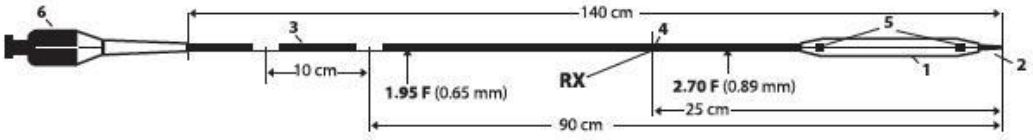
Yangtze® NC

NON-COMPLIANT PTCA RAPID EXCHANGE DILATATION CATHETER

STERILE. SINGLE USE ONLY. Sterilized with ethylene oxide gas. Non pyrogenic. Do not resterilize. Do not use opened or damaged packages. Destroy product after use. After use, eliminate the product according to safety requirements related to product contaminated by blood. Store in a dry place below 40° C, keep away from light.
These instructions apply to all balloon diameters and lengths.
CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE. FAILURE TO OBSERVE ALL WARNINGS AND PRECAUTIONS MAY RESULT IN COMPLICATIONS.

1. Description



The **Yangtze NC** Percutaneous Transluminal Coronary Angioplasty (PTCA) Rapid Exchange (RX) non-compliant dilatation balloon catheter is composed of a proximal single-lumen hypotube shaft (3), a dual-lumen distal shaft and a non-compliant balloon (1) at the distal tip (2). The hypotube shaft has a Luer-lock connector (hub) for balloon inflation at its proximal end. The lumen of the distal shaft is dedicated to guide wire passage while the other, which continues all through the proximal shaft until the hub (6), allows for the inflation of the balloon as well as accommodating the hypotube transition construction for an optimal push-torque transmission through the full catheter length. The guide wire lumen permits the use of guide wires to facilitate advancement of the catheter to and through the stenosis to be dilated. The guide wire access port is located at the tip of the catheter while the exit port is located at 25 cm from the tip (rapid exchange) (4). Catheter length is 140 cm. Maximum guide wire diameter is 0.014" (0.36 mm). The minimum guiding catheter inner diameter is 5F (1.67 mm/ 0.0657").
The balloon is designed to reach specific diameters at specific pressures (see compliance table on the label). The balloon has two radiopaque markers (5) to aid in positioning the balloon relative to the stenosis. The radiopaque marker bands indicate the dilating section of the balloon.
The catheter includes a smooth, soft and tapered atraumatic tip to facilitate advancement of the catheter through the stenosis. A hydrophilic coating is present on the distal shaft in order to facilitate catheter advancing through the vascular district and the vessels stenosis.
The proximal shaft is made of a stainless steel hypotube. Proximal visual markers located approximately 90 cm and 100 cm from the distal tip aid catheter positioning without fluoroscopy assistance.
The **Yangtze NC** PTCA RX Dilatation Catheter is available in different balloon sizes. Nominal balloon diameter and length are printed on the hub and on the label.

2. Indications

The **Yangtze NC** PTCA RX Dilatation Catheter is 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. The **YANGTZE NC** PTCA catheter is therefore indicated to dilate the diseased segment(s) in a coronary artery or a coronary bypass, to improve myocardial perfusion. The **Yangtze NC** PTCA RX Dilatation Catheter is also indicated for balloon dilatation of a stent after implantation.

08020047 Rev.2012-12

3. Warnings

- PTCA procedures should only be performed in hospitals where emergency coronary artery bypass graft surgery can be immediately performed in the event of potentially injurious or life threatening complications.
- These devices should be used only by physicians trained in PTCA and stent implantations. It is recommended to the physician to consult current peer-reviewed publications on the interventional cardiology techniques.
- Ensure that the medical team is trained on the products and their reference system to avoid any error in choosing equipment.
- PTCA in patients who are not acceptable candidates for coronary artery bypass graft surgery requires careful consideration, including possible hemodynamic support during the procedure, as treatment of this patient population carries special risk.
- The **YANGTZE NC** PTCA catheter must be used in patients who have been exclusively appropriately prepared with an anti-coagulant or anti-platelet therapy.
- Since the use of this device carries the associated risk of sub-acute thrombosis, vascular complications and/or bleeding events, judicious patient selection is necessary.

