since May 4, 2009.

“The GORE EXCLUDER® AAA Endoprosthesis is backed by more than 11 years of commercial data that consistently shows the excellent performance of the device,” said David Abeyta, Aortic Business Unit Leader at Gore. “It has become a leading option for physicians in North America for the treatment of AAA. The unique design of the 31 mm device allows physicians to treat patients with a larger range of anatomies, and the fact that it can be implanted using a minimally invasive procedure means that most patients recover faster and more comfortably.”

The 31 mm GORE EXCLUDER® Device is available in 13, 15 and 17 cm lengths, along with a new 32 mm x 4.5 cm Aortic Extender Component. Both the new Trunk-Ipsilateral Leg and Aortic Extender Components are 20 Fr introducer sheath compatible.



31 mm
now
AVAILABLE
in the US

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EXCLUDER®

AAA ENDOPROSTHESIS

IN THE NEWS

GORE RELEASES UPDATES ON GORE PROPATEN® VASCULAR GRAFT STUDIES

Encouraging interim results from several multi-center, multi-year, worldwide studies of the GORE PROPATEN® Vascular Graft were recently announced. The studies report encouraging outcomes for below-knee bypass and dialysis access. The data were presented to clinical audiences at the 35th Annual VEITHsymposium™ in New York and Deutsche Gesellschaft für Gefäßchirurgie in Germany.

The primary patency of the GORE PROPATEN® Vascular Graft in below-knee bypass was reported to be 59% at five years. Additionally, in dialysis access, the GORE PROPATEN® Vascular Grafts were found to have a significant 20% improvement in clot-free survival at one year as compared to the non-heparin bonded graft control group. The study updates presented support the use of the GORE PROPATEN® Vascular Graft as the prosthetic graft of choice in lower limb and dialysis access applications. All dialysis access studies have been conducted in the US. To view complete text please visit: www.goremedical.com/propaten/news.

FIRST DATA ON GORE VIABAHN® ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE PRESENTED AT TCT

The GORE VIABAHN® Endoprosthesis with Heparin Bioactive Surface has surpassed its non-heparin predecessor in units sold within the United States and is continuing to gain traction in Europe after its recent approval. While numerous multi-limb studies document the performance of the non-heparin GORE VIABAHN® Endoprosthesis in the treatment of superficial femoral artery (SFA) obstructive disease, data is emerging that characterizes the performance of the GORE VIABAHN® Endoprosthesis with Heparin Bioactive Surface. An abstract published from the 2008 Transcatheter Therapeutics annual meeting in Washington, DC, demonstrates short-term safety of the heparin-bonded device. The study examines platelet count change, heparin-induced thrombocytopenia type II (HIT) occurrence, and graft occlusion rate in 45 patients treated with the GORE VIABAHN® Endoprosthesis with Heparin Bioactive Surface for their SFA disease. Additionally, at the six month follow-up interval, there were no occurrences of HIT or graft occlusion. “We believe for long segment SFA occlusions and stenosis that the heparin

bonded GORE VIABAHN® Device is a safe alternative to self-expanding nitinol stents used in the SFA,” says Dr. Tanvir Bajwa, the Milwaukee group’s principal investigator. While limited in scope and early in follow-up, this study begins to explore the clinical impact of the GORE VIABAHN® Endoprosthesis with Heparin Bioactive Surface in SFA disease.

FDA APPROVAL RECEIVED FOR MODIFICATIONS TO THE GORE TAG® THORACIC ENDOPROSTHESIS

Gore has received approval from the US Food and Drug Administration (FDA) to market a modified version of the GORE TAG® Thoracic Endoprosthesis for the treatment of thoracic aortic aneurysms (TAAs). The improved delivery catheter enhances the previous version of the GORE TAG® Thoracic Endoprosthesis by adding a soft flexible tip to the leading end of the delivery system. The soft tip improves flexibility at the wire / catheter interface to facilitate tracking through challenging aortic anatomy. The hub component has also been modified to improve ease of use and durability. Gore has already begun distribution of the upgraded delivery system, and plans to have this completed across the US within the next few months.

