GORE PERIPHERAL VISION

Nº 001

FEBRUARY 2009

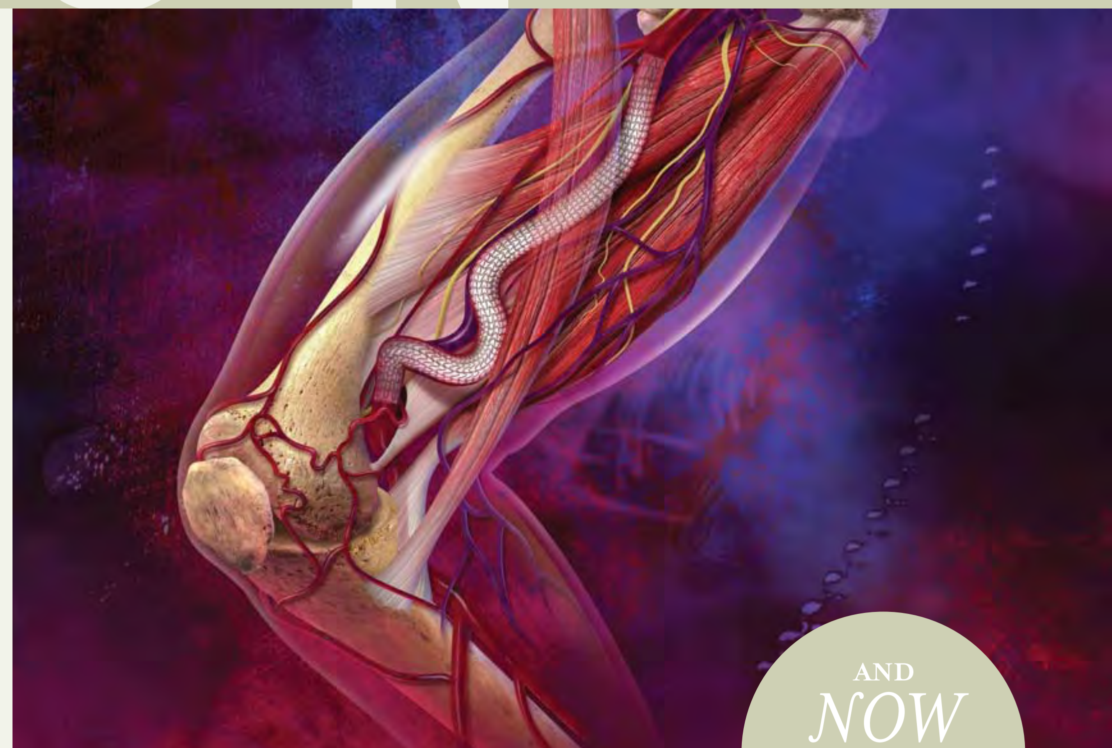
GORE LAUNCHES THIRD GENERATION *GORE VIABAHN®* ENDOPROSTHESIS IN EUROPE

W. L. Gore & Associates (Gore) formally launched their third generation GORE VIABAHN® Endoprosthesis at the recent CIRSE meeting in Copenhagen, Denmark. The launch was accompanied by talks from Eric Verhoeven, MD, University Medical Center, Groningen, Paramjit "Romi" Chopra, MD Rush University, Chicago, and Professor Johannes Lammer Medizinische Universitat, Wien.

Dr. Verhoeven of University Medical Center, Groningen, presented improved patency rates in patients receiving GORE VIABAHN® Endoprosthesis for treatment of lower limb arterial disease when Clopidogrel was prescribed in tandem with aspirin compared to aspirin alone. Dr. Chopra, Rush University, Chicago, indicated that patients suffering from lifestyle-limiting claudication may be candidates for GORE VIABAHN® Endoprosthesis in the treatment of their disease. Professor Lammer, Medizinische Universitat, Wien, summarized the performance of the GORE VIABAHN® Endoprosthesis by stating that the stent-graft has demonstrated encouraging mid-term patency rates even in long lesions.

Also in Europe during September, Dennis Gable, MD of Baylor University, Dallas, presented at the ESVS meeting in Nice, France his group's 24-month follow-up of patients receiving surgical bypass or GORE VIABAHN® Endoprosthesis for the treatment of their superficial femoral artery disease. The study randomized 50 patients to each arm and demonstrated primary patency for the stent-graft group of 82%, 73%, and 62% for six months, one year, and two years, respectively. For the same respective time points, primary patency for the surgical group, comprised of non-heparin-bonded, mostly polyester grafts, was 88%, 79%, and 65%. The comparable performance between the two groups may support the use of GORE VIABAHN® Endoprosthesis as an alternative to surgical bypass in some patients.

