Logo	
BELGIAN TAVI DATA BASE	Patient initials: ..-.. Patient study ID: …. Number Centre: …

FORM 1

HOSPITAL IDENTIFICATION

Name:
Address:
Riziv-nr:

PATIENT IDENTIFICATION

First name:	Name:
Address:	Country (foreigners):
Date of Birth: DD/MM/YYYY	
Gender: ❍ male ❍ female	
Social security organism number): … (3 digits or NA for foreigners)	
INSZ/NISS number: ……- …-.. (6-3-2 digits or NA for foreigners)	

BASELINE DATA

CARDIO- VASCULAR BASELINE DATA

Date	DD/MM/YYYY

NYHA Class	❍ NYHA I
	❍ NYHA II
	❍ NYHA III
	❍ NYHA IV
Date:	

Echography	❍ Yes	❍ No
Date:		

Hemodynamic parameters (Echo)	EOA	…..	cm^2
	Ejection Fraction	…..	%

Detailed medical report of the multidisciplinary consult	add document
Date:	

Patient initials: *(linked to identification sheet)*	Number Centre: *(linked to identification sheet)*
	Patient study ID: *(linked to identification sheet)*

PATIENT INDICATION FORM

INCLUSION CRITERIA FOR THE TARGET POPULATION			
• Degenerative aortic valve stenosis with echocardiographic mean systolic Doppler gradient of > 40 mmHg ***and/or*** transstenotic flow velocity of > 4.0 m/s ***and/or*** initial ostium surface of the aortic valve < 0.8 cm^2 • **AND** presence of symptoms due to aortic valve stenosis: functional NYHA class ≥ II • **AND** need for correction of the aortic valve stenosis translated into an expected substantial improvement of quality of life after successful aortic valve replacement • **BUT** inoperable due to anatomical contraindications, whose severity make surgical access impossible:			
❍ A severe calcification of the aorta ascendens (Porcelain aorta) ***or***	❍ Yes ❍ No		
❍ Important chest wall deformation ***or***	❍ Yes ❍ No		
❍ Previous radiotherapy of the thorax and more specifically the sternum ***or***	❍ Yes ❍ No		
❍ Repeated (min. 2) previous sternotomies :	❍ 2	❍ 3	❍ 4
AND / OR mediasinitis	❍ Yes	❍ No	
AND / OR sternitis	❍ Yes	❍ No	

EXCLUSION CRITERIA	
Primary hypertrophic cardiomyopathy with or without obstruction	❍
Severe ventricular dysfunction with Left Ventricular Ejection Fraction (LVEF) < 20%	❍
Cerebrovascular accident or TIA (transient ischemic attack) less than 6 months before planned TAVI	❍
Renal insufficiency (chronic or acute) with creatinine level >3 mg/dl or with dialysis	❍
Severe senile dementia or other invalidating neurological diseases avoiding normal daily activities	❍
Life expectancy of less than 1 year due to other comorbidities of non-cardiac origin	❍
Myocardial infarction less than 30 days before planned TAVI	❍
Untreated and clinically relevant significant coronary artery disease which requires revascularisation	❍
Hemodynamic instability with need of inotropic medication or mechanical support	❍
Non-calcified aortic valve or Congenital abnormality of the aortic valve : unicuspid or bicuspid aortic valve	❍
Mixed aortic valve disease (aortic valve stenosis and aortic valve insufficiency) with predominance of regurgitation > 3+	❍
Severe mitral valve calcifications or mitral valve insufficiency (> 3+)	❍
Echocardiographic evidence of an intra-cardiac mass, thrombus or vegetations	❍
Native annulus aortae dimensions (measured by echocardiography) incompatible with dimensions of the intended to be used valve	❍
Other anatomical abnormalities that could hinder a successful treatment	❍
Acute peptic ulcer or high gastrointestinal bleeding less than 3 months before planned TAVI	❍
Blooddyscrasia defined as : leukopenia (WBC < 3000/mm^3), acute anemia (Hb < 9mg%), thrombocytopenia (< 50.000 cells/mm^3), previous bleeding diathesis or coagulopathy	❍
Known hypersensitivity or contraindication for acetylsalicylacid, heparin, ticlopidine (Ticlid®), clopidogrel (Plavix ®) or other antiaggregants; known hypersensitivity for contrast fluids (and for which no adequate pre-medication is available)	❍
Need for urgent surgery for whatever reason	❍

Signature: **Interventional cardiologist** **Cardiothoracic surgeon** **Geriatrician**

FORM 2

Patient initials: ***(linked to identification sheet)***	**Number Centre:** ***(linked to identification sheet)***
	Patient study ID: ***(linked to identification sheet)***

INTERVENTION DATA FORM

Date of procedure	DD/MM/YYYY *(with link to page 1)*

Access site	❍ Transapical		
	❍ Transfemoral	❍ Percutaneous	❍ Surgical
		❍ Right	❍ Left
	❍ Trans sub-clavian/axillary	❍ Percutaneous	❍ Surgical
		❍ Right	❍ Left
	❍ Direct aortic		
	❍ Aorta carotis	❍ Right	❍ Left
	❍ Truncus brachiocephalicus		

