



FOR IMMEDIATE RELEASE

FIRST EUROPEAN IMPLANTATION OF GORE® TAG® THORACIC BRANCH ENDOPROSTHESIS

MDR CE mark approval signifies the first off-the-shelf single-branch thoracic endoprosthesis for patients requiring zone 2 treatment.

PUTZBRUNN, GERMANY (February 1, 2024) — W. L. Gore & Associates, Inc. (Gore) today announced the first ever implantation of the GORE® TAG® Thoracic Branch Endoprosthesis (TBE) in Europe. The patient was treated by Prof. Dittmar Boeckler, Chief of the Department of Vascular Surgery and Endovascular Surgery at University Hospital Heidelberg, Germany.

Introducing the MDR CE mark approved GORE® TAG® Thoracic Branch Endoprosthesis

The device is indicated for endovascular repair of lesions in the descending thoracic aorta of patients with the appropriate anatomy, including isolated lesions, such as aneurysms, traumatic transections and Type B dissections, while maintaining flow into the left subclavian artery.

Rigorous in vitro and in vivo testing and extensive clinical trials have demonstrated the safety and performance of the device, which has become the first endovascular graft for the aortic arch to be granted both FDA and MDR CE mark approval.

The pivotal study conducted in the United States enrolled 238 patients requiring treatment across multiple aortic pathologies, including the left subclavian artery (LSA). All subjects were enrolled with a technical success rate of 95.8 percent, reintervention rate of 2.9 percent, LSA branch patency of 99.2 percent and disabling stroke rate of 3.4 percent through 12 months of follow-up.

“As a complete, single-device system, the GORE TAG Thoracic Branch Endoprosthesis simplifies the treatment of zone 2 revascularization by eliminating the need for surgical LSA debranching.”

Prof. Dr. med. D. Boeckler
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"Treating aortic arch disease has traditionally posed challenges. Current options involve procedures like open surgery, hybrid approaches with surgical revascularization, or those that use non-CE mark devices. As a complete, single-device system, the GORE TAG Thoracic Branch Endoprosthesis simplifies the treatment of zone 2 revascularization by eliminating the need for surgical LSA debranching. The ability to endovascularly perfuse the left subclavian artery plays a key role in minimizing surgical procedures and related risks. We are excited about this next significant step in treating a broader range of patients with this innovative device," Prof. Dittmar Boeckler.

Designed for long-term durability, the GORE TAG Thoracic Branch Endoprosthesis is the first off-the-shelf Aortic branched zone 2 device to be approved in Europe under the new MDR CE mark regulation. "The GORE TAG Thoracic Branch Endoprosthesis combines the proven conformability and durability of the GORE TAG Conformable Device with the ability to endovascularly perfuse the left subclavian artery," said Eric Zacharias, Medical Products Division Leader at Gore. "This approval is another step in our continuing efforts to offer the broadest endovascular treatment capabilities on the market."

The GORE TAG Thoracic Branch Endoprosthesis builds on more than 25 years of Gore experience in thoracic aortic innovation and was designed with a purpose-built bridging stent for durably treating the challenging anatomy of the aortic arch.* The GORE TAG Thoracic Branch Endoprosthesis is part of the growing family of endovascular products that share the mission to effectively treat aortic disease, backed by Gore's dedicated clinical support team and educational offerings. The branched portfolio of products also includes an off-the-shelf iliac branch device, the GORE EXCLUDER Iliac Branch Endoprosthesis (IBE), which is indicated for the endovascular treatment of common iliac artery aneurysms or aortoiliac aneurysms. The recently FDA approved GORE EXCLUDER Thoracoabdominal Branch Endoprosthesis (TAMBE) is currently an investigational device in the European Union and not yet CE-marked.

For more information, visit
<https://www.goremedical.com/eu/products/tbe>

* 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 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.

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.
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