A.S.A.P. LP™

ASPIRATION CATHETER KIT

ASPIRATION CATHETER

INSTRUCTIONS FOR USE

MERIT MEDICAL®

English

ASAPLP™ Aspiration Catheter

INSTRUCTIONS FOR USE

Indications for Use
The Merit **ASAP**LP Aspiration Catheter is intended for the removal of fresh, soft thrombi in patients with large residual thrombus burden undergoing primary percutaneous coronary intervention.

Clinical Benefits
The Merit **ASAPLP** Aspiration Catheter may provide the following benefits during primary percutaneous coronary intervention in patients with large residual thrombus burden

- Improved flow (TIMI ≥2).
- Improved angiographic visualization to facilitate target vessel treatments.

Contraindications
Do not use in vessels less than 1.5 mm in diameter.
The venous system.
The removal of fibrous, adherent or calcified material (i.e. chronic clot, atherosclerotic plaque).
Not for use in the cerebral vasculature.

Cautions
℞ **ONLY** Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.
Read instructions prior to use.
Store in a cool, dry place.
Inspect contents prior to use.
Do not expose to organic solvents such as alcohol.
Product is intended for single use only.
Do not reuse or re-sterilize; do not autoclave.
Do not use if package is opened or damaged.
The **ASAP**LP Aspiration Catheter should be used by physicians with adequate training in the use of the device.
Kit components should not be substituted.
Contents of unopened, undamaged package are sterile and non-pyrogenic.
Crossing a freshly deployed drug-eluting stent could damage the delicate drug coating.

In the EU, any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the applicable member state.

Warnings
The **ASAP**LP Aspiration Catheter must be used with a guide catheter with a minimum internal diameter of 0.066" (1.68 mm) or greater.
Do not use a bent, kinked or damaged catheter as this may lead to vessel injury and/or an inability to advance or withdraw the catheter.
Do not advance the guide wire if resistance is met.
Do not place more than 60 mLs of fluid in the MicroStop™ fluid collection basin.
Do NOT flush the system while the catheter is still inside the patient vasculature.
Do not perform high pressure contrast injections around the **ASAP**LP Aspiration Catheter while using a 6F guide catheter. High pressure contrast injection may damage the **ASAP**LP Aspiration Catheter, making it difficult to remove from the 6F guide catheter.

Potential Complications
Potential complications include, but are not limited to:
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; acute myocardial infarction; emergent surgery; abrupt closure or total occlusion of treated graft or vessel; distal embolization of debris resulting in pulmonary compromise and/or limb ischemia; death, myocardial infarction; coronary or bypass graft thrombosis or occlusion, myocardial ischemia; stroke/CVA; emergent or non-emergent fibrillation; hemorrhage; hypotension; pseudo aneurysm at access site. Risks normally associated with percutaneous diagnostic and/or interventional procedures.

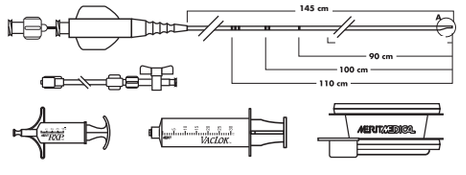
Reuse Precautions Statement
For single patient use only. Do not reuse, reprocess, or resterilize. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or lead to device failure, which in turn may result in patient injury, illness, or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient.

Additional Equipment Required But Not Supplied
Guiding catheter with an internal diameter of at least 0.066" (1.68 mm)
Guide wire with diameter of ≤0.014" (0.36 mm)
Rotating hemostasis valve (RHV)
Sterile, heparinized normal saline for system flushing 10 mL syringe

Product Description
The **ASAP**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 is removed to allow for the removal of thrombus by aspiration. The catheter has a maximum outer diameter of 0.055"(1.397 mm) and a working length of 145 cm, allowing delivery through standard 6F≥ .066" ID guide catheters. The catheter has a radiopaque marker band located approximately 2 mm proximal to the distal tip. The catheter has three (3) nonradiopaque positioning marks located approximately 90 cm, 100 cm, and 110 cm proximal of the distal tip. Catheter has a distal hydrophilic coated section of 30 cm.

