What Are the Possible Risks of the Stenting Procedure?

Cardiac catheterization and stent insertion carries certain risks. Potential complications and related adverse effects associated with stent implants include, but are not limited to:

- Femoral Artery Injury, Thrombosis or Pseudoaneurysm
- Stent Migration - movement of the stent away from original implant site
- Stent Stenosis - growth of tissue within the stent, leading to return of the blockage
- Stent Fracture - break in the frame of the stent
- Aortic Aneurysm/Pseudoaneurysm – weakening or injury of the aorta wall
- Vessel Rupture/Tear - perforation or tearing of the aorta, causing internal bleeding
- Stent Malposition – poor position of stent, requiring a 2nd stent
- Hematoma - bruising at the site where the device is introduced into the body
- Sepsis/infection - infection
- Thrombosis/Thromboembolism - formation or presence of a blood clot
- Femoral artery occlusion - injury to artery used for implant, possibly requiring surgical repair
- AV fistula formation - abnormal passageway between an artery and a vein
- Transitory arrhythmia - irregular heartbeat
- Endocarditis - infection within the stent
- Bleeding - at the site of where the device is introduced into the body
- Cell necrosis at the site of implant - death of cells at the implant site
- Cerebrovascular Incident - stroke
- Death

Stent Fracture

Stent fracture (when the stent breaks) can occur with the G-Armor Stent®. In most cases, the ability of the stent to hold the aorta open remains unchanged even when the stent fractures. In some instances, an additional procedure may be needed to place another stent within the fractured stent. Your physician will decide what will work best for you. There is up to a 2 out of 10 chance that the stent will fracture within two years of placement.

What Are the Possible Benefits of the G-Armor Stent® therapy?

Stent therapy for coarctation of the aorta offers a non-surgical alternative to traditional operative repair of the aortic obstruction with similar results and complications. There is less chance of aortic wall injury or return of aortic narrowing when stents are used, compared to balloon dilation alone.

MRI Safety Information

MRI scans can be performed with the G-Armor Stent® under certain conditions. Please inform your physician or MRI Technician that you have a G-Armor Stent® before undergoing an MRI scan.

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G-Armor Stent®

CAUTION: This device is restricted to sale by or on the order of a physician

Information for Patients and their Families

This booklet is designed to provide you and your family more information about the G-Armor Stent®. This device is not for everyone. Please discuss any questions with your cardiologist. Only your physician can determine the right therapy for you.

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For any non-medical questions about any of the G-Armor Stent® family of products, you can contact NuMED at (877) 686-3327.

What is Coarctation of the Aorta?

An aortic coarctation is a partial blockage or narrowing in the aorta, the body's main blood vessel distributing blood to all parts of the body. This blockage of the aorta makes the heart work harder to pump blood to your body and can weaken the heart muscle. Furthermore, this blockage can cause severe upper body hypertension (high blood pressure), increasing the risk of stroke. This blockage is present from birth.

What are your Treatment Options?

At this time you have already undergone either surgical repair or balloon dilatation and have a re-narrowing (re-coarctation) of the aorta, or the blockage has been developing slowly enough to only require repair now. Your cardiologist believes that relief of the blockage is important for your health and safety. There are two ways to relieve the blockage: by surgery or by stent implantation without surgery.

Surgical Therapy

Surgical treatment of the blockage is usually performed through an incision on the side of the chest, approaching the aorta by spreading the ribs. The narrowed portion of the aorta is removed and then the aorta is sewn back together. For more complicated coarctation, surgery might be performed from the front of the chest, opening the breast bone and using heart lung bypass. For some patients a benefit of a surgical approach is that the repair can be performed without the use of man-made materials. However, for other (especially adult) patients a man-made tube graft or patch may be needed. Please consult with your surgeon regarding his or her approach. For younger patients, surgery results in a lower need for a second procedure to keep up with growth when compared to balloon or stent therapy.

Risks of surgery include: pain from the surgical incision, prolonged fluid drainage from the chest after surgery, chest or wound infection, longer recovery time compared to stent therapy, prolonged postoperative rib discomfort and increased risk of very high blood pressure occurring after immediately after surgery, requiring intravenous therapy in an ICU, compared to stent repair. There is a low risk, probably less than 5%, of developing an aneurysm (weakened areas of the aorta) in the area of surgery in the years following stent therapy, making CT or MRI imaging an important part of follow up care.

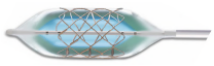
Stent Therapy (without surgery)
A stent is an expandable metal tube that is implanted into your aorta to keep it open. Surgery is not required for this procedure. The stent is implanted using a thin hollow tube (catheter) with a balloon on the end. The catheter with stent is inserted through the artery in the upper leg. The balloon and stent are then moved to the appropriate position to the narrowed part of your aorta. Once in place, the balloons are inflated to expand the stent against the aortic wall. The catheter is then removed from the body and the stent remains in place.

