Europa ultra™ FAMILY

Information for Users

ENGLISH

DEVICE NAME

EUROPA ULTRA™ Family Coronary Balloon Catheters by Rontis The generic name of the device is a Rapid Exchange or/and O(Over The Wire) type Percutaneous Translummal Coronary Angioplasty Dilatation Catheter.

The Europa family includes the following types:

- Europa Ultra™ -Semi Comliant Coronary Balloon Catheter-0,014"
- Europa Ultra CTO™ - Chronic Total Occlusion Coronary Balloon Catheter
- Europa Ultra NC™ - Non-Compliant Coronary Balloon Catheter

The Europa Ultra™ Family catheters are intended to dilate the obstructed (stenotic) arteries in the coronary vessel system.

The Europa Ultra CTO™ Catheter is especially used in the application of the extreme obstructed vessels dilation, where the blood stream is totally occluded (Total occlusions) and where the blood stream is blogged fully without flow for more than 3 months "Chronic Total Occlusion (CTO) case".

The Europa Ultra NC™ Catheter is used for post stent dilatation or in heavily calcified lesions where high pressure required without over expansion of the vessel. The balloon behaves between the Nominal pressure and the rated burst pressure point as Non-Compliant.

DESCRIPTION

The EUROPA ULTRA™ Family Percutaneous Transluminal Coronary Angioplasty (PTCA) Dilatation Catheter, from Rontis, is a rapid exchange or/and OTW (Over The Wire) type catheter with a balloon located near the distal tip. The distal section of the catheter is dual lumen and coaxial. The outer lumen is used for inflation of the balloon and the inner lumen permits the use of guide wires (< 0,014" or 0.36 mm) to facilitate advancement of the catheter to and through a stenosis that is to be dilated. For the rapid exchange type the proximal section of the catheter is a single lumen, stainless steel hypotube with a single luer port for inflation / deflation of the balloon. Proximal visual markers located approximately 90cm and 100cm from the distal tip aid catheter positioning without fluoroscopy assistance. The balloon is designed to provide an inflatable segment of known diameter and length at recommend pressures.

A balloon protector is placed over the balloon to maintain a low profile and a mandrel is placed into the lumen to protect the patency. The catheter includes a tapered and rounded tip to facilitate advancement of the catheter to and through a stenosis. In addition, a hydrophilic coating is applied from the distal tip to the guide wire port for increased lubricity.

INDICATIONS

The EUROPA ULTRA™ Family PTCA Dilatation Catheters are intended for use in the treatment of patients with clinical symptoms of myocardial ischemia related to the pathological condition of one or more coronary arteries. EUROPA ULTRA™ balloon catheters are therefore indicated to dilate diseased segment(s) in coronary arteries or coronary bypass graft stenoses, thereby improving myocardial perfusion.

EUROPA ULTRA™ balloon dilatation catheters (models 2.25mm - 4.0mm diameter) are also indicated for post-delivery expansion of balloon expandable stents.

The patients should fulfill one or more of the following criteria:

- Patients must be judged to be acceptable candidates for coronary bypass graft surgery.
- Patients with single vessel atherosclerotic lesion(s), non calcified, subtotal and accessible to dilatation with guide wire and catheter.
- Certain multi-vessel diseased patients may also be candidates for this procedure.
- Certain patients, who have undergone previous coronary bypass graft surgery with recurrence of symptoms and progression of the disease in the coronary artery, or stenosis and closure of the grafts, may also be candidates.

NOTE: Bench testing was conducted with EUROPA ULTRA™ Family PTCA Dilatation Catheters and other marketed balloon expandable stents. Consideration should be taken when this device is used with different manufacturers' stents due to differences in stent design.

CONTRAINDICATIONS

- Coronary artery spasm in the absence of a significant stenosis
- Severe stenosis of the unprotected left main coronary artery
- Patients who are judged not to be candidates for coronary artery bypass surgery
- Diffuse, multiple and calcified lesions
- Arterial spasm
- Possible or confirmed presence of thrombus inside the target vessel lumen
- Patients presenting cardiogenic shock antecedent
- Patients presenting renal malfunctions or nephropathies
- Lesions in the left main trunk for which no compensation of blood flow by pass or collateral circulation is available. Failure to observe this warning could result in acute coronary occlusion.

