Patient Device Information

COPY-CORDIS-23024 Rev.1

PRECISE PRO RX® Nitinol Stent System

What PRECISE PRO RX® Nitinol Stent System is Used For

The PRECISE PRO RX Nitinol Stent is indicated for use in patients with atherosclerotic disease and non-atherosclerotic lesions of the carotid artery(ies)

Product Description

The PRECISE PRO RX® Nitinol Stent is a self-expanding stent made from nitinol. Nitinol is a metal alloy of nickel and titanium with unique properties, including superelasticity or pseudoelasticity and "shape memory" properties. That means nitinol can remember its original shape and return to it when heated. It also provides excellent flexibility in complex vessels.

Active Ingredient

- Nitinol

About Your Carotid Stent Procedure

You may be given a mild sedative to help you relax, but you will not be put to sleep. There are two reasons for this. Firstly, most people find they experience little to no discomfort from the procedure. Secondly, your doctor may need to ask you to take a deep breath while X-rays are being taken, to improve the quality of the pictures.

Your procedure will be performed in a Cardiac Catheterization laboratory or an Interventional Radiology lab. You will lie on an X-ray table, and an X-ray camera will move over your chest during the procedure. The staff will monitor your heart by attaching several small patches to your chest and using a specialized monitor.

The blood vessel at the top of your thigh is the most common site for catheter insertion and requires a very small skin incision. The area will be shaved and cleaned with an antiseptic, and you will be given a local anesthetic to numb the area. This incision will allow an introducer sheath (short tube) to be inserted into your femoral artery (the main artery of the thigh, supplying blood to the leg). Your doctor will then insert a guiding catheter (a long flexible tube) into the introducer sheath and advance it to where the carotid arteries branch off to the brain. A flexible guide wire is then advanced through the guiding catheter to the narrowing in the carotid artery. This helps carry all the necessary devices required during the stenting procedure.

Additional options for catheter insertion include an arm artery (brachial artery) on the inside of your elbow and the wrist (radial artery).

After the catheters are advanced to your heart, your doctor will inject fluid (contrast dye) through the guiding catheter into your artery to view the narrowing. Your doctor will watch the injection on an X-ray monitor, much like a TV screen. While these X-rays are being taken, your doctor may ask you to take a deep breath and hold it for a few seconds. You may also be asked to cough after the X-ray picture is completed, to help speed the removal of the contrast dye from the arteries.

ANGIOGUARD® RX Emboli Capture Guidewire System is placed in the artery. The filter, called an embolic protection device, is inserted beyond the narrowing to catch any debris that may break off from the narrowed area of artery during the procedure.

The balloon tip is threaded into the narrowed area and inflated to push the plaque to the side and widen the vessel.

A small metal mesh tube (stent) may be placed in the newly opened vessel. The expanded stent provides support that helps prevent the artery from narrowing again. The stent may be coated in a drug that is released slowly over time to help prevent restenosis. The filter, sheath, catheter and balloon are removed. Pressure is applied to the small catheter insertion site to prevent bleeding.

When the procedure is done, you lie still in one position while pressure is applied to the site to stop bleeding. You generally won't have stitches, but a dressing is applied to cover the small incision site. You'll then be taken to the recovery area.

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Caution

The PRECISE PRO RX® Nitinol Stent contains Nitinol. The stent should not be used on patients with a known allergy to nickel or titanium.

Before undergoing implantation of any stent, speak with your doctor if you plan to have any type of surgery that may require you to stop taking antiplatelet medications.

Adverse Effects

The risks of using the PRECISE PRO RX® Nitinol Stent are similar to those that are associated with other standard carotid stent procedures. For more information regarding the risks, consult your doctor.

Device Interaction and MRI Information

If you require **a magnetic resonance imaging (MRI)** scan, tell your doctor or MRI technician that you have a stent implant. MRI may be performed immediately following the implantation of the PRECISE PRO RX® Nitinol Stent(s). Your Patient Implant Card has detailed information regarding the safest MRI conditions to be used after implantation of the PRECISE®PRO RX® Nitinol Stent.

Post-Procedure Care

You will be asked to lie flat for four to six hours following the procedure and to not bend your leg or arm, depending on which area your doctor used to insert the catheters. Pressure will also be placed on the area.

A vascular closure device may be used to seal the incision site in your groin or arm. You will be allowed to get up and walk around sooner if this type of device is used.

The catheter site may remain tender, swollen and bruised for a few days. There may be a small area of discoloration or a small lump in the area of the puncture. You may take acetaminophen (Tylenol, others) in the recommended dose as needed for discomfort, or other medication as prescribed by your doctor.

You may need to avoid strenuous activity and heavy lifting for 24 hours after the procedure. Please talk to your doctor about any limitations in your activities following your procedure.

Take All Medications as Instructed

After you leave the hospital, your doctor will instruct you to take a daily dose of Aspirin and another blood thinning antiplatelet drug. Your doctor will tell you how long you should continue taking these antiplatelet drugs. It is very important that you take these medications exactly as your doctor instructs you:

- Follow your medication schedule exactly to avoid possible complications after you receive your stent. Do not miss any doses.

Call your doctor if you cannot keep taking your medications because of side effects such as rash, bleeding, or upset stomach.

Do not stop taking your prescribed medications unless you are instructed to do so by the doctor who performed your stent procedure.

Daily Activities

Day of discharge

- No driving

Modify activity for a minimum of 3 days

- No heavy lifting of anything over 5 pounds or 2.3 kgs (equivalent to a 1/2 gallon or 1.9 liters of milk)
- No pushing or pulling
- No vigorous activity or straining
  - Avoid stairs unless necessary: if necessary, take them slowly.
  - Coughing, sneezing, or straining for a bowel movement: support your groin by pressing with your palm on top of the dressing/ bandage
  - Sexual activity: check with your doctor
- No strenuous exercise
- Avoid driving unless necessary

Talk to your doctor about returning to work, which depends on your type of work, your procedure, and any medication you may be taking.

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Precaution

Any serious incident that occurs in relation to the device should be reported to Cordis US Corp. and to the Therapeutic Goods Administration (TGA).

Cordis US Corp.
14201 North West 60th Avenue
Miami Lakes, Florida 33014, USA
email: anz-product-complaints@cordis.com

TGA:
http://www.tga.gov.au/reporting-problems

Discharge Information

You will be discharged to the care of your physician or family doctor. You should be able to return to your normal activities soon.

Your doctor will ask you to return for follow-up visits. The first visit is usually two to four weeks after your stents are implanted, with follow-up visits every six months for the first year. Be sure to keep all appointments for follow-up care, including blood tests.

Notify your doctor immediately if you experience stroke like symptoms, such as weakness on one side of your body, trouble speaking or sudden vision problems, especially in the first month after a procedure. These symptoms may indicate a re-narrowing in your carotid arteries.

Legal Manufacturer

Cordis US Corp.
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Miami Lakes, Florida 33014, USA