In the United States, Gore received approval from the US Food and Drug Administration in August, 2008, for the GORE VIABAHN® Endoprosthesis indicated for improving blood flow in patients with symptomatic peripheral arterial disease in the iliac artery. The stent-graft is the only one of its kind to receive approval for the treatment of both the superficial femoral and iliac arteries.



AND NOW APPROVED FOR ILIAC ARTERIES

IN THIS ISSUE

Gore Launches Third Generation GORE VIABAHN® Endoprosthesis in Europe ---- 1
Gore Receives CE Mark for GORE VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface ---- 2
New Line Extensions for GORE PROPATEN® Vascular Grafts ---- 3
Case Study: GORE PROPATEN® Vascular Graft and Heparin Induced Thrombocytopenia ---- 4
Gore Makes Headway with Currrent Clinical Studies ---- 6
2009 Events ---- 7
Reimbursement Update ---- 7
Literature Recommendation ---- 8

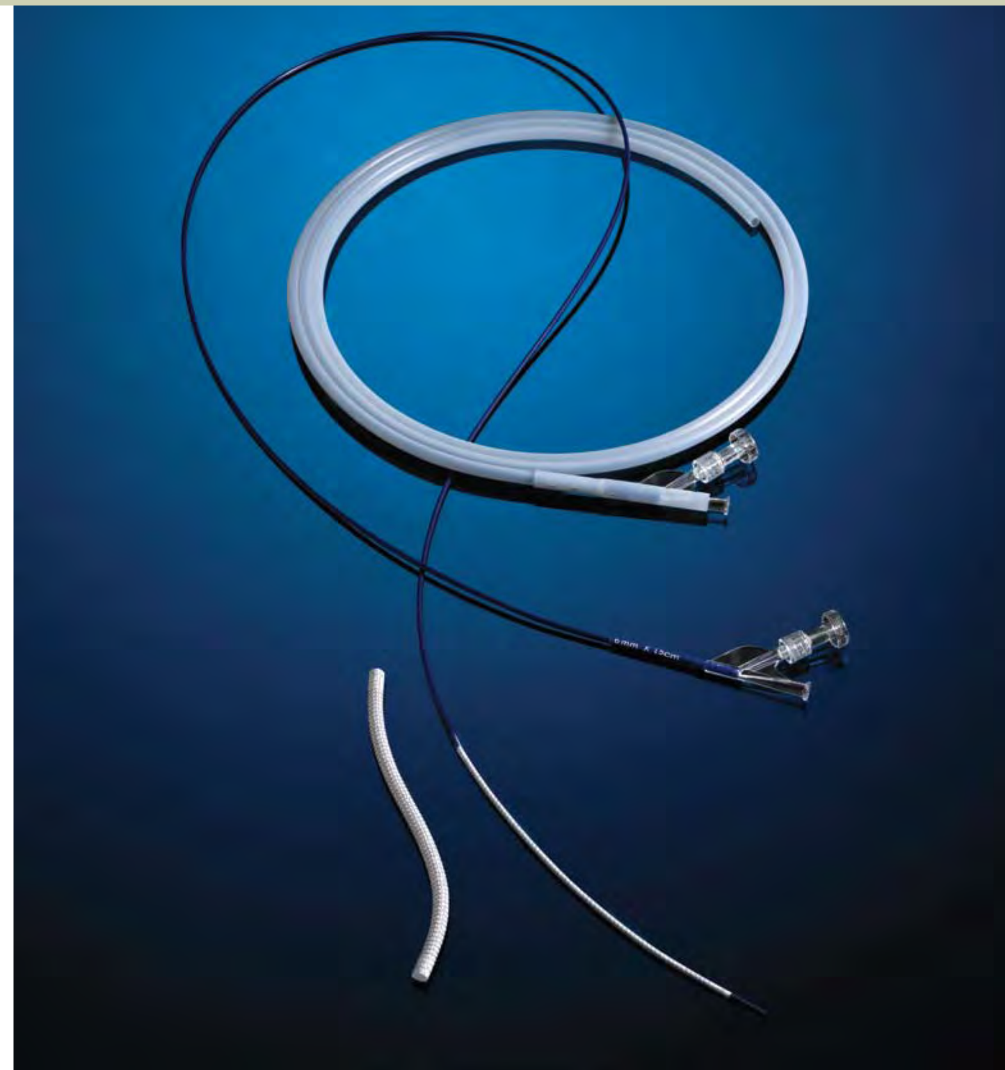
GORE VIABAHN® ENDOPROSTHESIS

IN THE NEWS

GORE RECEIVES CE MARK FOR *GORE VIABAHN®* ENDOPROSTHESIS WITH *PROPATEN®* BIOACTIVE SURFACE

Gore received approval to apply the CE Mark and commence commercial distribution of its GORE VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface in the European Union. Additionally, Gore recently received approval by the Therapeutic Goods Administration to commence commercial distribution in Australia. The GORE VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface combines Gore's proprietary heparin surface with the proven performance of the GORE VIABAHN® Endoprosthesis for treatment of arterial vascular disease. GORE VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface is indicated for the endovascular grafting of peripheral arteries.

GORE VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface (5 to 8 mm devices) is available with a low-profile delivery system that gives interventionalists a more streamlined approach to re-line the peripheral arteries.