The **ASAP**LP Aspiration Catheter kit consists of the following components. These components may be packaged together or separately.

(1) **ASAP**LP Aspiration Catheter
(1) Stiffening stylet (preloaded in aspiration lumen of catheter)
(1) Extension tubing set (8 1/2" (21.5 cm) total length) with one-way stopcock
(2) 70 micron pore filter baskets
(2) 30 mL VacLok® syringes
(1) MicroStop™ fluid collection basin with lid
(1) RXP® flushing syringe (4 mL)



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 **ASAP**LP 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 **ASAP**LP Aspiration Catheter and other kit components from the tray. Attach one of the 30 mL VacLok 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 **ASAP**LP 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. Using one of the VacLok 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 stylet is used. Turn the stopcock to the open position and flush with the heparinized saline solution to remove all air from the system.

6. VacLok syringe setup: To create and maintain vacuum, withdraw the VacLok syringe plunger to the desired position and rotate the plunger clockwise to position one of the locking fins behind the stop pin. Turn the plunger counterclockwise to release. (see fig. A below)

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 catheter (stopcock in the closed position) with VacLok syringe attached. The **ASAP**LP Aspiration Catheter is completely prepped and is ready for use.

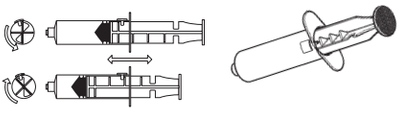


Figure A

Use of the ASAPLP **Aspiration Catheter during an Interventional Procedure**

1. Cannulate the vessel using the appropriate guide wire 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 ≥0.066"(1.68 mm) or greater to accommodate free movement of the **ASAP**LP Aspiration Catheter.

2. Back-load the rapid exchange lumen of the **ASAP**LP 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/VacLok have been connected to the catheter prior to placement through guide catheter.

4. Open the RHV 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 **ASAP**LP 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 **ASAP**LP 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. Stop advancement of the **ASAP**LP Aspiration 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 guide wire against resistance may result in damage to the catheter, or vessel perforation.

6. After fluoroscopically confirming **ASAP**LP Aspiration Catheter position, remove the stopcock, extension tubing, and VacLok assembly from the stiffening stylet, remove the stiffening stylet, and reattach stopcock (in closed position), extension tubing system, and VacLok syringe assembly.

7. Reapply negative vacuum pressure on the VacLok syringe and aspiration catheter system.

8. Open the stopcock to begin aspiration. Slowly advance the **ASAP**LP Aspiration Catheter distally away from the guiding catheter. Blood will enter the VacLok syringe until all vacuum is gone.
Warning: 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. Repeat steps 2-8.
Warning: If aspiration 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. Repeat steps 2-8.

NOTE: If air is noted in the syringe during extraction, a leak may be present in the system. Turn the stopcock to the closed position 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.

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

10. Remove the **ASAP**LP 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 emboli and/or thrombi (larger than 70 micron) that have been aspiratedshould remain in the filter basket.
d. If necessary, use the second filter basket included in the kit to continue filtering blood.
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-DI: 088445048795EM

SYMBOL	DESIGNATION
REF	Catalog Number
LOT	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
STERILE EO	Sterilized using Ethylene Oxide
	Do not use if package is damaged.
	Single Use
	Use By
	Do Not Resterilze
	Non-pyrogenic
	Keep away from sunlight
	Single sterile barrier system with protective packaging inside
	Manufacturer
EC REP	Authorized Representative in European Community
MD	Medical Device
	Date of Manufacture
UDI	Unique Device Identifier
	6F Guide Catheter Compatible
	5.2F Catheter

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CE 2797

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