**Tric Valve®**

Self-expandable Vena Cava Valve for Tricuspid Regurgitation (TR) treatment

**FAQ (Frequently asked questions)**

**Question:** What is the intended use for the Tric Valve®?

**Answer:** The Tric Valve® is for use in patients presenting with severe symptomatic Tricuspid Regurgitation (TR) and hemodynamic proof of venous back flow into the caval veins who are classified by a heart team, to be at high risk for surgical therapy.

**Question:** What are the Inclusion Criteria?

**Answer:** Severe tricuspid regurgitation has to be confirmed by echocardiography: large central regurgitant jet, vena contracta >=7 mm. Systolic haptic vein flow.

Right heart catheterization: to register pressure tracings in pulmonary artery, right ventricle, right atrium, and superior and inferior vena cava (2cm from right arterial flow): demonstrating a large atrial V-Wave (> 30 mmHG) at least only modest elevated RV-enddiastolic pressure < 20 mmHG and modest pulmonary vascular resistance (< 500 dyn cm s-5).

Contrast Computer Tomography: (with visualization of venous phase) to determine the anatomic size and suitability of the superior and inferior vena cava for valve implantation.
Question: **When is it recommended to implant a TricValve® on IVC and SVC and when we should implant a Tric Valve® on the IVC only? Any concerns if we implant Tric Valve® only on the IVC?**

Answer: We perform only bicaval valve implantations. Single valve implantation into the IVC only is not 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 IVS-valve implantation but experience shows that patients benefit from single IVC-valve implantation is only mode.

Question: **What are the contraindications of the Tric Valve® implantation if any?**

Answer:  
- The patient has to be suitable according to anatomic criteria which are determined in a preop CT-Angiography (the diameter of the caval veins has to be in the treatment range). 
- Concomitant valvular disease beside TR. 
- Contra indication to effective long-term anticoagulation, which is required after valve implantation  
- Severally impaired RV-function 
- Significant pulmonary hypertension 
- Ongoing sepsis, including active endocarditis.

Question: **Is Tric Valve® indicated for patients suffering from fixed pulmonaryhypertension? Or Type I or Type II pulmonary hypertension?**

Answer: 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.
Question: Can the device being used for patients having pacemakers and defibrillators
Answer: Yes, it is possible

Question: Is surgical back up on site required?
Answer: Yes, in the current state of technology we require surgical on site back-up.

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

Question: What is the size of the delivery System?
Answer: 27F

Question: Is transfermoral access being used?
Answer: Yes. The Tric Valve® is inserted into the femoral vein without a sheath and delivered to the implantation side by the use of fluro and TEE.

Question: Which material is being used to manufacture the leaflets?
Answer: Bovine pericardium made from a single layer

Question: What kind of products will be needed during the procedure?
Answer: 2x Sheath 6F
1x Standard Guidewire 0.0035
1x Amplatz Superstiff guidewire
1x Dilatator 14 F
1x 5F Pigtail
1x Standard Swan Ganz-Catheter (as used for right heart cath)
10l of Iced Saline
separate sterile table for loading
1 large bowl and 3 cups for flushing and rinsing of the valves skin suture
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 Tric Valve® Implantation? What should be the INR ratio pre operation?

Patients require anticoagulation, we aim at an INR-level >2.5. Most patients, however, have other comorbidities requiring oral anticoagulation so this drug is new only for a minority.

Which drug is being used for the anticoagulation?

Warfarin none of the New Oral Anticoagulants (NOACs).

Right ventricular overload after CAVI?

Caval valve implantation (CAVI) results in ventricularization of the right atrium (RA). From a hemodynamic standpoint the RA becomes part of the right ventricle. The venous capacity for blood pooling is reduced after CAVI. Hemodynamic data from human cases demonstrate an initial rise of systolic and mean right atrial pressure reaching values similar to pressure in the right ventricle. However, it is yet unclear whether this increase in RA pressure persists and whether it has a clinical impact. As the procedure is performed in patients with already massively dilated right heart chambers the compliance of the right atrium in these patients is reduced, making these chambers less susceptible for further enlargement early after implantation. During chronic follow-up over the course of 4-8 weeks, a decrease of RA pressure and right atrial volumes (measured by CT angiography) has been observed in multiple human cases.