

G O R E P E R I P H E R A L V I S I O N

PERFORMANCE through collaboration

45 mm GORE® TAG® THORACIC ENDOPROSTHESIS NOW AVAILABLE IN THE US

*Expanding Thoracic Aortic Treatment Range up to 42 mm with FDA
Approval of 45 mm GORE® TAG® Device*

W. L. Gore & Associates (Gore) received approval from the US Food and Drug Administration (FDA) to market a 45 mm diameter version of the GORE® TAG® Thoracic Endoprosthesis for treatment of aneurysms of the descending thoracic aorta. The larger diameter device allows treatment of thoracic aortic aneurysms with proximal and distal neck diameters ranging from 37 – 42 mm and is now available for commercial use in the US.

“The availability of the 45 mm GORE® TAG® Device will provide physicians treating thoracic aneurysms with more options,” explained Dr. Michel Makaroun, Chief of the Division of Vascular Surgery and Professor of Surgery at the University of Pittsburgh Medical Center (UPMC). Dr. Makaroun acted as the National Principal Investigator for the 45 mm GORE® TAG® Device clinical study.

The 45 mm GORE® TAG® Device is available in 10, 15 and 20 cm lengths. In addition, all GORE® TAG® Devices, including the 45 mm device are delivered on a modified delivery catheter that is designed for enhanced trackability and deliverability. The modified GORE® TAG® Device delivery catheter is a simple, single-step deployment system engineered to optimize placement and control. The novel sheathless delivery catheter provides flexibility for navigating tortuous anatomy and low deployment forces.

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45 mm GORE® TAG® DEVICE....

The GORE® TAG® Device was first approved by the FDA in March 2005. With more than 40,000 devices sold worldwide, the GORE® TAG® Device is a leading option for the less invasive treatment of TAA. The GORE® TAG® Device is also the only endovascular thoracic device with more than ten years of worldwide commercial data. Five year follow-up data from the clinical study indicates that subjects treated with the GORE® TAG® Device have improved aneurysm-related survival and a consistently lower incidence of major adverse events compared to subjects treated with open surgical repair.

Clinical studies are currently under way in the US to evaluate the safety and efficacy of the next generation Conformable GORE® TAG® Device in three primary etiologies: aneurysms of the descending thoracic aorta (DTA), traumatic aortic transection of the DTA, and acute complicated type B dissection.

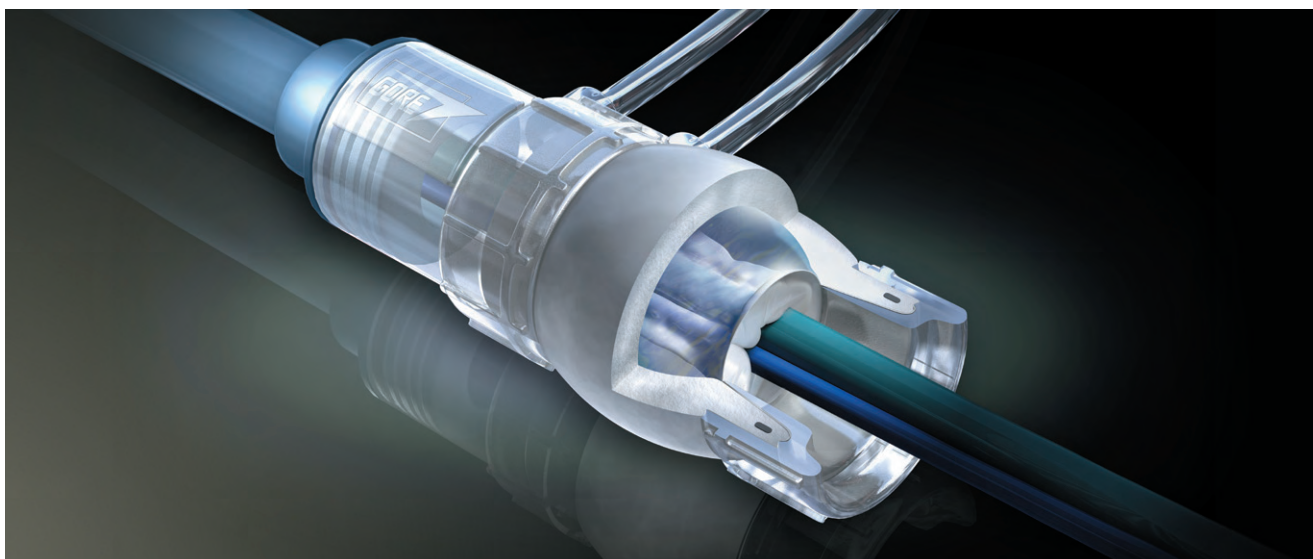
REVOLUTIONARY GORE® DRYSEAL SHEATH NOW AVAILABLE

