

Tubing Kit

Instructions for Use

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Carefully read all instructions prior to use.

DEVICE DESCRIPTION/CONTENTS

The Tubing Kit consists of one piece of Distal Tubing, one Large Bore 1-way Stopcock, and one piece of Proximal Tubing.

INDICATIONS FOR USE

The SOFIA® Flow Plus Aspiration Catheter with the Gomco® 405 Aspiration Pump and MicroVentio® 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 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 or illness. 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 or illness of the patient.

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

WARNINGS

The Tubing Kit should only be used by physicians who have received appropriate training in interventional techniques.

The Tubing Kit is provided sterile and non-pyrogenic. Do not use if the packaging is breached or damaged.

Inspect the Tubing Kit prior to use. Do not use the device if any damages or irregularities are observed.

PRECAUTIONS

Exercise care in handling the Tubing Kit to reduce the chance of accidental damage.

Verify compatibility of the Tubing Kit 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.

COMPATIBILITY

Refer to product label for device dimensions. Use the information on labeling provided with other devices to determine device compatibility.

PREPARATION FOR USE

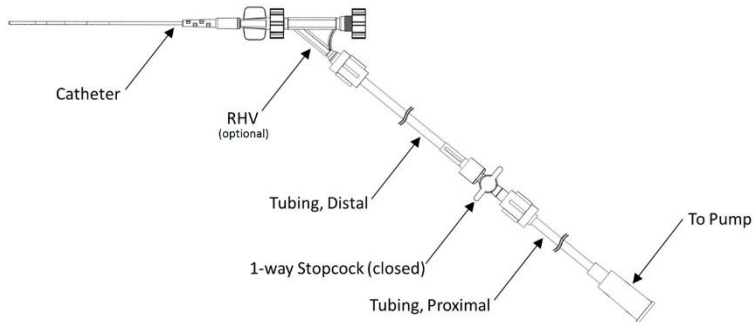
1. Carefully remove the Tubing Kit from the package.
2. Inspect the Tubing Kit for any damage.
WARNING: Do not use the device if any damages or irregularities are observed.

Using the Tubing Kit

- a. Connect the distal and proximal Tubing to the 1-way Stopcock.
- b. Connect the proximal end of the Tubing Kit to the vacuum source.
- c. Turn on the vacuum source.

- d. Turn the 1-way Stopcock to the closed position.
- e. At the proximal end of the catheter, remove the perfusion line and attach the Distal Tubing to the side port of the RHV or to the female luer of the catheter, shown in **Figure 1**.

Figure 1 – Tubing Kit



- f. For further instructions and information refer to the Instructions for Use that accompanies the catheter to be used in combination with the Tubing Kit.

The physician has the discretion to modify described manipulations of the Tubing Kit 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 Tubing Kit 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 Tubing Kit is not manufactured with natural rubber latex or di-2-ethylhexyl phthalate (DEHP).

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 and MicroVention 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.

SYMBOLS

	Batch code		Do not re-use
	Catalogue Number		Caution
	Non-pyrogenic		Use-by-date
	Keep dry		Keep away from sunlight
	Sterilized using ethylene oxide		Date of manufacture
	Manufacturer		Contents



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