Together, improving life

MEDIA UPDATE

NOW INDICATED FOR AAA PATIENTS WITH HIGHLY ANGULATED NECKS

GORE® EXCLUDER® Conformable AAA Endoprosthesis with ACTIVE CONTROL System.

FLAGSTAFF, Ariz. (April 30, 2024) — W. L. Gore & Associates (Gore) announces FDA approval of an expanded indication for the GORE® EXCLUDER® Conformable AAA Endoprosthesis, now indicated for patients with aortic neck angulation ≤ 90° and a minimum length of 10 mm.

With the expanded indication, the GORE EXCLUDER Conformable AAA Device is now the only FDA-approved endovascular device solution indicated for patients with aortic neck angulation up to 90° and neck length of 10 mm.

"This is a landmark indication for an EVAR device, equipping physicians with an on-label solution for more patients with hostile neck anatomy," said Robert Rhee, M.D., national principal investigator of the GORE EXCLUDER Conformable AAA Endoprosthesis pivotal study and Chief of Vascular and Endovascular Surgery at Maimonides Medical Center.

There were 95 patients enrolled in the high neck angulation sub-study. Through one year, patients experienced a low incidence of Type I endoleaks and zero Type III endoleaks, zero reported aneurysm-related mortality, migrations, ruptures or stent fractures.

"We deliberately studied performance in both highly angulated and short necks, and the results demonstrate that we can safely and effectively treat these patients — providing an improved potential for favorable outcomes despite hostile anatomy," Dr. Rhee added.

Introduced in the U.S. in 2020, the GORE EXCLUDER Conformable AAA Endoprosthesis with ACTIVE CONTROL

"This is a landmark indication for an EVAR device, equipping physicians with an on-label solution for more patients with hostile neck anatomy."

Robert Rhee, M.D.
National Principal Investigator
GORE EXCLUDER Conformable AAA Endoprosthesis Pivotal Study
Brooklyn, NY

W. L. Gore & Associates
1500 North Fourth Street, Flagstaff, AZ 86004
T +1 928 864 2927 **F** +1 800 942 5315 gore.com

System is the first AAA device to feature angulation control, empowering operators with two opportunities to achieve orthogonal placement in the aortic blood flow lumen. This unique degree of control, along with nesting stent rows and individual stent rings, helps maximize the conformability and seal of the device.

Today's announcement is "the culmination of years of deep collaboration with physicians to understand and overcome treatment challenges in highly angulated necks," according to Gore Aortic Business Leader Willy Davison. "Today, we celebrate the incredible work that got us here. And tomorrow, we get back to work on what's to come. Physicians embrace challenges every day — we're proud and privileged to do the same."

Moving forward, the GORE EXCLUDER Conformable AAA Device will also be studied as part of the 10,000-patient Together Registry, with up to 10-year follow-up and minimal inclusion and exclusion criteria to align with real-world clinical care practice. Uniquely, prospective imaging will also be collected for most patients.

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 13,000 Associates and a strong, team-oriented culture, Gore generates annual revenues of $4.8 billion. gore.com

# # #

Products listed may not be available in all markets.

24AR1022-EN01 APRIL 2024

W. L. Gore & Associates
1500 North Fourth Street, Flagstaff, AZ 86004
T +1 928 864 2927 **F** +1 800 942 5315 gore.com