The first use of the revolutionary GORE® DrySeal Sheath occurred at The Methodist Hospital (TMH) in Houston, Texas on April 30, 2010. The hemostatic GORE® DrySeal Valve is unique in two important ways — it is pressurized to create a seal, minimizing blood loss, and this unique seal has the ability to accommodate multiple wires and catheters simultaneously.

The first case was performed during a Gore-sponsored Acute Symptomatic AAA Workshop held in The Methodist DeBakey Heart and Vascular Center in Houston. The procedure was conducted by Alan Lumsden, MD, chairman of the Department of Cardiovascular Surgery. “The ability of the GORE® DrySeal Valve to accommodate multiple devices during difficult procedures with minimal blood loss

keeps the operating field free from excess blood, while helping to prevent unnecessary blood loss to the patient,” Dr. Lumsden said. “The GORE® DrySeal Sheath requires no intra-procedural manipulation of the valve, delivering consistent performance throughout the procedure and allowing the physician to maintain focus on the endovascular procedure — without being concerned about blood loss at the patient access site.”

Gore recently received FDA clearance to market the GORE® DrySeal Sheath, which is comprised of the GORE® DrySeal Valve attached to the introducer sheath, a dilator and a 2.5 ml valve inflation syringe. The valve consists of a silicone outer tube and an inner film tube that create an effective hemostatic seal that easily adapts to the profiles of the inserted devices. The device is available in profiles from 12 to 26 Fr, in 2 Fr increments, and has a working length of 28 cm.



Q50 STENT GRAFT BALLOON CATHETER LAUNCHES IN US

Another addition to the Gore Endovascular Portfolio is the Q50 Stent Graft Balloon Catheter, which became broadly available in the US earlier this month. Designed for use with aortic stent grafts that treat abdominal aortic aneurysms (AAA), this balloon catheter is ideal for use with the flexibility of the GORE® EXCLUDER® AAA Endoprosthesis in challenging anatomies.



The Q50 device is a full occlusion / modeling balloon catheter that is uniquely conformable to help aortic stent grafts fully expand and seal in both tortuous and straightforward vessels ranging

from 10 – 50 mm in diameter. No other single stent graft balloon features this broad range of inflation diameters. With its 8 Fr diameter and 65 cm length, the catheter is ideal for abdominal aneurysm procedures and contributes to enhanced operator control, ease-of-use and patient safety.

The short, flexible tip increases trackability through challenging anatomy, and a compliant conformable polyurethane balloon inflates and deflates rapidly to give physicians more control. The Q50 Stent Graft Balloon Catheter is compatible with standard 0.035" guidewires and low-profile 12 Fr introducer sheaths.

“I am pleased with the tracking of the Q50 Balloon and with the more convenient, shorter catheter length during a procedure with a GORE® EXCLUDER® Device,” said Jason Dew, MD. “I believe that it has much better tactile feel during inflation and it is convenient that one balloon can be used with a broader range of stent graft diameters, helping us to minimize inventory challenges for the hospital,” said Andrew Hearn, MD, both of Carolina Vascular and Vein in Burlington, North Carolina.

