

# Dilation using Expandable Intraluminal Device with Growth Technology

**Evan Zahn, MD, FACC, FSCAI**

Director, Guerin Family Congenital Heart Program, Cedars-Sinai

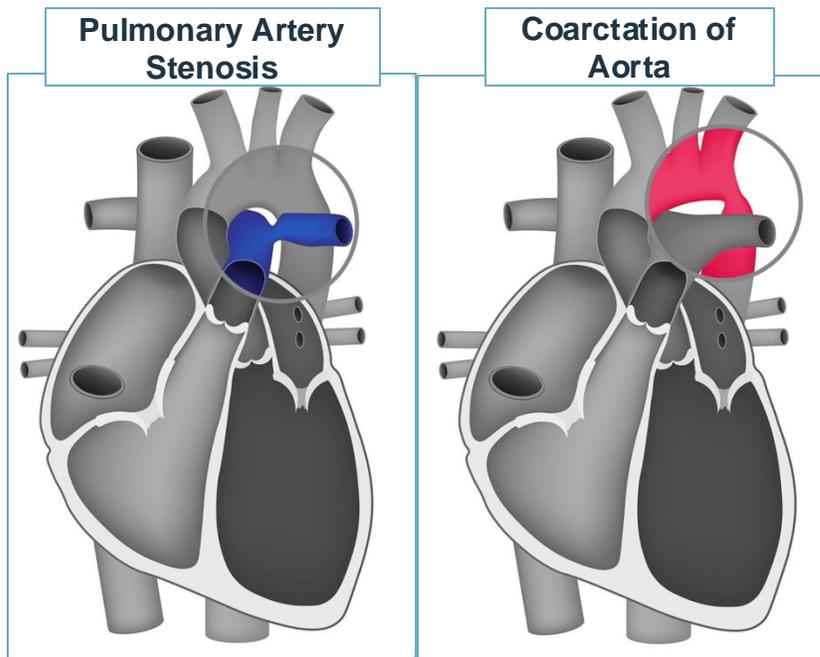
Director, Division of Pediatric Cardiology, Cedars-Sinai

Chief Medical Officer, Renata Medical

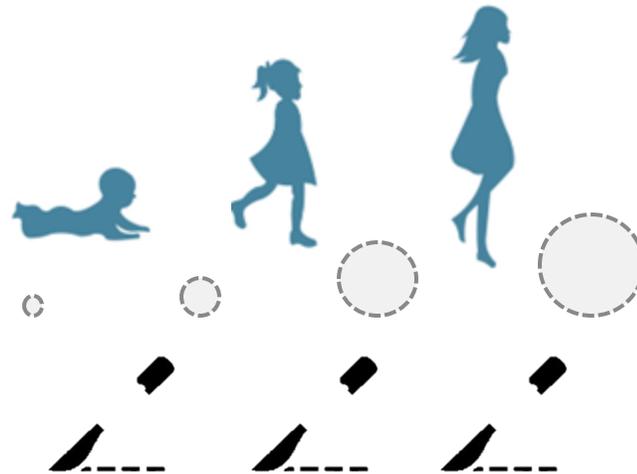
**ICD-10 Coordination and Maintenance Committee Update  
Spring 2025**

# Surgery is the Gold Standard for Neonates & Infants with Congenital Vascular Stenosis

Narrowing of critical cardiac vessels can be life-threatening



Vessel needs to be opened repeatedly as the child grows



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Multiple open-heart surgeries



# The Minima Stent System Received FDA Breakthrough Device Designation by Meeting The Following Criteria:

## 1. No approved or cleared alternatives exist

- Percutaneous Repair of Coarctation of Aorta and Branch Pulmonary Artery Stenosis in infants >1.5kg
- Provides a **new indication** not currently offered by other stent technology

## 2. It introduces Breakthrough Technology

- Growth Technology designed to be re-expanded to accommodate somatic growth to adulthood

## 3. The device provides more effective treatment of life-threatening disease

- Pre-mounted & Assembled
- Covered system while navigating tortuous anatomy
- Offers sheath-less vessel access
- Integrated contrast injection capability



# Minima Growth Stent is Indicated for Neonates & Infants >1.5 kg and Designed to be Re-Expanded to Adult Sizes.



< 2 mm



Pre-mounted stent, suitable for neonate & infant vessel access (4 Fr).



5.1 - 8.5 mm



Implantable diameters tailored for neonate & infant sized vessels.



