

# ACURATE TA\* Transapical Aortic Bioprosthesis for Implantation in Patients with Severe Aortic Stenosis

Published: 25-04-2012

Last updated: 28-04-2024

Primary: To evaluate the safety of the study device in patients presenting with severe aortic stenosis (AS) considered to be high risk for surgery. Secondary: To evaluate adverse events and study device performance.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Will not start
<b>Health condition type</b>	Cardiac disorders, signs and symptoms NEC
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON37451

### Source

ToetsingOnline

### Brief title

2011-01 ACURATE TA\*

### Condition

- Cardiac disorders, signs and symptoms NEC
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

### Synonym

Severe Aortic Stenosis

### Research involving

Human

### Sponsors and support

**Primary sponsor:** SYMETIS S.A.

**Source(s) of monetary or material Support:** SYMETIS S.A.

## Intervention

**Keyword:** ACURATE TA<sup>®</sup>, Aortic Stenosis, Implantation, Transapical

## Outcome measures

### Primary outcome

Primary: Freedom from all-cause mortality at 30 days follow-up

### Secondary outcome

Secondary:

1. Rate of major cardiac and cerebrovascular event (MACCE) at 30 days and at 12 months
2. Functional improvement from baseline as per NYHA functional classification at 30 days and at 12 months
3. Procedural success post-implant
4. Device success at 30 days and at 12 months

## Study description

### Background summary

The patient will be asked to participate in the investigational study because the patient suffers from severe aortic stenosis.

### Study objective

Primary: To evaluate the safety of the study device in patients presenting with severe aortic stenosis (AS) considered to be high risk for surgery.

Secondary: To evaluate adverse events and study device performance.

### Study design

- A single arm, prospective, multicenter, non-randomized and open trial;
- 150 implanted patients at up to 15 European sites.

## Intervention

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## Study burden and risks

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## Contacts

### Public

SYMETIS S.A.

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1024 Ecublens  
CH

### Scientific

SYMETIS S.A.

Chemin de la Venoge, 11  
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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

1. Patients 70 years of age and older
2. Additive EuroSCORE \* 9

3. Severe aortic stenosis characterized by mean aortic gradient > 40 mmHg or peak jet velocity > 4.0 m/s or aortic valve area of \*1.0 cm<sup>2</sup>
4. NYHA Functional Class > II
5. Aortic annulus diameter from \* 21mm up to \* 27mm by TEE
6. Patient willing to participate in the study and provides signed informed consent

## Exclusion criteria

1. Congenital unicuspid or bicuspid aortic valve
2. Severe eccentricity of calcification
3. Severe mitral regurgitation (> 2°)
4. Pre-existing prosthetic heart valve in any position and / or prosthetic ring
5. Severe transapical access problem, non-reachable LV apex
6. Previous surgery of the LV using a patch, such as the Dor procedure
7. Presence of apical LV thrombus
8. ECHO evidence of intracardiac mass, thrombus, or vegetation
9. AMI within 1 month prior to the procedure
10. PCI within 1 month prior to the procedure
11. Previous TIA or stroke in the last 3 months
12. Untreated coronary artery disease (CAD) requiring revascularization
13. Hemodynamic instability: systolic pressure <90mmHg without afterload reduction, shock, need for inotropic medication or IABP
14. LVEF < 30% by ECHO
15. Calcified pericardium
16. Septal hypertrophy unacceptable for transapical procedure
17. Primary hypertrophic obstructive cardiomyopathy (HOCM)
18. Active infection, endocarditis or pyrexia
19. Active peptic ulcer or gastrointestinal (GI) bleeding within the past 3 months
20. Liver failure
21. Severe COPD requiring home oxygen
22. Blood dyscrasias: leukopenia (WBC < 3000/mm<sup>3</sup>), acute anemia (Hb < 9 mg%), thrombocytopenia (platelet count < 50,000 cells/mm<sup>3</sup>), history of bleeding diathesis or coagulopathy
23. Chronic renal dysfunction with serum creatinine > 2.5 mg/dL or renal dialysis
24. Neurological disease severely affecting ambulation or daily functioning
25. Senile dementia
26. Another surgical or percutaneous procedure scheduled at the same time
27. Emergency procedure pre-implant
28. Life expectancy < 12 months due to non-cardiac co-morbid conditions
29. Known hypersensitivity/contraindication to study medication, contrast media, or nitinol
30. Currently participating in an investigational drug or another device study

## Study design

### Design

**Study type:** Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

### Recruitment

NL

Recruitment status: Will not start

Enrollment: 10

Type: Anticipated

### Medical products/devices used

Generic name: ACURATE TA<sup>®</sup> Transapical Aortic Bioprosthesis and ACURATE TA<sup>®</sup> Transapical Delivery System

Registration: Yes - CE outside intended use

## Ethics review

Approved WMO

Date: 25-04-2012

Application type: First submission

Review commission: METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

## 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
Other	France (AFSSAPS): 2011-A00838-38
CCMO	NL37774.068.11