4. Precautions for use

- The **YANGTZE NC** PTCA catheter is supplied sterile and is designed and intended for single use. Check that the sterile pouch is not damaged before use. In case of re-use, device sterility shall be lost and performances altered. Do not resterilize or re-use, as this can potentially result in compromised device performance and increase risk of complications (patient infection, transmission of infectious disease, etc…). Destroy product after use. Use the product before the expiry date clearly shown on the packaging.
- Do not use the device if damaged or if the outer or the inner package is damaged or opened.
- Inspect the catheter prior to use for any kinks, curves or potential catheter damage, which could alter catheters performances (see procedure for preparing the **YANGTZE NC** as specified below).
- Do not use, or try to straighten a bent or kinked catheter: not following these instructions could result in the shaft rupture. In case of defective product, use another catheter.
- Precautions to prevent or reduce clotting should be taken when any catheter is used. Flush or rinse all products entering the vascular system with sterile isotonic saline or a similar solution via the guide-wire access port prior to use. Consider the use of systemic heparinization.
- Do not expose the catheter to ionizing radiation or ultraviolet light, organic solvents, e.g. alcohol.
- Use only diluted contrast medium to inflate the balloon. Do not use air or any gaseous medium.
- The size of the inflated balloon should be selected not to exceed the diameter of the artery immediately distal or proximal to the stenosis.
- Connect only 6% Luer lock fitting to the catheter hub.
- The catheter must always be introduced, moved and or withdrawn over a guide wire 0.014” (0.36mm).
- Never advance the catheter without the guide wire extending from the tip.
- Immediately before the insertion of the balloon catheter, it is recommended to wet the distal shaft with a sterile saline solution in order to activate the hydrophilic coating.
- When the PTCA catheter is exposed to the vasculature, it should be manipulated while under high-quality fluoroscopic observation.
- Do not advance the catheter against significant resistance. The cause of resistance should be determined via fluoroscopy and remedial action taken before proceeding.
- To reduce the potential for damage in coronary vessels and to avoid any balloon rupture, the balloon inflation pressure should not exceed the rated burst pressure (RBP; see labeling).
- Inflation of the balloon should be monitored by a manometer system to prevent over pressurization.
- Never attempt to move the guide wire when the balloon is inflated.
- Prior to withdrawing the balloon catheter from the lesion, the balloon must be completely deflated under vacuum. If resistance is met during manipulation, determine the cause of the resistance before proceeding.

- Catheters and accessories (hoop, protection tubing and protection wire) should be discarded after one procedure. They are extremely difficult to clean adequately after being exposed to biological materials and may cause adverse patient reactions if reused. Cleaning these products may alter their structural properties.

Accordingly, Minvasys will not be responsible for any direct, incidental or consequential damages resulting from reuse of the catheter.

5. Contra-indications

- Patients who are judged not to be candidates for coronary artery bypass surgery,
- Patients with totally obstructed coronary arteries ,
- Possible or confirmed presence of thrombus inside the target vessel lumen,
- Inability to cross lesion with a guide wire,
- Pregnant women or women of childbearing potential.
- Patients with a contraindication for anti-platelet/anticoagulant therapy. 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.
- Target lesions distal to a 50% or greater stenosis, which cannot be predilated or target lesions proximal to untreatable areas of significant flow compromising disease.
- Resistant (fibrotic or calcific) lesions, which cannot be predilated (lesions resistant to complete balloon inflation below RBP).

6. Adverse events

Possible complications linked to the use of the balloon catheter during the procedure:

- Dissection or perforation of the coronary artery
- Injury or rupture of the coronary artery
- Total occlusion of the coronary artery or bypass graft
- Thrombosis
- Arterial spasm
- Ventricular fibrillation
- Disturbance of cardiac conductibility
- Embolism
- Arteriovenous fistula
- Hypotension, Arrhythmias
- Sepsis, Infection
- Endocarditis
- Ischemia

These complications can directly result in the patient’s death.

Possible complications that could occur following an angioplasty procedure with balloon catheter, on short and medium term:

- Restenosis of the dilated artery
- Unstable angina
- Acute myocardial infarction
- Bleeding complications or haematoma

These complications can directly result in the patient’s death.

Complications related to concomitant medication, e.g.:

- Drug reactions
- Bleeding from anticoagulation/antiplatelet medication
- Allergic reactions to contrast medium

7. Instructions for use

Prior to angioplasty, carefully examine all equipment to be used during the procedure, including the dilatation catheter, to verify proper function. 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 the **YANGTZE NC** specified below). Also verify that the catheter and the sterile inner packaging have not been damaged in shipment and that the catheter size is suitable for the specific procedure for which it is intended.

7.1 Choice of the YANGTZE NC catheter

The expanded diameter of the balloon should not exceed the inner diameter of the artery proximal and distal to the stenosis. Verify that the selected accessories accommodate the balloon catheter as labeled. Prepare the inflation device according to the manufacturer's instructions.

7.2 YANGTZE NC preparation

1. Remove the catheter from the hoop and carefully remove protection tubing and protection wire from the balloon.
2. Attach a needle to a 10 or 20cc syringe filled with sterile saline solution and insert it carefully into the distal tip of the catheter. Flush the guide wire lumen.

All air should be expelled from the balloon and inflation lumen prior to inserting the dilatation catheter. Do not attempt pre-inflation technique to purge the balloon lumen.