Gore is the exclusive US distributor of the Q50 Stent Graft Balloon Catheter for QXMédical, a medical device company based in Montreal, Canada specializing in the design, development and manufacturing of state-of-the-art medical devices. The US Food and Drug Administration (FDA) cleared the catheter for marketing in October 2009.

GORE® VIABAHN® ENDOPROSTHESIS RECEIVES NEW APPROVALS ABROAD



GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface* was recently approved for distribution in Australia and is marketed under the tradename GORE® VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface. The GORE® VIABAHN® Endoprosthesis has been available in Australia for ten years, but now we will be able to offer these customers a further innovation to the product, with the Heparin Bioactive Surface.

Other recent GORE® VIABAHN® Endoprosthesis approvals include Brazil, Thailand and South Korea. “As a global organization, we are diligent in our efforts to make this innovative product line available to interventionalists and PAD patients around the world.” said Chris Tieché, PhD, Gore Product Specialist.

** The GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface may be sold under different tradenames in different markets.*

CASE STUDY

TREATMENT OF AN ILIAC CHRONIC TOTAL OCCLUSION

Barry S. Weinstock, MD

Orlando Regional Medical Center, Orlando, Florida

Clinical Challenge

The patient is a 77-year-old woman evaluated for right buttock claudication. She has past medical history notable for spine surgery, severe hypertension with left ventricular hypertrophy, and hyperlipidemia. She also has a history of smoking. Current medications include lisinopril, olmesartan, aliskiren, metoprolol, aspirin, and fish oil. Lower extremity Doppler exam revealed reduced ankle-brachial index (ABI) of 0.55 in the right lower extremity and 0.70 in the left lower extremity. CT angiogram showed flush ostial chronic total occlusion of the right common iliac artery with reconstitution of the proximal common femoral artery. There was 50% stenosis of the left common iliac artery and no femoro-popliteal disease or significant trifurcation vessel disease. The occlusion was not felt to be well-suited to percutaneous revascularization but the patient declined surgical revascularization.

Procedure

The patient underwent angiography via a left common femoral approach. This confirmed flush ostial total occlusion of the right common iliac artery with reconstitution of the proximal right common femoral artery (Figures 1, 2). Access was planned for the proximal right superficial femoral artery but a short 6 cm, 7 Fr sheath was inadvertently placed in the proximal profunda femoris. The sheath was exchanged for a 11 cm, 7 Fr sheath and the iliac occlusion was crossed retrograde but subintimally using a 90 cm Spectranetics QUICKCROSS® Catheter and a 0.035" Terumo GLIDEWIRE® Guidewire. A Cordis OUTBACK® LTD® Catheter was used to advance a 0.014"