PRODUCT UPDATE

NEW LINE EXTENSIONS FOR *GORE PROPATEN®* VASCULAR GRAFTS

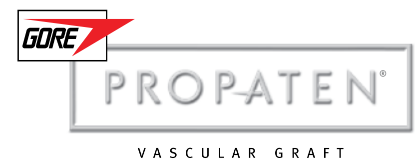
The GORE PROPATEN® Vascular Graft was commercialized in the US in December 2006. Since its introduction, the GORE PROPATEN® Vascular Graft has become the standard-of-care vascular graft in several prestigious institutions around the world. In order to meet physician and patient needs, we have been actively working to release new line extensions and anticipate having a full portfolio of available catalogue numbers in the near future.

RECENTLY RELEASED

Catalogue Number	Description	Internal Diameter (mm)	Ringed Section Length (cm)	Length (cm)
H060080A	Standard-walled, stretch technology	6	N / A	80
HT070080A	Thin-walled, stretch technology	7	N / A	80
HR060545A	Standard-walled, fixed ring, stretch technology	6	5	45
H460045A	Standard-walled, tapered, stretch technology	4 – 6	N / A	45

AVAILABLE SOON

Catalogue Number	Description	Internal Diameter (mm)	Ringed Section Length (cm)	Length (cm)
HT087090A	Thin-walled, removable ring, stretch technology	8	70	90
HT057090A	Thin-walled, removable ring, stretch technology	5	70	90
H080040A	Standard-walled, stretch technology	8	N / A	40
H080080A	Standard-walled, stretch technology	8	N / A	80



CASE STUDY

GORE PROPATEN® VASCULAR GRAFT AND HEPARIN INDUCED THROMBOCYTOPENIA

Karthikeshwar Kasirajan, MD
Division of Vascular Surgery
Emory University School of Medicine, Atlanta, GA.

CLINICAL CHALLENGE

The patient was a 41-year-old female with gangrene of the first and fifth toes of the right foot for six months. The patient had a history of heavy smoking (> 20 cigarettes / day) without any other significant risk factors.

Angiography of the right lower extremity revealed total Superficial Femoral Artery (SFA) and popliteal occlusion with reconstitution of the anterior tibial artery with continuous run-off to the foot.

