Caution: Not available for sale in the U.S.A.

STERILE. Sterilized with ethylene oxide gas. Nonpyrogenic. Radiopaque. For single use only. Do not autoclave.

Do not exceed the rated burst pressure recommended on the label. The rated burst pressure is based on the results of in-vitro testing. At least 99.9% of the balloons (with a 95% confidence), will not burst at or below their rated burst pressure. Use of a pressure monitoring device is recommended to prevent over-pressurization.

Use the stent and delivery system prior to the "Use By" date specified on the package.

Use only the recommended balloon inflation medium (a 50/50 mixture by volume of contrast medium and normal saline). Never use air or any gaseous medium to inflate the balloon.

Persons with allergic reactions to stainless steel may suffer an allergic response to this implant.

The safety of the PALMAZ GENESIS Stent on CORDIS AMIIA .014" Delivery System have not been established for use in patients for treatment of athereosclerotic disease of the femoral artery.

As with any type of intravascular implant, infection, secondary to contamination of the stent, may lead to thrombosis, pseudoaneurysm or rupture into a neighbouring organ of the retroperitoneum.

The stent may cause a thrombus, distal embolization or may migrate from the site of the implant down the arterial lumen.

Overstretching of the artery may result in rupture and life threatening bleeding.

When stenting renal arteries, exercise great care to reduce the risk of plaque embolization.

Avoid stent placement which would obstruct access to a vital side branch.

It is recommended that stents not be implanted in patients with confirmed pregnancies.

**v. Warnings**

- Do not exceed the rated burst pressure recommended on the label. The rated burst pressure is based on the results of in-vitro testing. At least 99.9% of the balloons (with a 95% confidence), will not burst at or below their rated burst pressure. Use of a pressure monitoring device is recommended to prevent over-pressurization.

- Use the stent and delivery system prior to the "Use By" date specified on the package.

- Use only the recommended balloon inflation medium (a 50/50 mixture by volume of contrast medium and normal saline). Never use air or any gaseous medium to inflate the balloon.

- Persons with allergic reactions to stainless steel may suffer an allergic response to this implant.

- The stent and delivery system have not been established for use in patients for treatment of athereosclerotic disease of the femoral artery.

- As with any type of intravascular implant, infection, secondary to contamination of the stent, may lead to thrombosis, pseudoaneurysm or rupture into a neighbouring organ of the retroperitoneum.

- The stent may cause a thrombus, distal embolization or may migrate from the site of the implant down the arterial lumen.

- Overstretching of the artery may result in rupture and life threatening bleeding.

- When stenting renal arteries, exercise great care to reduce the risk of plaque embolization.

- Avoid stent placement which would obstruct access to a vital side branch.

- It is recommended that stents not be implanted in patients with confirmed pregnancies.
V. Potential Complications
Potential complications associated with peripheral artery stent implantation may include, but are not limited to, the following:

• Sepsis/infection
• Stent migration
• Embolization of atheroembolic or thrombotic material
• Acute or subacute stent thrombosis
• Amputation
• Arteriovenous fistula
• Emergency surgery to correct vascular complications
• GI bleeding from anticoagulation/antiplatelet medication
• Hemorrhage/hematoma
• Artery injury, including perforation and dissection
• Rupture of the retroperitoneum or neighboring organ

VI. Instructions for Use

Pre-Procedure

1. The patient may be started on enoxaparin or low molecular weight heparin, as well as antiplatelet agents, at least 30 minutes prior to the procedure. The choice of antiplatelet agents should be as early as possible. This may be considered a procedural requirement.

2. The percutaneous placement of the stent in a stenotic or obstructed artery should be done in an angiography procedure room. Angiography should be performed to map out the extent of the lesion(s) and the collateral flow. If thrombus is present or suspected, thrombolytics should precede stent deployment using standard acceptable practice. Access vessels must be sufficiently patent, or sufficiently revascularized, to proceed with further intervention. Patient preparation and sterile precautions should be the same as for any angioplasty procedure.