≤ 24 mm\*

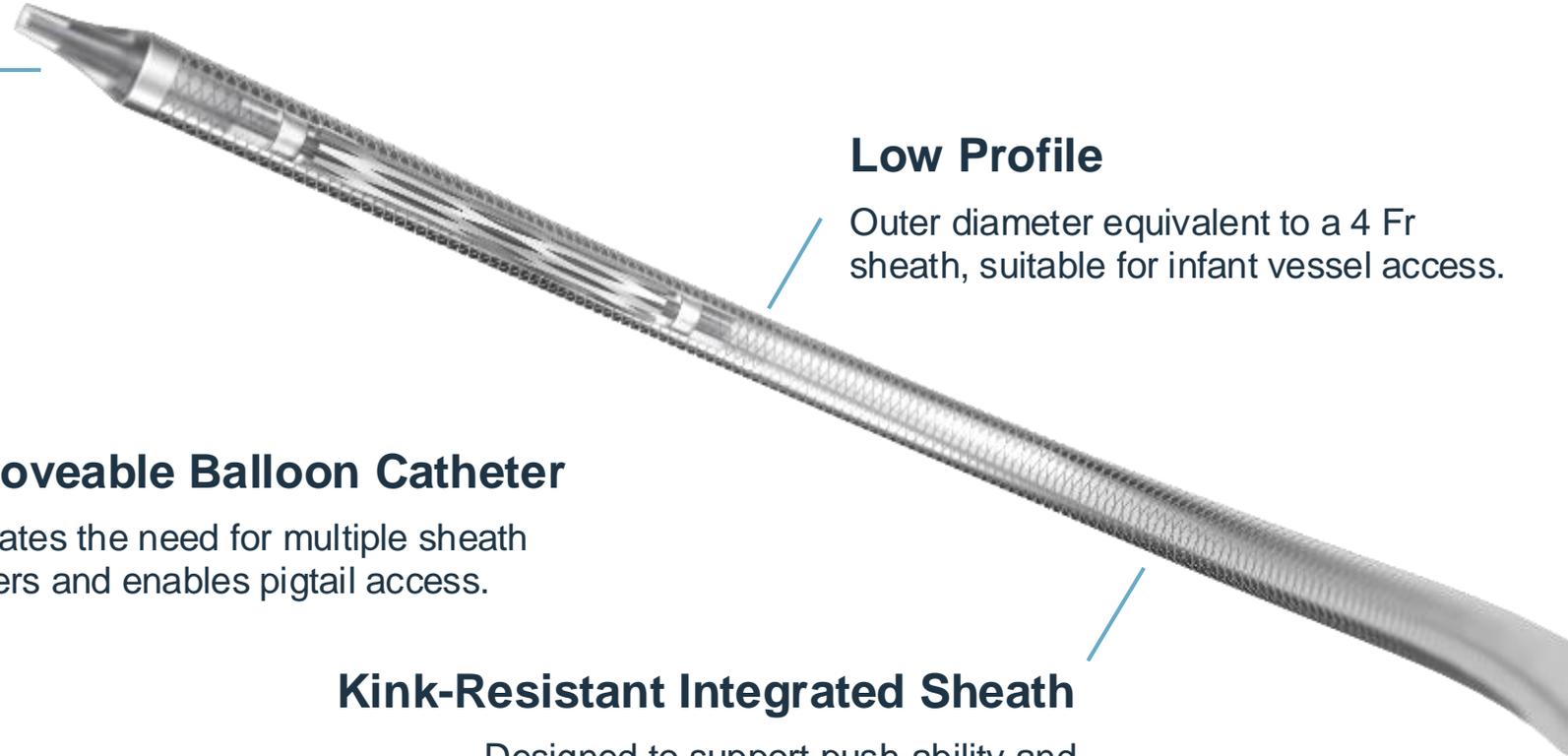


Designed for planned re-expansion to adult vessel sizes throughout somatic growth period\*

# The Minima Stent System is Customized for Delivery into Neonate & Infant Patients

## Tapered, Atraumatic Tip

Seamless transition during direct arterial or venous access



## Low Profile

Outer diameter equivalent to a 4 Fr sheath, suitable for infant vessel access.

## Removeable Balloon Catheter

Eliminates the need for multiple sheath transfers and enables pigtail access.

## Integrated Contrast Port

Offers "spot angiograms" following stent deployment

## Kink-Resistant Integrated Sheath

Designed to support push-ability and trackability through tortuous infant anatomy.

