LP Aspiration Catheter is a dual lumen, rapid exchange catheter with related accessories. The smaller wire lumen of the catheter is able to accommodate guide wires that are ≤0.014" (0.36 mm) in diameter. The larger aspiration lumen comes preloaded with a stiffening stylet that resists kinking during placement but allows the smaller wire lumen of the catheter to accommodate guide wires that are ≤0.014" (0.36 mm). High pressure contrast injections can damage the delicate drug coating.

Use of unopened, undamaged package is sterile and non-pyrogenic.

Do not use if package is opened or damaged.

Do not reuse or re-sterilize; do not autoclave.

Do not expose to organic solvents such as alcohol.

Inspect contents prior to use.

Product Description

The Merit ASPALP Aspiration Catheter is dual lumen, rapid exchange catheter with related accessories. The smaller wire lumen of the catheter is able to accommodate guide wires that are ≤0.014" (0.36 mm) in diameter. The larger aspiration lumen comes preloaded with a stiffening stylet that resists kinking during placement but allows the smaller wire lumen of the catheter to accommodate guide wires that are ≤0.014" (0.36 mm). High pressure contrast injections can damage the delicate drug coating.

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Use of the ASAPLP Aspiration Catheter during an Interventional Procedure

1. Cannulate the vessel using the appropriate guide wire and guiding catheter with attached RHF. Flush the guiding catheter and RHF using standard technique. NOTE: The guide catheter must have a minimum I.D. of 0.046" (1.16 mm) or greater to accommodate free movement of the ASAPLP Aspiration Catheter.

2. Back-load the rapid exchange lumen of the ASAPLP Aspiration Catheter onto the guide wire. Advance the catheter on the guide wire until the wire exits the opening in the rapid exchange lumen.

3. Confirm that the stopcock/tubing set has been connected to the catheter prior to placement through guide catheter.

4. Open the RHF thumbscrew and introduce the catheter assembly, being careful to keep the guide wire in the rapid exchange 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.

5. Continue to advance the ASAPLP Aspiration Catheter Assembly through the guide catheter, under fluoroscopy, and continue to advance the catheter over the guide wire to the selected vascular site. The ASAPLP Aspiration Catheter has three nonradiopaque printed positioning marks indicating 90 cm, 100 cm & 110 cm from the catheter tip. Position the distal tip marker proximal to the desired site and release the vacuum. Using one of the VacLock syringes included in the kit, (or a 10 mL syringe), fill with heparinized saline solution to remove all air from the system. Use of the ASAPLP Aspiration Catheter if any resistance is encountered.

6. Never advance or withdraw an intravascular device against resistance until the cause of the resistance is determined by fluoroscopy. Movement of the catheter or guide wire against resistance may result in damage to the catheter, or vessel perforation.

7. After fluoroscopically confirming ASAPLP Aspiration Catheter position, remove the stopcock, extension tubing, and VacLock assembly from the stiffening stylet, remove the stiffening stylet, and reattach stopcock (in closed position), extension tubing system, and VacLock syringe assembly.

8. Reapply negative vacuum pressure on the VacLock syringe and aspiration catheter system.

9. After completing the aspiration process, turn the stopcock to the closed position and remove the ASAPLP Aspiration Catheter, or attach a second syringe and repeat aspiration.

10. Remove the ASAPLP Aspiration Catheter. If necessary, loosen the rotating hemostasis valve to allow easy withdrawal of the catheter.

11. Blood and thrombus extracted into the syringe may be filtered for subsequent laboratory analysis using the MicroStop 70 micron filter basket.WARNING: After use, dispose of device in a manner consistent with standard protocols for biohazard waste disposal.

Use of the MicroStop Basin and Filter Baskets

a. Wet the mesh of the filter basket with heparinized saline to allow fluid flow.

b. Place filter basket in MicroStop fluid collection basin.

c. Carefully dispense extracted blood into filter basket (Blood will go through filter basket and collect in MicroStop) and filter the extracted blood through the filter basket.

