# COMPASSION S3 - Evaluation of the SAPIEN 3 Transcatheter Heart Valve in Patients With Pulmonary Valve Dysfunction

Status: RECRUITING

## Eligibility Criteria

Sex: ALL
Age:
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion Criteria:

1. Weight ≥ 20 kg (44 lbs.)
2. Dysfunctional RVOT conduit or previously implanted valve in the pulmonic position with a clinical indication for intervention and with a landing zone diameter ≥ 16.5 mm and ≤ 29 mm immediately prior to study device insertion as per the Instructions for Use
3. Subject presents with at least moderate PR and/or mean RVOT gradient ≥ 35 mmHg.
4. The subject/subject's legally authorized representative has been informed of the nature of the study, agrees to its provisions and has provided written informed consent.

Exclusion Criteria:

1. Active infection requiring current antibiotic therapy (if temporary illness, subject may be a candidate 2 weeks after discontinuation of antibiotics)
2. History of or active endocarditis (active treatment with antibiotics) within the past 180 days
3. Leukopenia, anemia, thrombocytopenia or any known blood clotting disorder
4. Inappropriate anatomy for femoral introduction and delivery of the study valve
5. Need for concomitant atrial septal defect or ventricular septal defect closure or other concomitant interventional procedures other than pulmonary artery or branch pulmonary artery stenting or angioplasty
6. Angiographic evidence of coronary artery compression that would result from transcatheter pulmonic valve implantation (TPVI)
7. Interventional/surgical procedures within 30 days prior to the TPVI procedure.
8. Any planned surgical, percutaneous coronary or peripheral procedure to be performed within the 30 day follow-up from the TPVI procedure.
9. History of or current intravenous drug use
10. Major or progressive non-cardiac disease resulting in a life expectancy of less than one year
11. Known hypersensitivity to aspirin or heparin and cannot be treated with other antiplatelet and/or antithrombotic medications
12. Known hypersensitivity to cobalt-chromium, nickel or contrast media that cannot be adequately premedicated
13. Participating in another investigational drug or device study that has not reached its primary endpoint.
14. Female who is lactating or pregnant

## Conditions & Interventions

Interventions:
DEVICE: SAPIEN 3/SAPIEN 3 Ultra RESILIA THV, DEVICE: SAPIEN 3 THV, DEVICE: SAPIEN 3 Ultra RESILIA THV
Conditions:
Complex Congenital Heart Defect, Dysfunctional RVOT Conduit, Pulmonary Valve Insufficiency, Pulmonary Valve Degeneration
Keywords:
Tetralogy of Fallot, Aortic Valve Defect/Disease Resulting in Ross Procedure, Pulmonary Atresia, Pulmonary Stenosis, Truncus Arteriosus, Transposition of the Great Arteries, Transcatheter pulmonary valve implantation, Transcatheter pulmonary valve replacement, TPV, TPVR, TPVI

## More Information

Description:
This study will demonstrate the safety and effectiveness of the Edwards Lifesciences SAPIEN 3/SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve (THV) Systems in subjects with a dysfunctional right ventricular outflow tract (RVOT) conduit or previously implanted valve in the pulmonic position with a clinical indication for intervention.

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