Transcatheter Heart Valve Program

Pre-procedure data

Personal Data

| Name | MRN |
|------|-----|
| DOB | / / | Age |
| Gender | □ Male □ Female | Hometown |
| Weight | kg | Height | m |
| BMI | kg/m² | BSA | m² |
| Marital status | □ Single □ Married □ Divorced □ Widow |
| Occupation | |
| Phone 1 | Phone 2 |
# Medical history and comorbidities

| Critical preoperative state | □ No      | □ Yes      |
|----------------------------|-----------|-----------|
| Angina                     | □ No      | □ Yes      |
| CCS class                  | □ I       | □ II      | □ III | □ IV |
| SOB                        | □ No      | □ Yes      |
| NYHA class                 | □ I       | □ II      | □ III | □ IV |

**Katz Index**

\[ \_ / 6 \]

**CSHA Score**

- □ 1 = Very fit: robust, active, energetic, well motivated & fit; these people commonly exercise regularly & are in the most fit group for their age.
- □ 2 = Well: without active disease, but less fit than people in category 1
- □ 3 = Well, with treated comorbid disease: disease symptoms are well controlled compared with those in category 4
- □ 4 = Apparently vulnerable: although not frankly dependent, these people commonly complain of being "slowed up" or have disease symptoms
- □ 5 = Mildly frail: with limited dependence on others for instrumental activities of daily living
- □ 6 = Moderately frail: help is needed both with instrumental and non-instrumental activities of daily living
- □ 7 = Severely frail: completely dependent on others for the activities of daily living, or terminally ill

**DM**

- □ No
- □ Yes (dietary control) □ Yes (oral Rx)
- □ Yes (insulin) □ Yes (newly diagnosed)

**HTN**

- □ No □ Yes

**Smoking**

- □ Never smoked □ Ex-smoker □ Current smoker

**Creatinine:**

\[ \_ \text{ mg/dL} \]

**CrCl:**

\[ \_ \text{ ml/min/1.73m}^2 \]

**On Dialysis**

- □ No □ Yes

**Previous MI**

- □ No □ MI <6 hours □ MI 6-24 hours
- □ MI 1-30 days □ MI 31-90 days □ MI >90 days
| Pulmonary disease       | □ No                                      | □ COPD/emphysema                     |
|-------------------------|-------------------------------------------|-------------------------------------|
| □ Asthma                | □ Other: ______________________________ |                                     |
| FEV1: ______ % of predicted: ______ |                                         |
| FVC: ______ % of predicted: ______ |                                         |
| Liver disease           | □ No                                      | □ Mild                               |
| □ Severe                |                                           |                                     |
| Child Pugh Class: ______ (class C is severe) |                           |
| MELD Score: ______ (score ≥10 is severe) |                                         |
| □ Portocaval, spleorenal or TIPS |                                     |
| □ Biopsy proven cirrhosis with portal hypertension or hepatocellular dysfunction |                       |
| INR: ______ Albumin: ______ Bilirubin: ______ |                                   |
| Neurological disease    | □ No                                      | □ TIA                                |
| □ CVA with full recover | □ CVA with residual defect               |                                     |
| If +ve history of CVA   |                                           |                                     |
| □ Ischemic              | □ Hemorrhagic                             |                                     |
| □ Unknown               |                                           |                                     |
| Extracardiac arteriopathy | □ No                                      | □ Yes                                |
| If yes                  |                                           |                                     |
| □ Aortic aneurysm       | (history or evidence)                     |                                     |
| □ >50% carotid stenosis |                                           |                                     |
| □ Peripheral vascular disease (history, evidence or prior intervention) |          |
| Poor mobility           | □ No                                      | □ Yes                                |
| If yes                  |                                           |                                     |
| □ Due to musculoskeletal disease | □ Due to neurological dysfunction |                           |
| Previous Cardiac Surgery| □ No                                      | □ Yes                                |
| If yes                  |                                           |                                     |
| □ CABG                  | □ Valve surgery [specify: ______________ ] |                                   |
| □ Other [specify: ______________ ] |                                      |
| Previous Intervention   |                                         |                                     |
| Previous BAV            | □ No                                      | □ Yes [date:                          ] |
| Previous TAVI           | □ No                                      | □ Yes [date:                          ] |
| Previous PCI            | □ No                                      | □ Yes (standalone)                   |
|                          |                                           | □ Yes (part of a staged or hybrid procedure) |
| Psychosocial support    | □ Good                                    | □ Fair                               |
|                         |                                           | □ Poor                               |
ECG

