

## **PACLITAXEL COATED CORONARY BALLOON DILATION CATHETER**

### **Description**

Paclitaxel coated coronary balloon dilation catheter is a rapid exchange catheter used for percutaneous coronary intervention (PCI). The distal end of the catheter has a balloon that can be enlarged and two radiopaque markers (proximal and distal), to facilitate the balloon positioning under X-ray fluoroscopy. The balloon surface is coated with 3.0 µg of paclitaxel per 1 mm<sup>2</sup>, and the balloon is inflated to a known diameter and length at recommended inflation pressure (refer to the compliance chart). The proximal end of the catheter has a single female Luer-Lock port to inflate/deflate the balloon. The Paclitaxel coated coronary balloon dilation catheter with a working length of 140 cm and compatible with guide wires of 0.014" (0.36 mm) diameter and guiding catheters with 6F.

### **Intended use**

Paclitaxel coated coronary balloon dilation catheter is applied for dilatation of small diameter coronary artery lesions.

### **Indication**

Paclitaxel coated coronary balloon dilation catheter is indicated for patients with coronary artery stenosis having a reference vascular diameter of 2.0 mm to 2.75 mm undergoing percutaneous coronary intervention (PCI) to increase the coronary lumen diameter.

### **Contraindications**

- Known sensitivity to Paclitaxel.
- Patients who are not candidates for coronary bypass surgery.
- Patients with totally obstructed coronary arteries.
- Patients who exhibit angiographic evidence of existing extensive thrombus.
- Patients with contraindication for anti-platelet/anticoagulant therapy, including allergy. This includes patients who have had major surgery, an obstetrical delivery, organ biopsy, or puncture of a non-compressible vessel within 14 days of this procedure. Also excluded are those patients with a history of gastrointestinal bleeding, recent C.V.A., diabetic hemorrhagic retinopathy, of any other condition compromised by prolonged anti-coagulation.
- Pregnant women or women of childbearing potential.

Lesions that cannot undergo adequate pre-dilation, such as severe fibrotic or calcified lesions.

- Resistant (fibrotic or calcific) lesions, which cannot be pre-dilated.

### **Warning**

- Check that the sterile pouch is not damaged before use.
- Paclitaxel coated coronary balloon dilation catheter is for single use only, do not be cleaned, disinfected, re-sterilized or re-use, destroy product after use.
- Paclitaxel coated coronary balloon dilation catheter cannot be reused or overlapped at the same lesion site.
- Touching of the balloon or contact with liquids prior to insertion should be strictly avoided, as this could damage the balloon coating.

- A pre-dilation with a conventional balloon in complex lesions is recommended.
- For patients only used Paclitaxel coated coronary balloon dilation catheter, the recommended treatment duration for dual antiplatelet therapy is 3 months.
- Connect only Luer lock fitting to the hub of the Paclitaxel coated coronary balloon dilation catheter.
- Should unusual resistance be met at any time during lesion access, must remove both balloon catheter and guiding catheter as a single unit.
- When the balloon catheter is exposed to the vasculature, it should be manipulated while under high-quality fluoroscopic observation.
- To reduce the potential for damage in coronary vessels and to avoid any balloon rupture, the balloon pressure should not exceed the rated burst pressure.
- Do not use if the hydrophilic coating is shedding.
- Do not soak or wipe the product with liquids containing organic solvents such as alcohol (which may cause hydrophilic coating detachment and affect lubrication performance).

#### **Precautions for use**

- The cardiology team must be sufficiently familiar with the products and their reference systems to avoid errors in the selection of equipment.
- Only physicians who have received appropriate training should use the device.
- Ensure that the medical team is trained on products and their reference system to avoid any error in choosing equipment.
- After use, eliminate the product according to safety requirements related to the products contaminated by blood.

#### **Potential Adverse Effects / Complications**

- Complications that may result from this procedure include :
- Possible allergic reactions to Paclitaxel or iodophorol.
- Acute myocardial infarction or unstable angina pectoris
- Disturbance of cardiac conductivity
- Arrhythmia
- Ventricular fibrillation
- Atrial Fibrillation
- Cardiac Arrest
- Cardiogenic Shock
- Heart Failure
- Emergency cardiac surgery
- Cardiac perforation
- Pericardial effusion/cardiac tamponade
- Injury or rupture of the coronary artery
- Coronary spasm;
- Coronary embolism
- Air embolism
- Coronary thrombosis
- Dissection of the coronary artery

- Aneurysm formation
- Vessel recoil and restenosis
- Latrogenic arteriovenous fistula formation
- Bleeding complications or haematoma
- Resulting from possible injuries of the vascular wall
- Schemia/Ischemia Stroke
- Dyspnea/Respiratory Arrest
- Chest Pain
- Soft tissue injury
- Local inflammatory reactions
- Sepsis/infection
- Hypotension/Hypertension
- Kidney or Urinary Problem
- Acute exacerbation of chronic obstructive pulmonary disease
- Revascularization
- Death

Balloon catheter events:

- Failure to reach or cross lesion
- Inflation difficulties
- Balloon rupture or pinholes
- Balloon deflation difficulties

### **Operation Instructions**

#### **Choice of the Paclitaxel coated coronary balloon dilation catheter:**

The balloon diameter, when the balloon has been inflated to its nominal pressure should not be larger than the artery proximal and distal to the stenosis.

#### **Catheter preparation**

Prior to using the Paclitaxel coated coronary balloon dilation catheter from the package, inspect for bends, kinks, and other damage. Do not use if any defects are noted.

