TERUMO

PriorityOne® AC

Aspiration Catheter

INSTRUCTIONS FOR USE

Contents
Contents

Order No.
Order number

REF
Code number

LOT
Batch code

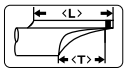
STERILE EO
Sterilized using ethylene oxide


Use by date

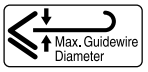

Manufacturer


Single use only

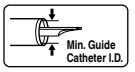

Read the instructions for use



<L>Guidewire Lumen Length
<T>Tip Hole Length



Max. Guidewire Diameter



Min. Guide Catheter I.D.

Catheter

Stylet

30 mL Syringe

Extension Line

Filter Basket

Flushing Tool

SPECIFICATIONS

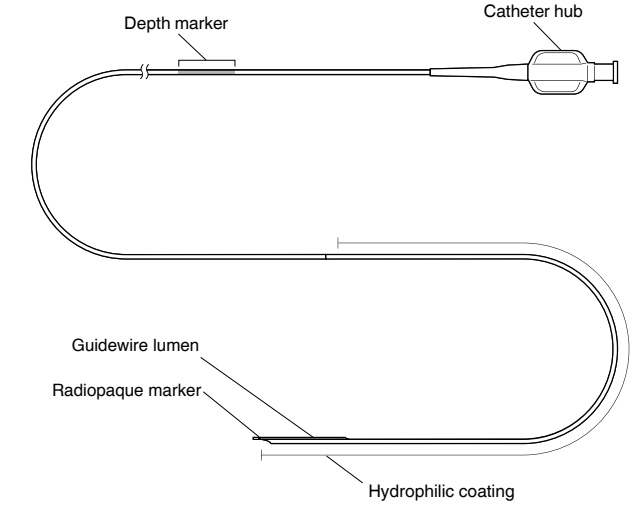
Model	Min. Guide Catheter I.D.	Max. Guidewire Diameter
6Fr	1.78mm (0.070")	0.36mm (0.014")
7Fr	2.03mm (0.080")	0.36mm (0.014")

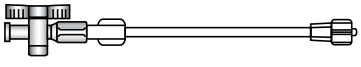
OTHER MATERIALS REQUIRED BUT NOT INCLUDED

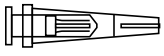
- Guide catheter with an I.D. of at least 1.78mm / 0.070" - for 6Fr Aspiration Catheter
- Guide catheter with an I.D. of at least 2.03mm / 0.080" - for 7Fr Aspiration Catheter
- Rotating hemostatic valve (RHV) (Tuohy-Borst type)
- Guidewire with maximum diameter of 0.36mm / 0.014"
- 10mL syringe (for flushing wire lumen)
- Heparinized saline (for system flushing)

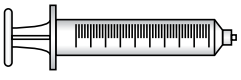
NAME OF EACH PART AND COMPONENTS

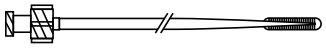
Aspiration catheter

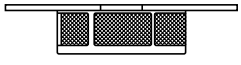



Extension line (25 cm) with stopcock


Flushing tool for flushing of guidewire lumen


Aspiration syringe (30mL) × 2


Stiffening stylet for protection of the catheter from kinking


Filter basket for filtering thrombus after extraction

CAUTION

Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.

DESCRIPTION

<INDICATIONS>
PriorityOne AC is indicated for the removal of fresh, soft emboli and thrombi from vessels in the coronary and peripheral vasculature.

<DESCRIPTION>
PriorityOne AC is a dual lumen rapid exchange catheter. The guidewire lumen is used to facilitate passage of a guidewire which must not exceed 0.014" (0.36mm) in diameter.
The larger extraction lumen allows for the removal of thrombus (thrombi) by use of the included aspiration syringe through the extension line.
The catheter has a proximal stiff region and a distal flexible region that is coated with hydrophilic polymer which generates lubricity when wet.
On the distal tip a radiopaque marker band is incorporated. The catheter shaft has a non-radiopaque depth marker located approximately 90cm and 100cm proximal of the distal tip to indicate point at which aspiration catheter exits guide catheter. The proximal end of the catheter incorporates a standard luer adapter to facilitate the attachment of catheter to the included extension line, stopcock, and syringes.
The Provided stylet can be inserted in the catheter to assist in the delivery of the catheter to the vascular lesion.
The included flushing tool is used for flushing the guidewire lumen in preparation.
A filter basket is included for assistance in filtering the blood removed during the procedure for laboratory analysis.

Please read all instructions prior to use.

CAUTIONS FOR USE

1. Contraindications
- Do not use a 6Fr catheter in vessels < 1.8 mm in diameter.
- Do not use a 7Fr catheter in vessels < 2.05 mm in diameter.
- Do not use for the removal of fibrous, adherent or calcified material.
- Do not use within the venous system.
- Do not use within the cerebral vasculature.

