

Advancements in Stents For Children

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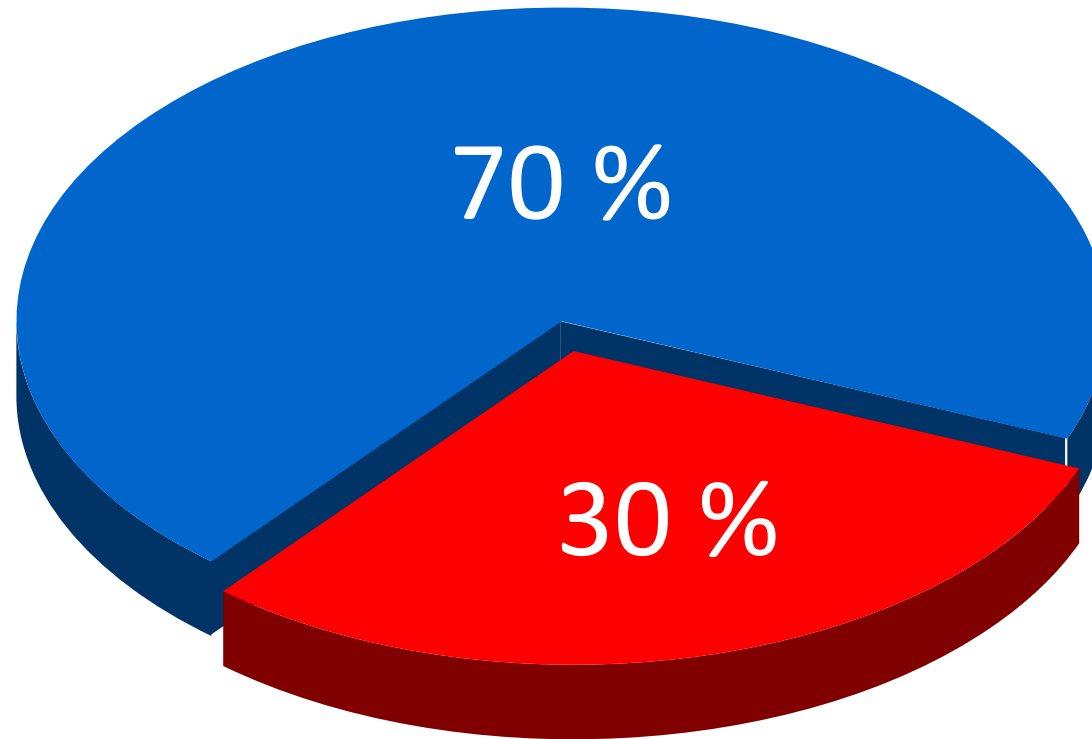


Facts about Congenital Heart Disease

- 0.8-1% of all live birth born in the U.S.
- CHD affects ~40,000 babies born in the U.S. each year
- Critical CHD
 - ~20% of these U.S. live births
 - ~8000 live births per year in the U.S.
- ~1.4 million children and adults living in the U.S. with CHD