PRODUCT UPDATES



ENHANCED *GORE* TRI-LOBE BALLOON CATHETER AVAILABLE SOON

Recently approved for CE Mark and cleared by the FDA, the enhanced *GORE* Tri-Lobe Balloon Catheter is a low-pressure, compliant, tri-lobed polyurethane balloon catheter designed to assist in the dilation of self-expanding endoprostheses in large diameter blood vessels. The lobed design of the balloon catheter allows for inflation without complete blockage of aortic blood flow. The enhancements made to the new *GORE* Tri-Lobe Balloon Catheter include a change from silicone to polyurethane balloons, decreased inflation and deflation times, more uniform and simultaneous inflation of the three lobes, smoother transitions on the leading end of the balloon catheter, and a reinforced catheter hub.

The *GORE* Tri-Lobe Balloon Catheter with enhanced design will be available in two sizes, both of which are 18 Fr introducer sheath compatible. The small balloon catheter is approved for use in aortic inner diameters from 16 mm to 34 mm. The large balloon catheter is approved for use in aortic inner diameters from 26 mm to 42 mm.

GORE RECEIVES FDA CONDITIONAL APPROVAL TO BEGIN CLINICAL STUDIES FOR THE NEXT GENERATION *GORE TAG*® THORACIC ENDOPROSTHESIS

Gore has received conditional approval from the US Food and Drug Administration (FDA) to begin investigation of the Next Generation *GORE TAG*® Device for the treatment of descending thoracic aortic aneurysm, traumatic aortic transection, and acute complicated type B dissection. Three distinct clinical studies are being initiated to establish safety and efficacy in the three primary etiologies for which the *GORE TAG*® Device is implanted. All three studies will be prospective, multicenter and non-randomized.



The Next Generation *GORE TAG*® Device is designed to improve conformability, resist compression, and expand the treatment range of the commercially available device to treat aortic neck diameters ranging from 16 – 24 mm.

NEW *GORE PROPATEN*® VASCULAR GRAFT LINE EXTENSIONS RELEASED

To continue to meet your needs, we have released three additional catalogue numbers to the family of *GORE PROPATEN*® Vascular Grafts.

Catalogue Number	Description	Internal Diameter (mm)	Ringed Section Length (cm)	Length (cm)
H470080A	Standard-walled, stretch technology	4 – 7	N/A	80
H060060A	Standard-walled, stretch technology	6	N/A	60
H080060A	Standard-walled, stretch technology	8	N/A	60
HT074050A	Thin-walled, removable ring, stretch technology	7	40	50
HT076080A	Thin-walled, removable ring, stretch technology	7	60	80

ENDO UPDATES

79 YEAR-OLD PIZZA DELIVERY BOY SAVED BY FAST ACTING GORE SALES ASSOCIATE AND GORE EXCLUDER® DEVICE

An inspiring story about the use of the GORE EXCLUDER® Device appeared in the *Oregonian*, the daily newspaper in Portland, Oregon, on March 22, 2009. The article, written by reporter Margie Boule, profiles Roger Jehan, a 79 year-old pizza delivery “boy” who has survived two ruptured abdominal aortic aneurysms. The article notes that his most recent rupture was treated using a stent-graft (GORE EXCLUDER® Device) that could be placed in Roger’s aneurysm through an incision in his groin.

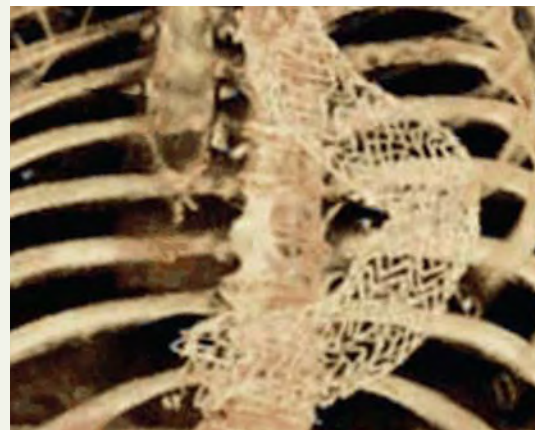
Roger’s treating physician, Dr. Kent Williamson, did not have a graft in stock that was the right size, but called his good friend Bob Cook, a Gore Field Sales Associate. Bob was able to race the graft over to the hospital in only ten minutes. Dr. Williamson treated Roger with the GORE EXCLUDER® Device and he was able to go home in only four days.