Prepare the inflation device according to the manufacturer's instructions.

- Do not let the balloon come into contact with fluids prior to insertion.
- Do not allow the balloon to come into contact with the skin.
- Fill a 10 or 20 cc syringe with sterile saline solution.
- Remove the protection sheet and wire from the balloon of the catheter and discard them.
- Prepare a diluted solution of contrast medium and sterile saline solution, in accordance with the contrast medium manufacturer's instructions.
- Fill a 10 or 20 cc luer lock syringe with 1 to 3 cc of the diluted 1:1 contrast medium.
- Connect a stopcock to the hub of the Paclitaxel coated coronary balloon dilation catheter.
- Connect the syringe to the stopcock, Position the syringe vertically with the plunger pointing upwards. Apply strong suction with the syringe to evacuate all air from the balloon.
- Maintain the suction for 15 to 20 seconds and make sure that no more bubbles are seen passing through the diluted contrast medium. Release the plunger carefully and, if necessary, repeat the procedure, in case of residual bubbles.

- Maintain the vacuum in the Paclitaxel coated coronary balloon dilation catheter and close the stopcock.

### **Catheter manipulation**

Attach the “Y” connector to the guiding catheter, which has been previously placed in the vasculature. The choice of the guide wire and the “Y” connector remains the responsibility of the physician within a compatibility limit of 0.014" for the guide wire.

Insert the guide wire (0.014" max.) into the guiding catheter and advance it through the tip.

To avoid any movement of the guide wire, tighten the knob of the “Y” connector so that it closes firmly around the guide wire.

Back load the guide wire into the distal tip of the catheter ensuring that it exits through the notch located approx.

Open the valve and advance the catheter to the distal end of the guiding catheter. Caution: Always advance the catheter fully deflated and always on the guide wire. Continue the procedure according to accepted coronary angioplasty technique. The radiopaque markers aid the positioning of the balloon in the stenosis.

### **Balloon dilatation and Paclitaxel release**

To ensure an effective release of Paclitaxel to the lesion site of the artery wall, the balloon should be inflated at the lesion with an effective balloon dilatation pressure between the nominal balloon inflation pressure up to the rated burst pressure, for the duration of at least 30-60 seconds. Do not exceed the rated burst pressure!

### **Catheter exchange procedure**

Loosen the “Y” connector.

Hold the guide wire and the “Y” connector in one hand, while grasping the catheter balloon shaft in the other hand.

Maintain the guide wire’s position in the coronary artery by holding the wire stationary and begin pulling the dilatation catheter out of the guiding catheter.

### **Packaging**

Delivered in a peelable pouch and cardboard box.

One unit per box . Sterilized with Ethylene Oxide Gas.

Do not use if the package is opened or damaged. Use before the expiry date clearly indicated on the label.

### **Transportation and storage**

- During transportation, this product should be protected from moisture, direct sunlight, rain exposure, high temperatures, heavy pressure, and impact.
- Store at 0°C–30°C.
- Use the catheter before the 'expiration date' indicated on the packaging label.
- Do not use this catheter if the packaging is opened or damaged.
- Do not expose the catheter to organic solvents.

## Sterilization

This product is a single-use sterile product sterilized by ethylene oxide.

## Shelf life

The product has a shelf life of two years under conditions that comply with storage requirements.

## Date of manufacture and use-by date

See label

## SUPPLEMENTARY INFORMATION







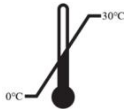









The Summary of Safety and Clinical Performance (SSCP) of this device is available in the European database on medical devices (Eudamed) by searching the basic UDI-DI "XXXXXXXXXXXXXXXXXX " at: <https://ec.europa.eu/tools/eudamed>.

Basic UDI-DI:XXXXXXXXXXXXXXXXXX

The following patients material is available for this product:

Online patient information guide: <http://www.ydbmed.com>

## Explanation of symbols used on the package labels

	Sterilized using ethylene oxide		Do not re-use		Do not re-sterilize
	Keep dry		Keep away from sunlight		Protect from heat and radioactive sources
	Temperature limit		Date of manufacture		Use-by Date
	Batch code		Catalogue number		Do not use if package is damaged and consult instructions for use
	Consult instructions for use		Caution		Manufacturer
	Authorized representative in the European Community/ The Netherlands				

Appendix 1: Product specification table

Balloon diameter(mm)	Balloon length(mm)			
	15	20	25	30
2	YYQ-20015	YYQ-20020	YYQ-20025	YYQ-20030
2.25	YYQ-22515	YYQ-22520	YYQ-22525	YYQ-22530
2.5	YYQ-25015	YYQ-25020	YYQ-25025	YYQ-25030
2.75	YYQ-27515	YYQ-27520	YYQ-27525	YYQ-27530

Appendix 2: Balloon compliance table

Pressure		Balloon diameter					
atm	kPa	1.5mm	1.75mm	2.0mm	2.25mm	2.5mm	2.75mm
4	405	1.46	1.70	1.94	2.18	2.42	2.70
6	507	1.50	1.75	2.00	2.25	2.50	2.75
8	811	1.56	1.81	2.06	2.31	2.56	2.79
10	1013	1.62	1.87	2.12	2.37	2.62	2.84
12	1216	1.67	1.93	2.18	2.44	2.70	2.88
14	1419	1.70	1.97	2.22	2.5	2.78	2.93
16	1621	1.74	2.01	2.26	2.54	2.82	2.98



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