☐ Sinus  ☐ Afib/flutter  ☐ 1st AVB  ☐ RBBB  ☐ LBBB
☐ CHB  ☐ Paced rhythm  ☐ VF or sustained VT
☐ Other abnormal rhythm [specify: _____________ ]
☐ Other abnormal conduction [specify: _____________ ]

Notes
Heart Valve Team Meeting

Date:
Attended by:

| STS PROM: | EuroSCORE II: |
|-----------|---------------|
| Low Risk  | Intermediate Risk | High Risk | Prohibitive Risk |
| STS Score | <4 % | 4-8 % | >8 % | Risk of death or major morbidity >50% at 1-year |
| Katz Index | 6/6 | 5/6 | 0-4/6 |
| Major Organ System Compromise | None | 1 organ system | 2 organ systems | ≥3 organ systems |
| Procedure Specific Impediment | None | Possible | Possible | Severe |

Katz Index of Independence in Activities of Daily Living
- Feeding, bathing, dressing, toileting, mobility, and continence

Major Organ System Compromise
- Cardiac: Severe LV systolic dysfunction, severe RV dysfunction, severe pulmonary HTN
- Pulmonary: FEV1 <50% of predicted, FVC <1.5 L
- Kidney: Estimated GFR < 60 ml/min/1.73m²
- Liver: Any history of cirrhosis, variceal bleeding, any history of encephalopathy, INR >1.5 (in the absence of VKA use), bilirubin >2 mg/dL
- CNS: Dementia, Alzheimer’s disease, Parkinson’s disease, CVA with residual physical limitation
- GIT: Inflammatory bowel disease, serum albumin < 3.0 mg/dL
- Cancer: Active malignancy

Procedure-specific impediment
- Heavily calcified ascending aorta
- Chest deformity
- Patent arterial graft adherent to posterior chest wall
- Radiation damage

Overall estimated risk of SAVR  □ Low  □ Intermediate  □ High  □ Prohibitive

MDT Decision
## Echocardiography

| Parameter                  | Value          |
|----------------------------|----------------|
| LVEDD                      | RVD<sub>1</sub>|
| LVESD                      | RVD<sub>2</sub>|
| FS                         | RVD<sub>3</sub>|
| EF                         | TAPSE          |
| SWT “diastole”             | Estimated PASP|
| PWT “diastole”             | TR severity    |
| LA AP diameter             | Stroke volume  |
| LA volume                  | Indexed stroke volume |
| LA volume index            | Cardiac index  |
| RWMA                       |                |
| Mitral Regurgitation       |                |
| □ No                       | □ No           |
| □ Mild                     | □ Mild         |
| □ Moderate                 | □ Moderate     |
| □ Severe                   | □ Severe       |
| Aortic Regurgitation       |                |
| □ No                       | □ No           |
| □ Mild                     | □ Mild         |
| □ Moderate                 | □ Moderate     |
| □ Severe                   | □ Severe       |
| Aortic valve/root dimensions |                |
| - Aortic Annulus           | _______ mm     |
| - Sinuses of Valsalva      | _______ mm     |
| - STJ                      | _______ mm     |
| - Ascending aorta          | _______ mm     |
| Aortic valve disease etiology |              |
| □ Congenital               | □ Bicuspid     |
| □ Degenerative             | □ Tricuspid    |
| □ Rheumatic                |                |
| □ Bioprosthetic            |                |
| □ Previous IE              |                |
| □ Other                    |                |
| AV peak gradient           |                |
| AV mean gradient           |                |
| AV area                    | Indexed AV area|

### Final Diagnosis and Notes
**TAVI - CT ASSESSMENT FORM**

| Optimal Projection |  |
|-------------------|--|
| Valve size        |  |
| Calcium score     |  |

