



Xtract™ Aspiration Catheter INSTRUCTIONS FOR USE

R Only

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The Xtract Aspiration Catheter system consists of One Catheter, Two 30ml Syringes, One Extension Tube with Stopcock, and One 40µm Cell Strainer.

DEVICE DESCRIPTION

The Xtract Aspiration Catheter is a single-user, 0.014" guidewire compatible, intravascular extraction and aspiration catheter with a distal radiopaque tip marker, a varying stiffness shaft, a rapid exchange port, and a proximal luer-lock hub.

INDICATIONS FOR USE

The Xtract Aspiration Catheter is indicated for the removal of fresh, soft emboli and thrombi from vessels in the arterial system.

CONTRAINDICATIONS

- Vessels < 1.75 mm in diameter
- The removal of fibrous or adherent material.

WARNINGS

- The system is supplied sterile and non-pyrogenic for single use only. Do not resterilize and/or reuse the device.
- Do not use the 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 use the syringe, extension line, and stopcock inside the human body.
- Only physicians trained in percutaneous, intravascular techniques and procedures should use the system.
- Refer to the instructions supplied with any interventional devices to be used in conjunction with the system for their intended uses, contraindications, warnings, precautions, and instructions for use.
- Exercise care when handling and loading the catheter over the proximal end of the guidewire to avoid wire or catheter kinking.
- Use an appropriately sized guiding catheter or a guiding sheath with touhy-borst adapter.

CAUTIONS

- Crossing a freshly deployed drug eluting stent could damage the delicate drug coating.

PRECAUTIONS

- Store the device in a dark, dry place.
- Do not autoclave or expose the device to organic solvents.
- Confirm the compatibility of the catheter diameter and length with the guide catheter and guidewire prior to use.
- Use catheter prior to the “Use Before” date noted on the package.
- Prior to use, carefully inspect the catheter for bends, kinks or other damage. Do not use damaged or suspected damaged catheter.
- Exercise care handling the catheter before and during a procedure to reduce the possibility of damage...
- 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.
- Never advance or withdraw the catheter against resistance until the cause of the resistance is determined by fluoroscopy. Movement of catheter against resistance may result in damage to the catheter or vessel perforation.
- If blood does not fill syringe during aspiration and catheter blockage is suspected, do not flush the catheter while in the patient.

Possible adverse effects include, but are not limited to, the following:

- Access site complication (i.e., AV fistula, dissection, hematoma, hemorrhage, pseudoaneurysm)
- Acute myocardial infarction
- Allergic, or other reactions, to contrast medium, procedure medications or device materials
- Arrhythmias (including life-threatening ventricular fibrillation)
- Bleeding requiring a blood transfusion
- CVA/ stroke or transient ischemic attacks
- Damage or migration of implanted stents
- Death
- Device failure
- Embolization of air, tissue, thrombus or device
- Emergency surgical or percutaneous intervention
- Hemolysis
- Hemorrhage
- Infection
- Ischemic infarction of tissue or organ
- No or slow reflow of treated vessel
- Pain
- Pericardial tamponade
- Renal insufficiency/ renal failure
- Severe hypotension or hypertension
- Total occlusion or thrombosis of the vessel
- Vessel spasm, dissection, perforation, rupture, or injury
- Unstable angina

MATERIALS REQUIRED FOR USE WITH THE XTRACT ASPIRATION CATHETER

Appropriately sized arterial guiding sheath and/or guiding catheter with touhy-borst adapter in the necessary configuration to access target vessel.

INSTRUCTIONS FOR USE

PREPARATION

1. Remove the catheter from the protective packaging tube, being careful not to remove the loading tool.
2. Fill the syringe with 10-20ml of a saline or equivalent solution.
3. Attach the extension tube with stopcock to the catheter and the syringe to the extension tube.
4. Open the stopcock and flush the entire catheter with solution in the syringe.
5. Close the stopcock.
6. Remove the syringe and set aside for future use.