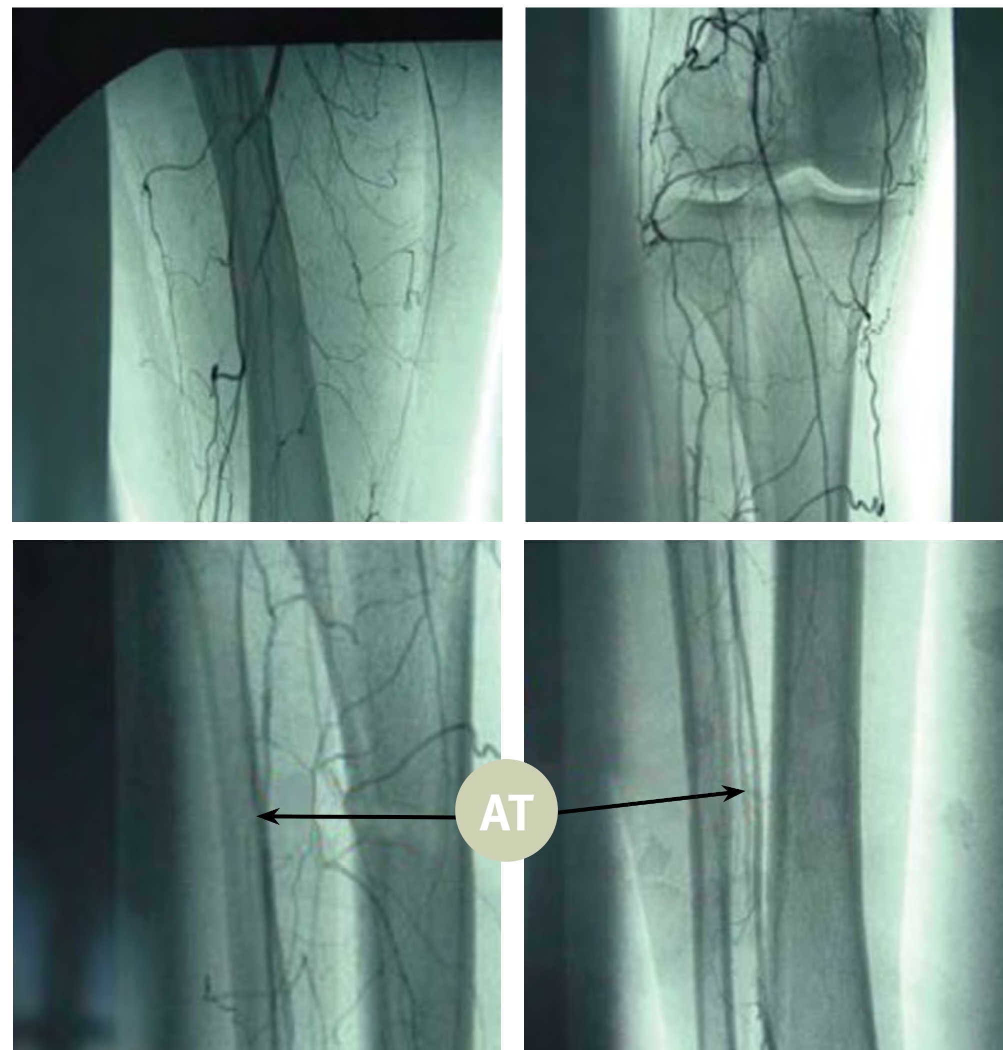
The patient had a usable single segment Greater Saphenous Vein (GSV) greater than 3 mm in diameter.

PROCEDURE

A femoral to anterior tibial bypass with the ipsilateral reversed GSV was performed. A palpable DP pulse was acquired on completion. Intraoperative heparin was administered with heparin drip post-operatively.

The GSV bypass thrombosed on day four. The patient was re-explored and a graft thrombectomy and completion angiogram were performed. No technical issues were noted on completion angiogram, but the graft re-thrombosed on the table. The vein graft was excised and a 6 mm GORE PROPATEN® Vascular Graft was sewn to a small cuff of vein that was left attached to the proximal and distal anastamosis.

Platelet count was at 78,000 post-op day one, a marked reduction from the pre-procedure platelet count of 293,000. All heparin use was discontinued and the ELISA test came back Heparin Induced Thrombocytopenia (HIT) positive. The graft was patent at this point and it was decided not to explant it. ARGATROBAN® Therapy was initiated for anticoagulation. Platelet counts were found to be recovering the next day and returned to normal three days after the systemic heparin was discontinued. The patient was converted to COUMADIN® Tablet Therapy with a normal platelet count in five days. HIT panel was repeated and was again positive.