Congenital Heart Disease Population

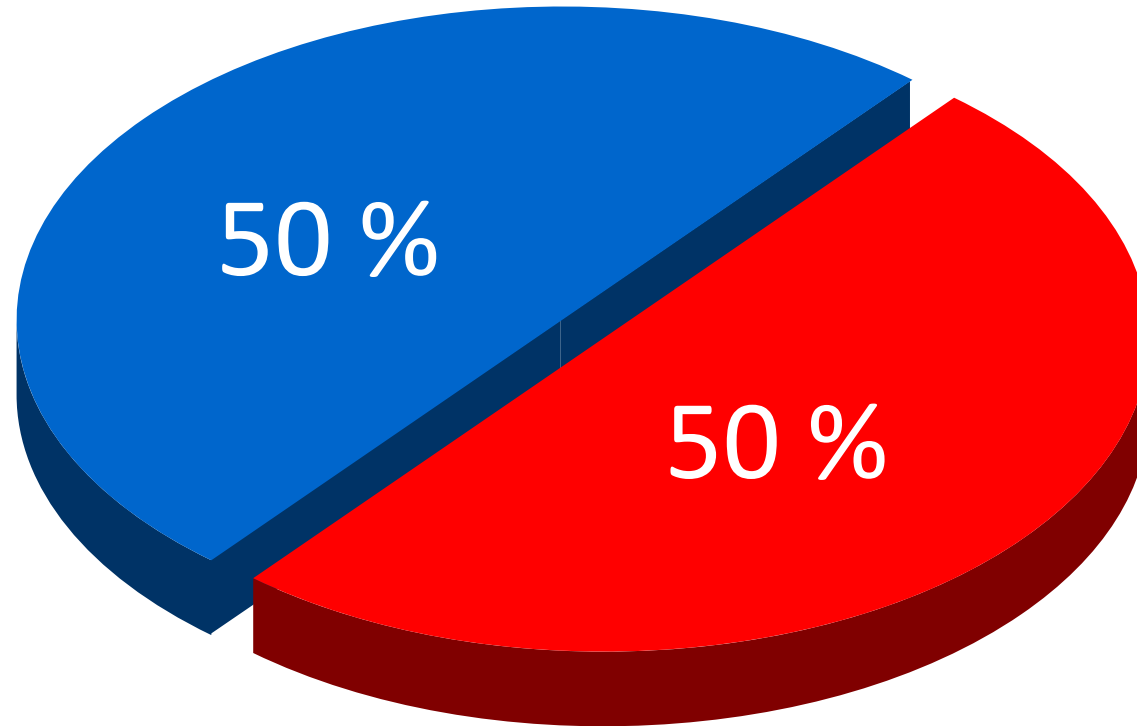
Children
Adults



1965

Congenital Heart Disease Population

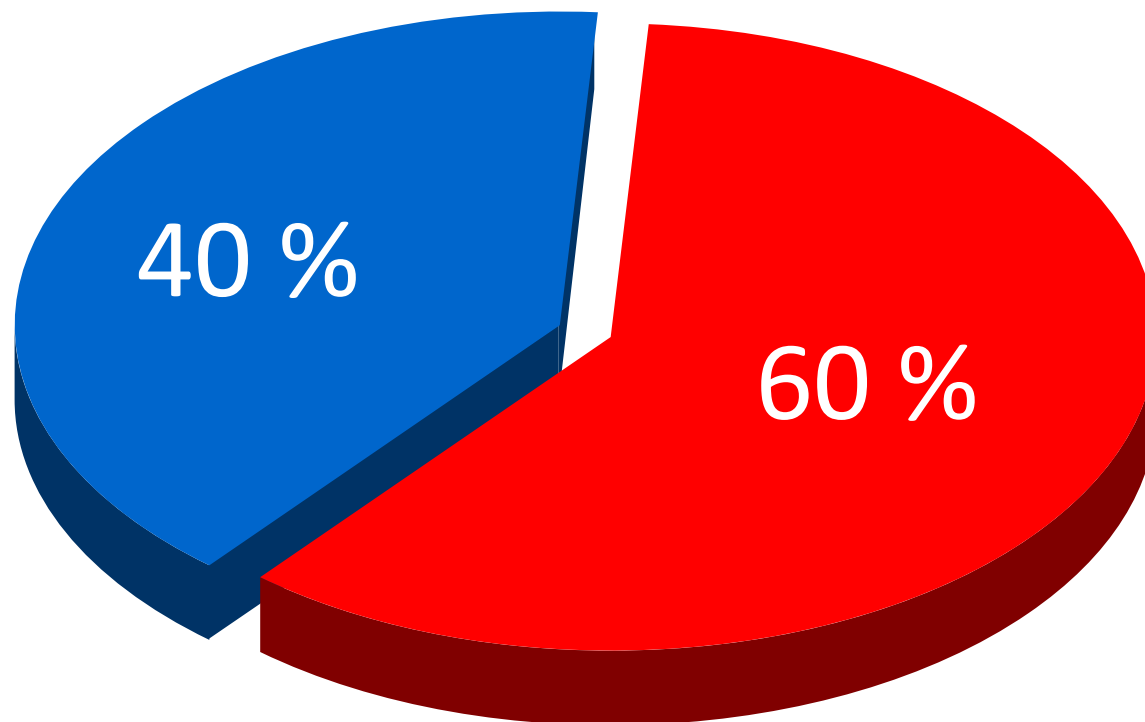
 Children
 Adults



2000

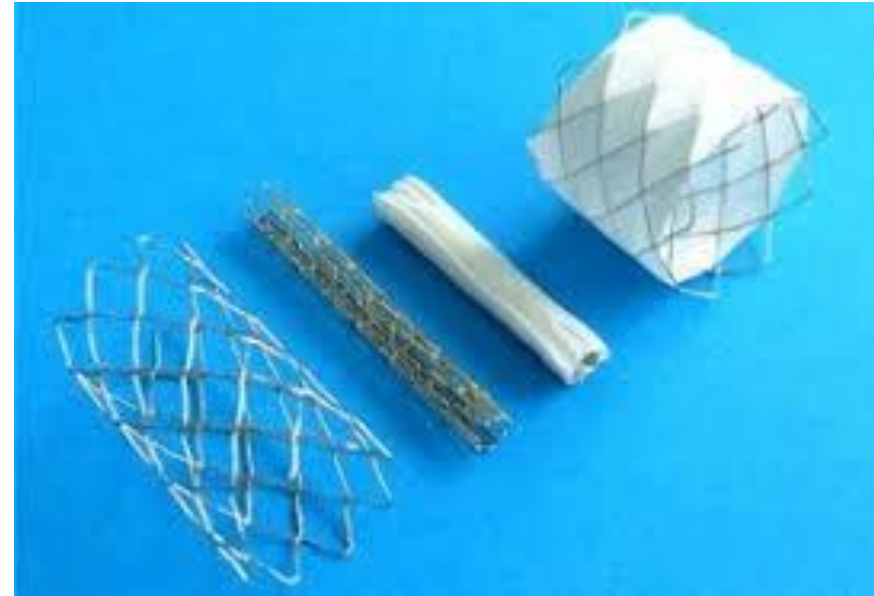
Congenital Heart Disease Population

 Children
 Adults



2010

Stents: 1991 - 2023



Stents: What about the babies?

- CHD affects ~40,000 babies born in the U.S. each year
- Critical CHD
 - ~20% of these
 - ~8000 live births per year in the U.S.



WHATS NEW?



