CorMatrix Cor TRICUSPID ECM Valve Replacement Study

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 1 year to 85 years old
Healthy Volunteers: This study is also accepting healthy volunteers
Inclusion Criteria:

1. Patient with a regurgitant or absent tricuspid valve requiring surgical treatment including those patients having concomitant cardiac procedures
2. Male or female
3. Patient/authorized legal guardian understands the nature of the procedure, is willing to comply with associated follow-up evaluations, and provides written informed consent and the pediatric patient (if applicable) provides written assent (if able) prior to procedure
4. Patient/patient's authorized legal guardian is geographically stable (or willing to return for required study follow-up) and understands and is willing to fulfill all of the expected requirements of this clinical protocol
5. Children with congenital disease where the Cor PEDIATRIC Tricuspid ECM Valve would be the physiological right-sided valve

Exclusion Criteria:

1. Tricuspid annulus too small (< 10mm) to accommodate the Cor Tricuspid ECM Valve
2. Left ventricular ejection fraction (LVEF) < 25%
3. Mean pulmonary pressure > 50mm Hg or pulmonary vascular resistance greater than 6 Woods Units
4. Emergency cardiac procedure. An example would be a person requiring resuscitation and in cardiogenic shock. An unscheduled or unplanned emergency surgery
5. Cardiac transplant patient
6. Acute transmural myocardial infarction (MI) within 7 days of enrollment that results in cardiogenic shock
7. Patients with a single ventricle where the Cor Tricuspid ECM Valve would be the systemic AV valve
8. Documented primary coagulopathy or uncorrected platelet disorder, including thrombocytopenia (absolute platelet count <30k). Patient can be enrolled regardless of these parameters if in the opinion of the Investigating Surgeon the coagulopathy can be adequately reversed by transfusions. An example would be the reversal of thrombocytopenia by transfusion of platelets
9. Documented evidence of intrinsic hepatic disease (defined as liver enzyme values (aspartate aminotransferase (AST), alanine aminotransferase (ALT), or total bilirubin) that are > 5 times the upper limit of reference range within 30 days of enrollment, except in association with acute/reversible decompensation as determined by the Investigator)
10. Documented evidence of significant renal dysfunction (serum creatinine > 4.0mg/dl or GFR< 30 on the modified Schwartz formula)
11. Stroke within 30 days prior to enrollment
12. Major or progressive non-cardiac disease (liver failure, renal failure, cancer (CA)) that has a life expectancy of less than one year
13. Known cancer (cancer-free <1 year; does not include non-metastatic basal cell carcinoma or cervical carcinoma) and/or undergoing treatment including chemotherapy and radiotherapy
14. Hematological disorders (e.g., aplastic anemia) or patients taking bone marrow suppressant drugs
15. Known sensitivity to porcine materials
16. Contraindication to anticoagulation/antiplatelet therapy (aspirin (ASA) and/or Plavix)
17. Patients who are pregnant (method of assessment Investigator's discretion)
18. Patients who are currently enrolled in another investigational study or registry that would directly impact the treatment or outcome of the current study, without CorMatrix written approval

Conditions & Interventions

Interventions:
DEVICE: CorMatrix Cor TRICUSPID ECM Valve
Conditions:
Tricuspid Valve Disease

More Information

Description:
The Pivotal Study of the Cor TRICUSPID ECM Valve (or Cor PEDIATRIC Tricuspid ECM Valve). This study follows the EFS and is now to determine the safety and efficacy of the Cormatrix Cor TRICUSPID Valve for any patients requiring surgical replacement of the tricuspid valve.

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Phase: NA
IRB Number:
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