

# StemiCath

## ASPIRATION CATHETER

Carefully read all instructions prior to use, observe all warnings and precautions noted throughout these instructions. Failure to do so may result in complications.

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. Store in a dry place below 40° C, keep away from light. Read instructions prior to use.

### 1 Description

The **StemiCath** Aspiration Catheter is a single-use design, dual lumen catheter to be used with a 0.014" guidewire. It has a distal radiopaque tip marker and a proximal luer-lock port. The proximal luer-lock port is used for connection of the aspiration line (supplied) and the aspiration syringe (supplied).

The larger extraction lumen comes pre-loaded with a stiffening stylet that resists kinking during delivery but is removed to allow for the removal of thrombus by aspiration.

### 2 Indications

The **StemiCath** Aspiration Catheter is indicated for use in the central and peripheral circulatory system, including saphenous vein grafts, to contain and aspirate embolic material (thrombus/debris) while performing percutaneous transluminal coronary angioplasty (PTCA), percutaneous transluminal angioplasty (PTA) and/or stenting procedures.

### 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, PTA 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.
- As in any elective coronary intervention, it is recommended that the patient have a mean systolic blood pressure greater than or equal to 90mm Hg in concomitant of IV pressors or Intra Aortic Balloon Pump augmentation.
- The **StemiCath** Aspiration Catheter must be used in patients who have been exclusively appropriately prepared with an anti-coagulant or anti-platelet therapy.

#### 4 Precautions for use

- Prior to use the **StemiCath** Aspiration Catheter, the packaging and product should be inspected for any sign of damage. Never use a damaged product or a product from a damaged package.
- The **StemiCath** Aspiration Catheter 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 resterilise or re-use, destroy product after use.
- Use the product before the expiry date clearly shown on the packaging.
- When the **StemiCath** Aspiration Catheter 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.
- 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.
- Inspect the catheter prior to use for any kinks, curves or potential catheter damage, which could alter catheters performances.

#### 5 Contra-indications

- In case of use in the coronary territory, patients who are judged not to be candidates for coronary artery bypass surgery.

#### 6 Adverse events

As with most percutaneous interventions, possible complications linked to the use of the **StemiCath** Aspiration Catheter include: Death, Myocardial Infarction, Coronary or Bypass Graft Thrombosis or Occlusion, Myocardial Ischemia, Stroke/CVA, Emergent or Non-emergent Bypass Graft Surgery, Emboli (air, tissue or thrombotic), Dissection, Arterial Perforation, Arterial Rupture, Ventricular Fibrillation, Hemorrhage, Hypotension, Pseudoaneurysm at Access Site, Arteriovenous Fistula, Infection at Access Site, Other Bleeding Complications at Access Site.

#### 7 Instructions for use

Prior to use, carefully examine all equipment to be used during the procedure, including the **StemiCath** Aspiration 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.

##### 7.1 Materials required for use with the **StemiCath** aspiration and infusion system

- See labelling for compatibility in term of minimum internal diameter of the arterial or venous introducer sheath or femoral guiding catheter to be used with the product. Arterial or venous introducer sheath or femoral guiding catheter shall be chosen in the appropriate configuration to cannulate the vessel (preferably with side holes if ostial narrowing is present or the guiding catheter is occlusive).
- Guide wire diameter recommended with the **StemiCath** Aspiration Catheter is 0.014”.
- Push-pull or rotating hemostatic valve
- Heparinized normal saline.

Recommendation:

If the use of a second guide wire in addition to StemiCath Aspiration Catheter is required, please note that an increased size of guiding catheter shall be used in order to avoid friction issues.

Example: for a 6F StemiCath Aspiration Catheter, use a 7F Guiding Catheter.

## 7.2 StemiCath preparation

The catheter is packaged in a protective hoop; carefully remove the catheter from the package.

The **StemiCath** Aspiration Catheter is supplied with an aspiration line, a locking aspiration syringe and two filters.

