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## FDA Clears GORE PROPATEN Vascular Graft

*GORE Transcends Mechanical Solutions for Lower-Limb Surgery with A ePTFE-Heparin Combination*

FLAGSTAFF, Ariz.--(BUSINESS WIRE)--W. L. Gore & Associates (GORE) today announced that the U.S. Food & Drug Administration (FDA) has given the company clearance to market its GORE PROPATEN Vascular Graft for peripheral use, including lower-limb bypass and dialysis access surgery. The GORE PROPATEN Vascular Graft is the first ePTFE vascular graft that reduces thrombosis<sup>1</sup>—or clotting—and is designed to address the clinical problem of thrombotic vascular graft failure. The GORE PROPATEN Vascular Graft is the first and only ePTFE-heparin combination in an emerging class of medical products that combine mechanical and biological elements. It is designed to address the gap in clinical performance between synthetic and vein grafts by bonding the anticoagulant drug heparin to the surface of the graft using proprietary heparin end-point covalent bonding.

As many as 12 million Americans over the age of 50 are affected annually by Peripheral Arterial Disease (PAD). PAD manifests as a built-up of plaque in the wall of an artery resulting in either narrowing or blocking of the artery, limiting blood flow to the limbs. Surgical vascular bypass is a common treatment for PAD. The use of autologous veins as a bypass conduit has been the standard of care for below-knee bypasses as synthetic grafts historically have not matched their clinical performance.

Over 10,000 GORE PROPATEN Vascular Grafts have been successfully implanted worldwide in four years of commercial availability overseas. The average one-year primary patency for the GORE PROPATEN Vascular Graft in below-knee bypasses has been reported to be 80 percent.<sup>2</sup> This compares favorably to the average one-year patencies for autologous vein grafts (81 percent) and ePTFE synthetic grafts (66 percent) in the same application.<sup>3</sup>

According to Dr. Marc Bosiers, M.D., Head, Department of Vascular Surgery, A.Z. St. Blasius Hospital, Dendermonde, Belgium, the use of the heparin-bonded ePTFE graft "...may represent a viable alternative for below-knee bypasses, which have traditionally yielded less than desirable outcomes." His study, *Heparin-bonded expanded polytetrafluoroethylene vascular graft for femoropopliteal and femorocrural bypass grafting: 1-year results*, appears in the *Journal of Vascular Surgery*, February 2006.

"With the FDA clearance of the GORE PROPATEN Vascular Graft, Gore expands its portfolio of advanced medical solutions to offer a real alternative for below-knee surgery," said Robert Thomson, product specialist for the GORE PROPATEN Vascular Graft. "The GORE PROPATEN Vascular Graft has provided breakthrough clinical performance by transcending mechanical solutions," added Deenu Kanjickal, also product specialist for the GORE PROPATEN Vascular Graft.

### ABOUT W. L. GORE & ASSOCIATES

The Gore Medical Products Division has provided creative therapeutic solutions to complex medical problems for three decades. During that time, more than 18 million innovative Gore Medical Devices have been implanted, saving and improving the quality of lives worldwide. The extensive Gore Medical family of products includes vascular grafts, endovascular and interventional devices, surgical meshes for hernia repair and sutures for use in vascular, cardiac and general surgery. Gore was recently named the fifth best company to work for by *Fortune* magazine.

Products listed may not be available in all markets pending regulatory clearance. GORE and PROPATEN are trademarks of W. L. Gore & Associates.

<sup>1</sup> Begovac PC, Thomson RC, Fisher JL, Hughson A, Gällhagen A. Improvements in GORE-TEX® Vascular Graft performance by Carmeda® bioactive surface heparin immobilization. *European Journal of Vascular and Endovascular Surgery* 2003;25(5):432-437.

<sup>2</sup> Walluscheck KP. Heparin-bonded expanded polytetrafluoroethylene vascular graft for occlusive vascular disease of the lower extremity. *Italian Journal of Vascular & Endovascular Surgery* 2006;13(3):137-147.

<sup>3</sup> Data based on an analysis of current literature: several Medline searches were performed to identify publications pertaining to ePTFE synthetic vascular graft and vein infragenicular bypasses. Search criteria included (1) articles published from January 2000 to September 2005, (2) key words used were below knee, polytetrafluoroethylene, prosthetic, bypass, patency, (3) articles in English language, (4) N equal or greater than 30 bypasses, (5) clinical publications, (6) reviews, case reports or meta-analysis articles were excluded, (6) articles containing the key word AV access (including synonyms) were excluded. Articles that did not meet the above criteria were deemed ineligible for this analysis. Data of analysis on file.

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