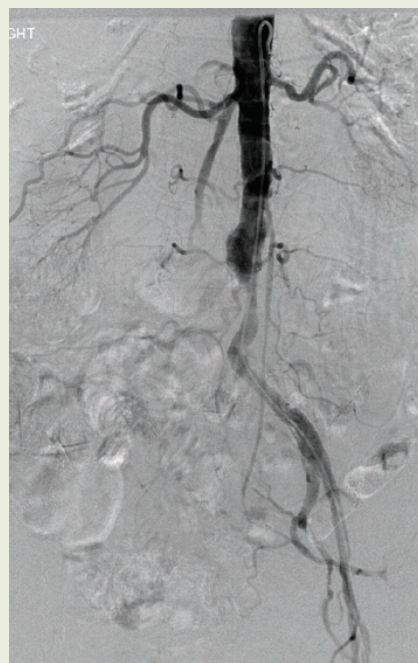


FIGURE 1

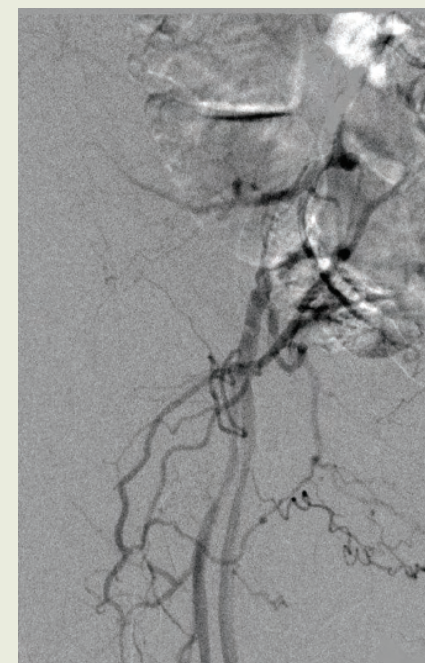


FIGURE 2

Abbott ASAHI Grand Slam Guidewire into the aorta with re-entry at the aorto-iliac bifurcation.

The entire iliac artery was dilated with 5 x 100 mm and 7 x 100 mm angioplasty balloons (Figure 3). The ostial right iliac artery was stented with a 7 x 59 mm Atrium iCAST Balloon Expandable Covered Stent. The remainder of the common iliac artery and the entire external iliac artery were stented with a single 7 x 150 mm GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface which extended to the site of reconstitution in the proximal common femoral artery. Post-dilatation of both stent-grafts was performed with a 7 x 100 mm angioplasty balloon.

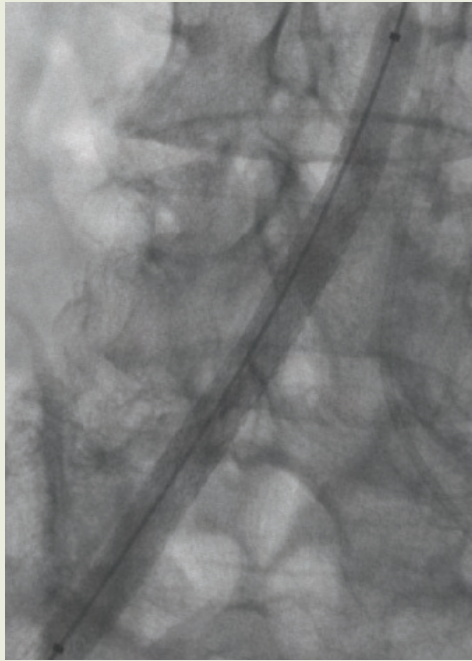


FIGURE 3

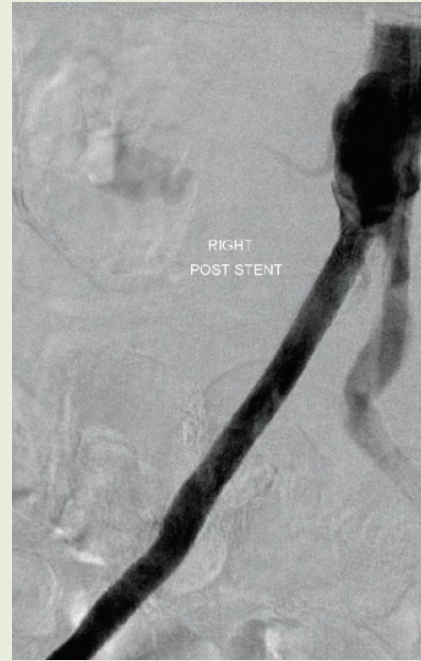
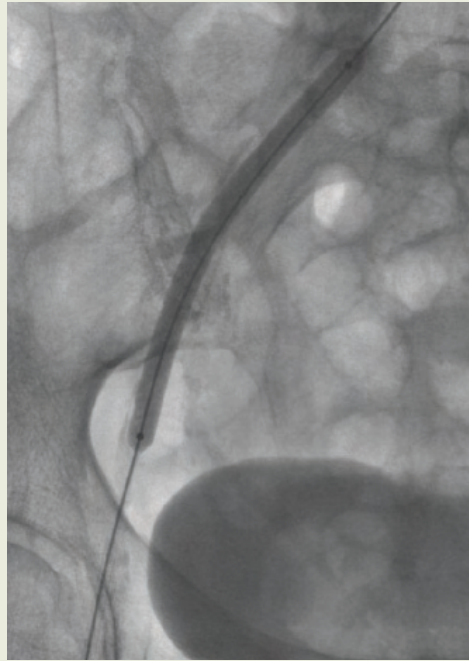