# Procedure Using The Minima Stent System

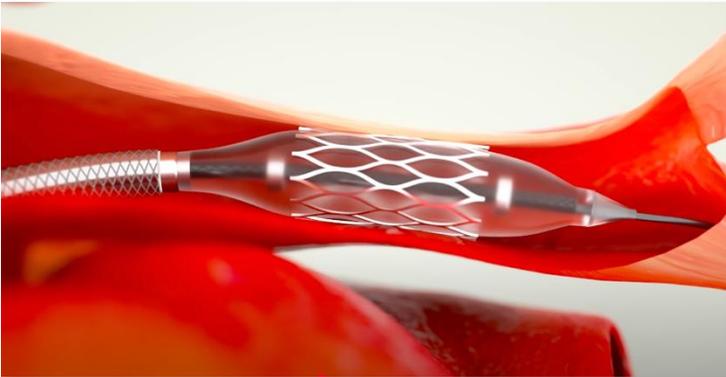
1. Sheath-less femoral access to venous or arterial blood vessels (4 Fr). The system is tracked over a .014" or .018" guidewire.



2. Integrated outer sheath protects the Minima Stent. The stent comes pre mounted and front loaded on a 6 mm or 8 mm balloon.



3. The outer sheath is retracted to expose the Minima Stent and begin expansion to repair the narrowing



4. Contrast can be injected through the outer sheath for intraoperative angiography.



# Stenting of Aortic Coarctation or Pulmonary Artery Stenosis in Neonates & Infants: Procedural Steps

## Slide 1 of 2

Procedure Step	Description
1	Prepare the patient for a standard transcatheter procedure.
2	Once vascular access is achieved, administer anticoagulation to achieve an activated clotting time (ACT) of greater than 250 seconds prior to device placement, unless the patient has a significant risk for bleeding and is unable to be anticoagulated.
3	Perform a right and/or a left heart catheterization as indicated. Access is obtained using conventional methods.
4	The covered system allows for sheathless delivery, with the entire system having an outer diameter equivalent to a 4 Fr sheath, making it suitable for use in neonates, infants, and young children. If a physician elects to use a sheath, a 6 Fr sheath is required. Hemodynamic measurements are taken, as indicated.
5	Perform selective angiography of the target lesion to measure stenosis diameter as well as the adjacent non-stenotic vessel diameter both proximal and distal to the target lesion. Measure the desired stent length to treat the target lesion. Based on these measurements, choose the appropriate pre-mounted stent balloon diameter.
6	Prepare the device. Start by ensuring the lock is engaged with the hypotube. Then flush the guidewire lumen of the balloon catheter and the injection port of the outer shaft using saline until saline visibly exits the distal end of the guidewire lumen and outer shaft.

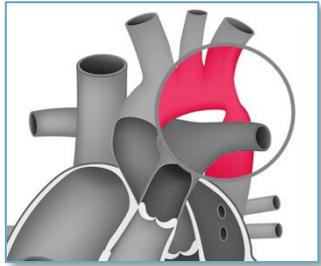
# Stenting of Aortic Coarctation or Pulmonary Artery Stenosis in Neonates & Infants: Procedural Steps

## Slide 2 of 2

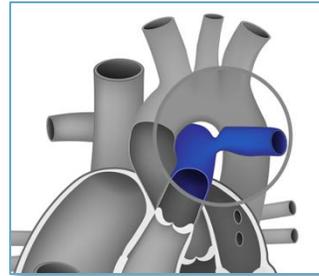
Procedure Step	Description
7	Attach a balloon inflation device to the y-connector. De-air the balloon using a saline and contrast mixture.
8	Introduce either a .014 or .018 guidewire into the vasculature and advance across the target lesion.
9	Track the stent delivery system over the guidewire to the target lesion. Once at the intended deployment position, unlock the outer shaft and unsheath the stent by pulling the outer shaft back while holding the balloon shaft stationary. Ensure the outer shaft is fully retracted with the balloon y-connector flush with the handle.
10	Deploy the stent by inflating the balloon to the pressure needed to achieve the desired stent diameter as listed on the sterile insert card provided in the packaging. When the desired stent expansion is obtained, deflate the balloon.
11	Confirm proper stent deployment using a contrast injection through the outer sheath injection port. After confirmation, the balloon catheter is retracted and removed.
12	Perform a final angiogram to make sure the stent is properly positioned, the stenosis has been adequately repaired, and there is no vascular damage.