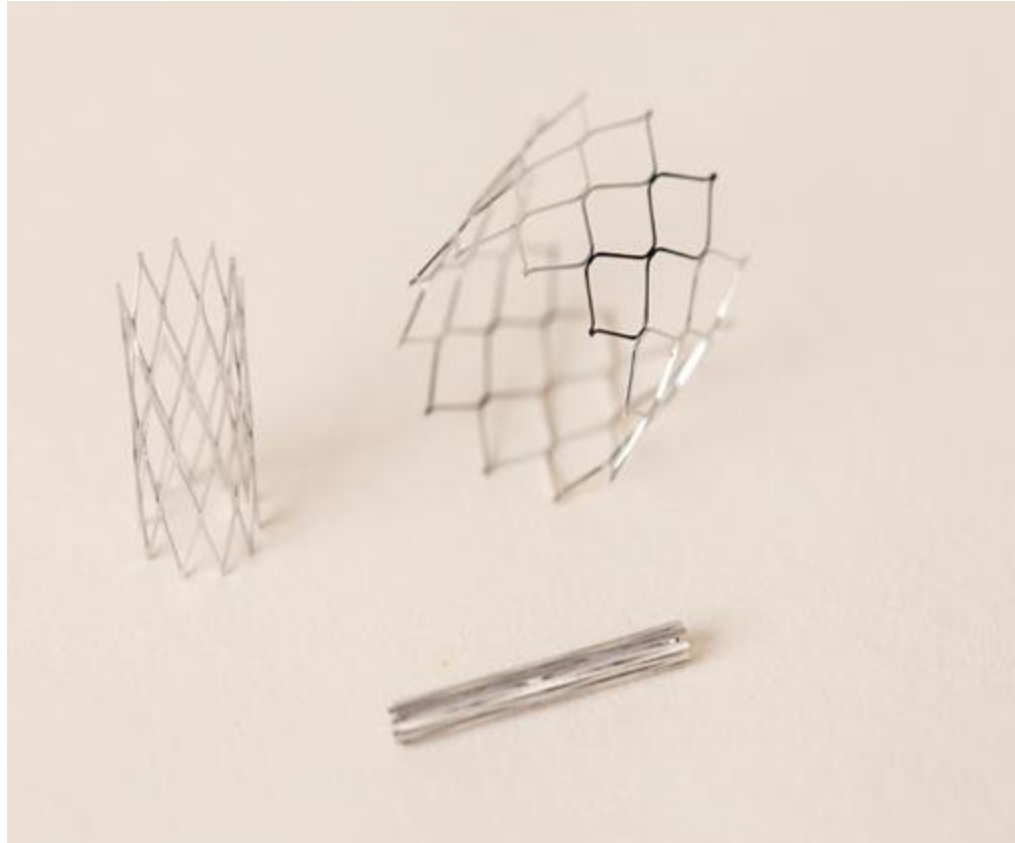
Stents: 2024



R E N A T A

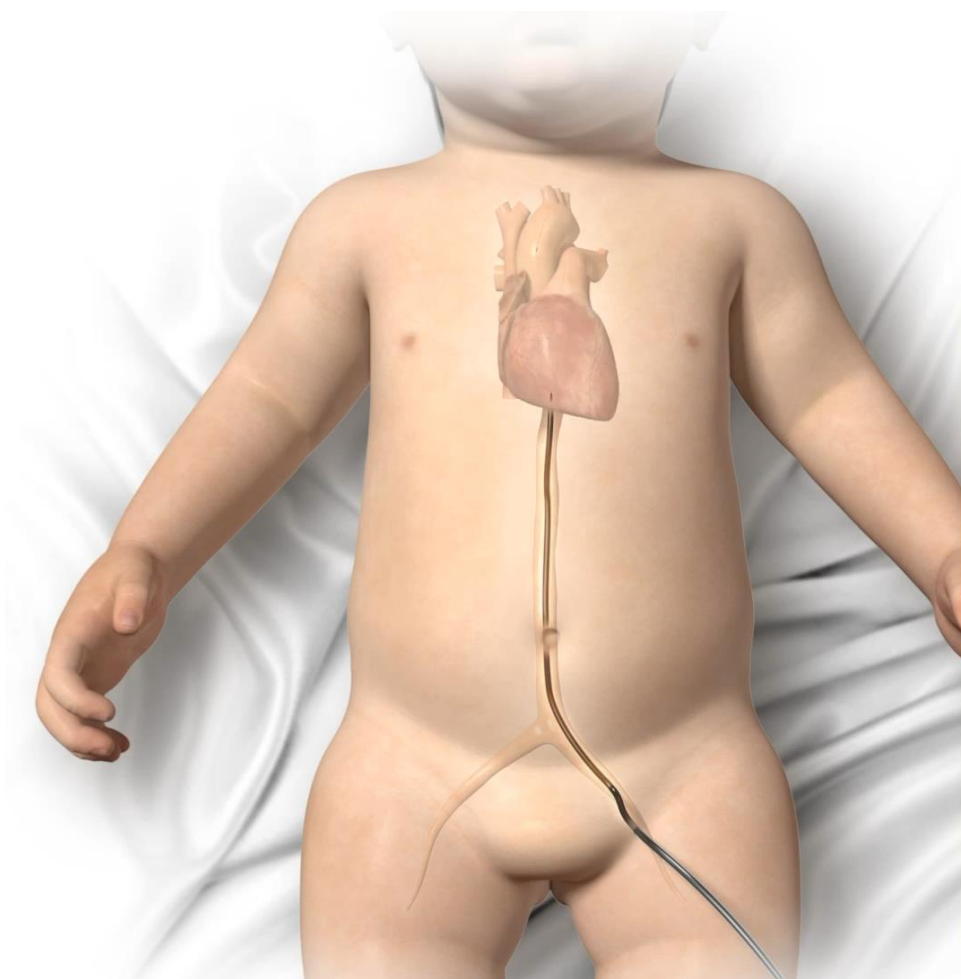
PURPOSEFUL DEVICES FOR UNMET PEDIATRIC NEEDS

