INSTRUCTIONS FOR USE

3V XTRA

[Aspiration Catheter 6F / 7F]

CE

CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE. OBSERVE ALL WARNINGS AND PRECAUTION NOTED THROUGHOUT THESE INSTRUCTIONS. FAILURE TO DO SO MAY RESULT IN COMPLICATIONS.

STERILE. Sterilized with ethylene oxide gas. Non pyrogenic. For one procedure only. Do not re-sterilize. Do not use opened or damaged packages. Destroy product after use. Store in a dry place below 40° C, keep away from light. Refer to accompanying Instructions for Use.

1. Description

The 3V XTRA Aspiration Catheter is a single-user design, dual lumen catheter. It has a distal radiopaque tip marker and proximal luer-lock port, the proximal luer-lock port is for connection of the Aspiration Line (supplied) and Aspiration Syringe (supplied).

The larger XTRAction 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 and Intended Use

The 3V XTRA 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 and/or stenting procedures.

3. Warnings

- Prior to use the packaging and product should be inspected for signs of damage.
- Never use damaged product or product from a damaged package.
- The 3V XTRA Catheter should be handled carefully. Prior to use inspect the 3V XTRA Catheter carefully for bends, kinks, or other damage.
- Do not use a damaged 3V XTRA Catheter.
- The 3V XTRA Catheter is designed and intended for single use.
- Check that the sterile pouch is not damaged before use.
- Do not re-sterilize or re-use, destroy product after use. Reuse may create a risk of patient or user infection, compromise the structural integrity and essential material and design characteristics of the device, which may lead to device failure, and/lead to injury, illness or death of the patient.

4. Precautions for use

- The 3V XTRA Aspiration Catheter and accessories should be used in conjunction with fluoroscopic guidance and proper anticoagulation agents.
- This device is designed and intended for single patient use only. DO NOT re-sterilize and/or reuse it.
- As in any elective coronary intervention, it is recommended that the patient have a mean systolic blood pressure greater than or equal to 90 mm Hg in concomitant of IV pressors or Intra-Aortic Balloon Pump augmentation.

As with most percutaneous interventions, other potential adverse events 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, Pseudo aneurysm at Access Site, Arterio-venous Fistula, Infection at Access Site, Other Bleeding Complications at Access Site.

5. Materials required for use with the 3V XTRA Aspiration and Infusion System

- Minimum 6F or 7F Arterial or Venous Introducer Sheath and minimum 6F or 7F Femoral Guiding Catheter in the appropriate configuration to cannulate the vessel (preferably with side holes if ostial narrowing is present or the guide catheter is occlusive).
- Push pull or Rotating Hemostatic Valve
- Heparinized normal saline.

Recommendation

- If the use of a second guide wire in addition to 3V XTRA 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 3V XTRA Aspiration Catheter, use a 7F Guiding Catheter

6. Directions for Use

Preparation of the 3V XTRA Catheter

The 3V XTRA Aspiration Catheter is supplied with an Aspiration Line, one locking Aspiration Syringe and 2 filters.

1. Remove the 3V XTRA 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 3V XTRA Catheter.
Ensure that the stiffening stylet is in place in the extraction lumen and secured to its luer hub. Connect the aspiration line and the syringe to the stylet hub.

3. Open the stopcock on the Aspiration Line and flush the entire length of the 3V XTRA Catheter using all of the heparinized saline contained in the Aspiration Syringe. Close the stopcock.

4. 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 3V XTRA Catheter is completely prepped and is ready for use.

5. Perform aspiration using the 3V XTRA Catheter:

a. Load and advance the prepped 3V XTRA Catheter over the Guide Wire to the tip of the Guiding Catheter.

b. Under fluoroscopy advance the 3V XTRA Catheter and position the distal tip marker proximal above the embolic particles. Stop advancement of the 3V XTRA Catheter if any resistance is encountered.
After fluoroscopically confirming catheter position, disconnect the aspiration line and remove the stiffening stylet. Connect the aspiration line directly to 3V XTRA catheter and open the stopcock to begin XTRAction.

c. Begin aspiration by opening the stopcock on the Aspiration Line. Slowly retract the 3V XTRA 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 3V XTRA Catheter outside of the patient, either flush the aspiration lumen

or use a new 3V XTRA Catheter. DO NOT flush the system while the catheter is still inside the patient vasculature.

- During performance testing, the 3V XTRA Catheter demonstrated the ability to evacuate fluid and debris at a minimum rate of 1 ml/second.

d. After completing the aspiration process turn the Aspiration Line stopcock to close off the Aspiration Syringe.

6. Remove the 3V XTRA Catheter

a. Withdraw the 3V XTRA Catheter

b. Slowly retract and remove the 3V XTRA Catheter. If necessary, loosen the Tuohy-Borst of the hemostatic 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 3V XTRA Catheter with heparinized saline before each re-use Empty the Aspiration Syringe, reattach to extension line, close the stopcock, and retract the plunger to the fully extended lock position.

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

7. How Supplied

The 3V XTRA Catheter is supplied with an Aspiration Line, one locking Aspiration Syringe and 2 filters; it is supplied sterile and non-pyrogenic in a tray in its own pouch. The 3V XTRA Aspiration Catheter including all of its components is intended to be used for one procedure only.

NOTE ALTHOUGH THE 3V XTRA ASPIRATION CATHETER, HEREAFTER REFERRED TO AS 'PRODUCT', HAS BEEN MANUFACTURED UNDER CAREFULLY CONTROLLED CONDITIONS, S3V VASCULAR TECHNOLOGIES PRIVATE LIMITED HAVE NO CONTROL OVER CONDITIONS UNDER WHICH THIS PRODUCT IS USED. S3V VASCULAR TECHNOLOGIES PRIVATE LIMITED THEREFORE DISCLAIMS ALL WARRANTIES, BOTH EXPRESSED AND IMPLIED, WITH RESPECT TO THE PRODUCT, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OR MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE SHALL NOT BE LIABLE TO ANY PERSON OR ENTITY FOR ANY MEDICAL EXPENSES OR ANY DIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES CAUSED BY ANY USE. DEFECT, FAILURE OR MALFUNCTION OF THE PRODUCT, WHETHER A CLAIM FOR SUCH DAMAGES IS BASED UPON WARRANTY, CONTRACT, TORT OR OTHERWISE NO PERSON HAS ANY AUTHORITY TO BIND S3V VASCULAR TECHNOLOGIES PRIVATE LIMITED TO ANY REPRESENTATION OR WARRANTY WITH RESPECT TO THE PRODUCT.

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9. Storage Requirements

- Use before the expiry date clearly indicated on the label.
- Store at room temperature below 40°C, in a dry place, protected from light.

15. Symbols Meaning

Qty	Quantity per box
Ø	Diameter
⟷	Length
	Single use
	Store protected from sun
	Store in a dry place
Ø	Min. guiding catheter internal diameter
Ø	Maximum guide wire diameter
	Temperature limitation
	Manufacturer
	Manufacturing Date
LOT	Lot Number
	Expiry Date
CE	CE Mark
EC REP	European Representative

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