Any fresh, soft embolus and/or thrombi (larger than 70 micron) that have been aspirated should remain in the filter basket.

d. If necessary, use the second filter basket included in the kit to continue filtering blood.

Instructions for Use

The following instructions provide technical direction but do not obviate the necessity of formal training in the use of extraction or aspiration catheters. 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.

Preparation and Directions for Use:

1. Open the ASAPLP Aspiration Catheter Kit box. Using aseptic technique, open the Tyvek® header bag and transfer the tray onto the sterile field. (Tyvek® is a registered trademark of E.I. du Pont de Nemours and Company).

2. Remove the catheter hoop containing the ASAPLP Aspiration Catheter and other kit components from the tray. Attach one of the 30 mL VacLoc syringes included in the kit, (or a 10 mL syringe), filled with heparinized saline to the flush port on catheter hoop, flush hoop completely to activate hydrophilic coating on distal portion of catheter.

3. Remove the ASAPLP Aspiration Catheter from the carrier tube and inspect for any bends or kinks. Remove the wire stylet from the rapid exchange lumen.

4. Use 4 mL RXP syringe filled with heparinized saline to flush rapid exchange lumen.

5. Ensure that the stiffening stylet is in place in the aspiration lumen and secured to its luer hub. Flush extension tubing set with heparinized saline prior to use. Place one of the VacLoc syringes, draw 5-10 mL of heparinized saline into the syringe, attach the extension tubing set with stopcock to the catheter hub, or the stiffening stylet, if used is turned. Turn the stopcock to the open position and flush with the heparinized saline solution to remove all air from the system.

6. VacLoc syringe setup: To create and maintain vacuum, withdraw the VacLoc syringe plunger to the desired position. Press the plunger clockwise to position one of the locking fins behind the stop pin. Turn the plunger counterclockwise to release. (see fig. A below) and transfer the tray onto the sterile field. (Tyvek® is a registered trademark of E.I. du Pont de Nemours and Company).

7. Turn the stopcock to the closed position after the catheter system is properly flushed.

8. Check that all fittings are secure so that air is not introduced into the extension line or syringe during aspiration. At this time verify that the extension tubing set with stopcock is on the (stopcock in the closed position) with VacLoc syringe attached. The ASAPLP Aspiration Catheter is completely prepped and is ready for use.

9. If aspiration flow into the syringe stops or is restricted, DO NOT attempt to flush the extraction lumen tubing, and transfer the tray onto the sterile field. (Tyvek® is a registered trademark of E.I. du Pont de Nemours and Company).

10. If aspirated blood or thrombus is present in the syringe during a withdrawal of the catheter, or vessel perforation.

11. Blood and thrombus extracted into the syringe may be filtered for subsequent laboratory analysis using the MicroStop 70 micron filter basket. WARNING: After use, dispose of device in a manner consistent with standard protocols for biohazard waste disposal.
e. Locate the lid for the MicroStop Waste Basin (underneath the MicroStop Basin in the kit tray).
f. Place the lid on MicroStop Waste Basin until lid snaps into place.
g. Dispose of closed waste basin according to designated guidelines for the disposal of contaminated human waste.

For a copy of this device's current European summary of safety and clinical performance (SSCP) please go to the European database on medical devices (Eudamed), where it is linked to the basic UDI-DI. https://ec.europa.eu/tools/eudamed.

Basic UDI DK: 088445048795EM

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**Catalog Number**

**Lot Number**

**Caution**

Consult Instructions for Use. For electronic copy scan QR Code, or go to www.merit.com/ifu and enter IFU ID Number. For printed copy, call U.S.A or E.U. Customer Service

**Sterilized using Ethylene Oxide**

**Single Use**

**Use By**

**Do Not Resterilize**

**Non-pyrogenic**

**Keep away from sunlight**

**Single sterile barrier system with protective packaging inside**

**Manufacturer**

**Authorized Representative in European Community**

**Medical Device**

**Date of Manufacture**

**Unique Device Identifier**

**6F Guide Catheter Compatible**

**5.2F Catheter**