Instructions for Use

SureFlex® Steerable Guiding Sheath

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Read all instructions prior to use. Observe all warnings and precautions noted in these instructions. Failure to do so may result in patient complications. Baylis Medical Company relies on the physician to determine, assess and communicate to each individual patient all foreseeable risks of the procedure. CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

DEVICE DESCRIPTION

The SureFlex Steerable Guiding Sheath kit is indicated for introducing various cardiovascular catheters to the heart, including the left side of the heart through the interatrial septum. The SureFlex Steerable Sheath is designed for safe and easy catheterization and angiography of specific heart chambers and locations. The sheath provides superior torque control and is flexible. The radiopaque tip maximizes visualization of the sheath during manipulation. The dilator provides support for the sheath and has a tapered tip. INDICATIONS FOR USE The SureFlex Steerable Guiding Sheath kit is indicated for introducing various cardiovascular catheters to the heart, including the left side of the heart through the interatrial septum.

WARNINGS

- Laboratory staff and patients can undergo significant X-ray exposure during interventional procedures due to the continuous use of fluoroscopic imaging. This exposure can result in acute radiation injury as well as increased risk for somatic and genetic effects. Therefore, adequate measures must be taken to minimize this exposure.
- Use standard technique to position the guidewire only. Do not attempt to sterilize and reuse the SureFlex Steerable Guiding Sheath kit. Reuse can damage the guidewire.
- Insert the guidewire through the sheath only when distal end is completely straight.
- Thoroughly flush the sheath, guidewire and dilator with heparinized saline solution prior to use.

2. Inserting Sheath and Dilator

- Perform a standard vein puncture using an access needle (not supplied).
- Introduce the guidewire and advance to required depth. If resistance is encountered, DO NOT use excessive force to advance or withdraw the guidewire. Determine the cause of resistance before proceeding.
- Leaving the guidewire in place, withdraw the needle.
- Enlarge the cutaneous puncture site as necessary.
- Insert the dilator/sheath assembly over the guidewire using a slight twisting motion under fluoroscopic guidance.

3. Guiding Sheath/Dilator Assembly

- Use standard technique to position the sheath/dilator assembly into the desired heart chamber.
- Turn the sheath knob in direction of desired distal deflection. Sheath stays in desired position until sheath handle is turned again.
- If resistance is encountered, DO NOT use excessive force to deflect the sheath.
- If transseptal puncture is required, refer to the Instructions for Use of the transseptal puncture device.

4. Removing Steerable Sheath

- Straighten distal end of sheath as much as possible prior to removal.
- After removal of the sheath, use standard technique to achieve hemostasis.
- Discard all kit equipment after removal from body.

Cleansing and Sterilization Instructions

Do not clean or re-sterilize the SureFlex Steerable Guiding Sheath kit. The SureFlex Steerable Guiding Sheath kit is intended for single use only.

Customer Service and Product Return Information

If you have any problems with or questions about Baylis Medical Equipment contact our technical support personnel.

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- The sterile packaging and all components should be visually inspected prior to use. Do not use if the device, packaging or sterile barrier have been compromised or damaged.
- Do not attempt to use the SureFlex Steerable Guiding Sheath kit before thoroughly reading the accompanying Instructions for Use.
- Only physicians or personnel trained in aseptic techniques should perform aseptic presentation.
- Only physicians thoroughly trained in the techniques of the approach to be used should perform interventional procedures.
- Do not use device after its “Use By” date.
- Avoid deflecting distal end of sheath during delivery and removal, otherwise damage to vessels may occur.

ADVERSE EVENTS

Adverse events that may occur while using the SureFlex Steerable Guiding Sheath kit include:

- Infection

- Local nerve damage

- Dissection

- Air embolus

- Pseudoaneurysm

- Arrhythmias

- Hematoma

- Stroke

- Myocardial infarction

- Pulmonary edema

- Vessel trauma

- Hemorrhage

- Pericardial/pleural effusion

- Pulmonary edema

- Coronary artery spasm and/or damage

- Perforation and/or tamponade

- Coronary artery spasm

- Pacemaker/defibrillator lead displacement

- Coronary artery spasm and/or damage

- Perforation

- Pulmonary edema

- Coronary artery spasm and/or damage

- Pericardial/pleural effusion

- Coronary artery spasm and/or damage

- Perforation

- Pulmonary edema

- Coronary artery spasm and/or damage

- Pericardial/pleural effusion
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The warranty periods for Baylis Medical products are as follows:

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<tr>
<th>Product Type</th>
<th>Warranty Period</th>
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<tr>
<td>Disposable Products</td>
<td>The shelf life of the product</td>
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<td>90 days from the shipment date</td>
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