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Gore Announces FDA Approval and First Commercial Implant of Large-Diameter Thoracic Tapers

New tapered sizes broaden treatment options for patients with thoracic aortic disease states.

FLAGSTAFF, Ariz. (March 24, 2025) — W. L. Gore & Associates (Gore) today announced the expansion of the GORE® TAG® Conformable Thoracic Stent Graft with ACTIVE CONTROL System product line, following FDA approval of four new large-diameter tapered designs — 34x28 mm, 37x31 mm, 40x34 mm and 45x37 mm.

News of the approval comes in conjunction with the first U.S. commercial implant, completed at Keck School of Medicine of USC by Sukgu Han, M.D., M.S., Chief of the Division of Vascular Surgery and Endovascular Therapy at USC.

For Dr. Han, the new large-diameter tapers “provide a welcome addition to the available treatment options for patients and expands applicability for the existing Gore technology.”

First approved in 2019, the GORE® TAG® Conformable Thoracic Stent Graft with ACTIVE CONTROL System is indicated for the endovascular repair of all lesions of the descending thoracic aorta, including aneurysms, transections and Type B Dissections. See full indications for use below.

With its staged delivery system designed for controlled precision, the Gore device has become a trusted treatment choice in thoracic aortic disease.

“The right device sizing is always critical,” Dr. Han emphasized, “and even more so when treating in a narrow true lumen. These additional tapered designs will help us achieve optimal sizing for a broader range of aortic diameters while continuing

“I found the device to perform with reliable conformability and controlled, staged delivery mechanism. And now, I know that I have the sizes I need for more of the patients I need to treat.”

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to leverage the proven performance and properties of this device system."

"The GORE® TAG® Conformable Thoracic Stent Graft with ACTIVE CONTROL System is an outstanding technology. I found the device to perform with reliable conformability and controlled, staged delivery mechanism. And now, I know that I have the sizes I need for more of the patients I need to treat," he concluded.

"The new large-diameter tapers reflect a deeply held conviction at the core of Gore Medical: We believe that better outcomes for patients begin with better options for physicians," remarked Jason Belzer, Americas Business Leader, Medical Products Division.

He continued, "When those two areas of improvement align, the results are a privilege to witness. We're delighted to play our part with new tapered sizes that will allow more patients to be treated with Gore technology."

"By combining the best minds in design with a deep understanding of physician needs, Gore continues to deliver for physicians and the patients in their care," he concluded.



Medical Products

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 approximately 13,000 Associates and a strong, team-oriented culture, Gore generates annual revenues of \$5 billion. gore.com

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INDICATIONS FOR USE IN THE U.S.: The GORE® TAG® Conformable Thoracic Stent Graft is intended for endovascular repair of all lesions of the descending thoracic aorta, including: isolated lesions in patients who have appropriate anatomy, including: adequate iliac/femoral access, aortic inner diameter in the range of 16-42 mm, ≥ 20 mm non-aneurysmal aorta proximal and distal to the lesion; Type B dissections in patients who have appropriate anatomy, including: adequate iliac/femoral access, ≥ 20 mm landing zone proximal to the primary entry tear; proximal extent of the landing zone must not be dissected, diameter at proximal extent of proximal landing zone in the range of 16-42 mm.

CONTRAINDICATIONS: Patients with known sensitivities or allergies to the device materials; patients who have a condition that threatens to infect the graft. Refer to *Instructions for Use* at eifu.goremedical.com for a complete description of all applicable indications, warnings, precautions and contraindications for the markets where this product is available. Refer to *Instructions for Use* at eifu.goremedical.com for a complete description of all applicable indications, warnings, precautions and contraindications for the markets where this product is available. ^{Rx} Only

Products listed may not be available in all markets.
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