



16. With the SOFIA Flow Plus Aspiration Catheter outside of the patient body, flush the catheter to clear the catheter of any thromboembolic material that may be inside.  
**WARNING:** Do not attempt to clear inner lumen of the SOFIA Flow Plus Aspiration Catheter by infusion while keeping the device in the patient body. Remove the SOFIA Flow Plus Aspiration Catheter from the patient body before attempting to clear the lumen.
17. If repeated access to the vasculature with the same device is desired, flush and clean the inner lumen of the device by infusion. Inspect the device for any damage. Reintroduce the SOFIA Flow Plus Aspiration Catheter into the body and follow steps 6 & 7 in the “Delivery of the SOFIA Flow Plus Aspiration Catheter” section to navigate the catheter to the target site.  
**WARNING:** Do not use the device if any damage or irregularities are observed.
18. Aspiration may be attempted up to 3 times, for a total of 2 minutes of aspiration per attempt with the SOFIA Flow Plus Aspiration Catheter.
19. Once aspiration is completed, remove the SOFIA Flow Plus Aspiration Catheter from the patient body.
20. Obtain a post-treatment angiogram by injecting contrast media through the sheath or guide catheter.

The physician has the discretion to modify the above described manipulations of the SOFIA Flow Plus Aspiration Catheter to accommodate the complexity and variation in procedures. Any technique modification must be consistent with previously described instructions, warnings, precautions and patient safety information.













### STORAGE

Avoid exposure to water, sunlight, extreme temperatures and high humidity during storage. Store the SOFIA Flow Plus Aspiration Catheter under controlled room temperature. See the product label for the device shelf life. Do not use the device beyond the labeled shelf life.

### MATERIALS

The SOFIA Flow Plus Aspiration Catheter is not manufactured with natural rubber latex, polyvinylchloride (PVC), or di-2-ethylhexyl phthalate (DEHP).

### SYMBOLS

	Lot Number		Use-by Date
	Catalog Number		Date of Manufacture
	Contents		Manufacturer
	Sterilized Using Ethylene Oxide		Non-pyrogenic
	Do Not Reuse		For Prescription Use Only
	Caution		Consult Instructions for use

### WARRANTY

MicroVention warrants that reasonable care has been used in the design and manufacture of this device. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness. Handling, storage, cleaning and sterilization of the device as well as factors relating to the patient, diagnosis, treatment, surgical procedure and other matters beyond MicroVention’s control directly affect the device and the results obtained from its use. MicroVention’s obligation under this warranty is limited to the repair or replacement of this device through its expiration date. MicroVention Inc. shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this device. MicroVention neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device. MicroVention assumes no liability with respect to devices reused, reprocessed or resterilized and makes no warranties, expressed or implied, including, but not limited to, merchantability or fitness for intended use, with respect to such device.

Prices, specifications and model availability are subject to change without notice.

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# SOFIA™ Flow Plus Aspiration Catheter

## Instructions for Use

Carefully read all instructions prior to use.

### DEVICE DESCRIPTION

The SOFIA Flow Plus Aspiration Catheter is a single-lumen, flexible catheter equipped with coil and braid reinforcement. The distal segment is steam-shapeable to facilitate vessel selection and also has a hydrophilic coating to aid navigation through the vasculature. A radiopaque marker is located at the distal end of the catheter for visualization under fluoroscopy. The SOFIA Flow Plus Aspiration Catheter is designed to remove thrombus from the vasculature using continuous aspiration.

### CONTENTS

One Aspiration Catheter  
One Introducer Sheath  
One Shaping Mandrel

### INDICATIONS FOR USE

The SOFIA Flow Plus Aspiration Catheter with the Gomco 405 Aspiration Pump and MicroVention Tubing Kit is intended for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral – M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.

### CONTRAINDICATIONS

There are no known contraindications.

### CAUTION

**Rx Only:** Federal (USA) law restricts this device to sale by or on the order of a physician.

Do not use if pouch is opened or damaged.