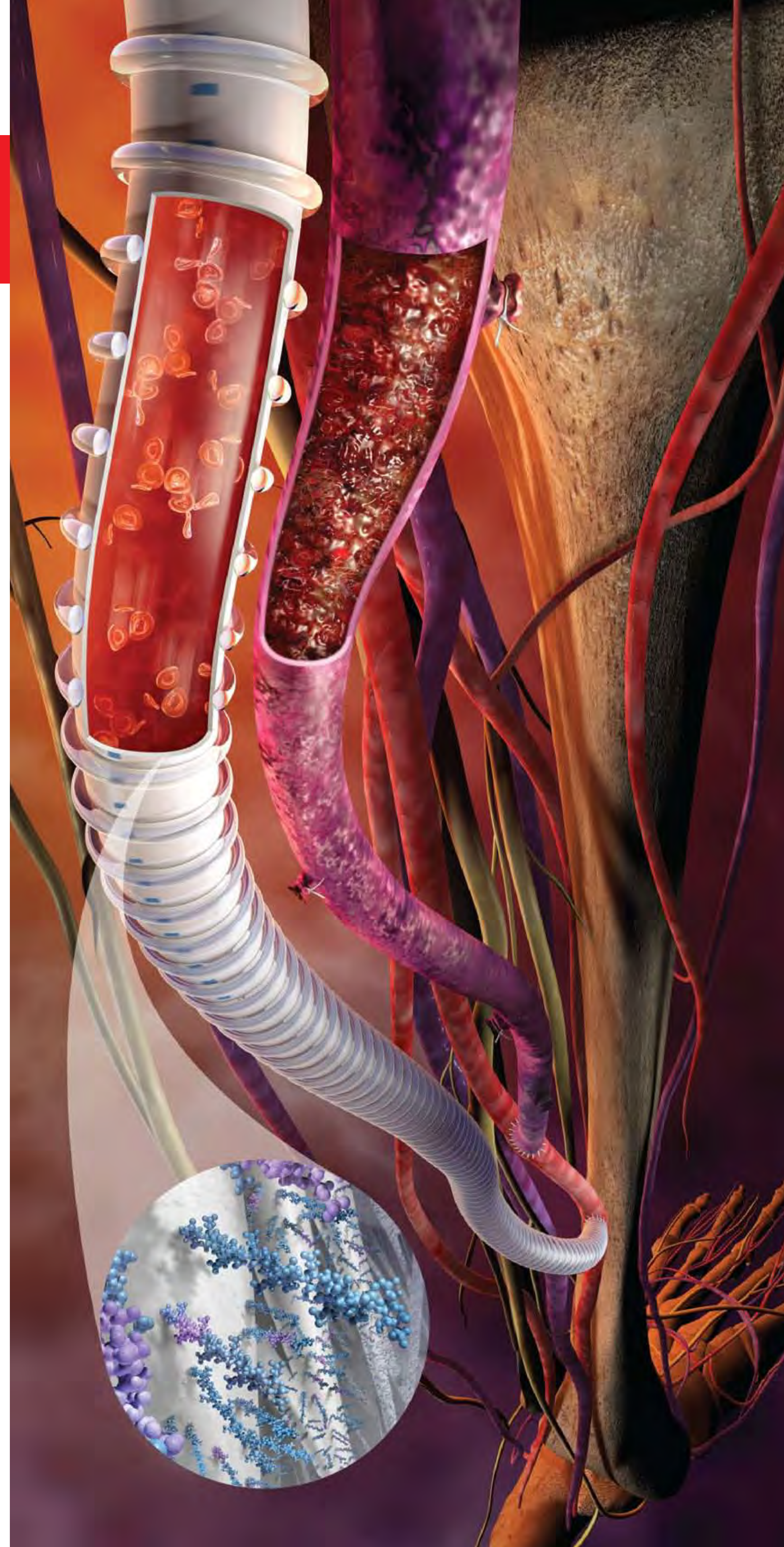


RESULTS

The patient is currently at her nine-month follow-up with duplex evidence of a patent GORE PROPATEN® Vascular Graft, palpable DP pulse and healed toes.

PHYSICIAN COMMENTS

The GORE PROPATEN® Vascular Graft remained patent and viable where a single segment GSV with a diameter greater than 3 mm did not in the face of HIT syndrome. The heparin-bonded graft does not appear to elicit HIT as the graft remained patent, despite heparin on the luminal surface of the graft being exposed to the systemic circulation, and the condition resolved. This incidence of HIT appears to be related to the systemic administration of heparin. With few other reports of similar cases of patent GORE PROPATEN® Vascular Grafts in patients with HIT secondary to systemic heparin administration, it allows us to be cautiously optimistic that in the event of similar clinical situations, the graft may be left in-situ.



CLINICAL STUDIES

GORE MAKES HEADWAY WITH CURRENT CLINICAL STUDIES

The Gore VIPER Patient Registry is a prospective, single-arm, multi-center evaluation of the GORE VIABAHN® Endoprosthesis with Heparin Bioactive Surface in the treatment of superficial femoral artery obstructive disease that will collect important performance data of the device. Forty subjects have been enrolled at six centers in the US. Subjects will be followed for one year.

