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FIRST EUROPEAN IMPLANTS FOR THE GORE® EXCLUDER® THORACOABDOMINAL BRANCH ENDOPROSTHESIS PIVOTAL STUDY

This pivotal study will determine safety and effectiveness of a modular device designed to be a completely off-the-shelf endovascular solution for aortic aneurysms involving the visceral branch vessels.

FLAGSTAFF, Ariz. (November 23, 2021) — W. L. Gore & Associates, Inc. (Gore) today announced the first patients have been enrolled in Europe in a pivotal study of the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis.* Surgeries were performed the week of June 21, with the first cases taking place at the Imperial College Healthcare NHS Trust, St. Mary's Hospital by Mr. Richard Gibbs, Mr. Michael Jenkins and Professor Mohamad Hamady, followed by Guy's and St. Thomas' NHS Foundation Trust by Mr. Said Abisi and Professor Bijan Modarai. Each of these fully endovascular procedures were performed in patients diagnosed with Crawford extent IV thoracoabdominal aortic aneurysm involving complex visceral branch vessels, including those supplying the kidneys, liver, stomach and intestines.

"Currently, treatment options for these patients include an invasive open surgery or the use of a physician modified or custom manufactured endovascular device, often without validation of stent compatibility," said Mr. Gibbs. "The Gore investigational device allowed me to treat this patient with a ready-made, conformable and fully endovascular solution appropriate for complex pararenal and thoracoabdominal aortic aneurysms," said Mr. Jenkins. "The ability to reposition the device orientation provided additional control during the procedure," said Professor Hamady.

The GORE EXCLUDER Thoracoabdominal Branch Endoprosthesis is an investigational device with a modular design comprised of

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five components. The device utilizes an investigational aortic component in combination with commercially available devices for the branch components (GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis), the distal bifurcated component (GORE® EXCLUDER® Iliac Branch Endoprosthesis), and the iliac components (GORE® EXCLUDER® AAA Endoprosthesis) Contralateral Leg or Iliac Extender, each of which are being further evaluated for compatibility in this study. Further, an optional thoracic component (GORE® TAG® Conformable Thoracic Stent Graft with ACTIVE CONTROL System) may be used to obtain proximal extension.

The device's aortic, side branch and iliac components are designed to maximize patient fit and withstand the durability challenges of thoracoabdominal and pararenal aortic aneurysms. The conformable, kink-resistant side branch component features CBAS Heparin Surface. The investigational aortic component offers multi-stage deployment with proximal, distal and rotational repositionability to aid in branch vessel access and deployment accuracy.

"While thoracoabdominal aortic aneurysms constitute a low percentage of aortic aneurysms, the involvement of multiple vessels supplying the kidneys and visceral organs makes their repair one of the more challenging tasks in aortic surgery," added Mr. Abisi. "With this device, Gore aims to offer a versatile, modular endovascular solution that allows appropriate patients to be treated without the need to wait for a custom-built stent graft," said Professor Modarai.

The pivotal study follows the Early Feasibility Assessment of the GORE EXCLUDER Thoracoabdominal Branch Endoprosthesis in the Treatment of Type IV Thoracoabdominal Aortic Aneurysms Involving the Visceral Branch Vessels Study conducted in the United States and Brazil, which had first implants in 2014.

"Today marks important progress in our ability to provide patients with an advanced technological option for the treatment of thoracoabdominal and pararenal aortic aneurysms," said Mary Mulder, Ph.D., a Vascular Business Leader at Gore. "Results from this pivotal study could help in obtaining approval from the FDA for this innovative solution to better address challenging aortic anatomies and provide physicians with an even more complete device portfolio for the treatment of aortic aneurysms."

Gore's growing family of endovascular products share a mission to effectively treat the full range of challenging aortic anatomies, backed by Gore's highly rated clinical support team and educational offerings.† The comprehensive portfolio of products includes the GORE TAG Conformable Thoracic Stent Graft with ACTIVE CONTROL System for the treatment of thoracic aneurysms, transections and Type B dissections.

[*] The GORE EXCLUDER Thoracoabdominal Branch Endoprosthesis is exclusively for Clinical Investigation and not available for sale.

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

Gore engineers medical devices that treat a range of cardiovascular and other health conditions. With more than 50 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 11,000 Associates and a strong, team-oriented culture, Gore generates annual revenues of $3.8 billion.
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