This device is intended for single use only. Do not reuse, reprocess or re-sterilize. Reuse, reprocessing or re-sterilization 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 re-sterilization 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.

After use, dispose in accordance with hospital, administrative and/or local government policy.

### WARNINGS

The SOFIA Flow Plus Aspiration Catheter should only be used by physicians who have received appropriate training in interventional techniques.

The SOFIA Flow Plus Aspiration Catheter is provided sterile and non-pyrogenic. Do not use if the packaging is breached or damaged.

Inspect the SOFIA Flow Plus Aspiration Catheter prior to use. Do not use the device if any damages or irregularities are observed.

The SOFIA Flow Plus Aspiration Catheter should be manipulated under fluoroscopic guidance. Do not advance or withdraw the device when excessive resistance is met until the cause of resistance is determined.

Do not use the SOFIA Flow Plus Aspiration Catheter with Ethiodol or Lipiodol contrast media or other Lipiodol-based contrast agents.

Do not use organic solvents as the device may be damaged.

Do not make an angle greater than 90 degrees on the Shaping Mandrel. Steaming of the distal tip with an angle greater than 90 degrees may result in damage to the device.

Do not steam the same device more than once, which may result in damage to the device.

Torqueing the SOFIA Flow Plus Aspiration Catheter excessively while kinked may damage the device resulting in separation of the device. Withdraw the entire device (the device, microcatheter, and guidewire) if the device is severely kinked.

The Introducer Sheath is not intended for use inside the patient body. Ensure that the Introducer Sheath is removed from the SOFIA Flow Plus Aspiration Catheter once the distal shaft of the SOFIA Flow Plus Aspiration Catheter is placed inside the patient body.

Do not wedge the tip of the SOFIA Flow Plus Aspiration Catheter in the vessel, as this may result in perforation or dissection of the vessel wall.

Excessive aspiration with the distal tip of the SOFIA Flow Plus Aspiration Catheter covered by the vessel wall may cause vessel injury. Carefully investigate location of the distal tip under fluoroscopy prior to aspiration.

Do not attempt to clear the inner lumen of the SOFIA Flow Plus Aspiration Catheter by infusion while keeping the device in the patient body.

When flow from the lumen stops or becomes stagnant during aspiration, do not attempt to clear the inner lumen of the SOFIA Flow Plus Aspiration Catheter by infusion while keeping the device in the patient body. Remove the SOFIA Flow Plus Aspiration Catheter from the patient body before attempting to clear the lumen.

## PRECAUTIONS

Administration of anticoagulants and antiplatelets should be suspended until 24 hours post-treatment. Medical management and acute post stroke care should follow ASA guidelines. Any neurological deterioration should be evaluated by urgent CT scan and other evaluations as indicated according to clinical best practice.

Exercise care in handling the SOFIA Flow Plus Aspiration Catheter to reduce the chance of accidental damage.

Verify compatibility of the SOFIA Flow Plus Aspiration Catheter when using other ancillary devices commonly used in intravascular procedures. The physician must be familiar with percutaneous, intravascular techniques and possible complications associated with the procedure.

Use caution when manipulating the SOFIA Flow Plus Aspiration Catheter in tortuous vasculature to avoid damage. Avoid advancing or withdrawal against resistance until the cause of resistance is determined.

The presence of calcification, irregularities, or other devices may damage the SOFIA Flow Plus Aspiration Catheter and potentially affect its insertion or removal.

Maintain perfusion of heparinized saline for inner lumen of the SOFIA Flow Plus Aspiration Catheter to prevent thrombus formation.

When performing aspiration, ensure that the aspiration source is open for only the minimum time needed to remove thrombus. Excessive aspiration or failure to close the aspiration source when aspiration is complete is not recommended.

Do not use automated high-pressure contrast injection equipment with the SOFIA Flow Plus Aspiration Catheter because it may damage the catheter.