What is the G-Armor Stent®?

The G-Armor Stent® is balloon expandable and intended to permanently stay in your body. The stent is composed of heat-treated metal (90% platinum and 10% iridium) wire that is arranged in laser welded rows with a "zig" pattern. The number of rows will determine the unexpanded length of the stent.

Stents (Unexpanded and Expanded)

The NuMED BIB® (Balloon in Balloon) Catheter is a specially designed double balloon catheter (one balloon inside another balloon). The purpose of the two balloons is to expand the stent (which is placed on the outside of the bigger balloon) in two steps. The inner balloon provides initial expansion of the stent and also acts as a tool to hold the stent in place while the outer balloon is inflated. The outer balloon is then inflated securing the stent against the vessel wall.



Stent mounted on a BIB Catheter

Is the G-Armor Stent® the right treatment for you?

Your cardiologist can help you decide if the G-Armor Stent® is the right treatment for you.

The following patients should NOT receive the G-Armor Stent®:

- Patients who are too small to allow the stent to pass through their arteries without damaging the artery;
- Patients with a stiff aorta that does not get larger with balloon dilation.
- The stent should not be placed in curved or tortuous portions of the aorta
- Patients with blocked leg arteries making it difficult or unsafe to move the catheter and stent to the narrowed aorta;
- Patients with any signs of infection;
- Patients with active infection in the heart or blood vessels (endocarditis);
- Patients with a known allergy to aspirin, other antiplatelet agents, or heparin;
- Pregnancy.

What Happens During the Procedure?

The procedure is performed in a special radiology room, called the catheterization laboratory (cath lab, for short). There you will either receive deep sedation or general anesthesia, depending on your preference, as agreed on with your doctor. The stent is implanted using a thin hollow tube (catheter) with a balloon on the end. The stent is available in two configurations: a) already mounted on the catheter (pre-mounted) or b) not mounted on the catheter (unmounted). If your physician uses an unmounted stent, he/she will place the stent on the balloon at the start of your procedure. The catheter with the stent is then placed through the skin, typically into the artery in your upper leg. The balloon and stent are moved to the appropriate position at the narrowed part of your aorta. Once in place, the balloons are inflated to expand the stent against the aortic wall. The catheter is then removed from the body and the stent stays in place.

What Happens After the Procedure?

An over-night stay in the hospital is typical after the procedure and your blood pressure will be measured before you go home. The location on your skin where the catheter entered your body requires minimal care after leaving the hospital. It is important to keep the site clean until healing has completed, typically in 3 or 4 days. Instructions will be given to you by your cardiologist. It is important to follow these instructions to produce the best possible results from your procedure. Follow-up visits at one month, six months and one year from implant are often recommended. Computed Tomography (CT) or Magnetic Resonance Imaging (MRI) scanning may be recommended by your physician one to two years after the implant to check for any signs of injury to the aortic wall in the area where the stent was placed. Your physician will give you instructions regarding exercise activity and whether antibiotics are need for any dental or surgical procedures.

Clinical Data

The following data is based on the NuMED CP Stent®, another version of the G-Armor Stent®. It was tested and found to be safe and effective to widen the narrow part of the aorta related to coarctation of the aorta. A study was conducted with 105 patients weighing more than 77 lbs at the time of implant. Most patients (98%) were treated with one CP Stent®.

On average arm systolic blood pressure was 27 mmHg higher than the leg pressure before the procedure. A reduction of a gradient to 15mmHg or less following the procedure suggests that the blockage is reduced effectively. By one month after bare metal stent placement the average leg pressure was 1 mmHg higher than the arm pressure. Two years after implant, 91% of patients had arm blood pressures less than 15 mmHg above their leg blood pressure which suggests that most of the treated aortas did not re-narrow. An overview of complications and additional treatments provided after the stenting procedure is shown below:

- Serious complications related to the CP Stent® or implant procedure, such as: injury to the aortic wall and leg artery-vein fistula (an abnormal passageway between the artery and vein), were identified in 1 out of 20 (5%) patients within the first month of implant.
- No patients needed surgery to repair the aorta, remove the stent or repair the arterial access site.
- 1 out of 20 (5%) patients developed small aneurysms (weakened areas of the aorta) in the area of stent placement in the years following stent therapy, making CT or MRI imaging an important part of follow up care. However, none of the patients who developed aneurysms demonstrated symptoms or required surgery. All were successfully treated with covered stent placement.
- Approximately 3 out of 20 (15%) patients required repeat cardiac catheterization for a second dilation of the stent, mostly to keep up with the size of the patient as he/she grew and for some to repair aortic wall injuries as noted above.