

PERIGON PIVOTAL TRIAL

What is the Purpose of the Study?

The purpose of the PERIGON Pivotal Trial is to test the safety of the new Medtronic Model 400 aortic valve bioprosthesis works. This valve is very similar to other stented valves that are implanted through open-heart surgery. It is made of bovine (cow) tissue. The valve is investigational because it has not been approved by the US Food and Drug Administration (FDA), Health Canada or other global regulatory agencies.

1300 patients will be enrolled and implanted with the Model 400 valve at up to 40 centers across the United States, Canada and Western Europe. The trial will include male and female patients who are of legal age to provide informed consent in the country where they enroll in the trial, and who require replacement for a diseased, damaged, or malfunctioning native or prosthetic aortic valve. Patients will be followed and assessed after implant for up to 5 years.

Estimated Study Completion Date: December 2022

Am I a Candidate?

You may be a candidate to participate in this trial, if you are of legal age to provide informed consent, meet the study criteria and are able to visit a participating health center for all follow-up visits. In addition, you and your doctor will need to review the risks and requirements of the trial. Please [CLICK HERE](#) to review that information in detail.

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study.

Contacts and Locations:

For general information and a list of participating study locations, see [ClinicalTrials.gov](https://clinicaltrials.gov). Please refer to this study by its [ClinicalTrials.gov](https://clinicaltrials.gov) identifier: NCT02088554

The treatment options that are best or most appropriate for you should be discussed with your physician.

Medtronic Contacts:

North American Contact: Aimee Weber (763) 514- 9757 aimee.weber@medtronic.com

European Contact: Myriam Demas (+31-43) 3566 869 myriam.demas@medtronic.com