Minima Stent System Post- Approval Study (PAS)

Status: RECRUITING

Eligibility Criteria

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

- The subject's legally authorized representative has been informed of the nature of the device treatment, agrees to its provisions, and has provided written informed consent
- Indicated for treatment with the Minima Stent System per the IFU.

Exclusion Criteria:

- Active bloodstream infection requiring antibiotic therapy within 3 days prior to stent implantation
- History of or active endocarditis (active treatment with antibiotics) within 180 days prior to stent implantation
- Aortic or pulmonary artery aneurysm in the location targeted for treatment
- Body weight < 1.5 kg
- Anatomic location of lesion judged by the investigator to not lend to the safe placement of a stent
- Target vessels larger or smaller than the Minima System balloon size ranges
- Known genetic syndrome known to be associated with vasculopathies such as but not limited to Williams syndrome, Loeys-Dietz syndrome, etc
- Clinical scenario requiring that more than one vessel needs stent implantation at the time of the trial procedure.
- Currently participating in an investigational drug study or another device study
- Major or progressive non-cardiac disease resulting in a life expectancy of less than six months
- Known hypersensitivity to aspirin or heparin and cannot be treated with other antiplatelet and/or antithrombotic medications
- Known hypersensitivity to cobalt-chromium or contrast media that cannot be adequately premedicated

Conditions & Interventions

Interventions:
DEVICE: Minima Stent System
Conditions:
Pulmonary Artery Stenosis, Aortic Coarctation
Keywords:
Vascular Stenosis, Minima, Minima Stent, Minima Stent System, Renata Medical, Renata, infant stent

More Information

Description:
This Post-Approval Study is a single arm, prospective, multi-center, open-label study of patients treated with the Renata Minima Stent System in the United States. The objective of the study is to continue the assessment of device performance and capture outcome data on use of the device in real-world use.

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