

# CordaBASE - Cohort of Patients Who Underwent Aortic Valve Replacement with Bioprosthesis

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## General

### Identification

Detailed name Cohort of Patients Who Underwent Aortic Valve Replacement with Bioprosthesis

Sign or acronym CordaBASE

CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation CNIL: 910300

### General Aspects

Medical area Cardiology

Health determinants Healthcare system and access to health care services  
iatrogenic

Keywords valve deterioration, cardiology, thoracic surgery, prosthesis, aortic valve bioprosthesis, Mitroflow, cardiovascular

### Scientific investigator(s) (Contact)

Name of the director Roussel

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Organization Nantes University Hospital

### Collaborations

Participation in projects, networks and consortia Yes

|  |  |
|--|--|
| Details  | Nantes University Hospital Thorax Institute  |
| <b>Funding</b>   |  |
| Funding status   | Public   |
| Details  | Nantes university Hospital   |
| <b>Governance of the database</b>                                      |  |
| Sponsor(s) or organisation(s) responsible                              | CHU Nantes   |
| Organisation status  | Public   |
| <b>Additional contact</b>  |  |
| <b>Main features</b>   |  |
| <b>Type of database</b>  |  |
| Type of database   | Study databases  |
| Study databases (details)  | Cohort study   |
| Database recruitment is carried out by an intermediary                 | A selection of health institutions and services  |
| Database recruitment is made on the basis of:                          | Another treatment or procedure   |
| Database recruitment is carried out as part of an interventional study | Yes  |
| Details  | Performed at individual level  |
| <b>Database objective</b>  |  |
| Main objective   | To provide specific information (incidence, mechanism, impact) regarding structural valve deterioration after fitting a Mitroflow valve.<br>To compare the results with other bioprosthesis.<br>To provide clinicians with information in order to choose the best solution for fitting a valve in the event of heart valve disease. |
| Inclusion criteria   | Patients who underwent consecutive operations for heart valve replacement with a bioprosthesis (SORIN Mitroflow® or Carpentier-Edwards Perimount®) within the Cardiac Surgery Department at Nantes University Hospital.  |

## Population type

|     |   |
|-----|---|
| Age | Adulthood (19 to 24 years)<br>Adulthood (25 to 44 years)<br>Adulthood (45 to 64 years)<br>Elderly (65 to 79 years)<br>Great age (80 years and more) |
|-----|---|

|                    |                 |
|--------------------|-----------------|
| Population covered | Sick population |
|--------------------|-----------------|

|           |   |
|-----------|---|
| Pathology | IX - Diseases of the circulatory system |
|-----------|---|

|        |               |
|--------|---------------|
| Gender | Male<br>Woman |
|--------|---------------|

|                |       |
|----------------|-------|
| Geography area | Local |
|----------------|-------|

|  |                  |
|--|------------------|
| French regions covered by the database | Pays de la Loire |
|--|------------------|

|                              |        |
|------------------------------|--------|
| Detail of the geography area | Nantes |
|------------------------------|--------|

## Data collection

### Dates

|  |      |
|--|------|
| Date of first collection (YYYY or MM/YYYY) | 2002 |
|--|------|

|   |      |
|---|------|
| Date of last collection (YYYY or MM/YYYY) | 2019 |
|---|------|

### Size of the database

|  |                             |
|--|-----------------------------|
| Size of the database (number of individuals) | [10 000-20 000[ individuals |
|--|-----------------------------|

|                                      |   |
|--------------------------------------|---|
| Details of the number of individuals | Sorin Mitroflow, Carpentier-Edwards Perimount 2900, Carpentier Edwards Magna Ease, St-Jude Trifecta, Medtronic Mosaic |
|--------------------------------------|---|

### Data

|                   |                         |
|-------------------|-------------------------|
| Database activity | Current data collection |
|-------------------|-------------------------|

|                        |                                    |
|------------------------|------------------------------------|
| Type of data collected | Clinical data<br>Paraclinical data |
|------------------------|------------------------------------|

|                        |                          |
|------------------------|--------------------------|
| Clinical data (detail) | Direct physical measures |
|------------------------|--------------------------|

|                                    |   |
|------------------------------------|---|
| Details of collected clinical data | Surgical assessment; surgical procedure; stay in ICU; progression within the department |
|------------------------------------|---|

|   |   |
|---|---|
| Paraclinical data (detail)  | Ultrasound  |
| Presence of a biobank   | No  |
| Health parameters studied   | Health event/morbidity<br>Health event/mortality<br>Health care consumption and services<br>Quality of life/health perception |
| Care consumption (detail)   | Hospitalization   |
| <b>Procedures</b>   |   |
| Data collection method  | By medical staff during hospital stay then during routine visits following surgery.   |
| Participant monitoring  | Yes   |
| Links to administrative sources   | Yes   |
| Linked administrative sources (detail)  | List of patient deaths and ultrasounds carried out in the city.   |
| <b>Promotion and access</b>   |   |
| <b>Promotion</b>  |   |
| Link to the document  | <a href="http://tinyurl.com/PUBMED-CordaBase">http://tinyurl.com/PUBMED-CordaBase</a>   |
| <b>Access</b>   |   |
| Terms of data access (charter for data provision, format of data, availability delay) | Contact the scientist in charge.  |
| Access to aggregated data   | Access on specific project only   |
| Access to individual data   | Access on specific project only   |