FIGURE 4

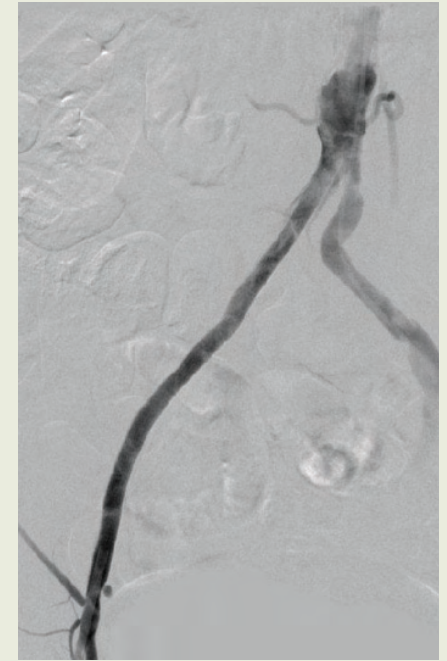


FIGURE 5

Results

Completion angiography reveals a widely patent right iliac artery with brisk flow and no residual stenosis (Figures 4, 5). Although the right hypogastric artery remains occluded, the left hypogastric artery is patent. At clinical follow-up, the patient was asymptomatic with no claudication. A follow-up Doppler exam revealed improvement in her right leg ABI from 0.55 to 1.0.

Physician Comments

The use of the GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface is ideal for treatment of iliac total occlusions, particularly when the hypogastric artery is chronically occluded. Restenosis rates with bare metal stents, particularly when placed after subintimal crossing of iliac occlusions,

is higher than desired. The flexibility of the GORE® VIABAHN® Endoprosthesis is also well-suited to the non-linear course of the external iliac artery. Overall, percutaneous treatment of iliac occlusions with the GORE® VIABAHN® Endoprosthesis is an excellent alternative to surgical revascularization.

HIGHLIGHTS OF THE MEDICARE FINAL PHYSICIAN CY2010 AND THE PROPOSED IPPS FFY2011 RULES

Medicare CY2010 Final Rule for the Physicians Fee Schedule Payment Policies

The Medicare CY 2010 final rule for Payment Policies paid under the Physicians Fee Schedule was effective on January 1, 2010. The final rule implemented two provisions that resulted in significant impact to physician payments.

The first provision was the implementation of the new survey data that CMS incorporated into the PE (practice expense) component of the RVU (relative value unit) calculation for CY2010. This resulted in significant RVU shifts between certain CPT® Codes. CMS maintains it is the most comprehensive PE source of data to date and therefore more accurate.

The second significant provision was the conversion factor amount which is used to convert the RVUs to the Physicians Fee Schedule Payments. The methodology is mandated by Congress and termed the SGR (sustainable growth rate). The proposed CY2010 SGR amount was a decrease of 21.5% from the CY2009 SGR amount. Congress passed a bill in December 2009 that was effective from January 1, 2010 through February 28, 2010 that avoided the negative 21.5% by implementing a zero percent update. Congress passed a second law in March 2010 to extend this zero percent update from March 1, 2010 to March 31, 2010. In April 2010, Congress passed a third law to again extend this zero percent update from April 1, 2010 to May 31, 2010. There are proposed bills in Congress to permanently revise the SGR calculation. Refer to the AMA and your specialty medical society websites for more information regarding this issue.

Medicare FFY2011 Proposed Rule for the Hospital Inpatient Prospective Payment System (IPPS)

The Medicare FFY 2011 Proposed Rule for the Hospital Inpatient Prospective Payment System (IPPS) was posted on April 19, 2010.

