

Patient Selection Guide

Medtronic CoreValve® **U.S. Pivotal Trial**

*For patients with
Severe Aortic Stenosis*

Select Patient Inclusion Criteria*

- Patient has severe aortic stenosis (AS)
- Patient is symptomatic from AS
- Patient is high or extreme risk for surgery

Select Patient Exclusion Criteria*

- Previous heart valve replacement
- Severe ventricular dysfunction (LVEF < 20%)
- End-stage renal disease requiring chronic dialysis
- Life expectancy less than 12 months
- Congenital bicuspid aortic valve
- Severe dementia

* For more patient and referral information regarding the trial visit aorticstenosistrial.com.

For details, including the complete list of inclusion and exclusion criteria, visit clinicaltrials.gov (and search for the trial under the reference NCT01240902).

Objective and Patient Population:

The Medtronic CoreValve® U.S. Pivotal Trial is designed to evaluate the safety and efficacy of the Medtronic CoreValve® System in the treatment of symptomatic severe AS in subjects who are at high or extreme risk for aortic valve surgery.

Trial Design:

More than 1,300 patients at up to 40 U.S. sites will be included in the trial. All patients will complete a minimum of 12 months of clinical follow-up.

**CAUTION: INVESTIGATIONAL DEVICE, LIMITED BY
FEDERAL LAW TO INVESTIGATIONAL USE.**

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