1. Remove the **StemiCath** Catheter and accessories from the package.
2. Fill the Aspiration Syringe with approximately 5-10 mL of heparinized saline and attach the aspiration line and syringe to **StemiCath** Catheter.
3. Ensure that the stiffening stylet is in place in the extraction lumen and secured to its luer hub.
4. Open the stopcock on the aspiration line and flush the entire length of the **StemiCath** Catheter using all of the heparinized saline contained in the aspiration syringe. Close the stopcock.
5. Verify that the stopcock on the aspiration line is in the closed position. Retract the plunger of the aspiration syringe and pull until it locks at the fully extended position. The **StemiCath** Catheter is completely prepped and is ready for use.

## 7.3 Procedure

1. Perform aspiration using the **StemiCath** Catheter:
  - a. Load and advance the prepped **StemiCath** Catheter over the guidewire to the tip of the guiding catheter.
  - b. Under fluoroscopy advance the **StemiCath** Catheter and position the distal tip marker proximal above the embolic particles. Stop advancement of the **StemiCath** Catheter if any resistance is encountered.
  - c. After fluoroscopically confirming catheter position, remove the stiffening stylet and open the stopcock to begin extraction.
  - d. Begin aspiration by opening the stopcock on the aspiration line. Slowly retract the **StemiCath** Catheter towards the guiding catheter. Blood will enter the aspiration syringe until the entire vacuum is gone (or the aspiration syringe is filled).

Notes:

- Should blood not begin filling the syringe within 5 seconds, check the guiding catheter tip placement. Unseat the guiding catheter if necessary to resume flow.
- If no blood is aspirated as a result of unseating the guiding catheter, turn the stopcock off and remove the StemiCath Catheter outside of the patient, either

flush the aspiration lumen or use a new StemiCath Catheter. DO NOT flush the system while the catheter is still inside the patient vasculature.

- During performance testing, the StemiCath Catheter demonstrated the ability to evacuate fluid and debris at a minimum rate of 1 mL/second.
- e. After completing the aspiration process turn the aspiration line stopcock to close off the aspiration syringe.
2. Remove the **StemiCath** Catheter
    - a. Withdraw the StemiCath Catheter.

**NOTE: Especially for peripheral intervention (or non-coronary): the guide-wire must be withdrawn simultaneously with the catheter to avoid any loop creation.**

- b. Slowly retract and remove the StemiCath Catheter. If necessary, loosen the Tuohy Borst of the haemostatic valve to allow easy withdrawal of the distal shaft.

Note: Remove the aspiration syringe and re-flush the aspiration lumen and wire lumen of the **StemiCath** Aspiration Catheter with heparinized saline before each re-use. Empty the aspiration syringe, re-attach to extension line, close the stopcock, and retract the plunger to the fully extended lock position.

3. Remove the catheters and follow standard hospital practice for management of the insertion site.

## 8 Sterilisation and Storage conditions

Refer to labelling.

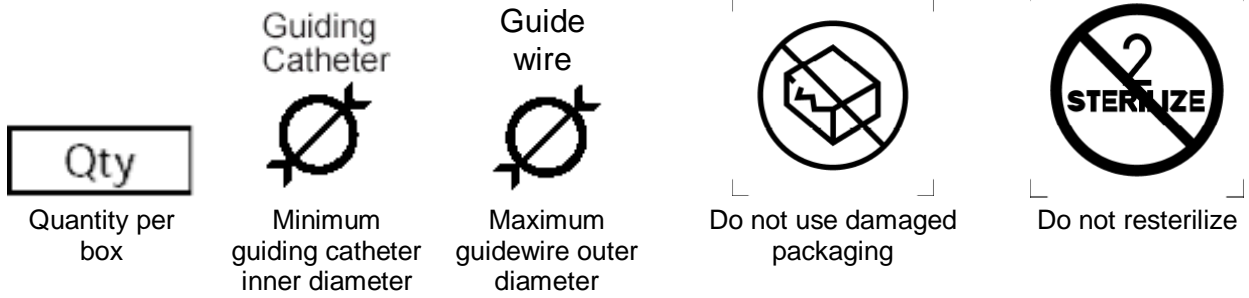
## 9 Liability

Minvasys has endeavoured 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

## 11 Symbols



CE 0459

Year CE marking obtained: 2010

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