CMS estimates that operating payments to all hospitals will be reduced in FFY2011 by 0.1 percent. This does not include any changes made by the Patient Protection and Affordable Care Act (PPACA). It does include a reduction to recover a portion of the excess payments due to coding and classification changes resulting from the transition to the MS-DRG methodology.

CMS published proposed hospital inpatient Quality Measures for FFY 2011, 2012, 2013, and 2014 as well as possible future measures. For FFY 2013, CMS has proposed that hospitals be required to choose one of four topic areas to report the identified measures to a qualified registry. The four topic areas are: ICD Complications, Stroke, Nursing Sensitive Care, and Cardiac Surgery. The identified measures for each topic can be found in the proposed rule. CMS is proposing a self-nomination process to approve qualified registries which must be submitted by October 15, 2010. CMS lists the criteria for a qualified registry in the proposed rule.

Public comments on the FFY2011 IPPS Proposed Rule may be submitted by June 18, 2010.

This information is provided as a general update. Consult the CMS website for updates and details on these rules.

Documentation Resource

CMS Website: <http://www.cms.hhs.gov>

Gore is available to answer your reimbursement questions.

For more information, contact Coverage, Coding and Reimbursement Specialists at Gore

Email: Asheen@wlgore.com

928.864.2420

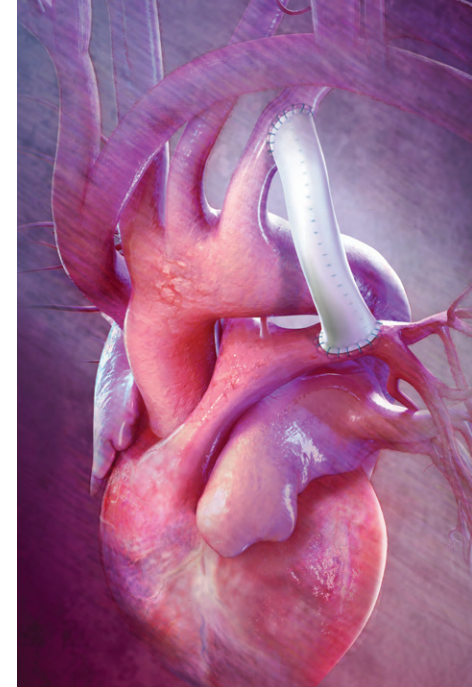
Toll free: 800.528.1866 Ext. 42420

PRODUCT UPDATES & 2010 EVENTS

INTRODUCING THE *GORE® PROPATEN®* VASCULAR GRAFT CONFIGURED FOR PEDIATRIC SHUNT

Gore has introduced a new category in pediatric shunts with the addition of PROPATEN Bioactive Surface. Pediatric shunts are small diameter (3 – 6 mm) vascular connections between systemic and pulmonary circulations. The shunts provide additional blood flow to the lungs as a palliative procedure in patients with cyanotic congenital heart disease. Expanded PTFE (ePTFE) vascular grafts are routinely used as pediatric shunts due to their superior performance and ease of use compared to native vessels. With the improvement of surgical techniques and postoperative care, pediatric cardiac surgeons are palliating and repairing increasingly complex lesions. Complications associated with the surgical procedure and the use of prosthetic shunts in these complex defects are multivariate and have not been completely eliminated. These complications, including shunt thrombosis, are experienced by all pediatric cardiac surgeons throughout the world. Although the use of ePTFE shunts are not without complications, to date it is reported in the literature as the best surgical strategy available. The addition of PROPATEN Bioactive Surface to the GORE Pediatric Shunt is designed to minimize thrombosis.

The GORE® PROPATEN® Vascular Graft Configured for Pediatric Shunt is an excellent addition to the product line.



