

What is Vascular Stenosis?

Vascular stenosis in infants refers to the narrowing of blood vessels, which can impact the normal flow of blood. It is commonly seen in the Aorta and/or Branch Pulmonary arteries.

Coarctation of the aorta (CoA)

is a congenital heart defect that causes a narrowing of the aorta. The aorta is the main artery carrying blood from the heart to the rest of the body. The heart working harder to pump blood across this narrowing can lead to many issues, and the body may not receive enough oxygen rich blood.

Branch Pulmonary Artery Stenosis (BPAS)

is a condition where there is a narrowing in one or both branches of the pulmonary artery. The pulmonary artery is the blood vessel that carries blood from the heart to the lungs. This narrowing can interfere with blood flow to the lungs. This can impact a child's heart and lung function.

WHAT ARE THE RISKS ASSOCIATED WITH THE MINIMA STENT?

Below is a list of the potential risks that may occur after your child gets the Minima Stent:

- Injury to the aorta wall (Aortic aneurysm/ pseudoaneurysm, dissection, or rupture)
- Irregular heartbeat (Arrhythmia)
- Bleeding
- Death
- Infection inside the stent (Endocarditis)
- Injury to the artery used for implant (Femoral artery injury, thrombosis, or pseudoaneurysm)
- Bruising at the site where the device is introduced into the body (Hematoma)
- Infection
- Blockage of vessels that come out of the main pulmonary arteries (Jailed side branches of the pulmonary arteries)
- Blockage of major arteries (Jailed subclavian artery)
- Heart attack (Myocardial infarction)
- Injury to the pulmonary artery (Pulmonary artery aneurysm/ pseudoaneurysm, dissection, or rupture)
- Break in the frame of the stent (Stent fracture with loss of structural integrity)
- Failure to deliver the stent to the site of the narrowing or movement of the stent, which may require surgical removal (Stent malposition dislodgement/migration or embolization requiring transcatheter or surgical adjustment or retrieval)
- Tissue growth inside the stent, leading to a return of the vessel narrowing (Stent stenosis)
- Reduced or blocked blood supply to the brain (Stroke or transient ischemic attack)
- Blood clots (Thrombosis)
- Vessel puncture/injury/dissection/rupture/tear

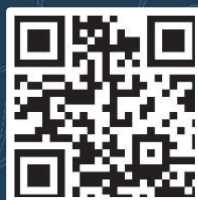


Discuss the Minima Stent System with your child's doctor now

Minima™
Stent System

The only stent system approved for infants and young children

Every 15 minutes, a child is born with a Congenital Heart Defect.¹ **You are not alone.**



More information available at
renatamedical.com

CAUTION: This brochure is intended to provide you with general information about the catheter-based treatment of aortic coarctation and pulmonary artery stenosis, which should be further discussed with a doctor. It is not intended to provide medical care or treatment. You should consult with a doctor regarding the diagnosis or treatment of your child's medical condition.
Federal (USA) law restricts this device to be sold by or on the order of a physician.

1. <https://www.childrensheartfoundation.org/about-chdfs/>
2. Data on file: RPT-0009 Rev. 7. Full clinical report available at www.clinicaltrials.gov

Minima™
Stent System

Tailored for infants. Designed for life.

What are the treatment options?

Your child's doctor is your best resource for learning about the treatment options available and the best course for your child's condition. Your child's doctor will determine their best method of treatment, but the standard options are:

Open-Heart Surgery

There are several techniques for performing open-heart surgery. Most surgeries to treat vessel narrowing involve accessing the heart through a cut in the chest. Recovery from these surgeries often means multiple days in the hospital and 6-8 weeks at home. Surgeries leave visible scarring. Your child may need more than one surgery as they grow.