Procedure for stenting

1. Perform standard diagnostic angiography to evaluate the lesion.
2. Selection of Stent Size
   a. Measure the length of the target lesion to determine the length of stent required. Select the stent length to extend slightly proximal and distal to the lesion. The appropriate stent length should be selected based on the length of the target lesion segment and individual characteristics of the patient. Carefully advance the stent delivery system and introduce the introducer tube and hemostasis valve.
   b. Measure the diameter of the reference vessel to determine the appropriate size stent and delivery system.
3. Preparation of Stent Delivery System
   a. Open the outer box and reveal the pouch containing the tray with the stent and delivery system, flushing needle and introducer tube.
   b. Open the pouch and carefully extract the tray with the stent and delivery system, flushing needle and introducer tube.
   c. Hold the tray in one hand. With the other hand, gently grasp the hub and carefully remove the stent/delivery system from the tray.
   d. Inspect the crimped stent for adherence to the balloon and centered placement in relation to the balloon marker bands. Do not reposition the stent or hand crimp.
   e. Attach a three-way stopcock to the catheter's inflation port.
   f. Prepare an angioplasty inflation system with diluted contrast medium (unexpanded).
   g. Open a bag of contrast medium.
   h. Attach the inflation system to the stopcock.
   i. Caution: Do not apply negative or positive pressure to the balloon at this time.
   j. Attach a syringe filled with sterile heparinized saline or similar isotonic solution to the flushing needle. Insert the needle into the distal tip of the delivery system. Flush the delivery system by gently applying pressure with the syringe for 10 seconds. Remove the syringe.
   k. Caution: Avoid manipulation of the stent during flushing of guidewire lumen, as this may disrupt the placement of the stent on the balloon.

Deployment Procedure

1. Insertion of Cordis Sheath Introducer (CSI), Guiding Catheter and Guidewire
   a. Gain access at the appropriate site using the CSI/guiding catheter size recommended on the label.
   b. Insert a guidewire across the lesion to be stented through the CSI/guiding catheter.
   c. Insert a guidewire across the lesion to be stented through the CSI/guiding catheter. The guidewire should be advanced to the target lesion.
   d. Attach a three-way stopcock to the catheter's inflation port.
   e. Prepare an angioplasty inflation system with diluted contrast medium

Through a CSI
1. Maintain neutral pressure on inflation device. Position the flared end of the introducer tube over the distal tip of the stented balloon and slide forward to protect the stent during CSI insertion. Backload onto the guidewire. Place the assembly through the CSI hemostasis valve and fluoroscopically as the stent is advanced through the CSI/guiding catheter to the site of the lesion.
2. Insertion of Cordis Sheath Introducer (CSI), Guiding Catheter and Guidewire
   a. Measure the diameter of the reference vessel to determine the appropriate size stent and delivery system.
   b. Insert a guidewire across the lesion to be stented through the CSI/guiding catheter.
   c. Attach a three-way stopcock to the catheter's inflation port.
   d. Prepare an angioplasty inflation system with diluted contrast medium
   e. Open a bag of contrast medium.

Through a CSI
1. Maintain neutral pressure on inflation device. Position the flared end of the introducer tube over the distal tip of the stented balloon and slide forward to protect the stent during CSI insertion. Backload onto the guidewire. Place the assembly through the CSI hemostasis valve and fluoroscopically as the stent is advanced through the CSI/guiding catheter to the site of the lesion.
2. Insertion of Cordis Sheath Introducer (CSI), Guiding Catheter and Guidewire
   a. Measure the diameter of the reference vessel to determine the appropriate size stent and delivery system.
   b. Insert a guidewire across the lesion to be stented through the CSI/guiding catheter.
   c. Attach a three-way stopcock to the catheter's inflation port.
   d. Prepare an angioplasty inflation system with diluted contrast medium
   e. Open a bag of contrast medium.

X. Magnetic Resonance Imaging (MRI) Compatibility

The stent may cause artefacts with MRI scans due to distortion of the magnetic field. The artefacts caused by the stainless steel stent should not be greater than those caused by metal surgical clips. In a study of larger size stainless steel stents, no stent migration was observed in an MRI field strength of 1.5 Telsa. However, an MRI scan should not be performed until the stent implantation site has had a chance to heal (estimated to be 2 weeks), in order to further minimize the risk of migration.

XI. Disclaimer of Warranty and Limitation of Remedy

There is no express or implied warranty, including without limitation any implied warranty of merchantability or fitness for a particular purpose, on the Cordis product(s) described in this publication. Under no circumstances shall Cordis be liable for any direct, incidental, or consequential damages other than as expressly provided.

Precautions

1. The introducer tube must be removed prior to stent implantation.
2. The introducer tube must be removed prior to stent implantation.
3. The introducer tube must be removed prior to stent implantation.
4. The introducer tube must be removed prior to stent implantation.
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References

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