Health Technology Review	
Technology Ref.:	HTA-23031
Technology Name:	TRICVALVE® Transcatheter Bicaval Valve System
Approvals by International Bodies:	• (CE Marked) - May 2021 • UAE MOHAP- devices that have obtained CE marking are accepted by MOHAP.
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Short Description of the Technology:	TricValve® Transcatheter Bicaval Valve System consists of two components: the TricValve® Bioprosthesis and the TricValve® Delivery System. The TricValve® Transcatheter Bicaval Valves are manufactured using a self-expanding nitinol structure and leaflets made out of bovine pericardium. The device is manufactured by suturing three bovine pericardium valve leaflets made from a single layer of bovine pericardium and a polyester skirt sewn onto the self-expanding, multi-level, radiopaque frame made of a nitinol alloy. The suture used to affix the bovine pericardium leaflets and polyester skirt is made from PET material. The polyester skirt is used to prevent hepatic vein occlusion and to reduce chances of paravalvular leak (PVL). The bioprosthesis leaflets are processed with anti-calcification treatment as well as chemical dehydration for preloading in the delivery system. The bioprosthesis is specifically designed to adapt to the anatomic features of the superior and inferior venae cavae and is available in two different sizes for each of the two locations. The biovalve is anchored in the cava atrium junction and its fixation is based on stent design, radial force, and oversizing during implantation. EachTricValve® Transcatheter Bicaval Valve is supplied pre-loaded on the delivery system.

Health Technology Assessment Team Recommendation:	**Approve**

Summary of Review:

The implantation of self-expanding valves into the superior and inferior vena cava effectively ablishes caval reflux and increases cardiac input by reducing backward regurgitant flow in patient with clinically relevant tricuspid regurgitation (TR). This will help eliminate peripheral venous congestion reducing right heart failure symptoms and improving the overall clinical condition of the patient.

Advantages	Disadvantages
It is CE Marked since May 2021	Not full FDA approval obtained.
Patient treated with this technology showed significant improvements in New York Heart	Accelerated deterioration of the bioprosthesis may occur in patients with an altered

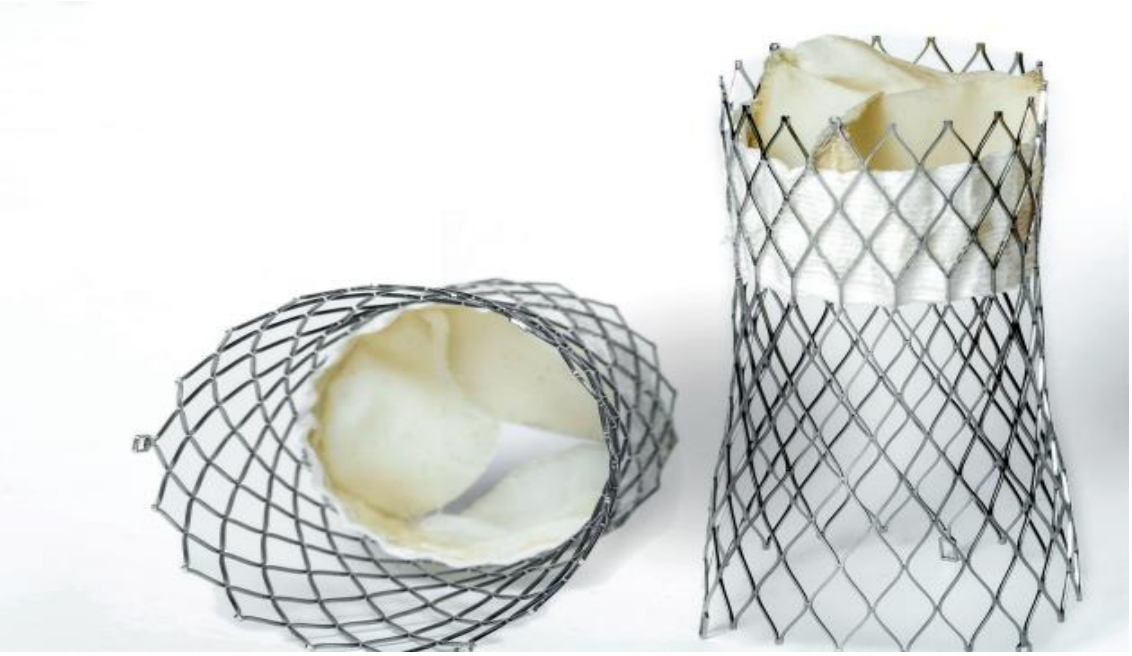
Association (NYHA) functional class at 6-month follow-up compared with baseline.	calcium metabolism.
Patients treated showed significant increases in quality of life (QoL) at 6-month follow-up compared with baseline	
The TricValve system is safe and effective for treating severe symptomatic TR.	
No reported safety alert or recalls associated with the device are recorded on EMA or MHRA databases.	

We recommend an **approval with limitation of using this technology** with the following conditions:

1. The procedure must include an interventional cardiologist, a cardiologist with expertise in heart valve disease and a cardiac surgeon.
2. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees.
3. Provision of regular updates and reports about the product to DoH upon request.
4. Any other documents or information requested regarding the product and cost to finalize the approval process.

Moreover, DoH has the right to stop the product at any stage if deemed necessary, initial conditions and any subsequent conditions must be satisfied before obtaining final approval. Failure to do so will reflect in provoking the approval.

Technology Image



Population, setting and intended user for Technology "TRICVALVE Transcatheter Bicaval Valve System"

- **Population/ Intended User**;
  - patients with symptomatic severe tricuspid regurgitation.
  - The patient must be 18 years of age or older.
- **To be performed by:**
  - Interventional cardiologist, and a cardiologist.
- **Clinical Setting:**
  - Hospitals, Special cardiology centers.
- **Condition of use:**
  - The Medical Device is indicated for treatment of hemodynamically significant tricuspid regurgitation (TR) and caval reflux in patients who have been determined to be at extreme risk for tricuspid valve surgery as determined by multidisciplinary heart team experienced in the evaluation and treatment of heart failure and tricuspid valve disease.
- **Exclusion criteria:**

  The TricValve Transcatheter Bicaval Valves System 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, bovine pericardium etc.
  - Known hypersensitivity to vitamin K antagonists, heparin and other oral anticoagulants, 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.
  - Creatinine clearance <20 ml / min.
  - Vascular conditions (e.g. stenosis, tortuosity) that make insertion and endovascular access impossible to the upper and lower vena cava.
  - Bleeding diathesis or coagulopathy or patient refusing blood transfusion.
  - Active gastritis or peptic ulcer.
  - Pregnancy.
  - inhibitor therapy.