

'Trans-Aspirator'

Aspiration Catheter

Instructions for use

Manufacturing Facility



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1.0 PRODUCT DESCRIPTION

The 'Trans-Aspirator' is an Aspiration Catheter

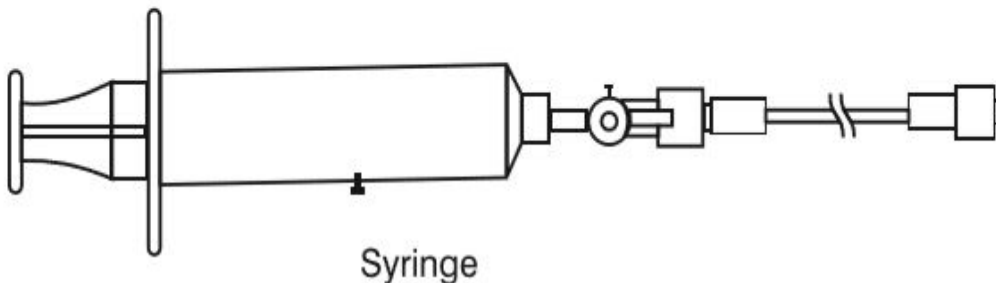
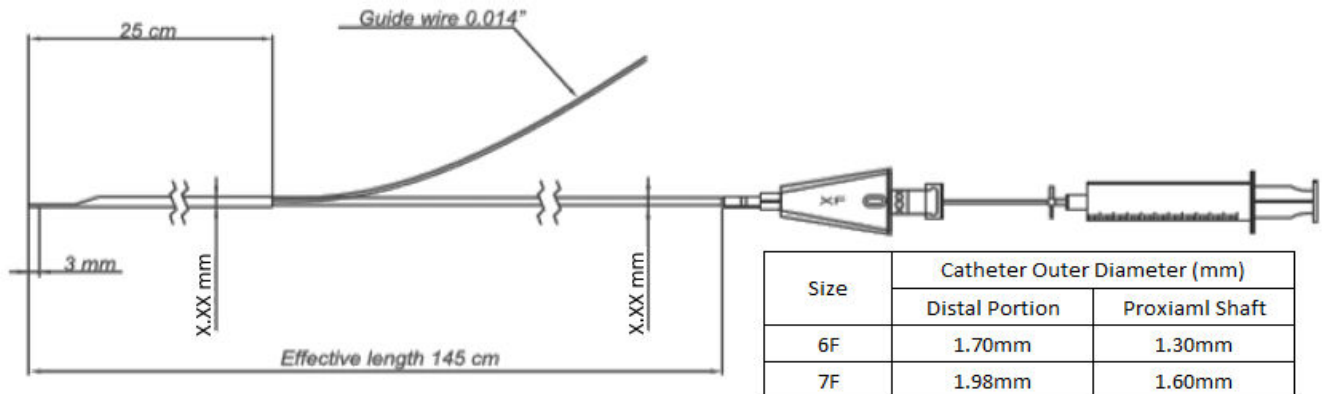
1.1 DEVICE COMPONENT DESCRIPTION

The Trans-Aspirator 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 and Aspiration Syringe.

The Trans-Aspirator Catheter is supplied with an Aspiration Line, one locking Aspiration Syringe and 2 filter.

Only for Trans-aspirator (with Stiff)

- 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.



1.2 TRANS-ASPIRATOR- Product Matrix with Product Reference No.

Product Name	Description	Ref No	Catheter Length (cm)	Diameter (F)
Trans-Aspirator	With Stiff	ASOR-6145	145	6
	With Stiff	ASOR-7145	145	7
	Without Stiff	ASOR-6145N	145	6
	Without Stiff	ASOR-7145N	145	7

2.0 INDICATIONS and INTENDED USE

The Trans-Aspirator 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 percutaneous transluminal angioplasty and/or stenting procedures.

3.0 CONTRAINDICATION

- For Single use only. Do not reuse, reprocess or re-sterilize.
- These components are contraindicated in the following lesion.
 - Left main trunk lesion unprotected by bypass graft or collateral circulation.