Renata Minima Stent & Delivery System

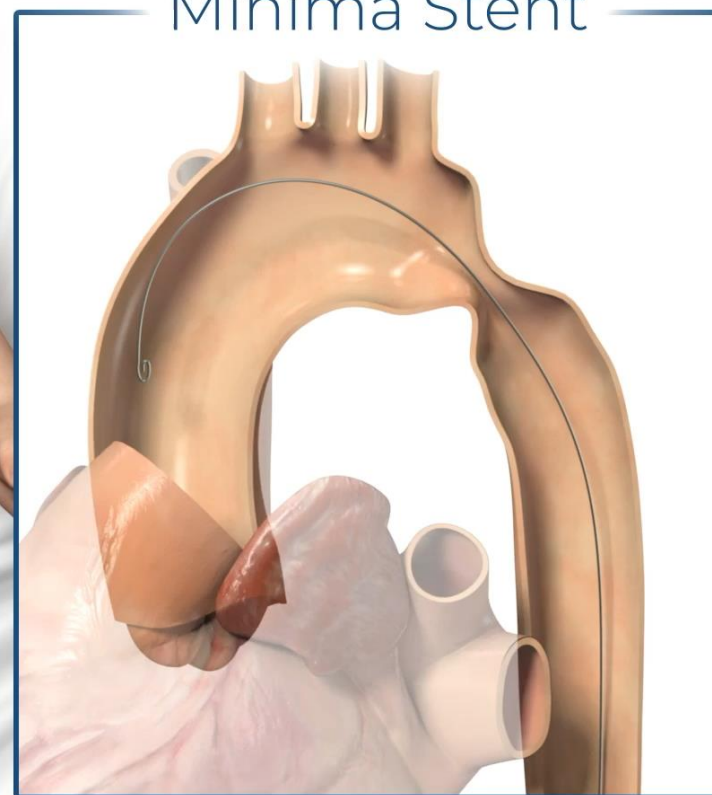


- Specifically designed for neonates and infants
- Stent with growth capabilities to adult size
- Low profile delivery system

