# CoreValve Advance, International Post Market Study
# A Multi-center, Interventional, Prospective, Post-Market Release Study

Published: 29-04-2010
Last updated: 20-06-2024

The study objective is to evaluate the clinical outcome of percutaneous aortic valve implantation in consecutive *real world* patients with severe aortic valve stenosis intended to be treated with the Medtronic CoreValve System.

| | |
|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Cardiac valve disorders |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON34858

**Source**
ToetsingOnline

**Brief title**
CoreValve Advance

### Condition

- Cardiac valve disorders

**Synonym**
severe aortic valve stenosis

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Medtronic B.V.

**Source(s) of monetary or material Support:** Medtronic

## Intervention

**Keyword:** Aortic Valve Bioprosthesis, CE mark, real-world data

## Outcome measures

### Primary outcome

The primary endpoint for this trial is Major Adverse Cardiac & Cerebrovascular Events (MACCE) at 30 days post procedure.

With MACCE defined as a composite of:

- All cause mortality
- Myocardial Infarction (Q-wave and non-Q-wave)
- Emergent cardiac surgery or percutaneous re-intervention
- Stroke

### Secondary outcome

- Device success, defined as a composite of:
- Successful device delivery;
- Stable device placement;
- Intact retrieval of the delivery catheter;
- Successful device function as assessed immediately post-procedure by angiography including non-compromised flow in coronary arteries (without obstruction) device position (no migration) and a mean gradient as determined invasively of <15mmHg and <= 2 aortic regurgitation

- Procedural success, defined as device success with absence of in-hospital

MACCE

- All cause mortality at discharge, 1 month and all subsequent follow-up visits
- Incidence of Myocardial Infarction (Q-wave and non-Q-wave) at discharge, 1 month, and all subsequent follow-up visits
- Incidence of emergent cardiac surgery or percutaneous re-intervention at discharge, 1 month, and all subsequent follow-up visits
- Incidence of stroke at discharge, 1 month, and all subsequent follow-up visits
- Incidence of composite endpoint of stroke and all cause mortality at discharge, 1 month, and all subsequent follow-up visits
- Evidence of structural valve deterioration at discharge, 1 month and all subsequent follow-up visits
- Evidence of non-structural valve dysfunction at discharge, 1 month and all subsequent follow-up visits
- Incidence of MACCE at discharge, 6 months and all subsequent follow-up visits
- Incidence of Acute Kidney Injury at baseline and discharge
- Incidence of bleeding events at discharge, 1 month, and all subsequent follow-up visits
- Incidence of pacemaker implantation as a result of new onset conduction disturbances at discharge, 1 month and all subsequent follow-up visits
- Functional improvement assessed by NYHA classification at 1 month and all subsequent follow-up visits compared to baseline
- All Serious Adverse Events and Serious Adverse Device Effects at discharge, 1 month and all subsequent follow-up visits
- Patient health status evaluated by Quality of Life Questionnaires (EQ-5D) at

baseline, 1 month and all subsequent follow-up visits

- Patient health status evaluated by Health Survey (SF-12) at baseline, 1 month

and all subsequent follow-up visits

- Incidence of stent placement due to access site vessel complications

- Incidence of vascular surgery due to access site vessel complications

# Study description

### Background summary

The 18F CoreValve ReValving* System (renamed to *Medtronic CoreValve System* after acquisition from CoreValve Inc. by Medtronic Inc. on 09 April 2009) was approved for CE marking effective March 1, 2007. CE Mark Approval is EU Certificate 252.673.

### Study objective

The study objective is to evaluate the clinical outcome of percutaneous aortic valve implantation in consecutive *real world* patients with severe aortic valve stenosis intended to be treated with the Medtronic CoreValve System.

### Study design

A Multi-center, Interventional, Prospective, Post-Market Release Study

### Intervention

Patients enrolled in this interventional PMR study should be treated according to normal hospital routine practice and in line with the applicable guidelines on percutaneous heart valve implantation.

### Study burden and risks

The risks associated with implantation of Medtronic CoreValve System are similar to the risks associated with any percutaneous procedure and with any surgical valve replacement, as well as those that are more specific to the Percutaneous Aortic Valve components and use.

There is no direct benefit associated to participation in this study. The main

benefit of the procedure is the restoration of aortic heart valve function.

The information obtained during this study may be used scientifically to help others who suffer from the same medical problem. The information from this study can help doctors to understand how to improve the handling and treatment of complications related to the Medtronic CoreValve aortic valve implantation, both in your case and in future patients. Information collected in this study can support the development of new devices and therapies.

# Contacts

**Public**
Medtronic B.V.

Endepolsdomein 5
6229 GW Maastricht
NL
**Scientific**
Medtronic B.V.

Endepolsdomein 5
6229 GW Maastricht
NL

# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

1. Patient with severe aortic valve stenosis requiring treatment.
2. Patient is an acceptable candidate for elective treatment with the Medtronic CoreValve

System and in conformity with the local regulatory and medico economic context.
3. Patient is above the minimum age as required by local regulations to be participating in a clinical study.
4. The patient has been informed of the nature of the study and has consented to participate, and has authorized the collection and release of his/her medical information by signing a consent form (*Patient Informed Consent Form*)

### Exclusion criteria

1. Currently participating in another trial
2. High probability of non-adherence to the follow-up requirements (due to social, psychological or medical reasons)
3. Pregnancy

## Study design

### Design

**Study type:** Interventional

| | |
|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Treatment |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 22-06-2010 |
| Enrollment: | 250 |
| Type: | Actual |

### Medical products/devices used

| | |
|---|---|
| Generic name: | CoreValve System |
| Registration: | Yes - CE intended use |

## Ethics review

| | |
|---|---|
| Approved WMO Date: | 29-04-2010 |
| Application type: | First submission |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |
| Approved WMO Date: | 23-09-2010 |
| Application type: | Amendment |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |

# Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

| Register | ID |
|---|---|
| ClinicalTrials.gov | NCT01074658 |
| CCMO | NL31841.060.10 |