Together, improving life

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FIRST PATIENTS ENROLLED IN THE GORE VBX FORWARD CLINICAL STUDY

This study aims to compare the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis primary patency to bare metal stenting to evaluate superiority in treating complex iliac occlusive disease with the goal of informing practice guidelines around which modality is best suited for patients with this condition.

FLAGSTAFF, Ariz. (JANUARY 16, 2024) — W. L. Gore & Associates, Inc. (Gore) announced today that the first patients have been enrolled in the Gore VBX FORWARD Clinical Study (NCT05811364), a global prospective, multicenter, randomized controlled trial to compare the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis (VBX Stent Graft) to bare metal stenting for patients with complex iliac occlusive disease.

"Our team is pleased to be among the first to enroll patients in this important study," said Fakhir Elmasri, M.D., Interventional Radiologist, Lakeland Vascular Institute, Lakeland, Florida. "Our first patient presented with complex, bilateral iliac disease and was randomized to treatment with VBX Stent Grafts. I look forward to seeing the results of the study to inform device selection for durable outcomes in the future."

"While stenting is common when treating complex iliac occlusive disease, the question around whether to use a covered or bare metal stent remains a source of debate," said Prakash Krishnan, M.D., Interventional Cardiologist, The Mount Sinai Hospital, New York City. "This trial is designed to answer the question as to whether covered stents are the superior modality among commonly used devices in contemporary practice."

The VBX FORWARD Study aims to enroll an estimated 244 subjects across 40 sites in the United States, Australia, New Zealand and Europe, randomizing them 1:1 to the VBX Stent Graft group or the control group (BMS) and conduct follow-up visits through five years from the initial procedure.

"This trial is designed to answer the question as to whether covered stents are the superior modality among commonly used devices in contemporary practice."

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"Treating complex iliac occlusive disease often comes with significant challenges, including tortuous anatomy and calcified lesions with the potential for rupture," said Melissa Kirkwood, M.D., Professor and Chief of Vascular Surgery, University of Texas Southwestern Medical Center, Dallas, Texas and VBX FORWARD Study Steering Committee Member. "The outcomes of this important trial will help determine whether the VBX Stent Graft, with its unique and versatile design, plays a meaningful role in addressing these challenges."

The VBX Stent Graft offers precise delivery and supports positive outcomes in complex aortoiliac applications.[1] Recently published long-term follow-up of patients treated with the VBX Stent Graft for aortoiliac occlusive disease (AIOD) demonstrates the robustness and durability of the device through five years.[1]

"Today marks important progress in our continuing effort to raise the bar on endovascular treatment outcomes that demonstrate a positive impact on the lives of patients who suffer from this disease," said Eric Zacharias, Medical Products Division Leader, W. L. Gore & Associates. "Not only can the results from this randomized controlled trial help determine which stent choice demonstrates better patency in patients with complex iliac occlusive disease, but it also aims to provide the quality of evidence necessary to inform practice guideline recommendations."

The GORE® VIABAHN® Device family of covered stent grafts, inclusive of the VBX Stent Graft and the GORE VIABAHN Endoprosthesis with Heparin Bioactive Surface[*, †], offers the flexibility and conformability to safely and confidently address even the most complex cases.[‡,2,3]

For more information about the GORE VIABAHN Device family of covered stent grafts, visit: https://www.goremedical.com/viabahn/device-family/devices

Additional information about the VBX FORWARD Study is available at: https://clinicaltrials.gov/ct2/show/NCT05811364

Gore engineers medical devices that treat a range of cardiovascular and other health conditions. With more than 55 million medical devices implanted over the course of more than 45 years, Gore builds on its legacy of improving patient outcomes through research, education and quality initiatives. Product performance, ease of use and quality of service provide sustainable cost savings for physicians, hospitals and insurers. Gore is joined in service with clinicians and through this collaboration we are improving lives. For more information, visit goremedical.com.

About Gore

W. L. Gore & Associates is a global materials science company dedicated to transforming industries and improving lives. Since 1958, Gore has solved complex technical challenges in demanding environments — from outer space to the world's highest peaks to the inner workings of the human body. With more than 13,000 Associates and a strong, team-oriented culture, Gore generates annual revenues of $4.8 billion. For more information, visit gore.com.

For complete indications and other important safety information for Gore commercial products referenced herein, refer to the applicable *Instructions for Use* (IFU).

* As used by Gore, Heparin Bioactive Surface refers to Gore's proprietary CBAS® Heparin Surface.

† Also referred to as the GORE VIABAHN Endoprosthesis with PROPATEN Bioactive Surface in some regions.

‡ The GORE VIABAHN VBX Balloon Expandable Endoprosthesis indication includes de novo or restenotic lesions in iliac arteries, including those at the aortic bifurcation. The GORE VIABAHN Endoprosthesis indication includes lesions in the iliac arteries only. See product indications.

1. Holden A, Takele E, Hill A, *et al*. Long-term follow-up of subjects with iliac occlusive disease treated with the Viabahn VBX Balloon-Expandable Endoprosthesis. *Journal of Endovascular Therapy.* In press.
2. Piazza M, Squizzato F, Dall'Antonia A, *et al*. Outcomes of self expanding PTFE covered stent versus bare metal stent for chronic iliac artery occlusion in matched cohorts using propensity score modelling. *European Journal of Vascular & Endovascular Surgery* 2017;54(2):177-185.
3. Panneton JM, Bismuth J, Gray BH, Holden A. Three-year follow-up of patients with iliac occlusive disease treated with the Viabahn Balloon-Expandable Endoprosthesis. *Journal of Endovascular Therapy* 2020;27(5):728-736.

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