



1. Description

The **Yangtze® μ sb** is a rapid exchange Percutaneous Transluminal Coronary Angioplasty (PTCA) catheter with a balloon located at the distal tip. The balloon features a long proximal cone in order to prevent an over-dilatation of the artery proximal to the carina in case of simultaneous inflation (kissing) in bifurcation lesions in conjunction with a PTCA catheter placed in the main branch.

The distal shaft comprises two lumens, one is used for inflation of the balloon and the other permits the use of a guide wire (0.014" max.) to enable advancement of the catheter to and through the stenosis. The balloon has two radio-opaque markers proximal and distal, to aid the balloon positioning under fluoroscopy. The balloon material provides an expandable segment of known diameter at specific pressure.

The rapid exchange part of the **Yangtze® μ sb** is covered with a hydrophilic coating. The balloon provides an expandable segment of known diameter at specific pressure. 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.

2. Indications

The **Yangtze® μ sb** is intended for use in the treatment of patients with clinical symptoms of myocardial ischemia related to the coronary artery disease located in the coronary bifurcations, excluding left main trunk, with the intention to treat the side branch.

3. Warning

- 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.
- Only physicians trained in PTCA should use this device. The physician should 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 haemodynamic support during the procedure, as treatment of this patient population carries special risk.
- Appropriate anticoagulant and vasodilator therapy should be administered before insertion of the catheter.

4. Precautions for use

- The **Yangtze® μ sb** is designed and intended for single use. In case of re-use, device sterility shall be lost and performances altered. Do not resterilise or reuse it. Use prior to "use before" date noted on the packaging. Do not use opened or damaged packages.
- When the **Yangtze® μ sb** is exposed to the vasculature, it should be manipulated while under high-quality fluoroscopic observation.
- If resistance is met during manipulation, determine the cause of the resistance before proceeding.
- Inspect the **Yangtze® μ sb** entirely prior to use for any kinks, curves or potential catheters damage, which could alter its performances.

- Do not attempt to inflate the balloon before it is correctly positioned at the level of the lesion to treat.
- Do not attempt to reposition a fully or partially inflated balloon. Attempting repositioning may result in severe vessel damage.
- Do not use, or try to straighten bent or kinked catheters; not following these instructions could result in the shaft rupture. In case of defective product, use another **Yangtze® μ sb.**
- Balloon pressure should be monitored via a manometer during inflation. To reduce the potential vessel damage and the burst of the balloon, the balloon inflation pressure should not exceed the rated burst pressure (RBP).
- Use only diluted contrast medium to inflate the balloon. Do not use air or any gaseous medium.
- In a bifurcation lesion, if the main branch vessel has been treated with a stent, great care must be exercised when crossing the struts of the deployed stent with a coronary guide wire or **Yangtze® μ sb** to avoid disrupting the deployed stent geometry and/or impairing the **Yangtze® μ sb.**

5. Contra-indications

- Patients who are judged not to be candidates for coronary artery bypass surgery,
- Bifurcation lesions of the left main trunk,
- Patients with totally obstructed coronary arteries,
- Arterial spasm,
- Patients with allergies to procedural medications, to anticoagulation and/or antiplatelet therapy or a sensitivity to contrast media
- Patients having experienced cardiogenic shock,
- Patients with bleeding diathesis or other disorder eg. Peptic ulceration or recent cerebrovascular accident, limiting the use of antiplatelet and/or anticoagulation therapy,
- Pregnant women or women of child bearing potential,
- Severe stenosis of the unprotected left main coronary artery,
- Diffuse, multiple and calcified lesions,
- Presence of definite or probable intra-luminal thrombus in the target vessel

6. Adverse events

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

- Nausea and vomiting
- Arterial fistula
- Dissection or perforation of the coronary artery
- Injury or rupture of the coronary artery
- Total occlusion
- Thrombosis
- Arterial spasm
- Ventricular fibrillation
- Disturbance of cardiac conductibility
- Bradycardia
- Embolism
- Entry site complications

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:

- Emergency or non emergency Coronary Artery Bypass Graft (CABG) Surgery
- Restenosis of the dilated artery
- Unstable angina
- Ischemia
- Acute myocardial infarction
- Disturbance of cardiac conductivity
- Bleeding complications or haematoma

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

7. Instructions for use

7.1. Choice of the Yangtze® μ sb PTCA 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.

7.2. Device preparation

- Check before use that the packaging has not been damaged in a way that might have rendered the product unsterile.
- Prepare the inflation device according to the manufacturer's instructions.
- Remove the Yangtze® μ sb catheter from its dispenser.
- Remove carefully the distal protective sheath from the system, the stylet placed in the balloon and flush the guide wire lumen according to routine procedure.
- Purge the balloon according to standard techniques.
- Connect the inflation system with the utmost care to avoid air bubbles entering the system.

7.3. Yangtze® μ sb coating

The coaxial distal portion of the Yangtze® μ sb is covered with a hydrophilic coating. Moisten the catheter before use and keep it moist throughout the procedure. Do not reinsert in dispenser.

7.4. Manipulation

Standard techniques for placement of an introducer sheath, guiding catheter and guide wire should be employed during use with the Yangtze® μ sb.

Back-load the guide wire into the distal tip of the Yangtze® μ sb ensuring that it exits through the notch located approximately 25 cm proximal to the dilatation catheter tip. Open the "Y" access system and advance the Yangtze® μ sb to the distal end of the guiding catheter.

The two markers located on the proximal part of the shaft may be used to estimate when the Yangtze® μ sb has reached the distal end of the guiding catheter (depending on whether the approach is brachial or femoral).

Advance the Yangtze® μ sb up to the target lesion located in the side branch of the bifurcation. If the main branch vessel has been treated with a stent, great care must be exercised when crossing the struts of the deployed stent with a coronary guide wire or Yangtze® μ sb to avoid disrupting the deployed stent geometry and/or impairing the Yangtze® μ sb.

Caution:

If resistance is felt, use fluoroscopy to determine the cause of resistance before proceeding.

Always advance the Yangtze® μ sb fully deflated and always on the guidewire.

The radio-opaque markers aid in the positioning of the balloon in the stenosis. Inflate the balloon. The inflation pressure should not exceed the Rated Burst Pressure (RBP, see the Compliance chart on the label of the peelable pouch and packaging box).

A simultaneous inflation (kissing) in the main and side branch may be performed with the **Yangtze® μ sb** in conjunction with a PTCA catheter placed in the main branch.

Deflate the **Yangtze® μ sb**.

After deflating the **Yangtze® μ sb**, slowly withdraw the balloon catheter, guide wire and guiding catheter.

8. Guiding catheter and Guide wire compatibility, Compliance chart, Packaging, Sterilisation and Storage conditions

Refer to labelling.

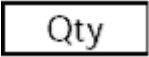








9. Liability

Minvasys has endeavoured to ensure that the products comply with all the 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 when 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

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

11. Symbols used

				
Quantity per box	Balloon diameter	Length	Nominal Pressure	Rated Burst Pressure
				
Minimum guiding catheter inner diameter	Maximum guidewire outer diameter	Do not use damaged packaging	Do not resterilize	

CE 0459

Year CE marking obtained: 2006



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