The Azule L605 cobalt chromium coronary stent is a PTCA balloon expandable vascular prosthesis. The stent is supplied mounted on a balloon catheter as a Coronary Stent Delivery System. The stent is designed to provide a fixed vascular stent for the treatment of coronary artery disease.

DELIVERY SYSTEM

The Azule coronary stent is mounted on a low-profile rapid exchange PTCA dilatation catheter with a working length of 130cm. The balloon is inflated and the stent is deployed by injecting dehydrated contrast solution through the tubing hub of the catheter. The guide wire lumen is accessed through the sidestore, which is covered by the catheter lumen. The guide wire is then advanced over the balloon catheter until it is flush with the proximal marker band and the balloon catheter is pulled back to its working length of the balloon. The stent is mounted on the balloon between the marker bands. The working length of the semi-compliant balloon is nominally 3.0mm longer than the stent at each end.

INDICATIONS

The Azule Coronary Stent Delivery System is indicated for use in a group of selected patients eligible for balloon angioplasty with symptomatic ischemic heart disease due to de novo and restenosis coronary artery lesions. The Azule Coronary Stent Delivery System is indicated for treatment of athrosclerotic or restenotic lesions with a length less than the nominal stent length in coronary arteries having reference vessel diameters which match the expanded stent diameters following primary inflation.

CONTRAINDICATIONS

The Azule Coronary Stent Delivery System is contraindicated for use in patients:

- With allergies to required medications and/or cobalt and/or chromium.
- Patients in whom anti-platelet and/or anti-coagulant therapy is contraindicated.
- Patients judged to have a reference vessel location or anatomy that precludes an angioplasty balloon or proper placement of the stent or delivery device.

WARNINGS

Use of any type of device is known to be associated with the following risks:

- Subacute thrombosis
- Increased vascular and/or bleeding complications (due to anticoagulation)
- Increased length of hospital stay relative to those of coronary balloon angioplasty alone. Judicious selection of patients to receive this device rather than balloon angioplasty alone is strongly advised.
- Infection secondary to contamination of the stent which may lead to thrombosis, pseudoaneurysm formation and infection.
- The stent may cause spasm, distal embolization, thrombosis, or migrate causing vessel tamponade or pseudoaneurysm formation.
- Excessive stretching of the artery may cause rupture and life-threatening hemorrhage.
- Stents can be partially deployed in particularly resistant lesions.
- Stent dislodgement from the balloon surface during deployment or dislodgment from the target site post-deployment can occur.
- Patients with a known hypersensitivity to cobalt chronium may suffer an allergic reaction to this implant.

PRECAUTIONS

Use of this product should be limited to hospitals where emergency coronary artery bypass graft surgery can be quickly performed in the event of a peri-procedural complication.

The Azule Coronary Stent Delivery System is intended for single use only. Under no circumstances should the Azule Coronary Stent Delivery System or any part thereof be resterilized or reused.

All equipment required for the implantation of this product include, but are not limited to, the following:

- Sterile normal saline
- Guiding Catheter
- Iodinated contrast medium
- Anticoagulant therapy
- Appropriate stent for the site
- Appropriate balloon catheter for the site
- Appropriate sheath set
- Appropriate stent delivery catheter set
- Appropriate positioner
- Appropriate angiographic technique
- Appropriate stent deployment technique
- Appropriate anticoagulant therapy
- Appropriate monitoring of the patient
- Appropriate patient selection
- Appropriate patient positioning
- Appropriate patient monitoring
- Appropriate patient follow-up

RECOMMENDED ADDITIONAL MATERIALS

- Sterile saline
- Appropriate vascular sheath introducer and dilator set
- Guiding catheter of appropriate size, tip shape, and length (i.e. at least 18F)
- Guide wire with maximum diameter of 0.014" (or 0.016"

- Iodinated contrast medium
- Appropriate stent delivery catheter set
- Appropriate positioner
- Appropriate angiographic technique
- Appropriate stent deployment technique
- Appropriate anticoagulant therapy
- Appropriate monitoring of the patient
- Appropriate patient selection
- Appropriate patient positioning
- Appropriate patient monitoring
- Appropriate patient follow-up

CLINICAL PROCEDURE

Use of a coronary stent and delivery system requires advanced angioplasty skills. The following instructions provide technical guidance but do not obviate formal training in the use of these devices. Use only your preferred technique of choice.