Renata Minima Stent & Delivery System



Nonsurgical Treatment with
Minima Stent

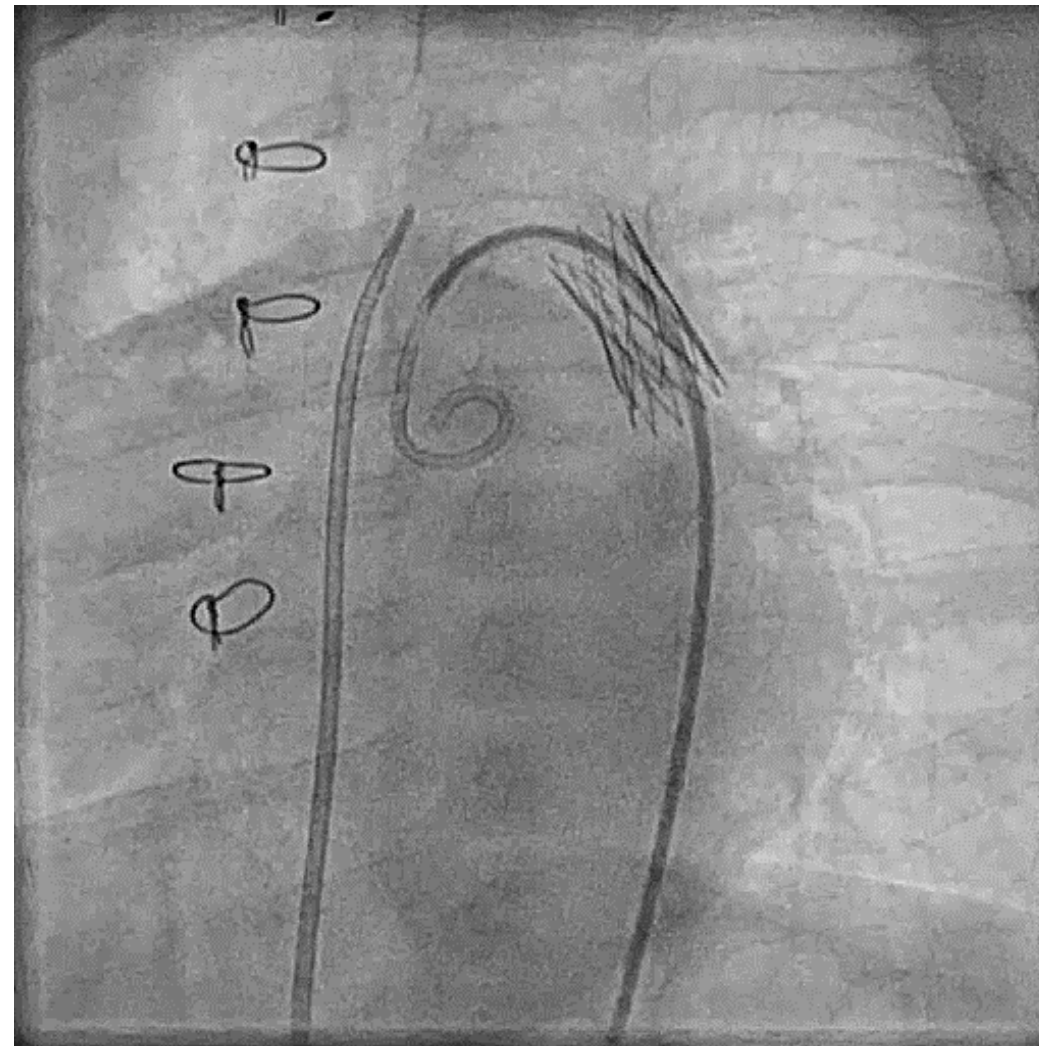


Renata Minima Stent: U.S. Clinical Trial

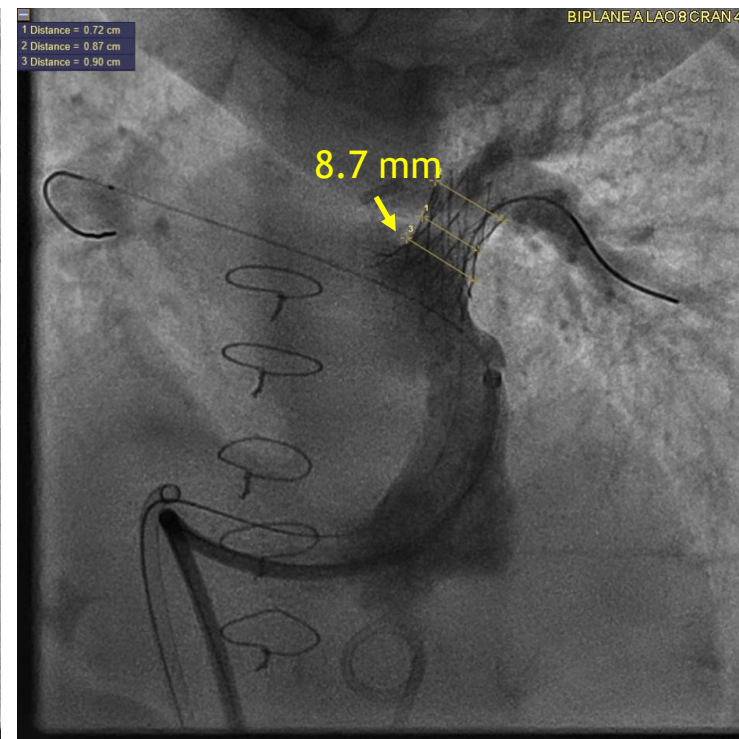
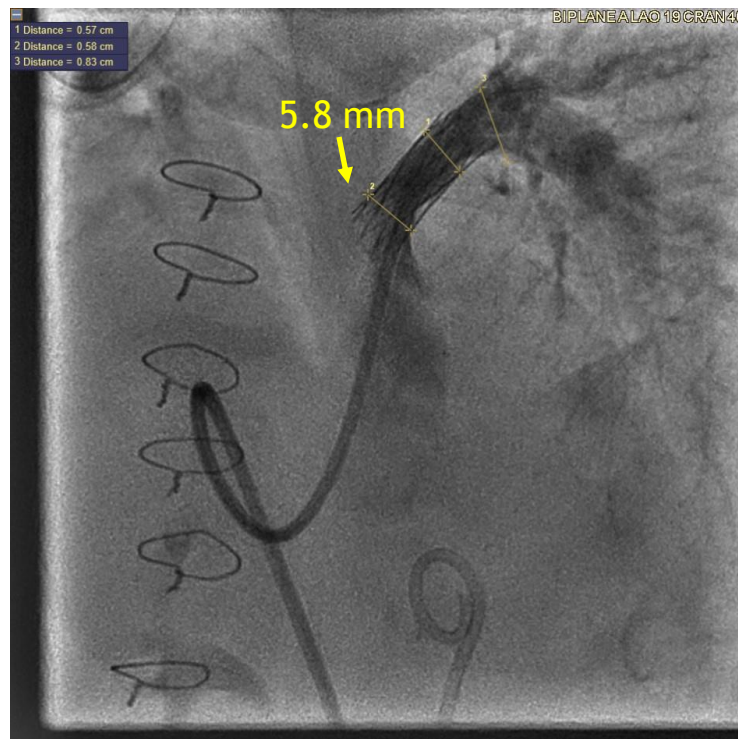
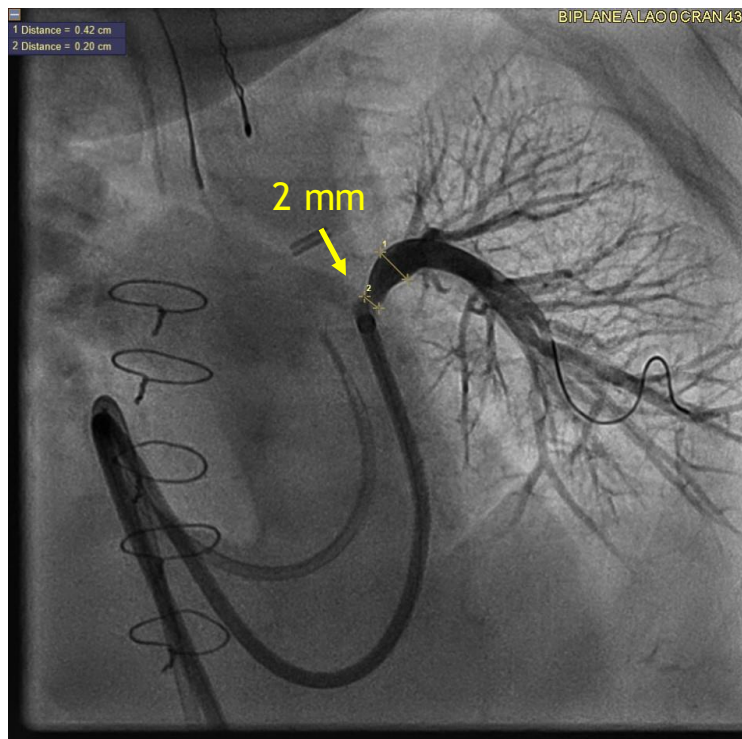


GROWTH: A Multicenter Pivotal Study of
Neonatal, Infant, and Young Child Vascular
Stenoses Studying the Renata Minima Stent

Renata Minima Stent: Growth Trial



Renata Minima Stent: Growth Trial



Stents: 2024

Renata Minima Stent: Growth Trial

- FDA approved on August 28, 2024
- First stent FDA approved for infants
- Designed to treat CoA or BPA stenosis



What's on the Horizon



Renata Medical - Expanding portfolio

Minima Pro: Next-Gen System



Shorter & Longer Minima Lengths



12 mm



16 mm



20 mm

Summary

- Collaboration leads to best outcomes
- Stents are an accepted treatment option for various forms of CHD
 - Options for our small growing patients remain limited
- Future is bright!
- 2024 – First FDA approved stent and delivery system for infants
- Tip of the iceberg
 - Rapid technological advancements
 - Endless determination
 - Thoughtful research
 - A variety of stent technologies in the pipeline

Thank you
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