

Minima Stent System Post- Approval Study (PAS)

NCT06828770

Status RECRUITING
Sponsor Renata Medical
Enrollment 100 participants

Key Eligibility Criteria

Inclusion (2)

- 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 (12)

- 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 \leq 1.5 kg
 - Anatomic location of lesion judged by the investigator to not lend to the safe placement of a stent
- ... and 7 more (see full listing online)

Locations (15 total)

Children's Hospital Los Angeles, Los Angeles, California, United States
Children's Hospital Colorado, Aurora, Colorado, United States
Nicklaus Children's Hospital, Miami, Florida, United States
... and 12 more locations