CAUTION: Do not attach the syringe to the catheter until it has been tracked in the vessel and positioned. Attaching the syringe prior to this will hamper navigation of the catheter.

INSERTION AND PLACEMENT

1. Taking care not to kink the guidewire, insert the wire's proximal end into the loading tool distal end which extends out the distal end of the catheter. Carefully advance the wire through the side port of the catheter.
2. Remove the loading tool.
3. Open the Touhy-Borst adapter and insert the catheter.
4. Under fluoroscopy, advance until the distal marker band on the catheter tip is proximal to the thromboemboli to be aspirated.

CAUTION: Stop advancement of the catheter if any resistance is encountered. If resistance is felt passing the catheter through a stent, pull back on the catheter and torque the catheter ¼ turn.

5. Verify catheter tip placement using fluoroscopic imaging.

ASPIRATION AND EXTRACTION

1. Attach the (30ml) locking syringe to the extension tube with stopcock assembly attached to the catheter hub. Verify stopcock is closed.
2. Retract and lock the syringe in the fully extended position (30ml).
3. Open the stopcock to begin the aspiration cycle. The catheter is designed to deliver effective aspiration vacuum for a minimum of 10-seconds.

NOTE: If blood is not filling the catheter within 5-seconds, check the catheter tip placement, unseat the catheter and reposition if necessary. 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.

4. Once aspirated fluid is visible in the syringe, advance the catheter as needed to capture target thromboemboli.

NOTE: If aspiration stops before the syringe has filled, close the stopcock and remove the catheter. Outside the patient, flush the catheter or use a new catheter. **DO NOT** flush the catheter while still in the patient.

5. Once the first syringe is filled, close the stopcock and remove the syringe. A second syringe is provided if additional aspiration is desired.
6. Upon completion slowly and carefully remove the catheter.

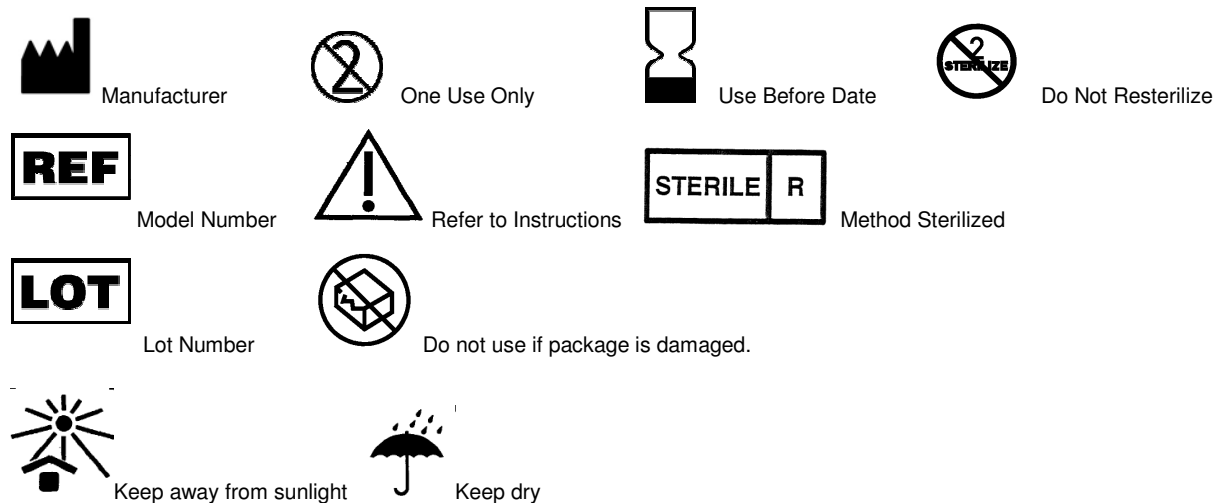
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