WARNINGS

- For single patient use only. Do NOT reuse, reprocess or re sterilize.Reuse, reprocessing or re-sterilization may compromise the structural integrity of the device and l or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or re- sterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious

disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
- Do not use the catheter if its package has been opened or damaged.
- After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.
- To reduce the potential for vessel damage the inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis.
- PTCA in patients who are not acceptable candidates for coronary artery bypass graft surgery requires careful consideration, including possible hemodynamic support during PTCA, as treatment of this patient population carries special risk.
- The PTCA in patients presenting with complex chronic total occlusions where there might be a requirement for the use of larger volumes of contrast media it is advised that operator be aware of the adverse effects relating to the use of contrast media.
- The PTCA of CTO cases is very important decision. The complexity.considerable variety of unsettled issues makes the revascularization procedure unapproachable with lower rates of procedural success. Based on advanced training of interventional cardiologist and under the guidance of proctors, must weigh the individual risk and benefits for each patient when deciding to attempt PCI of a CTO vs two other alternatives: aortocoronary bypass or medical therapy. Clinical, angiographic, and technical considerations must be considered in combination to decide the technique of approach.
- The use of Europa Ultra™ family PTCAcoronary balloon catheters for CTO cases might require longer procedure times due to the complexity and therefore longer fluoroscopy times it is advised that operators be aware of the associated complications and risks.
- When the catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum as this can potentially result in damage to the vessel wall. If resistance is met during manipulation, determine the cause of the resistance before proceeding.
- Do not exceed the rated balloon burst pressure. The rated burst pressure is based on the results of in vitro testing. At least 99.9 percent of the balloons (with a 95 percent confidence) will not burst at or below their rated burst pressure. Use of a pressure monitoring device is recommended to prevent over pressurization.
- Do not soak the catheter in sterilizing alcohol or drug solutions containing organic solvents, or wipe the catheter with drugs. Failure to observe this warning could damage or break the catheter or cause loss of lubricity.
- PTCA should only be performed at hospitals where emergency coronary artery bypass graft surgery can be quickly performed in the event of a potentially injurious or life-threatening complication.
- Use only the recommended balloon inflation medium.
- To prevent the possibility of an air embolus, never use air or any gaseous medium to inflate the balloon.
- Use the catheter prior to the Expiration Date specified on the package.

PRECAUTIONS

- These devices should be used only by physicians trained in PTCA and stent implantations. It is recom-mended to the physician to consult current peer-reviewed publications on the interventional cardiology techniques.
- Prior to angioplasty, the catheter should be examined to verify functionality and to ensure that its size and shape are suitable for the specific procedure for which it is to be used.
- Inspect the balloon prior to use for any kinks, curves or potential catheter damage, which could alter the catheters performances (see procedure for preparing the EUROPA ULTRA™ as specified below).
- The catheter system should be used only by physicians trained in the performance of Percutaneous Transluminal Coronary Angioplasty.
- Appropriate anticoagulation, antiplatelet and vasodilator therapy should be administered to the patient.
- When using two guide wires, care should be taken when introducing, applying torque and removing one or both guide wires to avoid entanglement. It is recommended that one guide wire be completely withdrawn from the patient before removing any additional equipment.
- Care should be taken to control the position of guide catheter tip during manipulation of the balloon catheter.
- Caution should be taken not to over tighten a haemostatic adapter around the dilatation catheter shaft as lumen constriction may occur, affecting inflation/ deflation of the balloon.
- When loading or exchanging the balloon catheter, it is recommended to thoroughly wipe the guide wire clean for better balloon catheter movement on the wire.

ADVERSE EFFECTS

Possible adverse effects include, but are not limited to, the following:
- death
- acute myocardial infarction
- total occlusion of the coronary artery or bypass graft
- coronary vessel dissection, perforation, rupture or injury
- re-stenosis of the dilated vessel
- hemorrhage or hematoma
- angina or unstable angina
- arrhythmias, including ventricular fibrillation
- drug reactions, allergic reaction to contrast medium
- hypo/hypertension
- infection
- coronary artery spasm arterio-venous fistula embolism
- stroke
- cardiovascular accident
- transient ischemic attack myocardial ischemia
- pseudoanyreusm (at site of catheter insertion)
- cardiac tamponade / pericardia! effusion
- renal failure
- coronary aneurysm
- vessel trauma requiring surgical repair or intervention
- cardiogenic shock
- coronary artery bypass graft surgery

INSTRUCTIONS FOR USE

a. Material Required for PTCA with the Europa Ultra™ Family Coronary Balloon Catheters

Suitable guide wire, refer to label claim for advancement of guiding

catheter
- Arterial sheath and dilator set (for femoral approach only)
- Suitable femoral or brachia! guiding catheters in the appropriate size and configuration to select the coronary artery, refer to label claim
- Appropriate inflation medium (e.g. 50:50 sterile mixture of a contrast medium and saline)
- Inflation device with manometer
- 20cc syringe for balloon preparation
- 10cc or smaller syringe for manual dye injections
- Haemostatic valve

