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GORE MEDICAL RECEIVES BREAKTHROUGH DEVICE DESIGNATION FOR THE GORE[®] EXCLUDER[®] THORACOABDOMINAL BRANCH ENDOPROSTHESIS

CAUTION: Investigational device. Limited by United States law to investigational use.

FLAGSTAFF, Ariz. (April 12, 2022) — Gore Medical has received Breakthrough Device designation from the U.S. Food and Drug Administration for the GORE[®] EXCLUDER[®] Thoracoabdominal Branch Endoprosthesis (TAMBE Device). The Breakthrough Devices Program is a voluntary program for certain medical devices and device-led combination products that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. The TAMBE Device is the third Breakthrough Device in the company's aortic endovascular portfolio to date, following the GORE[®] TAG[®] Thoracic Branch Endoprosthesis and the GORE[®] Ascending Stent Graft, two other investigational devices being developed.

In treating thoracoabdominal and pararenal aneurysms of the aorta, the investigational TAMBE Device is guided up through the femoral artery in the groin via a small incision. Using various imaging techniques, the physician deploys the device such that it seals off the aneurysm, allowing blood to flow directly through the endoprosthesis with the intent to reduce the risk of rupture. Because the disease frequently extends to adjacent vessels, the TAMBE Device has four built-in, pre-cannulated portals to facilitate placement of stent grafts into the arteries perfusing the internal organs within the abdomen.

"The TAMBE Device is a very promising technology that may give us the option to treat patients less invasively and, in some scenarios, repair their aneurysms that otherwise would not be possible with currently approved techniques."

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"Currently, there is no off-the-shelf device approved for this indication which is available for physicians to use in these indications," said Mark Farber, M.D., (UNC School of Medicine, Chapel Hill, NC). "The TAMBE Device is a very promising technology that may give us the option to treat patients less invasively and, in some scenarios, repair their aneurysms that otherwise would not be possible with currently approved techniques."

The TAMBE Device is currently being studied under an Investigational Device Exemption (IDE) at nearly four dozen medical centers within the U.S. and U.K. led by national Principal Investigators Dr. Mark Farber and Mr. Richard Gibbs, respectively. Enrollment in the primary study arm is complete with subjects continuing in follow up. The co-primary endpoints consist of a composite endpoint of technical success and 30-day safety events, and a 12-month reintervention and lesion-related mortality rate.

The TAMBE Device is based upon the proven performance of the GORE® EXCLUDER® Device family which has been used to treat over 400,000 patients. In over 20 years of worldwide clinical experience, the GORE® EXCLUDER® AAA Endoprosthesis is the most studied EVAR device based on review of peer-reviewed articles.

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

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. For more information, visit gore.com.

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