**Coronary Artery Disease**

- **LM** %
- **Prox LAD** %
- **Mid LAD** %
- **Prox Cx** %
- **Mid Cx** %
- **Prox RCA** %
- **Mid RCA** %

| Area | cm² |
|------|-----|
| Perimeter | mm |
| Min Diameter | mm |
| Max Diameter | mm |
| AD Diameter | mm |
| PD Diameter | mm |

| Apical Thrombus | Yes | No |
|-----------------|-----|----|
| LVOT calcification | No | Mild | Mod | Severe |
| Porcelain aorta | Yes | No |
| Shallow sinuses | Yes | No |

**Notes**
Cardiac Catheterization

| Pressures       |         |         |
|-----------------|---------|---------|
| AO              |         |         |
| LV              |         |         |
| Peak-to-peak gradient |   |         |

| Coronary angiography +/- PCI |         |         |
|------------------------------|---------|---------|
| Vessel                       | % Stenosis | PCI     |
| LMS                          | □ No     | □ Yes   |
| Proximal LAD                 | □ No     | □ Yes   |
| Mid LAD                      | □ No     | □ Yes   |
| Distal LAD                   | □ No     | □ Yes   |
| Prox LCx                      | □ No     | □ Yes   |
| Mid LCx                       | □ No     | □ Yes   |
| Distal LCx                    | □ No     | □ Yes   |
| Proximal RCA                 | □ No     | □ Yes   |
| Mid RCA                      | □ No     | □ Yes   |
| Distal RCA                   | □ No     | □ Yes   |

Notes

[Blank space for notes]
Pre-procedure laboratory investigations

| CBC       | Liver function tests |
|-----------|----------------------|
| Plt       | AST                  |
| WCC       | ALT                  |
| Plt       | Albumin              |
| Renal function | Proteins          |
| Urea      | T.Bilirubin          |
| Creatinine | D.Bilirubin         |
| Uric acid | Alkaline Phosph      |
| eGFR      | Coagulation profile  |
| Electrolytes | INR              |
| Na        | PC                   |
| K         | PTT                  |
| Mg        | Iron studies         |
| Ca        | Ferritin             |
| Thyroid profile | Iron            |
| TSH       | TIBC                 |
| FT3       | Lipid profile        |
| FT4       | Total cholesterol    |
| Blood glucose | LDL              |
| FBS       | HDL                  |
| HbA1C     | Triglycerides        |
# Procedure data

| Field                                      | Options                                                                 |
|--------------------------------------------|------------------------------------------------------------------------|
| Date of procedure                          | / /                                                                    |
| Surgeon(s)                                 |                                                                        |
| Cardiologists(s)                           |                                                                        |
| Proctored case                             | □ No  □ Yes                                                             |
| Procedure urgency                          | □ Elective  □ Urgent  □ Emergency  □ Salvage                           |
| Intraprocedural imaging                    | □ None  □ TTE  □ TEE  □ Other [specify: ________________ ]              |
| Anesthesia                                 | □ General  □ Other  □ Unplanned conversion to GA                        |
| Cerebral circulation protection device     | □ No  □ Yes                                                             |
| BAV prior to valve deployment              | □ Not done  □ Completed  □ Failed                                      |
| Delivery approach                          | □ Femoral - percutaneous  □ Femoral - surgical  □ Axillary              |
|                                            | □ Subclavian  □ Transapical  □ Direct aortic  □ Carotid                |
|                                            | □ Other [specify: ________________ ]                                   |
| Use of CPB                                 | □ No  □ Yes – elective  □ Yes – emergency                             |
| Valve manufacturer                         | □ Edwards  □ Medtronic  □ Boston Scientific  □ St. Jude                |
|                                            | □ Other [specify: ________________ ]                                   |
| Valve model                                | □ Sapien XT  □ Sapien 3  □ Corevalve  □ Lotus  □ Portico              |
|                                            | □ Other [specify: ________________ ]                                   |
| Valve serial no.                           | ___________________________                                           |
| Valve size                                 | ____ mm                                                                |
| Valve failure                              | □ No failure  □ Probably iatrogenic  □ Probably intrinsic              |
| Vascular closure technique                 | □ Manual pressure  □ Device closure  □ Planned surgical closure       |
|                                            | □ Bailout surgical closure (after failed percutaneous closure)         |
Procedure Outcome and Complications