Roger says he’s the luckiest man in the world to have survived the rupture of a second abdominal aortic aneurysm. He says if he had not been taken to St. Vincent’s Hospital where Dr. Williamson was on duty, and if Dr. Williamson had not been friends with Bob from Gore, and if Bob had not lived so close to the hospital, he would not be back to delivering pizza at age 79, making him the nation’s oldest pizza delivery boy.

The complete article can be viewed on the Oregonian’s Web site at the following link: http://www.oregonlive.com/news/oregonian/margie_boule/index.ssf?/base/living/123742232680310.xml&coll=7

LINC 2009 – LEIPZIG INTERVENTIONAL COURSE 2009 – JANUARY 14 – 17, 2009 – LEIPZIG GERMANY

For this year’s course debate, arguments were set forth for which treatment should be considered the first for AAA – open repair or endovascular therapy. Dr Marc RHM van Sambeek FESC Department of Vascular Surgery Catharina Hospital Eindhoven, The Netherlands argued that EVAR should be the primary option for all patients with suitable anatomy, citing results from EVAR and the DREAM trial. He emphasized the favorable results regarding fit patients. He also presented on how results have improved with newer generation endografts.



Dr. L. Sunder-Plassmann presented his ten-year experience using endovascular therapy to treat acute traumatic lesions of the descending thoracic aorta; he reported excellent mid-term results using GORE TAG® Devices. Recent concerns for excessive radiation exposure resulted in his group transitioning from CT angiography to MRI-angio for patient follow-up. He noted that the construction of the GORE TAG® Endoprosthesis provides excellent MRI quality¹. One interesting case he presented demonstrated the durability of the GORE TAG® Endoprosthesis. This patient had previously been implanted with two GORE TAG® Devices prior to being involved in a car accident and experiencing severe polytrauma (including rib fractures). Despite the accident, the stent-grafts remained undamaged.

¹ MRI Safety and Compatibility

Non-clinical testing has demonstrated that the GORE TAG® THORACIC Endoprosthesis is MR Conditional. It can be scanned safely under the following conditions:

- Static magnetic field of 1.5 or 3.0 Tesla
- Spatial gradient field of ≤ 720 Gauss / cm
- Maximum scanner displayed whole-body-averaged specific absorption rate (SAR) of 3.0 W / kg for 15 minutes of scanning.

3.0 Tesla Temperature Rise:

In non-clinical testing, the GORE TAG® Thoracic Endoprosthesis produced a temperature rise of 1.9° C at an MR system reported maximum whole body averaged specific absorption rate (SAR) of 3.0 W / kg for 15 minutes of MR scanning in a 3.0 Tesla, Excite, General Electric active-shield, horizontal field MR scanner using G3.0-052B Software and placed in a worst-case location in a phantom designed to simulate human tissue. The SAR calculated using calorimetry was 2.8 W / kg.

1.5 Tesla Temperature Rise:

In non-clinical testing, the GORE TAG® Thoracic Endoprosthesis produced a temperature rise of 1.8° C at an MR system reported maximum whole body averaged specific absorption rate (SAR) of 2.8 W / kg for 15 minutes of MR scanning in a 1.5 Tesla, Magnetom, Siemens Medical Solutions, active-shield, horizontal field MR scanner using Numaris / 4 Software and placed in a worst-case location in a phantom designed to simulate human tissue. The SAR calculated using calorimetry was 1.5 W / kg.

Image Artifact:

For each vascular device and assembly, the artifacts that appeared on the MR images were shown as localized signal voids (i.e., signal loss) that were minor in size relative to the size and shape of these implants. The gradient echo pulse sequence produced larger artifacts than the T1 – weighted, spin echo pulse sequence for the GORE TAG® Thoracic Endoprosthesis. MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the GORE TAG® Thoracic Endoprosthesis. Therefore, it may be necessary to optimize the MR imaging parameters to compensate for the presence of this implant.

