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Medical device manufacturer Medtronic has announced Japanese regulatory approval for the self-expanding transcatheter CoreValve System for patients with severe aortic stenosis (AS) unable to undergo surgery, and for whom treatment with the CoreValve is determined to be the best option.

Japanese regulatory authorities granted approval of the CoreValve system for transcatheter aortic valve implantation (TAVI) based on robust data from the CoreValve U.S. Pivotal Trials and the Medtronic CoreValve Japan Trial, which is the first study to evaluate a self-expandable transcatheter valve in the Japanese patient population.

The CoreValve self-expanding nitinol frame enables physicians to deliver the device to the diseased valve in a controlled manner, allowing for accurate placement. Valves are delivered via the smallest (18Fr, or approximately 1/4 inch) TAVR delivery system available, making it possible to treat patients with difficult or small vasculature.

Data from the Extreme and High Risk Studies in the CoreValve U.S. Pivotal Trial demonstrated that the CoreValve System is safe and effective with high rates of survival and some of the lowest rates of stroke and valve leakage reported. The CoreValve System, with a supra-annular valve design, has also achieved hemodynamics, or blood flow, post-implant with results similar to the gold standard, surgical valves.