1. In a sterile environment, remove the stent delivery system from the packaging and remove the sheath cover from the distal end of the catheter onto the protective mandrel.

2. Prior to use of the Azule Coronary Stent Delivery System, all equipment, including the Azule coronary stent and the delivery catheter should be visually examined for defects. Examine the Azule coronary stent and delivery catheter for kinks or bends in the catheter and damage to the stent. Do not use any equipment until the stent has been fully deployed in its ideal shape and does not have any sharp edges. If necessary, use light pressure to strip out the stent fingers and do not wipe down the stent mounted on balloon or this may cause the deployment of the stent from the delivery balloon.

3. Use standard techniques and the manufacturer's instructions to place the vascular sheath, guiding catheter and guidewire.

4. Stent delivery system preparation:

- With caution, advance the stent catheter, forming for uniformity, protuding and stent choice the position of the stent ends relative to balloon markers.
- The stent is deployed at its working length to avoid inadvertent dislodgment.
- The stent deployment is achieved by a combination of the balloon catheter and the delivery system. The working length of the balloon is maximally working length minus the balloon catheter.

5. Insertion of stent and delivery catheter:

- Do not attempt to reposition a partially deployed stent. Attempted repositioning may result in severe vessel damage.
- When increasing a recently inserted stent, care should be taken to assure the stent balloon is placed between the marker bands, not distal towards the stent and the vessel wall. Overinflation of the stent may occur.
- When stents from varying manufacturers are used to complete the stenting procedure, use only stent materials of similar composition.
- Whenever possible, when more than one stent is deployed in sequential order, the more proximal stent should be deployed first.
- Do not use oil-based contrast media, organic solvents or alcohol. There is a possibility of catheter leak, damage, or loss of function.
- Non-clearing latex has demonstrated that the Azule cobalt chromium alloy stent should be inflated under a maximum of 1.0 Bar for 15 minutes of MRI.
- MRI image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the Azule cobalt chromium alloy stent.

6. Use of azule cobalt chromium alloy stent will not prevent the deployment of the stent.

7. If the deployed stent size is still inadequate with reference to the vessel segment, a larger balloon may be used to further expand the stent. If the initial angiographic appearance is sub-optimal, the stent may be further expanded using a low profile, high profile, non-compliant balloon dilatation catheter. Deployed stents should not be left under-dilated. Caution: Do not dilate the stent beyond the following limits.

Nominal Stent Diameter (mm) | Dilatation Limit (mm)
--- | ---
2.75 | 2.0
3.0 | 2.5
3.5 | 3.0
4.0 | 4.5

8. Follow-up angiographic confirmation of complete and adequate stent expansion, remove the guidewire, guiding catheter and introducer sheath using the technique of choice.

9. Discard all disposable devices used during this procedure per local requirements for device waste disposal.

Manufacturer:
OrbusNeich Medical, B.V.
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AZULE™ COBALT CHROMIUM STENT

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REFERENCES

The physician should consult recent literature on current medical practice on coronary stent procedures and balloon dilatation, as well as the practices guidelines published by the European Society of Cardiology, American College of Cardiology, and the American Heart Association.

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EXPLANATION OF SYMBOLS

Description | Symbol
--- | ---
Catalog Number | REF
Lot Number | LOT
Stent Length | BALLOON
Balloon Diameter | STENT
Sterilized Using Ethylene Oxide | STERILE
Use By | EXPIRATION
Do Not Re-use | REUSE
Read Instructions Prior to Use | USE
MR Conditional | 0473
(Static magnetic field strength of 3 Tesla)
Guiding Catheter | Not Related

Contents (numeral represents quantity of units inside)


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