2. Complications

Complications associated with the use of PriorityOne AC may be similar to those associated with standard percutaneous interventional procedures. Possible complications may include, but are not limited to:

- Local or systemic infection
- Local hematomas
- Intimal disruption
- Arterial dissection, perforation, rupture or injury
- Arterial thrombosis
- Distal embolization of blood clots and plaque
- Arterial spasm
- Arteriovenous fistula formation, Pseudoaneurysm or Bleeding

Complication at Access Site

- Acute myocardial infarction
- Arrhythmias, including life-threatening ventricular fibrillation
- Stroke/CVA
- Death
- Emergent or Non-emergent Bypass Graft Surgery
- Hemorrhage
- Myocardial Ischemia
- Hypotension

3. Important safety instructions

WARNINGS
- **If the flow into syringe stops or is restricted, do not attempt to flush the extraction lumen while the catheter is still inside the patient's vasculature. Intravascular thrombus delivery, thrombo-embolic event and/or serious injury or death may result. Remove the catheter and, outside the patient, either flush the extraction lumen or use a new catheter.**
- **Never advance or withdraw an intravascular device against resistance until the cause of the resistance is determined by fluoroscopy. Movement of the catheter or guidewire against resistance may result in separation of the catheter or guidewire tip, damage to the catheter, or vessel perforation.**

CAUTIONS
- Do not use the catheter for the delivery or infusion of diagnostic, embolic or therapeutic materials into blood vessels.
- The stylet must be retrieved before initiation of thrombus aspiration.
- Do not use the syringes, extension line, stopcock or filter basket inside the human body.
- Inspect the catheter prior to use for any bends or kinks. Do not use a damaged catheter.
- Check that all fittings are secured so that air is not introduced into the extension line or syringe during use.
- Flush the guidewire lumen prior to use. (See DIRECTIONS FOR USE.)

- Do not use the aspiration catheter without a guide catheter. Attempting to insert or advance the aspiration catheter without a guide catheter could result in kinking.
- Avoid excessive rotation of the catheter during the procedure. Rotation beyond 1.5 turns may cause kinking which may diminish aspiration rate.
- When the catheter is in the body, it should be manipulated only under fluoroscopy. If resistance is met during manipulation, determine the cause of the resistance before proceeding.
- Do not cross the occlusive lesion with a guidewire while aspirating thrombus.
- If the catheter does not move through guide catheter, retrieve devices as a whole.

4. Precautions for application.

- PriorityOne AC should be used only by physicians trained in percutaneous, intravascular techniques.
- The entire operation should be carried out aseptically.

DIRECTIONS FOR USE

The techniques and procedures described do not represent all medically acceptable protocols, nor are they intended as a substitute for the physician's experience and judgement in treating any specific patient.

1. Preparation

1-1 Carefully remove the catheter in its holder and accessories from the package using a sterile technique.

1-2 Fill the holder with heparinized saline solution through the hub of the holder using the aspiration syringe, thoroughly wet the surface of the catheter.

1-3 Remove the catheter from the holder and inspect for any bends or kinks.

1-4 Connect the enclosed extension line to the stylet connector.

1-5 Fill the aspiration syringe with heparinized saline, connect it to the stopcock of the extension line, and flush the catheter.

1-6 Close the stopcock.

1-7 Fill 10mL syringe (not included) with heparinized saline and connect it to the Flushing tool. Insert the tip of the flushing tool into the guidewire lumen and flush.
Note: Flush only with the included flushing tool.

2. Insertion

2-1 Connect the Rotating Hemostatic Valve (RHV) to the appropriate guide catheter, and flush the guide catheter and RHV using standard technique.

2-2 Cannulate the vessel using the appropriate guidewire (≤ 0.36mm / 0.014") and guide catheter with attached RHV, and advance the guidewire to the selected vascular site using fluoroscopic guidance.

2-3 Backload the catheter carefully onto the guidewire.

2-4 Open the RHV thumbscrew and introduce the catheter into the vessel. Advance the catheter to the selected vascular site using fluoroscopic guidance. Tighten the hemostatic valve around the catheter just enough to prevent backflow.

CAUTIONS Overtightening the valve may damage the catheter. If the guidewire slips out of the guidewire lumen on the catheter during procedure, remove the guidewire and catheter, and re-insert the guidewire.

3. Aspiration Procedure

3-1 Keep the stopcock in "Off" position, pull back the plunger on the 30mL aspiration syringe to the desired amount of extraction volume. Twist the plunger to lock the syringe in the vacuum position.

CAUTION Before aspiration procedure, disconnect the extension line from the stylet connector, retrieve the stiffening stylet from the catheter, and connect the extension line to the catheter again.

3-2 Confirming catheter tip position fluoroscopically, open the stopcock of the extension line to begin aspiration.

WARNING **If the flow into syringe stops, close the stopcock, re-position the catheter and open the stopcock to begin aspiration again. If no blood is aspirated after re-positioning of the catheter, close the stopcock and remove the catheter. Outside the patient, flush the catheter or use a new catheter. Do not flush the catheter while in the patient.**

3-3 Blood and thrombus extracted into the syringe may be filtered for subsequent laboratory analysis using the filter basket.

3-4 After completing the aspiration process, close the stopcock and remove the catheter from the patient.

PRECAUTIONS FOR HANDLING

- For single use only. Do not reuse. Do not resterilize. Do not reprocess. Reprocessing may compromise the sterility, biocompatibility and functional integrity of the device.
- Sterile and non-pyrogenic in an unopened and undamaged unit package. Do not use if the unit package or the product have been damaged or soiled.
- The product should be used immediately after opening the package and be disposed safely and properly after use.

STORAGE

- Avoid exposure to water, direct sunlight, extreme temperature, or high humidity during storage.

Manufacturer:
TERUMO CLINICAL SUPPLY CO., LTD.

3, Kawashima-Takehayamachi, Kakamigahara, Gifu, 501-6024 Japan MADE IN JAPAN

PM-04844

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