3. Connect a stopcock to the connector of the balloon lumen. Flush through stopcock. Connect a syringe, partially filled with contrast medium and sterile normal saline, to the stopcock. Never use air or any gaseous medium to inflate the balloon. Hold the catheter with the distal tip pointing down.
4. Apply negative pressure with the syringe to evacuate all air from the balloon. Maintain the suction for 15 seconds and make sure that no more bubbles are seen passing through the diluted contrast medium. Release the plunger carefully, disconnect the syringe and evacuate the collected air. Reconnect the syringe and repeat this operation a couple of times until the balloon is completely free from air bubbles.
5. Maintain the vacuum in the catheter and close the stopcock. With the stopcock in close position, disconnect the syringe, applying a slight positive pressure.
6. Attach an inflation syringe/device to the stopcock. Ensure that a meniscus of contrast medium is evident in both the balloon port and the inflation device.

7.3 YANGTZE NC manipulation

<u>Introduction of the system</u>

1. The PTCA catheter is designed to be introduced percutaneously using the Seldinger technique.
2. At the time the catheter is ready for introduction into the vascular system, the balloon protection tubing and protection wire should be removed from the catheter.
3. Place the prepared catheter over a prepositioned guidewire and advance the distal tip of the balloon catheter over the proximal end of the guide wire.

Note: Perform all further catheter manipulations under fluoroscopy.

4. Position the catheter with the center of the balloon in the middle of the stenosis. The radiopaque marker bands indicate the stated length of the balloon.

Note: if the stenosis cannot be crossed with the desired catheter, use another catheter with smaller diameter to predilate the lesion and then facilitate the passage.
Note: To avoid kinking, advance the PTCA catheter slowly, in small increments until the balloon reaches the stenosis.
***Caution**: Always advance the* **YANGTZE NC** *fully deflated and always on the guidewire.*

<u>Dilatation of the balloon</u>

5. When an acceptable position has been reached, inflate the balloon at the appropriate pressure to achieve the desired dilatation (refer to the compliance table on the label).

Caution: Never attempt to move the guide wire when the balloon is inflated.

Caution: Do not exceed rated burst pressure (RBP). Higher pressures may damage the balloon or catheter or the artery.

6. Deflate the balloon by aspiration using the inflation syringe/device.
7. Maintaining the balloon deflated, withdraw the catheter into the guiding catheter while preserving guide wire position.
8. The results should be checked by angiography.

8. YANGTZE NC Compliance chart, Inflation pressure, Sterilization and Storage conditions

Refer to labeling.
Balloon compliance is measured at 37.5° C (In vitro Compliance).
The Balloon Nominal Pressure (**NP**) and Rated Burst Pressure (**RBP**) are indicated on the label affixed on both the inner package and the packaging box.
Do not exceed the RBP recommendation.

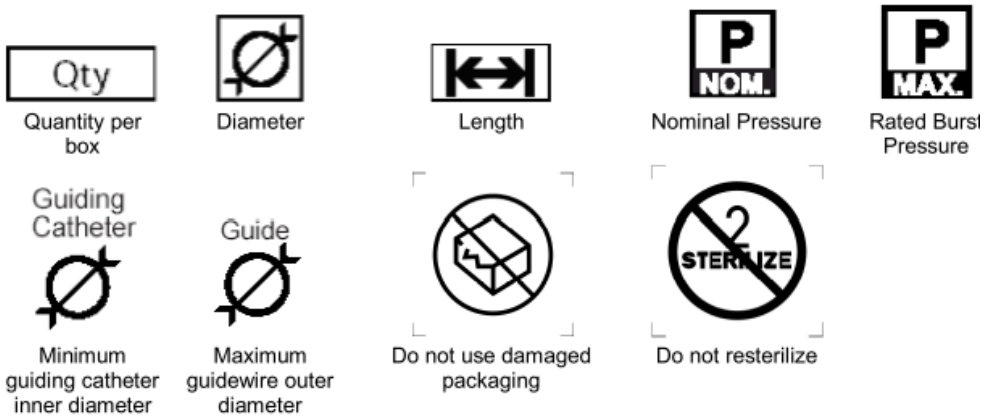
9. Liability

Minvasys has endeavored to ensure that the products comply with all relevant standards and regulations currently in force and to ensure that the quality of the products meets the requirements of the above mentioned standards and regulations for a period ending upon the indicated expiry date. The above statement does not apply where the products are used for a purpose other than its intended purpose. Where any loss or damage is caused (other than death or personal injury) due to a defective product, Minvasys shall not be liable for such loss or damage.

10. Conversion Chart

1 cc	1 mL		
1 French	0.0131”	0.33 mm	
1 bar	1.02 atm	14.5 PSI	10^5 Pa

11. Symbols



CE 0459 Year CE marking obtained: 2013

7, rue du Fossé Blanc
92230 Gennevilliers – France
Tel: +33 (0)1 47 90 70 30
Fax: +33 (0)1 47 91 05 85
www.minvasys.com