Prior to angioplasty, carefully examine all equipment to be used during the procedure, including the dilatation catheter, to verify proper function. Verify that the catheter and sterile packaging have not been damaged in shipment and that the catheter size is suitable for the specific procedure for which it is intended.
To verify the integrity, it is necessary during preliminary inflations tests to make sure that all the air is eliminated and that there is no leakage through any of the different connections (see procedure for preparing EUROPA ULTRA™ specified below).

b. Choice of EUROPA ULTRA™ Coronary Balloon Catheter
The inflation diameter of the balloon must not exceed the diameter of the coronary artery proximal and distal to the stenosis. If the stenosis cannot be crossed with the desired dilatation catheter, use a smaller diameter catheter to pre-dilate the lesion to facilitate passage of a more appropriate sized dilatation catheter.

c. Inflation Device Preparation
- Prepare the inflation device according to the manufacturer's instructions.
- Purge the system of air.

Preparation and Use of EUROPA ULTRA™ Coronary Balloon Catheter
a. Preparation
- Remove the catheter from the protective hoop.
- Remove the balloon protector and mandrel by grasping the balloon catheter just proximal to the balloon, and with the other hand, gently grasp the proximal section of the balloon protector and slide distally. If unusual resistance is felt during the product mandrel and/or balloon protector removal, do not use this product and replace with another. Follow product returns procedure for unused product.

b. Balloon Purging
Purge air from the catheter using a 20cc syringe filled with 2 to 3 ml of the inflation medium with the balloon catheter pointing downward. Use only appropriate balloon inflation medium (e.g., the equivalent of a 50:50 mixture of contrast medium and sterile normal saline). Do not use air or any gaseous medium to inflate the balloon.
- Connect a three-way stopcock to the port fitting on the EUROPA ULTRA™ Balloon catheter. Flush through the stopcock.
- Connect the syringe to the stopcock.
- Hold the syringe with the nozzle pointing downward and aspirate for 5 seconds. Release the plunger.
- Remove the syringe and evacuate all air from the barrel.
- Reconnect the syringe and aspirate until bubbles no longer appear during aspiration. If air bubbles persist, remove catheter from hoop and inflate the balloon to verify that there are no leaks present prior to insertion.
- Carefully insert the luer needle into the distal tip of the balloon catheter. Flush the wire lumen with sterile saline. Remove the needle from the distal tip. Do not discard the luer needle until the end of the procedure, as additional flushing may be required.

c. Inflation Device Connection
- To remove any air lodged in the distal luer fitting of the inflation device, purge approximately 1 ml (cc) of contrast medium.
- Applying positive pressure to the balloon, disconnect the syringe used in preparation. A meniscus will appear in the balloon port when the syringe is removed. Verify that a meniscus of contrast medium is evident in both the dilatation catheter balloon port and the inflation device connection. Securely couple the inflation device to the balloon port of the balloon dilatation catheter.
- Do not attempt pre-inflation technique to purge the balloon lumen

d. Insertion Technique of EUROPA ULTRA™ Balloon Catheter
- The coaxial distal portion of the EUROPA ULTRA™ is covered with a hydrophilic coating. Immerse the distal part of the catheter in a sterile saline solution before use. Do no reinsert in dispenser.
- Place the guiding catheter, with a haemostatic valve attached, in the orifice of the target coronary artery.
- Insert a guide wire through the haemostatic valve following the manufacturer's instructions or standard practice. Advance the guide wire carefully into the guiding catheter. When complete, withdraw the guide wire introducer, if used.
- Attach a torque device to the wire, if desired. Under fluoroscopy, advance the guide wire to the desired vessel, then across the stenosis.
- Advance the distal tip of the balloon catheter over the proximal end of the guide wire. Ensure that the guide wire exits the balloon catheter through the guide wire exit location.

NOTE: To avoid kinking, advance the dilatation catheter slowly, in small increments until the proximal end of the guide wire emerges from the catheter.
- Advance the catheter through the haemostatic valve slowly, while the balloon is fully deflated. If resistance is encountered, do not advance the dilatation catheter through the adapter. Caution should be taken not to over tighten the haemostatic adapter around the dilatation catheter shaft as lumen constriction may occur, affecting inflation / deflation of the balloon.
- Thoroughly aspirate and flush the guiding catheter in preparation for introduction of the dilatation catheter.
- Connect the side port of the guiding catheter haemostatic adapter to the proximal pressure recording / infusion line or manifold assembly, which permits proximal pressure recording or infusion through the guiding catheter.

e. EUROPA ULTRA™ Balloon Catheter Inflation
- Inflate the balloon to dilate the lesion using standard PTCA techniques.
- After each subsequent inflation the distal blood flow should be assessed.
- If a significant stenosis persists, successive inflations may be required to resolve the stenosis. Do not exceed the rated burst pressure (see labeling).

f. Removing the EUROPA ULTRA™ Balloon Catheter

- Apply negative pressure to the inflation device and confirm that the balloon is fully deflated.
- Withdraw the balloon catheter into the guiding catheter while preserving guide wire position.
- After the deflated balloon dilatation catheter is withdrawn, it should be wiped clean with gauze soaked with sterile normal saline.
- Inspect the balloon catheter integrity
- If reinserting the same balloon dilatation catheter, flush the guide wire lumen of the balloon dilatation catheter using the flushing needle as described in Directions for Use.
- Prior to reinsertion, the balloon dilatation catheter should be wiped clean with gauze soaked with sterile normal saline.