The Gore REVISE Clinical Study is a randomized, multi-center IDE trial in the US intended to establish efficacy and safety of the GORE VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface to revise arterio-venous (AV) grafts at the venous anastomosis in hemodialysis patients. The study will randomize patients to the GORE VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface and to percutaneous transluminal angioplasty (PTA). The study will involve approximately 280 subjects, 140 subjects in each treatment arm, at 30 sites. Subjects will be followed for a period of two years. To date, 10 sites are active and 11 subjects have been enrolled. Site start-up and initiation visits are continuing. GORE VIABAHN® Endoprosthesis with PROPATEN Bioactive Surface is based on the proprietary end-point covalent bonding of heparin to expand polytetrafluoroethylene first made commercially available by Gore with GORE PROPATEN® Vascular Graft.

The Gore PRODIGY Clinical Study is a prospective, randomized, multi-center study to compare the performance of the GORE PROPATEN® Vascular Graft, which features the anticoagulant drug heparin, to a disadvantaged autologous vein graft in a below-knee peripheral bypass application. The study will enroll approximately 280 patients throughout the US. The subjects will be followed for a period of three years and will be evaluated for primary patency, as well several other secondary outcomes, including safety, quality of life and limb salvage.

If you are interested in more information about these clinical studies, please contact your Gore Associate.

2009 EVENTS

Date	Name	Location	Website
February 19 –21	Sanctuary of Endovascular Therapy (SET)	Kiawah Island, South Carolina	www.setmeeting.org
February 26 – 28	European Vascular Course (EVC)	Maastricht, The Netherlands	www.evc-meeting.org
March 7 – 12	Society of Interventional Radiology (SIR)	San Diego, California	www.sirmeeting.org
March 16 – 19	The Society for Cardiovascular Angiography and Interventions Cabo Interventional Summit	Cabo San Lucas, Mexico	www.scai.org
March 18 – 20	Endovascular Therapy International (ETI)	Genova, Italy	www.eti-endovascular.org
March 18 – 21	Society for Clinical Vascular Surgery (SCVS)	Fort Lauderdale, Florida	www.scvs.vascularweb.org
March 22 – 23	6th International Workshop on Interventional Pediatric Cardiology	MIlano, Italy	www.workshopipc.com
April 4 – 7	Charing Cross 29th International Symposium	London, England	www.cxsymposium.com
April 22 – 24	6th Vienna Interdisciplinary Symposium on Aortic Repair (VISAR)	Vienna, Austria	www.visar.at
May 19 – 22	European Association of Percutaneous Cardiovascular Interventions (PCR)	Barcelona, Spain	www.europcr.com
May 29	Masterclass	London, England	
May 31 – June 2	European Sociaty of Thoracic Surgeons (ESTS)	Krakow, Poland	www.ests.org

REIMBURSEMENT UPDATE

The following items are to provide highlights of some updates and changes implemented by CMS (Medicare) effective in 2008.

PHYSICIAN NEWS

The CMS issued a correction to the Transitional PE Non-Facility RVU for two CPT® Codes, 37205 Transcatheter placement of an intravascular stent(s) (except coronary, carotid, and vertebral vessel), percutaneous; initial vessel and 37206 Transcatheter placement of an intravascular stent(s) (except coronary, carotid, and vertebral vessel), percutaneous; additional vessel. Initially the Transitional PE Non-Facility RVU for CPT® Code 37205 was published as 65.13 and corrected to 108.66, for CPT® Code 37206 was published as 38.41 and corrected to 66.45. These corrections were published in the CMS Transmittal 1528 dated May 30, 2008 and effective retroactive to January 1, 2008.

PHYSICIAN AND HOSPITAL OUTPATIENT NEWS

The NCCI Edit Manual published by CMS, provides additional CPT® Coding guidance for physicians and hospital outpatient providers. A revised NCCI Edit in Chapter 6, Section D, Paragraph 16, was issued by the CMS effective January 1, 2008 for coding atherectomy, angioplasty and stent placement procedures in the same vessel. There were requests from Medical Societies and other stakeholders to rescind this Edit as it did not conform with CPT® Coding Guidelines developed by the American Medical Association (AMA). In July 2008, the CMS rescinded this NCCI Edit and reverted to the original guidance. The NCCI Edit Manual is published on the CMS website. A detail article describing this issue has been published in the October 2008 Issue of *Endovascular Today*.