DUPLEX ULTRASONOGRAPHY ALONE IS SUFFICIENT FOR MID-TERM EVAR SURVEILLANCE: A PROSPECTIVE COST-ANALYSIS STUDY

Beeman BR, Doctor L, Dougherty MJ, Doerr K, McAfee-Bennett S, Calligaro KD. Duplex ultrasonography alone is sufficient for mid-term EVAR surveillance: a prospective cost-analysis study. Abstract presented at the 37th Annual Symposium of the Society for Clinical Vascular Surgery; March 18-21, 2009; Ft. Lauderdale, Florida

OBJECTIVES:

After initially performing both serial CT scans and DU in our early experience with EVARs, we performed a prospective study using DU as the sole surveillance study and determined cost savings and outcome using this strategy.

METHODS:

From September 21, 1998 to June 2, 2008, 276 patients underwent EVAR at a single institution. Until June 30, 2004, both CT and DU were performed every six months during the first year and then annually if no problems were identified (Group 1). Aneurysm sac size, presence of endoleak, and graft patency were compared between the two scanning modalities. After July 1, 2004, we prospectively used DU as the sole surveillance study unless a problem was detected (Group 2). CT and DU costs were compared using 2008 Medicare Procedure codes 74160/72193 (\$813) and 93979 (\$232), respectively. All DU examinations were performed in our accredited non-invasive vascular laboratory. Statistical analysis utilized Pearson's correlation coefficient and the paired t-test.

RESULTS:

Average follow-up was 24 months (range, 12-120). DU and CT scans were equivalent in detecting endoleaks ($p < 0.0001$), graft patency ($p < 0.0001$) and determining aneurysm sac diameter ($p < 0.0001$). Using DU alone would have reduced the cost of EVAR surveillance by 70% (\$282,924) in Group 1. Cost savings of \$334,956 were realized in Group 2 by eliminating CT scan surveillance. No Group 2 patients suffered an adverse event as a result of having DU performed as the sole follow-up modality.

CONCLUSIONS:

During mid-term follow-up, surveillance of EVAR patients can be performed both accurately and cost effectively with DU as the sole imaging study.