DATE	NAME	LOCATION
GORE EVENTS		
June 17 – 18	Advanced AAA Symposium	Morristown, New Jersey
June 21 – 22	AAA Percutaneous Workshop	Houston, Texas
June 24 – 25	Endo and Surgical Technology Forum	Flagstaff, Arizona
June 28 – 29	AAA Foundation Skills Workshop	Dallas, Texas
July 15 – 16	Aortic Technology Forum	Flagstaff, Arizona
July 19 – 20	AAA Percutaneous Workshop	Chicago, Illinois
July 22 – 23	Acute Symptomatic AAA Workshop	Albany, New York
July 22 – 23	Advanced AAA Symposium	Seattle, Washington
August 26 – 27	Endo and Surgical Technology Forum	Flagstaff, Arizona
SUPPORTED CONGRESSES		
June 10 – 13	Society of Vascular Surgery	Boston, Massachusetts
September 11 – 15	European Association of Cardio-Thoracic Surgery	Geneva, Switzerland
September 16 – 19	European Society of Vascular Surgery	Amsterdam, Netherlands
September 21 – 25	Transcatheter Cardiovascular Therapeutics	Washington, District of Columbia

LITERATURE RECOMMENDATIONS

AAA

The United Kingdom EVAR Trial Investigators. Endovascular versus open repair of abdominal aortic aneurysm. *New England Journal of Medicine* 2010;362(20):1863-1871.

The United Kingdom EVAR Trial Investigators. Endovascular repair of aortic aneurysm in patients physically ineligible for open repair. *New England Journal of Medicine* 2010;362(20):1872-1880.

Albertini JN, Favre JP, Bouziane Z, Haase C, Nourrissat G, Barral X. Aneurysmal extension to the iliac bifurcation increases the risk of complications and secondary procedures after endovascular repair of abdominal aortic aneurysms. *Annals of Vascular Surgery*. In press.

Hoshina K, Kato M, Mikuriya A, Ohkubo N. Successful endovascular repair in two cases of graft limb occlusion after endovascular aneurysm repair for abdominal aortic aneurysms. *Surgery Today* 2010;40(5):487-490.

Patterson BO, Holt PJ, Hinchliffe R, Nordon IM, Loftus IM, Thompson MM. Existing risk prediction methods for elective abdominal aortic aneurysm repair do not predict short-term outcome following endovascular repair. *Journal of Vascular Surgery*. In press.

Hayes PD, Sadat U, Walsh SR, *et al.* Cost-effectiveness analysis of endovascular versus open surgical repair of acute abdominal aortic aneurysms based on worldwide experience. *Journal of Endovascular Therapy* 2010;17(2):174-182.

Kopp R, Zürn W, Weidenhagen R, Meimarakis G, Clevert DA. First experience using intraoperative contrast-enhanced ultrasound during endovascular aneurysm repair for infrarenal aortic aneurysms. *Journal of Vascular Surgery* 2010;51(5):1103-1110.

Prenner SB, Turnbull IC, Malik R, *et al.* Outcome of elective endovascular abdominal aortic aneurysm repair in octogenarians and nonagenarians. *Journal of Vascular Surgery*. In press.

PERIPHERAL VASCULAR TREATMENT

Pedersen G, Laxdal E, Ellensen V, Jonung T, Mattsson E. Improved patency and reduced intimal hyperplasia in PTFE grafts with luminal immobilized heparin compared with standard PTFE grafts at six months in a sheep model. *Journal of Cardiovascular Surgery*. In press.

Pulli R, Dorigo W, Castelli P, *et al*; Propaten Italian Registry Group. Midterm results from a multicenter registry on the treatment of infrainguinal critical limb ischemia using a heparin-bonded ePTFE graft. *Journal of Vascular Surgery* 2010;51(5):1167-1177.

Have a story idea or case study to share?

Send your suggestions to peripheralvision@wlgore.com

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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 23-42 mm; ≥ 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 for a complete description of all warnings, precautions and adverse events. 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 ≤ 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. 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 for a complete description of all warnings, precautions and adverse events. Only

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