The catheter has hydrophilic coating over the distal 60 cm. Make sure to hydrate the coating before use with heparinized saline. Once the catheter is hydrated, do not allow it to dry.

As in all surgical interventions, monitoring of intra-procedural blood loss is recommended so that appropriate management may be instituted.

## POTENTIAL COMPLICATIONS

Potential complications include but are not limited to: vasospasm, hematoma at the site of entry, embolism, ischemia, intracerebral/intracranial hemorrhage, pseudo aneurysm, seizure, stroke, infection, vessel dissection, thrombus formation, and death.

Potential Risks Associated with X-ray Exposure: The use of the SOFIA Flow Plus Aspiration Catheter requires fluoroscopy, which presents potential risks associated with X-ray exposure. The risks of angiographic and fluoroscopic X-ray radiation doses to the patient include risks such as alopecia, burns ranging in severity from skin reddening to ulcers, cataracts, and delayed neoplasia that increase in probability as procedure time and number of procedures increase. The probability of adverse event occurrence increases as the procedure time and the number of procedures increase. Operators should take all necessary precautions to limit X-ray radiation doses to patients and themselves by using sufficient shielding, reducing fluoroscopy times, and modifying X-ray technical factors whenever possible.

## COMPATIBILITY

Refer to product label for device dimensions. Use the information on labeling provided with other devices to determine device compatibility. When using the SOFIA Flow Plus Aspiration Catheter, choose the appropriate size of femoral sheath/ catheter by referring to product label.

Catheter/sheath Recommendation*	≥ 0.086 in. ID
Microcatheter Recommendation	≤ 0.027 in. ID
Guidewire Recommendation	≤ 0.016 in.
Recommended vessel size	≥ 2.5 mm

\*Catheter/Sheath compatibility recommendation applies only to MicroVention brand catheter/sheaths.

## PREPARATION FOR USE

- Carefully remove the SOFIA Flow Plus Aspiration Catheter and introducer sheath from the package.
- Inspect the SOFIA Flow Plus Aspiration Catheter for any damage. **WARNING:** Do not use the device if any damage or irregularities are observed.

If steam shaping is desired, use the technique outlined in step 3. Otherwise proceed to step 4.

### 3. STEAM SHAPING

- Bend the shaping mandrel to desired shape. **WARNING:** Do not shape the tip to angles greater than 90 degrees. Steaming of the distal tip with an angle greater than 90 degrees may result in damage to the device.
- Carefully insert the shaping mandrel into the distal tip of the SOFIA Flow Plus Aspiration Catheter.
- With the shaping mandrel inserted, expose the distal segment of the SOFIA Flow Plus Aspiration Catheter to steam for 30 seconds.

- d. Immediately place the shaped distal segment into heparinized saline to set the shape.
  - e. Inspect the distal segment for damage.  
**WARNING:** Do not use the device if any damage or irregularities are observed.
  - f. Remove the shaping mandrel from the SOFIA Flow Plus Aspiration Catheter.  
**WARNING:** Do not steam the same device more than once, which may result in damage to the device.
4. Flush the lumen of the SOFIA Flow Plus Aspiration Catheter with heparinized saline. Attach a rotating hemostatic valve (RHV) to the proximal hub of the SOFIA Flow Plus Aspiration Catheter. Set up the line for perfusion of heparinized saline through the sidearm of the RHV.
  5. Hydrate the hydrophilic coating on the SOFIA Flow Plus Aspiration Catheter with heparinized saline before use. Keep the coating hydrated and do not allow the coating to dry.