# The Minima Stent System was Evaluated in the Prospective FDA Pivotal GROWTH Trial

21 Aortic



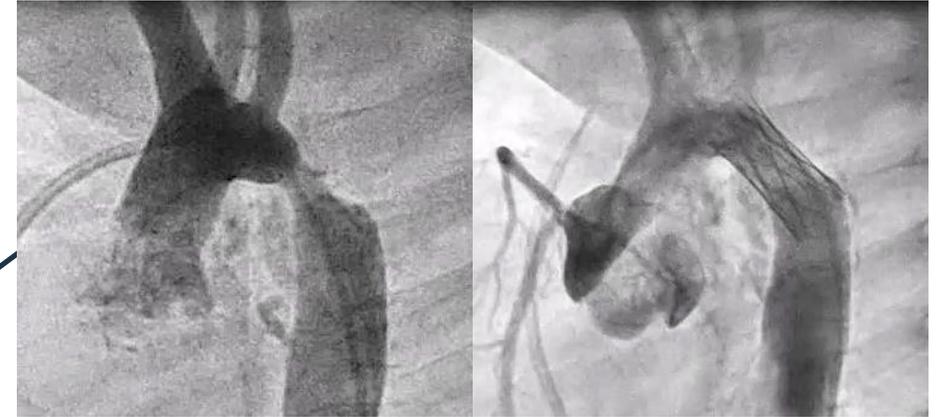
21 Pulmonary



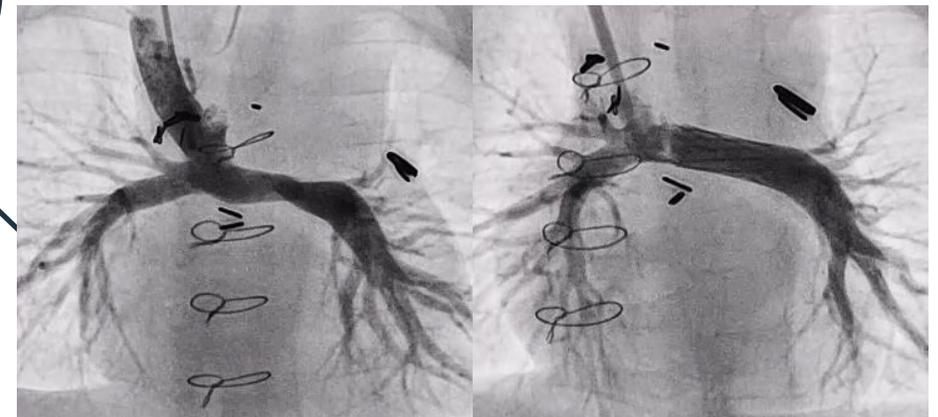
42  
Patients

**9 Months**  
Median Age  
(0 - 112 months)

**7.6 Kg**  
Median Wt.  
(3.4 – 28.3 kg)



Aortic Narrowing



Left Pulmonary Artery Narrowing

# The Pivotal GROWTH Trial Showed Minima Stent to be Safe & Effective for Treating Congenital Vascular Stenosis

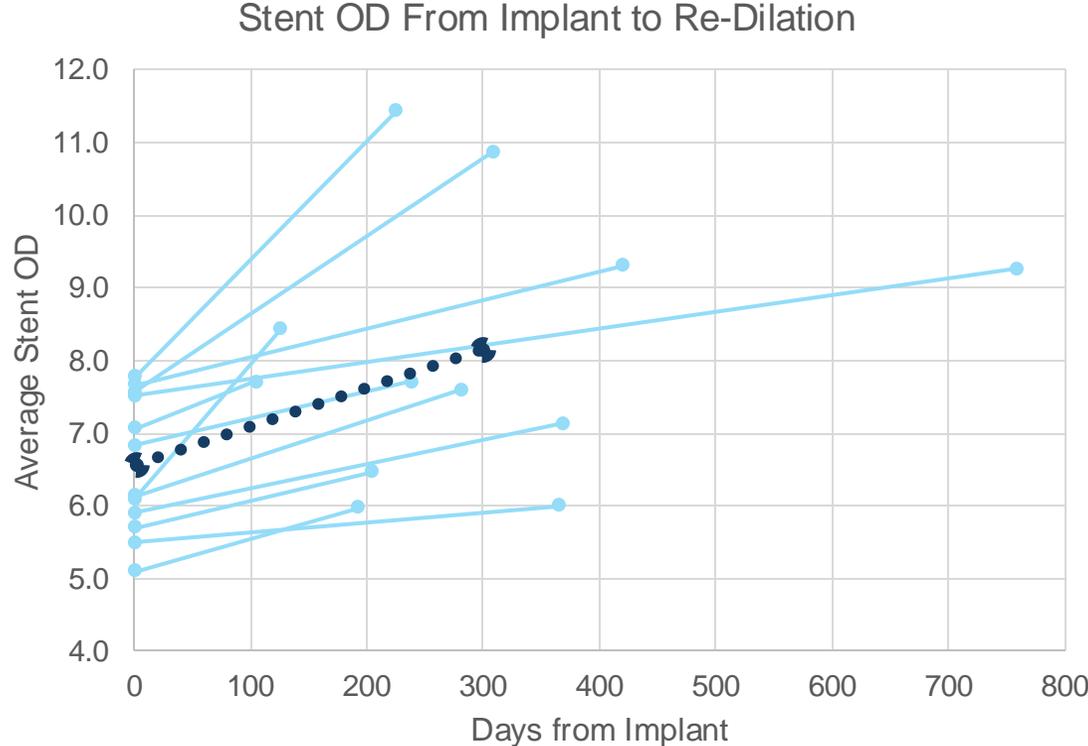
## Primary Efficacy Endpoint Analysis

	N	(%)
Stenosis Relief	41/42	<b>97.6%</b>
Freedom from Surgical Intervention	42/42	<b>100%</b>
Maintenance of Vessel Diameter	41/42	<b>97.6%</b>
Freedom from Device Related Severe Adverse Events	42/42	<b>100%</b>

## 100% Freedom from Device / Procedural SAEs

Variable	Result
Death	0
Cardiac arrest	0
Stroke	0
Limb loss	0
Vessel dissection/aneurysm	0
Cardiac perforation	0
Pacemaker required	0

# No Device Related Complications Have Occurred During Re-Expansion Procedures



**Average Growth 2 mm/year**

35% of patients experienced Minima re-expansions with growth

14% of patients experienced multiple Minima re-expansions

**No device related complications during re-expansion procedures**

# The Minima Stent Demonstrates Improved Outcomes & More Efficient Care Versus Surgical Re-Operation

	Surgical Re-Operation	Minima Stent System
Mortality Rate	6 – 13% <sup>1</sup>	0% <sup>5</sup>
Unplanned Re-Operation Rate	10 – 20% <sup>2</sup>	0% <sup>5</sup>
Days in Hospital	7 <sup>3</sup>	1 <sup>5</sup>
Days on Ventilator	3.4 <sup>4</sup>	0 <sup>5</sup>

1. Early Reoperations in a 5-Year National Cohort of Pediatric Patients With Congenital Heart Disease
2. <https://www.cincinnatichildrens.org/health/c/coarctation#:~:text=The%20rate%20of%20restenosis%20is,repair%20decreases%20in%20older%20children>