Valve successfully deployed

□ No  □ Yes  
If no, reason:
□ Access site complication  □ Failure to negotiate iliac vessels or aorta  □ Unable to cross aortic arch  □ Unable to cross aortic valve  □ Aborted due to vessel perforation/dissection  □ Aborted due to anticipated coronary obstruction  □ Aborted for other reason [specify: ________________ ]  □ Not deployed for technical reason  □ Other failure to deploy [specify: ________________ ]

Post deployment AV peak gradient  

____ mmHg

Post deployment AV mean gradient  

____ mmHg

AR at end of procedure

□ None  □ Mild  □ Moderate  □ Severe  □ Unknown  

AR evaluated by

□ Angiograph  □ TEE  □ TTE

Valve malpositioning

□ None  □ Valve migration  □ Valve embolization  □ Ectopic valve deployment

Bailout valve-in-valve

□ No  □ emergency during index procedure  □ Non-emergency during index procedure for suboptimal result

Post-implantation balloon dilatation

□ No  □ Yes  □ Not applicable

Further valve Intervention (not during index procedure but before discharge)

□ None  □ TAVI  □ Surgical AVR  □ BAV  □ Intervention on another valve  □ Other [specify: ________________ ]

Tamponade during/post procedure

□ No  □ Yes (requiring surgical intervention)  □ Yes (requiring percutaneous intervention)

Major apical cannulation complications

□ No  □ Yes
| Event                                  | No | Yes |
|----------------------------------------|----|-----|
| Conversion to full sternotomy          |    |     |
| Bailout PCI                            |    |     |
| Periprocedural MI                      |    |     |
| Permanent pacing                       |    | Yes |
| Yes - preprocedure therapeutic (including distant past) |    |     |
| Yes - pre-procedure prophylactic       |    |     |
| Yes - per-procedure                    |    |     |
| Yes - post-procedure                   |    |     |
| CVA                                    |    | Yes |
| Yes - Ischemic                         |    |     |
| Yes - hemorrhagic                      |    |     |
| Yes - undetermined                     |    |     |
| If yes, modified Rankin Score at 90 days |    |     |
| Vascular access site related complications |    |     |
| No                                      |    | Major |
| Minor                                   |    |     |
| Percutaneous closure device failure    |    | Yes |
| Not applicable                          |    |     |
| Bleeding                                |    | Yes |
| Yes – life threatening                 |    |     |
| Yes – major                            |    | Yes – minor |
| No of units of blood transfused        |    |     |
| AKI within 7 days of procedure         |    | Stage 1 |
| Stage 2                                 |    |     |
| Stage 3                                 |    |     |
| New RRT up to discharge                |    | Yes |
| Death to hospital discharge            |    | Yes |
| Date of discharge or death             |   /  / |
| Drugs at discharge - antithrombotic    | None | Warfarin |
| Dabigatran                              |    |     |
| Rivaroxaban                             |    |     |
| Apixaban                                |    | Other [specify: ________________ ] |
| Drugs at discharge - antiplatelet      | None | Aspirin |
| Clopidogrel                             |    |     |
| Prasugrel                               |    | Ticagrelor |
| Other [specify: ________________ ]      |    |     |
Follow up

Follow up at 1 year

Angina
□ No  □ Yes
CCS class  □ I  □ II  □ III  □ IV

SOB
□ No  □ Yes
NYHA class  □ I  □ II  □ III  □ IV

Follow up at 3 years

Angina
□ No  □ Yes
CCS class  □ I  □ II  □ III  □ IV

SOB
□ No  □ Yes
NYHA class  □ I  □ II  □ III  □ IV

Late valve stenosis
□ No  □ Yes

Date of Dx of significant stenosis
/  /

Late intrinsic valve regurgitation (not paravalvular)
□ No  □ Yes

Date of Dx of clinically significant regurgitation
/  /

Valve failure mode
□ Stent creep  □ Pannus  □ Calcification
□ Support structure deformation  □ Prosthesis-patient mismatch
□ Endocarditis  □ Valve thrombosis
□ Native leaflet impending prosthetic motion  □ malposition (too high/too low)
□ Leaflet wear/tear/perforation  □ Leaflet malcoaptation

Late paravalvular regurgitation
□ No  □ Yes – new
□ Yes – unchanged from existing  □ Yes – increased from existing
□ Yes – less than post-procedure

Date of Dx of clinically significant paravalvular regurgitation
/  /