

PRONTO[®] V3 Extraction Catheter



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PRONTO[®] V3 Extraction Catheter Model 5003

Instructions For Use

USA CAUTION

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

CAUTION

The PRONTO V3 extraction catheter procedure should be performed by physicians with adequate training in the use of the device.

DEVICE DESCRIPTION

The PRONTO V3 extraction catheter (PRONTO) is a dual lumen rapid exchange catheter with related accessories. The smaller wire lumen of the catheter is able to accommodate guidewires that are $\leq 0.014"$ / 0.36mm in diameter. The larger extraction lumen allows for the removal of thrombus by use of the included syringe through the extension line and stopcock. The catheter has a rounded distal tip with a protected, sloped opening of the extraction lumen to facilitate advancement of the catheter into the blood vessel and maximize extraction of thrombus through the extraction lumen. The catheter has a proximal stiff region and a distal flexible region with a lubricious hydrophilic coating. The catheter has an O.D. of 0.065" / 1.65mm and a working length of 140cm, allowing delivery through standard 6F guide catheters. The catheter has a radiopaque marker band located approximately 2mm from the distal tip. The shaft of the PRONTO catheter has two (2) non-radiopaque positioning marks located approximately 95cm and 105cm proximal of the distal tip. 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. A 70 μ m filter basket is included for assistance in filtering the blood removed during the procedure for laboratory analysis of any thrombosis.

The PRONTO catheter is able to be used with guidewires and guide catheters with the following dimensions:

PRONTO Catheter Model	Max. Guidewire Diameter	Min. Guide Catheter I.D.
5003	0.014" 0.36mm	0.070" 1.78mm

INDICATIONS

The PRONTO catheter is indicated for the removal of fresh, soft emboli and thrombi from vessels in the coronary and peripheral vasculature.

CONTRAINDICATIONS

The PRONTO catheter is contraindicated in:

- vessels < 2mm in diameter
- the removal of fibrous, adherent or calcified material (e.g. chronic clot, atherosclerotic plaque)
- the venous system
- cerebral vasculature

WARNINGS

The PRONTO catheter is supplied sterile for single use only. Do not resterilize and/or reuse the device.

STERILE EO

Do not use the PRONTO catheter for the delivery or infusion of diagnostic, embolic or therapeutic materials into blood vessels as it has not been designed for these uses.

Do not perform high pressure contrast injections around the PRONTO catheter while using a 6F guide catheter. High pressure contrast injection may damage the PRONTO catheter, making it difficult to remove from the 6F guide catheter.

Do not use the syringes, extension line, stopcock or filter basket inside the human body.

If flow into the 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, thromboembolic 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.

COMPLICATIONS

As with all catheterization procedures, complications with the PRONTO catheter may occur. These may include:

- local or systemic infection
- local hematomas
- intimal disruption
- arterial dissection
- perforation and vessel rupture
- arterial thrombosis
- distal embolization of blood clots and plaque
- arterial spasm
- arteriovenous fistula formation
- catheter fracture with tip separation and distal embolization

PRECAUTIONS

The PRONTO deployment procedure should be performed by physicians thoroughly trained in percutaneous, intravascular techniques and procedures. Do not use the PRONTO catheter if the packaging has been damaged.

Inspect the catheter prior to use for any bends or kinks. Do not use a damaged catheter because vessel damage and/or inability to advance or withdraw the catheter may occur.

Check that all fittings are secure so that air is not introduced into the extension line or syringe during extraction.

Exercise care in handling of the catheter during a procedure to reduce the possibility of accidental breakage, bending or kinking.

When the catheter is in the body, it should be manipulated only under fluoroscopy. Do not attempt to move the catheter without observing the resultant tip response.

Excessive tightening of a hemostatic valve onto the catheter shaft may result in damage to the catheter.

When using a 6F guide catheter, there will be insufficient room to deliver contrast around the PRONTO catheter.

CLINICAL PROCEDURE

The following instructions provide technical direction but do not obviate the necessity of formal training in the use of the PRONTO catheter. 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 judgment in treating any specific patient.