3. Green MD, Parker DM, Everett AD, Vricella L, Jacobs ML, Jacobs JP, Brown JR. Cardiac Biomarkers Associated With Hospital Length of Stay After Pediatric Congenital Heart Surgery. Ann Thorac Surg. 2021 Aug;112(2):632-637. doi: .1016/j.athoracsur.2020.06.059. Epub 2020 Aug 25. PMID: 32853571; PMCID: PMC7902730.
4. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7529086/#:~:text=The%20median%20time%20to%20normal,higher%20costs%20of%20index%20hospitalization>
5. Berman et al. (2024). Early Results of the Multicenter Pivotal Study of the Renata Minima Stent in the Treatment of Infant Vascular Stenosis

# Identifying the Minima Stent System in the Medical Record – Documentation & Terminology

- The Minima Stent System is intended for inpatient setting usage.
- The Minima Stent System is intended to be a permanently implanted device, designed for a lifetime.
- Naming conventions for procedure:
  - Branch Pulmonary Artery Stenosis
  - Coarctation of Aorta, Native
  - Coarctation of Aorta, Recurrent
  - Re-coarctation of Aorta
- Procedure may be performed in tandem with other procedures OR as a stand-alone procedure, depending on patient's etiology.
- Terms associated with the Minima Stent System for identification in the medical record:
  - Minima Stent
  - Minima System
  - Minima Stent System
  - Minima Stent System for Coarctation of Aorta
  - Minima Stent System for Pulmonary Artery Stenosis
  - Minima Growth Stent
  - Transcatheter/Percutaneous Growth Stent
  - Renata Minima Stent
  - Renata Stent

# FDA Approval of the Minima Stent System, provides...

- **1<sup>st</sup> and only** stent designed specifically for neonates & infants >1.5kg for coarctation of the aorta or branch pulmonary artery stenosis
- **1<sup>st</sup> and only** stent with a covered delivery system designed to track through tortuous neonate and infant anatomy
- **1<sup>st</sup> and only** stent with Growth Technology designed to accommodate somatic growth up to adult size in vessels.