HOSPITAL INPATIENT NEWS

The Medicare Inpatient Prospective Payment System (IPPS) payment rates and rules were published for the FFY 2009 annual update effective October 1, 2008. Coding Brochures for these FFY 2009 Medicare National Hospital Inpatient payment rates may be found on the Gore website, www.goremedical.com/reimbursement/. Also posted on the website are the Medicare IPPS Table 6I – MCCs list and Table 6J – CCs list which are utilized in the Medicare Severity Diagnosis Related Groups (MS-DRG) methodology.

LITERATURE RECOMMENDATIONS*

DIALYSIS

Morsy MA, Khan A, Chemla ES. Prosthetic axillary-axillary arteriovenous straight access (necklace graft) for difficult hemodialysis patients: a prospective single-center experience. *Journal of Vascular Surgery* ; in press.

PERIPHERAL VASCULAR TREATMENT

Banerjee S, Brilakis ES, Das TS. Covered stents for the treatment of SFA occlusive disease. *Endovascular Today* 2008;7(10):41-46.

Davies MG, Saad WE, Peden EK, Mohiuddin IT, Naoum JJ, Lumsden AB. Impact of runoff on superficial femoral artery endoluminal interventions for rest pain and tissue loss. *Journal of Vascular Surgery* 2008;48(3):619-625.

Dorigo W, Di Carlo F, Troisi N, *et al*. Lower limb revascularization with a new bioactive prosthetic graft: early and late results. *Annals of Vascular Surgery* 2008;22(1):79-87.

Heyligers JMM, Lisman T, Verhagen HJM, Weeterings C, de Groot PG, Moll FL. A heparin-bonded vascular graft generates no systemic effect on markers of hemostasis activation or detectable heparin-induced thrombocytopenia–associated antibodies in humans. *Journal of Vascular Surgery* 2008;47(2):324-329.

Hoeks SE, Smolderen KG, Scholte op Reimer WJM, Verhagen HJM, Spertus JA, Poldermans D. Clinical validity of a disease-specific health status questionnaire: The Peripheral Artery Questionnaire. *Journal of Vascular Surgery*; in press.

Ihnat DM, Duong ST, Taylor ZC, Leon LR, Mills JL Sr. Goshima KR, Echeverri JA, Arslan B. Contemporary outcomes after superficial femoral artery angioplasty and stenting: The influence of TASC classification and runoff score. *Journal of Vascular Surgery* 2008;47(5):967-974.

Peeters P, Verbist J, Deloose K, Bosiers M. Will heparin-bonded PTFE replace autologous venous conduits in infrapopliteal bypass? *Italian Journal of Vascular & Endovascular Surgery* 2008;15(3):143-148.

Powell RJ. Endovascular Treatment in the Superficial Femoral Artery: *Which Devices, Where? Seminars in Vascular Surgery* 2008;21(4):180-185.

Schmieder GC, Panneton JM. Endovascular Superficial Femoral Artery Treatment: *Can it Be as Good as Bypass? Seminars in Vascular Surgery* 2008;21(4):186-194.

TIPS

Pan JJ , Chen C, Geller B, *et al*. Is sonographic surveillance of polytetrafluoroethylene-covered transjugular intrahepatic portosystemic shunts (TIPS) necessary? A single centre experience comparing both types of stents. *Clinical Radiology* 2008;63(10):1142-1148.

* Literature recommendations are intended as information only. Gore does not necessarily support or endorse the content of these references.

Have a story idea or case study to share?

Send your suggestions to *peripheralvision@wlgore.com*

Please visit goremedical.com to subscribe to an online version of the *Gore Peripheral Vision*, or contact your local Gore Sales Associate to be added to the distribution list.

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

INTENDED USE / INDICATIONS: 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:** 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. Refer to Instructions for Use at goremedical.com for a complete description of all warnings, precautions and adverse events.

Products listed may not be available in all markets pending regulatory clearance. GORE, PROPATEN®, VIABAHN®, and designs are trademarks of W. L. Gore & Associates. ARGATROBAN® is a registered trademark of GlaxoSmithKline. COUMADIN® is a trademark of Bristol-Myers Squibb Co. CPT® is a trademark of the American Medical Association. © 2009 W. L. Gore & Associates, Inc. AM1059-EN1 JANUARY 2009

⚠ Attention, See Instructions for Use