## DELIVERY OF THE SOFIA Flow Plus ASPIRATION CATHETER

6. **Navigation through the vasculature**
  - a. Prepare an appropriate guidewire and / or microcatheter for navigation of the SOFIA Flow Plus Aspiration Catheter.
  - b. Insert the guidewire and / or microcatheter into the SOFIA Flow Plus Aspiration Catheter and advance the guidewire / microcatheter until the guidewire / microcatheter and the SOFIA Flow Plus Aspiration Catheter are aligned at the distal end.
  - c. Using the introducer sheath provided in the package, carefully insert the SOFIA Flow Plus Aspiration Catheter and the guidewire through a hemostatic valve of the femoral sheath.  
**WARNING:** Do not over-tighten the hemostatic valve on the sheath or guide catheter through which the SOFIA Flow Plus Aspiration Catheter is inserted. Over-tightening may result in damage to the SOFIA Flow Plus Aspiration Catheter.
  - d. Remove the introducer sheath from the SOFIA Flow Plus Aspiration Catheter once the distal shaft of the SOFIA Flow Plus Catheter is placed inside the patient body.  
**WARNING:** The introducer sheath is not intended for use inside the patient body.
  - e. Under fluoroscopic guidance, advance or withdraw the SOFIA Flow Plus Aspiration Catheter over the guidewire and / or microcatheter until the desired position is attained. Select vessels by slowly torqueing the SOFIA Flow Plus Aspiration Catheter if necessary.  
**WARNING:** Do not advance or withdraw the device when excessive resistance is met until the cause of resistance is determined.  
**WARNING:** Torqueing the SOFIA Flow Plus Aspiration Catheter excessively while kinked may damage the device resulting in separation of the device. Withdraw the entire device (the device, Microcatheter, and Guidewire) if the device is severely kinked.
7. Slowly remove the guidewire or the microcatheter if necessary. Make sure that continuous perfusion of heparinized saline is maintained through the sidearm of the RHV.  
**NOTE:** The microcatheter used to navigate the SOFIA Flow Plus Aspiration Catheter may be kept for the rest of procedure.

## ASPIRATION THROUGH THE SOFIA Flow Plus ASPIRATION CATHETER

8. Under fluoroscopic guidance, position the distal tip of the SOFIA Flow Plus Aspiration Catheter at the desired vessel location.  
**WARNING:** Do not advance or withdraw the device when excessive resistance is met until the cause of resistance is determined.  
**WARNING:** Torqueing the SOFIA Flow Plus Aspiration Catheter excessively while kinked may damage the catheter resulting in separation of the catheter. Withdraw the catheter system, including the SOFIA Flow Plus Aspiration Catheter, microcatheter, and guidewire if the SOFIA Flow Plus Aspiration Catheter is severely kinked.
9. Attach aspiration tubing to the aspiration pump and turn on the pump (refer to the directions for use of the aspiration tubing and aspiration pump manual). Confirm that the aspiration gauge reads -20 inHg. Ensure the stopcock on the aspiration tubing is in the closed position.
10. Remove the perfusion line from the side arm of the RHV that is connected to the SOFIA Flow Plus Aspiration Catheter and attach the aspiration tubing to the side arm of the RHV.
11. Tighten the RHV.
12. Make sure the distal tip of the SOFIA Flow Plus Aspiration Catheter is engaged with the embolus or thrombus under fluoroscopy.
13. To begin aspiration, turn the aspiration tubing stopcock to the open position and check to see if blood, thrombus, or embolus are aspirated through the system.
14. If after 10 seconds blood is still observed flowing through the system, stop aspiration. To stop aspiration, turn aspiration tubing stopcock to the closed position. Carefully reposition the distal tip of the SOFIA Flow Plus Aspiration Catheter to engage the thrombus and resume aspiration.
15. If flow is restricted or absent, maintain aspiration to make sure any thrombus or embolus is fully engaged with the distal tip of the SOFIA Flow Plus Aspiration Catheter. With the thrombus or embolus fully engaged, slowly pull back the SOFIA Flow Plus Aspiration Catheter and completely withdraw out of the patient.  
**WARNING:** Excessive aspiration with the distal tip of the SOFIA Flow Plus Aspiration Catheter engaged with vessel wall may cause vessel injury.