Balloon Angioplasty

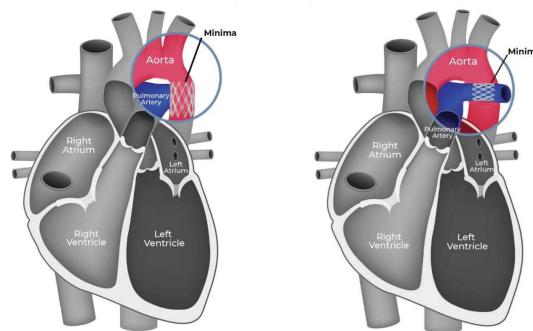
Balloon Angioplasty is a common, minimally invasive procedure where a small balloon is used to widen the narrowed vessel. Depending on the severity of the narrowing, this procedure can be a safe alternative to surgery. For many patients, it is not enough to keep the vessel open.



Minima Stent expanded on balloon

What is the MINIMA Stent?

A stent is a small, expandable metal mesh that is placed in a blood vessel to keep it open and prevent it from narrowing or closing again. A doctor passes the device through your child's blood vessels, places it in the target location (minimally invasive, catheter-based procedure), and then expands the stent using a balloon. The device remains in place permanently.



Minima expanded in the aorta (left) and pulmonary artery (right)

WHAT SHOULD MY CHILD EXPECT DURING THE PROCEDURE?

During the procedure, a doctor inserts a thin tube called a catheter into a blood vessel, often through the groin. This catheter has a balloon and the Minima Stent on the end. Using X-ray guidance, the doctor moves the catheter to the site of the narrowed vessel.

Once in position, the doctor inflates the balloon to expand the Minima Stent to widen the vessel. The stent acts as a scaffold to hold the vessel open and allow for blood flow.

Because the procedure does not involve opening the chest, recovery time will likely be fairly short. Many patients can leave the hospital within 24 hours. The Minima Stent is designed to be gradually re-expanded over time. Your child's doctor can discuss the potential for re-expansion with you when outlining benefits and risks of the procedure.



Minima Stent before expanding inside the vessel



Minima Stent while expanding inside the vessel

WILL MY CHILD BE ABLE TO FEEL THE DEVICE?

No, your child will not be able to feel the device once it's implanted.

HOW LONG WILL IT TAKE MY CHILD TO RECOVER? WHEN CAN NORMAL ACTIVITIES BE RESUMED?

Every person recovers differently. While many patients leave the hospital within 24 hours, your child's physician will determine the need for medication and activity limitations after the procedure.

HOW SAFE & EFFECTIVE IS THE MINIMA STENT?

During the clinical study (Pivotal Trial) of the Minima Stent, the safety and effectiveness of the Minima Stent was evaluated in 42 patients for 6 months following the implant. The primary results are summarized below:

- In 41 of the 42 patients (98%), the device expanded the narrow vessel to be at least 75% as wide as the nearby normal vessel.
- None of the patients had a serious adverse event related to the device. This includes events like:
 - Death
 - Heart attack
 - Emergency need for the use of a machine to support the heart and lungs (extracorporeal membrane oxygenation or ECMO)
 - Stroke
 - Loss of a limb
 - A tear in the vessel where the narrowing is (vessel dissection of target lesion)
 - Blood clots on the device or blockage inside the device (device thrombosis/occlusion)
 - A cut or tear in the heart needing treatment (cardiac perforation requiring percutaneous or open surgical intervention)
 - Irregular heartbeat (persistent cardiac arrhythmia) that needs treatment with a pacemaker)
- No patients needed surgery to treat any problems with the device after it was placed
- In 41 of the 42 patients (98%), after 6 months the narrowed vessel was still at least half as wide as it originally was right after the device was placed.

WHAT IS A PATIENT IDENTIFICATION CARD? WILL MY CHILD NEED TO CARRY IT WITH ME?

Your child should carry a patient identification card to identify themselves as having an implanted device. The patient ID card includes your child's name, implant date, your doctor's contact information, and information about the implanted device. Your doctor will give you this card after the procedure.

CAN MY CHILD TRAVEL WITH AN IMPLANTED DEVICE? WILL MY CHILD'S DEVICE TRIGGER AIRPORT SECURITY SYSTEMS?

Yes, your child can travel with the stent. Please talk to your child's doctor before traveling after the procedure. For metal detectors and MRI machines, please refer to the stent Implant Card for more information.