- The venous system.
- These components are contraindicated in the following patients
 - Patients who are responsive to surgical treatment
 - Patients with lateral distal stenosis of stent installed at bifurcated lesion.
 - Patients with serious blood coagulation abnormality.

4.0 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 Trans-Aspirator Catheter should be handled carefully. Prior to use inspect the Trans-Aspirator Catheter carefully for bends, kinks, or other damage. Do not use a damaged Trans-Aspirator Catheter.
- The Trans-Aspirator 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. Re use & re sterilization may compromise the device performance.

5.0 PRECAUTIONS

- The Trans-Aspirator 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, Haemorrhage, Hypotension, Pseudoaneurysm at Access Site, Arteriovenous Fistula, Infection at Access Site, Other Bleeding Complications at Access Site.

6.0 DIRECTION FOR USE

Preparation of the Trans-Aspirator Catheter

The Trans-Aspirator Catheter is supplied with an Aspiration Line, one locking Aspiration Syringe and 2 filters.

- 6.1 Remove the Trans-Aspirator Catheter and accessories from the package.
- 6.2 Fill the Aspiration Syringe with approximately 5-10 ml of heparinised saline and attach the aspiration line and syringe to Trans-aspirator Catheter.
Only for TRANS-ASPIRATOR (With Stiff)
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.
- 6.3 Open the stopcock on the Aspiration Line and flush the entire length of the Trans-Aspirator Catheter using all of the heparinized saline contained in the Aspiration Syringe. Close the stopcock.
- 6.4 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 Trans-Aspirator Catheter is completely prepped and is ready for use.
- 6.5 **Perform aspiration using the Trans-Aspirator Catheter:**
 - a. Load and advance the prepped Trans-aspirator Catheter over the Guide Wire to the tip of the Guiding Catheter.
 - b. Under fluoroscopy advance the Trans-Aspirator Catheter and position the distal tip marker proximal above the embolic particles. Stop advancement of the Trans-Aspirator Catheter if any resistance is encountered.
Only for TRANS-ASPIRATOR (With Stiff)
After fluoroscopically confirming catheter position, disconnect the aspiration line and remove the stiffening stylet. Connect the aspiration line directly to Trans-Aspirator catheter and open the stopcock to begin extraction.
 - c. Begin aspiration by opening the stopcock on the Aspiration Line. Slowly retract the Trans-aspirator 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 Trans-Aspirator Catheter outside of the patient, either flush the aspiration lumen or use a new Trans-Aspirator Catheter. DO NOT flush the system while the catheter is still inside the patient vasculature.
- During performance testing, the Trans-Aspirator Catheter demonstrated the ability to evacuate fluid and debris during at a minimum rate of 1 ml/second.

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

6.6 Remove the Trans-aspirator Catheter

a. Withdraw the Trans-Aspirator 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 Trans-Aspirator 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 Trans-Aspirator Catheter with heparinised 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.

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

7.0 MATERIALS REQUIRED FOR USE WITH THE TRANS- ASPIRATOR 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 Haemostatic Valve
- Heparinised normal saline.

Recommendation:

- If the use of a second guide wire in addition to Trans- Aspirator 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 Trans- Aspirator Catheter, use a 7F Guiding Catheter.











8.0 HOW SUPPLIED










The Trans-Aspirator 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 Trans-Aspiration Catheter including all of its components are intended to be used for one procedure only.

9.0 PACKAGING:

- **Sterile:** The device is sterilized with ETO gas.
- **Contents:** Trans-Aspirator- Aspiration Catheter
- **Storage:** Store in a cool, Dark, dry place below 40°C

10.0 SYMBOLS

Description	Symbol
Reference No.	
Batch No.	
Manufactured Date	 YYYY MM
Use By	 YYYY MM
Outer Diameter	
Inner Diameter	
Sterile and Method of sterilization	
Single use only & do not re-sterile	
Storage condition	
Medical Device	

Description	Symbol
Name & Address of Manufacturer	
Content : Trans-Aspirator	
Read the documents /Instruction for use	
Do not use if package open or damaged	
Keep away from direct sun light	
Keep dry	
Warning / Attention: See Instructions for Use	
Pyrogen Free	
Single Sterile barrier system	

11.0 DISCLAIMER OF WARRANTY AND LIMITATION OF REMEDY

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