NOTE: It is recommended that the guide wire and/or the balloon catheter remain across the lesion until the procedure is complete.
Contrast media have different viscosities and may affect the inflation/deflation time.

g. EUROPA ULTRA™ Balloon Catheter Exchange Procedure

Rontis brand of rapid exchange EUROPA ULTRA™ catheters have been specifically designed for rapid, single operator balloon exchanges.
To perform a catheter exchange:

- Loosen the knurled knob on the haemostatic valve
- Hold the wire and haemostatic valve in one hand, while grasping the balloon shaft in the other hand
- Maintain the guide wire position in the coronary artery by holding the wire stationary, and begin pulling the dilatation catheter out of the guiding catheter while monitoring the wire position underfluoroscopy.
- Withdraw the deflated catheter until the opening in the guide wire lumen Is reached. Carefully inch the flexible, distal portion of the balloon catheter of the guide wire while maintaining guide wire position across the lesion.
- Close the knurled knob on the haemostatic valve.
- Slide the distal tip of the catheter out of the haemostatic valve and tighten the knurled knob onto the wire to hold it securely in place. Completely remove the balloon from the wire.
- Prepare the next balloon catheter to be used as previously described. Backload the new catheter onto the guide wire as previously described under the "EUROPA ULTRA™ Coronary Balloon Catheter Preparation and use", and continue the procedure accordingly.

STORAGE REQUIREMENTS

Use before the expiry date indicated on the label.
Store at room temperature between 5-40°C, in a dry place, protected from light.
Non Pyrogenic
Contents supplied STERILE using an ethylene oxide (EtO) process.

LIABILITY

The product and each component of its system have been designed, manufactured, tested and packaged with all reasonable care. The warnings contained in Rontis' instructions for use are expressly to be considered as an integral part of this provision. Rontis warranties the prod ct until the expiry date indicated on the same. The warranty is valid provided that the use of the product was consistent with the instructions for use. Rontis disclaims any warranty of merchantability or fitness for a pa icula p rpose of the product. Rontis is not liable for any direct, indirect, 1nc1dental or consequential damages caused by the product. Except in the case of fraud or grave fault on the Rontis part, compensation of any damage to the buyer will not, in any event, be greater than the invoice price of the disputed products. The guarantee contained in this provision incorporates and substitutes the legal guaranties for defects and compliance, and excludes any other possible liability of Rontis, however originating, from his product supplied. These limitations of liability and warranty are not intended to contravene any mandatory provisions of law applicable. If any clause of the disclaimer is considered by a competent court t be invalid or to be in conflict with the applicable law, the remaining part of It shall not be affected and remain in full force and effect. The invalid clause shall be substituted by a valid clause which best reflects Rontis' legitimate interest in limiting its liability or warranty. No person has any authority to bind Rontis' to any warranty or liability regarding the product.

COMPLIANCE

Typical EUROPA ULTRA™ Balloon Catheter Compliance Chart
Nominal Pressure:

- Europa Ultra™: 8 bar
- Europa Ultra CTO™ Rx/OTW: 8 bar
- Europa Ultra NC™: 10 bar

Rated Burst Pressure recommendation (RBP):

- Europa Ultra™: 16 bar
- Europa Ultra CTO™ Rx/OTW: 18 bar
- Europa Ultra NC™: 20 bar (Ø2.0mm-4.0mm), 18 bar (Ø4.5mm-5.0mm)

PACKAGING

Delivered in a peelable pouch and cardboard box. One unit per box.
Balloon: diameters are available from Ø1.00 mm to Ø5.00 mm and Lengths from 08mm to 30mm.

CONVERSION CHART

1cc	1mL		
1French	0,0130''	0,33 mm	
1bar	0,987 atm	14,5 PSI	10^5 Pa

GRAPHICAL SYMBOLS FOR MEDICAL DEVICE LABELLING

 Do not reuse	 Use by	 Batch code
 Date of manufacture	 Sterilized using ethylene oxide	 Catalogue number
 Temperature limitation	 Consult instruction foruse	 Keep away from sunlight
 Keep dry	 Do not use if package is damaged	1x Single unit per box
 Do NOT Re-sterilize	 Legal Manufacturer	 Attention, see instructions for use
EC REP EC representative		