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W. L. Gore & Associates, Inc. (Gore) has announced that the Food and Drug Administration (FDA) has consented to the initiation of the clinical study for the new GORE EXCLUDER Conformable AAA Endoprosthesis and the Japanese clinical trial notification for the new device was accepted by Japan's Pharmaceuticals and Medical Devices Agency (PMDA).

Gore will conduct a clinical study in the US and Japan to assess the safety and effectiveness of the GORE EXCLUDER Conformable AAA Endoprosthesis in treating infrarenal abdominal aortic aneurysms (AAA) with challenging patient anatomy.

The new device is said to be the next generation of the GORE EXCLUDER AAA Endoprosthesis and includes several key design features, including increased conformability and a delivery system with angulation control.

The clinical trial consists of two sub-studies, each assessing the device for a different range of patient anatomies. The first sub-study will assess the device in proximal aortic neck angles of zero to 60 degrees and aortic neck lengths of 10 mm or greater.

The other sub-study will evaluate proximal aortic neck angles of 61 to 90 degrees and aortic neck lengths of 10 mm or greater. Gore claims that once approved, the GORE EXCLUDER Conformable AAA Endoprosthesis would be the only device indicated for aortic neck angles up to 90 degrees and aortic neck lengths as short as 10 mm.

The GORE EXCLUDER Conformable AAA Endoprosthesis is deployed via an enhanced delivery system that includes angulation control, giving physicians the option to angle or bend the device to achieve orthogonal placement to the aortic blood flow lumen and to maximize the conformability of the device. Like the GORE C3 Delivery System, the GORE EXCLUDER Conformable AAA Endoprosthesis delivery system will offer the ability to reposition the device after initial deployment if needed to achieve optimal device placement.