CASE STUDY

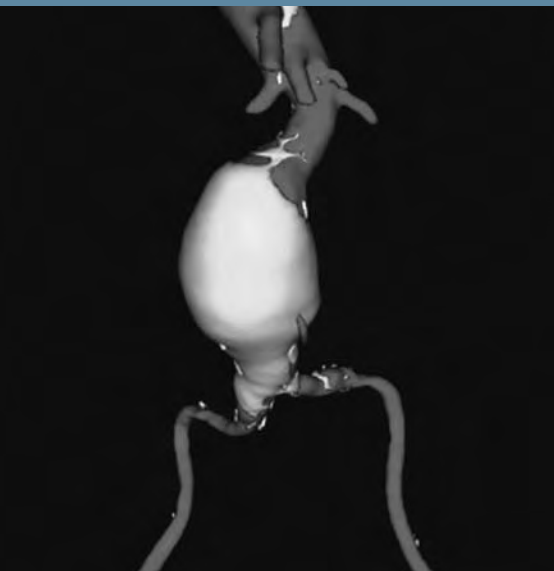


Figure 1



Figure 2

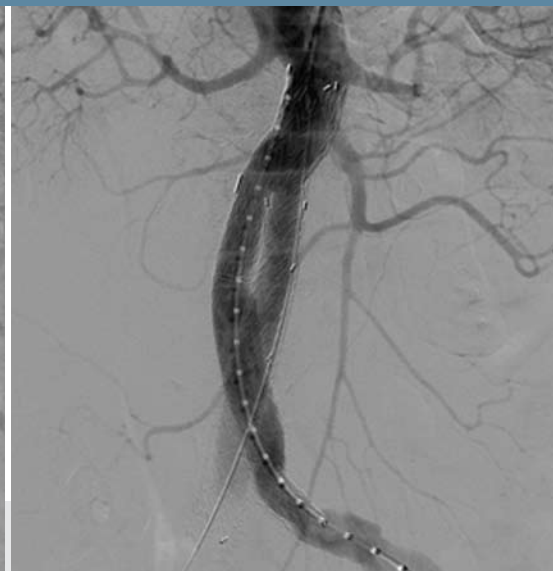


Figure 3

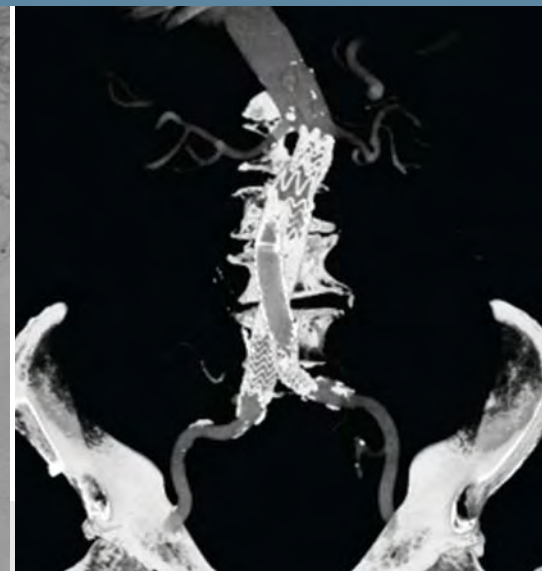


Figure 4

GORE EXCLUDER® AAA ENDOPROSTHESIS IN TORTUOUS ANATOMY

Heitham Hassoun, MD
Johns Hopkins Hospital
Baltimore, Maryland, USA

CLINICAL CHALLENGE

The patient is an active 85-year-old gentleman with a history of smoking and a family history of aortic aneurysm. He underwent a CT scan for transient abdominal pain at an outside hospital and a 6 cm infrarenal AAA was discovered. He has had no history of heart disease, and his ejection fraction by echocardiogram was 60%. He was recommended to undergo an open repair because of his tortuous left iliac artery. He subsequently self-referred to Johns Hopkins Hospital for a second opinion.

Review of his aortic anatomy revealed a 20 mm diameter angulated proximal neck, 18 mm distal aortic diameter, 16 mm diameter short right common iliac artery, and a 12 mm diameter left common iliac artery, and the treatment length was 16 cm bilaterally.

PROCEDURE

The patient underwent a totally percutaneous repair with the GORE EXCLUDER® AAA Endoprosthesis using the following devices: 23 mm X 14.5 mm X 12 cm trunk-ipsilateral, 18 mm X 10 cm contralateral limb as extension, and a 14 mm X 12 cm contralateral limb. Due to the angulated proximal neck and a lower left renal artery, we performed “slow deployment” with the shorter contralateral side attaining primary fixation below the right renal artery, thus allowing favorable “tilt” of the device to achieve greater seal.

RESULTS

The procedure was uncomplicated and the patient was discharged to home on post-operative day one. He resumed normal activities and a 3-phase CT scan was performed at one month which revealed aneurysm exclusion without endoleak (*figure 4*).

2009 EVENTS

(through October)

Date	Name	Location
GORE EVENTS		
August 3 – 4	AAA Workshop	Los Angeles, California
August 6 – 7	Advanced AAA Symposium	Chicago, Illinois
August 7	Aortic Technology Forum	Flagstaff, Arizona
September 1	Endo and Surgical Technology Showcase	Flagstaff, Arizona
October 2	Endo and Surgical Technology Showcase	Flagstaff, Arizona
SUPPORTED CONGRESSES		
September 3 – 6	European Society of Vascular Surgery	Oslo, Norway
September 19 – 23	Cardiovascular and Interventional Radiological Society of Europe	Lisbon, Portugal
September 22 – 26	Transcatheter Cardiovascular Therapeutics	San Francisco, California
October 17 – 21	European Association for Cardiothoracic Surgery	Vienna, Europe
October 19 – 22	Vascular Interventional Advances	Las Vegas, Nevada

LITERATURE RECOMMENDATIONS

TAA

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Criado FJ. Endograft repair in the thoracic aorta: *Poised to Grow! Vascular Disease Management* 2009;7(1):A4-A6.

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Peripheral Vascular Treatment

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AAA

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Have a story idea or case study to share?

Send your suggestions to peripheralvision@wlgore.com

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



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
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 Consult Instructions for 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; ≥ 2 cm non-aneurysmal aorta proximal and distal to the aneurysm. **CONTRAINDICATIONS:** There are no known contraindications for this device. Refer to *Instructions for Use* at goremedical.com for a complete description of all warnings, precautions and adverse events. 

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 ≤ 60°; 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 for a complete description of all warnings, precautions and adverse events. 

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 for a complete description of all warnings, precautions and adverse events. 

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