Together, improving life

FOR IMMEDIATE RELEASE

W. L. GORE & ASSOCIATES, INC. RECEIVES U.S. FOOD & DRUG ADMINISTRATION (FDA) APPROVAL FOR LOWER PROFILE **GORE® VIABAHN® VBX** BALLOON EXPANDABLE ENDOPROSTHESIS, NOW 6 FR SHEATH COMPATIBLE

With improvements to the stent graft delivery system enabling a 1 Fr profile reduction on the majority of sizes, the device now offers the most 6 Fr compatible configurations among balloon expandable stent grafts.

FLAGSTAFF, Ariz. (JANUARY 31, 2024) — As part of efforts to continuously improve medical solutions for patients with complex vascular disease, W. L. Gore & Associates, Inc. (Gore) announced recent FDA approval of a lower profile GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis (VBX Stent Graft).

FDA approval of this innovation builds on a proven device which has become an important tool for treating complex vascular disease. In addition to offering the longest balloon expandable stent on the market with its 79 mm configuration, and the widest range of stent diameter adjustability, the VBX Stent Graft now also offers the most 6 Fr compatible configurations among balloon expandable stent grafts.[1–3]

"Our team is pleased to be the first commercial implanter of the new lower profile VBX Stent Graft," said Darren Schneider, M.D., Chief of Vascular Surgery and Endovascular Therapy, Penn Medicine, Philadelphia, Pennsylvania. "Combined with

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the flexibility, strength and deployment accuracy I've always trusted with the device, the new lower profile will enable me to treat most of my complex cases with a 6 or 7 Fr device, reducing the risk of access complications while bringing trusted VBX Stent Graft outcomes to more of my patients."

No changes to the stent design were made to achieve the lower profile. By focusing on improvements to the delivery system only, the valued characteristics and trusted performance of the stent graft itself remain unchanged and are joined by the enhanced versatility a lower profile provides. Depending on the practice, physicians may be able to use the VBX Stent Graft with a broader set of patients, experience a lower risk of complications at the access site, find improved procedure efficiency and/or a general improvement in ease of use.

"With the recently published five-year outcomes data, and the active pursuit of evaluating superiority versus bare metal stents in complex iliac occlusive disease through the Gore VBX FORWARD Clinical Study (NCT05811364), this lower profile innovation gives me yet another reason to feel confident in the proven outcomes and broad versatility of this device in my practice," said Ehrin Armstrong, M.D., Interventional Cardiologist and Director of Clinical Research, Advanced Heart and Vein Center, Denver, Colorado.

Since its U.S. launch in 2017, more than 375,000 VBX Stent Grafts have been implanted worldwide.* Currently in the U.S., the device is indicated for the treatment of de novo or restenotic lesions found in iliac arteries with reference vessel diameters ranging from 5–13 mm and lesion lengths up to 110 mm, including lesions at the aortic bifurcation.

The lower profile device will be rolled out to the U.S. market over the coming months and is also being studied in the Type IV Thoracoabdominal Aortic Aneurysms (TAMBE) Trial (NCT02528500).

"The approval and release of the lower profile VBX Stent Graft serves as a demonstration of the Gore Medical Products Division's commitment to continual improvement and lifelong innovation in collaboration with physicians to solve tough challenges where there is a critical patient need," said Jill Paine, Peripheral Business Leader for Gore's Medical Products Division. "We look forward to supporting our physicians and their patients through the delivery of this exciting innovation to their treatment toolbox."

For more information about the lower profile VBX Stent Graft visit: goremedical.com/products/vbx

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Darren Schneider, M.D.,
Chief of Vascular Surgery
and Endovascular Therapy
Penn Medicine,
Philadelphia, Pennsylvania

* Data on file 2023; W. L. Gore & Associates, Inc.; Flagstaff, AZ.

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).

1. GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis [Instructions for Use]. Flagstaff, AZ: W. L. Gore & Associates, Inc; 2023. MD169334.
2. LIFESTREAM® Balloon Expandable Vascular Covered Stent [Instructions for Use]. Tempe, AZ: Bard Peripheral Vascular, Inc; 2019. BAW1345700 Rev. 5 06/19.
3. iCast covered stent system [Instructions for Use]. Merrimack, NH: Atrium Medical Corporation; 2023. AW009603-EN Rev 11.

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