Type Valve 1			
Serial Number 1	……		
Lot Number 1	……		
Valve Size 1			

Name valve 1	**Name delivery system 1**	**Reference valve 1**	**Reference delivery system 1**	**Identification code**

DEVICE SUCCESS *(add pop-up with VARC-2 consensus definitions- see table 11)*	❍ YES	❍ NO

ADVERSE EVENTS (< 72 h)	❍ YES *(link to separate adverse event form)*	❍ NO

Signature: **Interventional cardiologist** **Cardiothoracic surgeon**

FORM 3

Patient initials: ***(linked to identification sheet)***	**Number Centre:** ***(linked to identification sheet)***
	Patient study ID: ***(linked to identification sheet)***

DISCHARGE DATA FORM

Date of hospital discharge *(with link to page 1)*	DD/MM/YYYY

NYHA Class	❍ NYHA I	**Angina**	❍ Yes
	❍ NYHA II		❍ No
	❍ NYHA III	**Syncope**	❍ Yes
	❍ NYHA IV		❍ No

Echography	❍ Yes	❍ No

Hemodynamic parameters (Echo)	EOA	.....	cm^2
	Ejection Fraction	.....	%

Adverse Events	❍ YES	❍ NO
If yes, link with adverse event form		

FORM 4

Patient initials: (linked to identification sheet)	**Number Centre:** ***(linked to identification sheet)***
	Patient study ID: ***(linked to identification sheet)***

ADVERSE EVENTS FORM

Fill out one separate Adverse Event Form for each Adverse Event

Event onset date and time	Date: DD/MM/YYYY	Time: hh/mm

Related to	❍ Prosthetic Valve	❍ Procedure	❍ Co-morbidities

Conversion	❍ Conversion to conventional surgery

Valve related complications	❍ Valve migration		
	If yes	❍ Ventricle	❍ Aorta
	❍ Annulus rupture		
	❍ Coronary occlusion		
	❍ Valve thrombosis		
	❍ Valve thrombosis without occlusion		
	❍ Valve hemolysis		
	❍ Bioprosthesis degeneration		
	❍ Ectopic valve deployment		
	❍ TAV-in-TAV deployment		
	❍ Other (please specify)		

Cardiac Events	❍ Myocardial Infarction *(VARC-2)*		
	If yes	❍ Peri-procedural MI (≤ 72h)	❍Spontaneous MI (>72h)
	❍ Coronary obstruction *(VARC-2)*	*Pop-up to table 3 - 9*	
	❍ Cardiac failure		
	❍ Cardiac tamponade		
	❍ Pulmonary embolism		
	❍ Endocarditis		
	❍ Ventricular perforation		
	❍ Mitral valve damage or dysfunction		
	❍ Other (please specify)		

Bleeding Complications		
❍ Yes	GI bleeding: ❍ Yes	❍ No
	Gastro-intestinal	
❍ No		

Neurologic Complications			
	❍ Stroke *(VARC-2 pop-up to table 4)*		
	If yes	❍ Disabling	❍Non-disabling
	❍ TIA *(VARC-2 pop-up to table 4)*		

Acute Kidney injury	❍ Yes
	❍ No

Vascular access site and access-related complications *(VARC-2)*	❍ Yes
Pop-up to table 7	❍ No

FORM 5

Patient initials: ***(linked to identification sheet)***	**Number Centre:** ***(linked to identification sheet)***
	Patient study ID:***(linked to identification sheet)***

EXPIRATION DATA FORM

Date of Death	DD/MM/YYYY

Cause of Death	❍ Prosthetic valve related	❍ Procedure related	❍ Co-morbidities
	❍ Unknown		

Classification of Death	❍ Cardiovascular	*(drop-down)*
	❍ Non- Cardiovascular	*(drop-down)*

Pop-up to table 2 of VARC-2

FORM 6

Patient initials: ***(linked to identification sheet)***	**Number Centre:** ***(linked to identification sheet)***
	Patient study ID: ***(linked to identification sheet)***

FOLLOW-UP DATA FORM

Date of Follow-up	DD/MM/YYYY

Patient Status	❍ Alive
	❍ Expired
	❍ Lost to FU

Time of Follow-up	❍ 1 month	
	❍ 6 month	
	❍ 1 year	
	❍ 2 years	

NYHA Class	❍ NYHA I
	❍ NYHA II
	❍ NYHA III
	❍ NYHA IV

Echography	❍ Yes	❍ No

Hemodynamic parameters (Echo)	EOA	.....	cm^2
	Ejection Fraction	.....	%

Adverse Events	❍ YES	❍ NO
If yes, link with adverse event form		

Need for hospitalisation	❍ YES	❍ NO