

# Mitroflow® vs Perimount® international clinical evaluation

<b>Submission date</b> 23/11/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 02/01/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 09/05/2016	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
V10603

# Study information

## Scientific Title

Mitroflow® vs Perimount® international clinical evaluation

## Acronym

FLORENCE

## Study objectives

Comparison of haemodynamic data (mitroflow® vs perimount® valves)

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

To be submitted as of 23 November 2007

## Study design

Prospective randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

## Health condition(s) or problem(s) studied

Aortic stenosis

## Interventions

Aortic valve replacement (Mitroflow® vs Perimount® valves)

## Intervention Type

Other

## Phase

Not Specified

## Primary outcome measure

The following haemodynamic data will be assessed at one and six months post implantation:

1. Effective orifice area
2. Mean pressure gradient
3. Peak pressure gradient
4. Degree LV remodelling

### **Secondary outcome measures**

Morbidity and mortality. Duration of follow-up: Six months post implantation

### **Overall study start date**

01/01/2008

### **Completion date**

30/06/2009

## **Eligibility**

### **Key inclusion criteria**

Patients undergoing Aortic Valve Replacement (AVR) with annulus less than 25 cm

### **Participant type(s)**

Patient

### **Age group**

Not Specified

### **Sex**

Both

### **Target number of participants**

150

### **Key exclusion criteria**

1. Poor left ventricular function
2. Redo-aortic valve replacement
3. Other associated disorders
4. Aged greater than 70 years

### **Date of first enrolment**

01/01/2008

### **Date of final enrolment**

30/06/2009

## **Locations**

### **Countries of recruitment**

Belgium

England

Italy

Switzerland

United Kingdom

**Study participating centre**

**Department of Cardiothoracic Surgery**

Plymouth

United Kingdom

PL6 8DH

## **Sponsor information**

**Organisation**

Sorin Biomedica Cardio S.R.L (Italy)

**Sponsor details**

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**Sponsor type**

Industry

**Website**

<http://www.sorin.com/>

**ROR**

<https://ror.org/01ys7qn31>

## **Funder(s)**

**Funder type**

Industry

**Funder Name**

## Results and Publications

### Publication and dissemination plan

Not provided at time of registration

### Intention to publish date

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration