SOFIA® EX

Intracranial Support Catheter

INSTRUCTIONS FOR USE

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Carefully read all instructions prior to use.

DEVICE DESCRIPTION

The SOFIA® EX Catheter is a single-lumen, flexible catheter equipped with the coil and the braid reinforcement. The distal segment is designed to facilitate vessel selection with 55-65cm of distal shaft hydrophilic coating for navigation through the vasculatures. The radiopaque marker is located at the distal end of the catheter for visualization under fluoroscopy.

CONTENTS

One Catheter
One Introducer Sheath

INDICATIONS FOR USE

The SOFIA® EX Catheter is indicated for general intravascular use, including the neuro and peripheral vasculature. The SOFIA® EX Catheter can be used to facilitate introduction of diagnostic agents or therapeutic devices. The SOFIA® EX Catheter is not intended for use in coronary arteries.

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, 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.

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

WARNINGS

The SOFIA® EX Catheter should only be used by physicians who have received appropriate training in interventional techniques.

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

Inspect the SOFIA® EX Catheter prior to use. Do not use the device if any damage or irregularities are observed.

Appropriate anti-coagulation and anti-platelet therapy should be administered per standard medical practice.

The SOFIA® EX Catheter must be used 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® EX Catheter with Ethiodol or Lipiodol contrast media or other such contrast media which includes the components of those agents.

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

Do not exceed 2070 kPa (300 psi) maximum recommended infusion pressure. Excess pressure may damage the device or injure the patient. Carefully monitor placement of the distal tip when using a power injector to infuse.

Torqueing the SOFIA® EX 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® EX Catheter once the distal shaft of the SOFIA® EX Catheter is placed inside the patient body.

PRECAUTIONS

Exercise care in handling the SOFIA® EX Catheter to reduce the chance of accidental damage.

Verify compatibility of the SOFIA® EX 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® EX Catheter in tortuous vasculature to avoid damage. Avoid advancing or withdrawal against resistance until the cause of resistance is determined. Torqueing the device against resistance may result in damage to the vessel or device.

Presence of calcifications, irregularities, or other devices may damage the SOFIA® EX Catheter and potentially affect its insertion or removal.

Maintain perfusion of heparinized saline for inner lumen of the SOFIA® EX Catheter to prevent thrombus formation.

If removed from the patient, the hydrophilic coating on the SOFIA® EX Catheter should be hydrated with heparinized saline. Do not allow the coating to dry as this may impact the coating safety and performance.

Avoid pre-soaking devices for long durations when the device is not in use as this may impact the coating safety and performance.

Avoid wiping the device with dry gauze as this may damage the device coating. Avoid excessive wiping of the coated device.

Excessive torqueing of the catheter may cause damage which could result in kinking and possible separation along the catheter shaft. Should the system become severely kinked, withdraw the entire system if this occurs (SOFIA® EX catheter, guidewire and catheter sheath introducer).

Limit the exposure to X-ray radiation doses to patients and physicians by using sufficient shielding, reducing fluoroscopy times, and modifying X-ray technical factors, when possible. The risk of X-ray radiation exposure complications may increase as procedure time and number of procedures increase.

POTENTIAL COMPLICATIONS

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

Potential X-ray radiation exposure related adverse events include but are not limited to: alopecia, burns ranging in severity from skin reddening to ulcers, cataracts, delayed neoplasia, tissue necrosis, and risks associated with contrast dye.

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® EX Catheter as a single guiding catheter, choose the appropriate size of a femoral sheath, referring to product label.

PREPARATION FOR USE

1. Carefully remove the SOFIA® EX Catheter and the Introducer Sheath from the package.
2. Inspect the SOFIA® EX Catheter for any damage.
   WARNING: Do not use the device if any damages or irregularities are observed.
3. Flush the lumen of the SOFIA® EX Catheter with heparinized saline. Attach a rotating hemostatic valve (RHV) to the proximal hub of the SOFIA® EX Catheter. Set up the line for perfusion of heparinized saline through the sidearm of the RHV.
4. Hydrate the hydrophilic coating on the SOFIA® EX Catheter with heparinized saline before use. Allow at least 30 seconds for hydration. Keep the coating hydrated and do not allow the coating to dry as this may impact the coating safety and performance.

DELIVERY OF THE SOFIA® EX CATHETER

5. Go to step 6 or 7, depending on the situation described below and choose appropriate devices for navigation of the SOFIA® EX Catheter.
6. **Navigation through the vasculature, except for the intracranial vasculature**
   a. Prepare 0.035" or 0.038" Guidewire for navigation of the SOFIA® EX Catheter.
   b. Insert the guidewire into the SOFIA® EX Catheter and advance the Guidewire until the Guidewire and the SOFIA® EX Catheter are aligned at the distal end.
   c. Using the Introducer Sheath provided in the package, carefully insert the SOFIA® EX Catheter and the Guidewire through a hemostatic valve of the femoral sheath.
   d. Remove the Introducer Sheath from the SOFIA® EX Catheter once the distal shaft of the SOFIA® EX Catheter is placed inside the patient body.
      WARNING: Introducer Sheath is not intended for use inside the patient body.
   e. Under fluoroscopic guidance, advance or withdraw the SOFIA® EX Catheter over the guidewire until desired position is attained or before the intracranial position is achieved. Select vessels by slowly torqueing the SOFIA® EX Catheter if necessary.
      WARNING: The SOFIA® EX Catheter must be used under fluoroscopic guidance.
      WARNING: Do not advance or withdraw the device when excessive resistance is met until the cause of resistance is determined.
      WARNING: Torqueing the SOFIA® EX 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.

WARNING: Do not exceed 2070 kPa (300 psi) maximum recommended infusion pressure. Excess pressure may damage the device or injure the patient. Carefully monitor placement of the distal tip when using a power injector to infuse.

Catheter	Approximate Nominal Flow Rates at 100 and 300 psi Infusion Pressure					
	Saline		60% Contrast		76% Contrast	
Sofia® EX 5F 115cm	100 psi	300 psi	100 psi	300 psi	100 psi	300 psi
	12.1 mL/sec	23.8 mL/sec	10.3 mL/sec	21.0 mL/sec	9.3 mL/sec	19.7 mL/sec
Sofia® EX 5F 105cm	100 psi	300 psi	100 psi	300 psi	100 psi	300 psi
	12.3 mL/sec	23.5 mL/sec	10.6 mL/sec	21.3 mL/sec	9.7 mL/sec	20.6 mL/sec

f. Go to step 7 for navigation through the intracranial vasculatures. Otherwise proceed to step 8.

7. **Navigation through the intracranial vasculature**
   a. Prepare Microcatheter and compatible Guidewire for navigation of the SOFIA® EX Catheter.
   b. Slowly remove, if any, devices previously inserted in the SOFIA® EX Catheter. Insert the Microcatheter with the Guidewire into the SOFIA® EX Catheter.
   c. Under fluoroscopic guidance, advance or withdraw the SOFIA® EX Catheter over the Microcatheter and the Guidewire until desired position is attained. Select vessels by slowly torqueing the SOFIA® EX Catheter if necessary.
   WARNING: The SOFIA® EX Catheter must be used under fluoroscopic guidance.
   WARNING: Do not advance or withdraw the device when excessive resistance is met until the cause of resistance is determined.
   WARNING: Torqueing the SOFIA® EX 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.
   WARNING: Do not exceed 2070 kPa (300 psi) maximum recommended infusion pressure. Excess pressure may damage the device or injure the patient. Carefully monitor placement of the distal tip when using a power injector to infuse.
8. 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™ Catheter may be kept for the rest of procedure.

REMOVAL OF THE SOFIA® EX CATHETER

9. Under fluoroscopic guidance, withdraw the SOFIA® EX Catheter until the entire device has been removed from the patient.

The physician has the discretion to modify described manipulations of the SOFIA® EX 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® EX 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® EX Catheter is not manufactured with natural rubber latex, polyvinylchloride (PVC), or di-2-ethylhexyl phthalate (DEHP).

SYMBOLS

LOT	Lot Number
REF	Catalog Number
CONTENTS	Contents
STERILE EO	Sterilized Using Ethylene Oxide
CE	CE Mark
EC REP	Authorized European Representative
	Do Not Reuse
Rx ONLY	For Prescription Use Only
	Caution
	Use-by Date
	Date of Manufacture
	Manufacturer
	Non-Pyrogenic
	Consult Instructions for use
	Do not use if package is damaged

WARRANTY

MicroVention, Inc. 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.

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