Each PRONTO extraction catheter includes the following components:

- Single-use, disposable catheter
- Extension line (15cm) with attached stopcock
- 2 - syringes (30ml) with locking plunger
- Filter basket (70 micron mesh) for filtering thrombus after extraction

Other materials required but not provided are:

- Guiding catheter with an I.D. of at least 0.070" / 1.78mm to cannulate the vessel
- Rotating hemostatic valve (RHV) (Tuohy-Borst type)
- Guidewire with diameter $\leq 0.014"$ / 0.36mm
- 10ml syringe (for flushing wire lumen)
- Sterile heparinized saline (for system flushing)

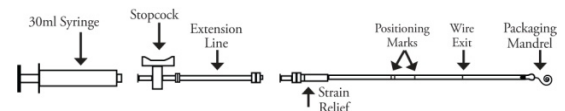
PREPARATIONS FOR USE

- Using sterile technique, open the pouch and transfer the tray into the sterile field.
- Attach a 10ml syringe filled with heparinized saline to the flushing luer of the carrier tube and completely flush to activate the hydrophilic coating.
- Remove the catheter from the carrier tube and inspect for any bends or kinks. Remove the wire stylet from the wire lumen.
- Thoroughly flush the catheter and wire lumen with heparinized saline.
- Draw 5ml of heparinized saline into the 30ml syringe. Connect the syringe to the stopcock, and connect the attached extension line to the catheter. Flush the entire connection to remove all air from the catheter, extension line, stopcock and syringe. Turn the stopcock to the "Off" position.
- With the stopcock in the "Off" position, pull back the plunger on the 30ml syringe to the desired amount of extraction volume. Twist the plunger to lock the syringe in the vacuum position.

Precaution: Check that all fittings are secure so that air is not introduced into the extension line or syringe during extraction.

DEPLOYMENT PROCEDURE

Review the schematic drawing of the PRONTO catheter below for terminology used in the following deployment procedure.



Deploy the PRONTO catheter according to the following steps:

- Cannulate the vessel using the appropriate guidewire and guiding catheter with attached RHV. Flush the guiding catheter and RHV using standard technique.

NOTE: The guide catheter must have a minimum I.D. of 0.070" / 1.78mm to accommodate free movement of the PRONTO catheter.

- Back-load the PRONTO catheter onto the guidewire. Advance the catheter on the guidewire until the wire exits the opening in the wire lumen.
- Open the RHV thumbscrew and introduce the catheter, being careful to keep the guidewire in the guidewire lumen slot of the catheter. Tighten the O-ring valve around the catheter just enough to prevent backflow, but not so tightly as to inhibit catheter movement.
- Continue to advance the catheter over the guidewire to the selected vascular site, using fluoroscopic guidance. Stop advancement of the catheter if any resistance is encountered.

Warning: 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.

5. After fluoroscopically confirming catheter position, open the stopcock to begin extraction. Slowly advance the catheter distally away from the guiding catheter. Blood will enter the syringe until all of the vacuum is gone. Should aspiration not begin filling the syringe within 5 seconds remove the catheter without releasing the vacuum. Outside the patient, either flush the extraction lumen or use a new catheter.

NOTE: During performance testing, the catheter demonstrated the ability to evacuate fluid at a minimum rate of 0.25ml/s.

Warning: If flow into the 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, thromboembolic 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.

NOTE: If air is noted in the syringe during extraction, a leak may be present in the system. Turn the stopcock "Off", tighten all luer connections, remove all air from the syringe, and repeat the extraction. If air is still noted, remove the catheter, obtain a new catheter and repeat the procedure.

6. After completing the extraction process, turn the stopcock to the "Off" position and remove the catheter, or attach second syringe and repeat extraction.
7. Blood and thrombus extracted into the syringe may be filtered for subsequent laboratory analysis using the 70 micron filter basket. To use the filter basket, wet the mesh to allow fluid flow, and filter the extracted blood through the filter basket.

PACKAGING & STORAGE

The PRONTO catheter has been sterilized with ethylene oxide.

Handle with care.

LIMITED WARRANTY

Vascular Solutions, Inc. warrants that the PRONTO extraction catheter is free from defects in workmanship and materials prior to the stated expiration date. Liability under this warranty is limited to refund or replacement of any product which has been found by Vascular Solutions, Inc. to be defective in workmanship or materials. Vascular Solutions, Inc. shall not be liable for any incidental, special, or consequential damages arising from the use of the PRONTO extraction catheter. Damage to the product through misuse, alteration, improper storage, or improper handling shall void this limited warranty.

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PATENTS AND TRADEMARKS

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