P&F PRODUCTS & FEATURES GmbH

TRICVALVE®
TRANSCATHETER BICAVAL VALVES

FAQs

(frequently asked questions)

WHAT IS THE INTENDED USE FOR THE TRICVALVE®?

TricValve® - Transcatheter Bicaval Valves is a system of two self-expanding biological valves for the treatment of patients with hemodynamically relevant tricuspid insufficiency and caval reflux. The prostheses are implanted percutaneously into the inferior and superior vena cava without disturbing the native tricuspid valve. It is especially intended for use for patients at extreme risk or who are inoperable for open surgical therapy.

WHAT ARE THE INCLUSION CRITERIA?

- 18 years and older
- Patient with severe symptomatic tricuspid regurgitation demonstrated by echocardiography with significant backflow in the lower (IVC) and/or upper (SVC) vena cava and with a v-wave ≥ 25 mmHg as demonstrated by right heart catheterization (measured in the IVC and/or SVC 2-4 cm above/ below RA inflow) within 8 weeks prior to the implantation
- Suitable for TricValve® implantation according to anatomic criteria by computed tomography
- The patient must have severe, tricuspid regurgitation leading to NYHA class III or IV
- The patient has LVEF ≥ 30%
- The patient shall be screened by a "Heart Team" – including an interventional cardiologist, cardiothoracic surgeon, and agreed as a candidate for the TricValve® Transcatheter Bicaval Valve System implantation
- Patient/authorized legal guardian understands the nature of the procedure, is willing to comply with associated follow-up evaluations, and provides written informed consent

WHAT ARE THE EXCLUSION CRITERIA?

- Known significant intracardiac shunt (e.g. ventricular septal defect) or congenital structural heart disease based on heart teams decision
- Requirement for other elective cardiac procedures e.g. PCI (percutaneous treatment of coronary artery) or CABG (coronary artery bypass surgery) up to 90 days after the procedure or 30 days before the procedure
- Right ventricular failure (TAPSE ≤13mmHg)
- Systolic pulmonary arterial pressure > 65 mmHg as assessed by Doppler echocardiography
- Liver cirrhosis Child C

WHEN IS IT RECOMMENDED TO IMPLANT A TRICVALVE® ON IVC AND SVC AND WHEN WE SHOULD IMPLANT A TRICVALVE® ON THE IVC ONLY? ANY CONCERNS IF WE IMPLANT TRICVALVE® ONLY ON THE IVC?

We perform only bicaval valve implantations. Single valve implantation into the IVC seems to be less effective due to only partial resolution of caval backflow and only partial diminution of TR. Up to know there are little published data on single IVC-valve implantation but experience shows that patients benefit from single IVC-valve implantation is only moderat.

WHAT ARE THE CONTRAINDICATIONS OF THE TRICVALVE® IMPLANTATION IF ANY?

The TricValve® Transcatheter Bicaval Valves is contraindicated in patients who have any of the following conditions:

- Evolutionary or recent stroke;
- Cerebrovascular accident (CVA) evolutionary or recent;
- Recent myocardial infarction (<30 days);
- Known hypersensitivity, allergy or contraindication to device's components, e.g. nitinol;
- Known hypersensitivity to vitamin K antagonists, heparin and other oral anti-coagulants, or sensitivity to contrast medium that cannot be adequately premedicated;
- Sepsis, including active endocarditis;
- Thrombosis of the lower venous system or vena cava filter;

- Contraindication against a Transesophageal echo (TEE) during the procedure;
- The Patient must be 18 years of age or older;
- Patients with Creatinine clearance <20 ml / min;
- Patients with vascular conditions (e.g. stenosis, tortuosity) that make insertion and endovascular access impossible to the upper and lower vena cava;
- Patients with bleeding diathesis or coagulopathy or patient refusing blood transfusion;
- Patients with active gastritis or peptic ulcer;
- Pregnancy.

IS TRICVALVE® INDICATED FOR PATIENTS SUFFERING FROM FIXED PULMONARY HYPERTENSION OR TYPE I OR TYPE II PULMONARY HYPERTENSION?

From current experience we tried to avoid patients with PA-pressure > 60mmHg, preferably not Type I PA-hypertension. Left heart valvular disease should be treated first.

CAN THE DEVICE BEING USED FOR PATIENTS HAVING PACEMAKERS AND DEFIBRILLATORS?

Yes, it is possible.

IS SURGICAL BACK UP ON SITE REQUIRED?

Yes, in the current state of technology we require surgical on site back-up.

IS GENERAL ANESTHESIA MANDATORY?

General anesthesia is not mandatory, however advisable in a less experienced team. Particularly as TOE is required for evaluation of device function.

WHAT IS THE SIZE OF THE DELIVERY SYSTEM?

27F

IS TRANSFERMORAL ACCESS BEING USED?

Yes. The TricValve® is inserted into the femoral vein without a sheath and delivered to the implantation side by the use of fluro and TEE.

WHICH MATERIAL IS BEING USED TO MANUFACTURE THE LEAFLETS?

Bovine pericardium made from a single layer.

WHAT KIND OF PRODUCTS WILL BE NEEDED DURING THE PROCEDURE?

The materials necessary for the implantation of the valve are:

- standard cardiac catheterization lab equipment;
- 2.000 ml sterile saline solution refrigerated at 0°C to 8°C (32°F to 46°F);
- 20 ml sterile syringe;
- Fluoroscopy (fixed, mobile or semi-mobile fluoroscopy systems appropriate for use in percutaneous coronary interventions)
- Transesophageal (TEE) or Transthoracic Echocardiography capabilities;
- 2x Sheath 6F;
- 1x Standard Guidewire 0.0035;
- 1x Amplatz Super stiff guidewire;
- 1x Dilatator 14 F;
- 1x 5F Pigtail;
- 1x Standard right-heart balloon-Catheter (as used for right heart Cath);
- separate sterile table for loading;
- 1 large bowl and 3 cups for flushing and rinsing of the valves;
- 2x Pro-glide (Optional).

WHAT HAPPENS WITH THE RIGHT VENTRICLE DURING AND AFTER THE PROCEDURE?

An initial increase of RA pressure can be observed. In the long run, RV-function improves due to reduced RV-volume load because of reduced TR; consequently IVC, SVC and RA pressure decrease.

ANY ANTICOAGULATION MEDICATION IS NEEDED PRE AND POST TRICVALVE® IMPLANTATION? WHAT SHOULD BE THE INR RATIO PRE OPERATION?

Prior to the procedure, unfractionated heparin will be administrated to the patients. Thereafter all patients should undergo anticoagulation therapy with Phenprocoumon (Marcoumar) for three months whereas an International Normalized Ratio (INR) between 2 and 3 is recommended. After this period, patients may be provided with anticoagulation therapy as judged by the investigator, lifelong anticoagulation is recommended.