

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:

- 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, possibly 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
- 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 CP Stent. In most cases, the ability of the stent to hold the conduit 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.

WHAT ARE THE POSSIBLE BENEFITS OF THE COVERED CP STENT PLACEMENT? The Covered CP Stent offers the physician an option for treating conduit tears while continuing to implant the Transcatheter Pulmonary Valve rather than implanting a new valve during emergency surgery. Secondly, the Covered CP Stent may significantly slow the free flow of blood from a conduit tear to stabilize the patient. This process may allow surgery to repair the injury to occur under conditions that are less rushed rather than resulting in the need for emergency surgery on patients that are unstable.

MRI SAFETY INFORMATION

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

Covered CP Stent™

Right Ventricular Outflow Tract

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 Covered CP 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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WHAT IS A RIGHT VENTRICULAR OUTFLOW TRACT? A Right Ventricular Outflow Tract (RVOT) is also known as a pulmonary conduit, and it is a tube that connects the heart to the lungs. Placement of an RVOT is typically associated in patients that have one of the following conditions: Pulmonary Atresia, Tetralogy of Fallot, or Double Outlet Right Ventricle. These three conditions can lead to pulmonary conduit failure.

WHAT ARE YOUR TREATMENT OPTIONS?

There are three ways to treat pulmonary conduit failure. One is a surgical conduit replacement, one is Balloon Valvuloplasty, and the last is Transcatheter Pulmonary Valve Replacement.

SURGICAL REPLACEMENT:

Surgical replacement of a pulmonary valve conduit involves a physician removing the narrow or leaking conduit and replacing it with an artificial valve.

BALLOON VALVULOPLASTY:

A thin hollow tube (catheter) with a balloon on the end is inserted into the artery in your upper leg and advanced to the pulmonary conduit. The balloon is then inflated to a specified pressure to open your conduit so that the blood will flow better. The catheter is then removed from the body.

TRANSCATHETER PULMONARY VALVE REPLACEMENT:

An artificial valve is mounted on a thin hollow tube (catheter) with a balloon on the end, and is inserted into the artery in your upper leg. It is then advanced to the pulmonary conduit and the balloon inflated to place the new artificial pulmonary valve. The catheter is then removed from the body.

WHAT IS THE COVERED CP STENT?

The Covered CP Stent is balloon expandable and intended to permanently stay in your body. The Covered CP Stent is used for treatment of right ventricle to pulmonary artery (right ventricular outflow tract) conduit disruptions that are identified during conduit pre-dilatation procedures performed in preparation for transcatheter pulmonary valve replacement (TPVR). The covering acts as a fluid barrier creating a fluid tight conduit through the stent length. Blood cannot flow across the covering.

The Covered CP 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 determines the unexpanded length of the stent. The ePTFE covering is then attached to the metal wire frame.

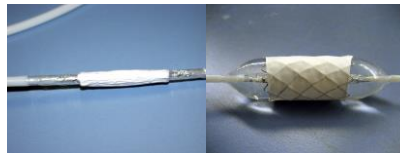


Covered CP Stents

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.



The Covered Mounted CP Stent is the Covered CP Stent mounted on the BIB balloon catheter.



(a)

(b)

Covered Mounted NuMED CP stents: (a) crimped, (b) expanded

IS THE COVERED CP STENT THE RIGHT TREATMENT FOR YOU?

Your cardiologist can help you decide if the Covered CP Stent is the right treatment for you.

The following patients should NOT receive the Covered CP Stent:

- Patients too small to allow safe delivery of the stent without injury to a systemic vein or to the right side of the heart;
- Clinical or biological signs of infection;
- Active endocarditis;
- 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. Once in place, the balloons are inflated to expand the stent against the pulmonary conduit. The catheter is then removed from the body and the stent stays in place. This is one step in the process of Transcatheter Pulmonary Valve Replacement. Please refer to the Patient Brochure for the artificial valve for the rest of the procedure steps.

WHAT HAPPENS AFTER THE PROCEDURE?

An over-night stay in the hospital is typical after the procedure. 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 are often recommended.

COVERED CP STENT CLINICAL DATA

The NuMED Covered CP stent was tested and found to be safe and effective to use as a Treatment of right ventricle to pulmonary artery (right ventricular outflow tract) conduit disruptions that are identified during conduit pre-dilatation procedures performed in preparation for transcatheter pulmonary valve replacement (TPVR). A study was conducted with 50 patients weighing an average of 58 kg. at the time of implant. Most patients (80%) were treated with one Covered CP stent.

Out of 49 patients treated with the Covered CP Stent (CCPS), 81.6% of them had device and lesion success with no adverse events attributed to the CCPS. Out of 49 patients treated with the CCPS, 93.9% of the patients had successful coverage of conduit disruption followed by successful implantation of an artificial valve. An overview of complications and additional treatments provided after the stenting procedure is shown below:

- Serious complications related to the CCPS or stent implant procedure, such as: stent embolization was identified in 1 out of 50 (2%) patients.
- 7 (14%) of the patients required a second CCPS, and (3) 6% of the patients required a third CCPS during the procedure. Of these 10 patients, 4 (40%) of them planned on having the second CCPS implanted before the procedure.