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Instructions for Use

SureFlex® Steerable Guiding Sheath

Baylis Medical Company Inc.
5959 Trans-Canada Highway
Montreal, Quebec, Canada, H4T 1A1
Tel: (514) 488-9801/ (800) 850-9801
Fax: (514) 488-7209
www.baylismedical.com

English

Carefully 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

I. DEVICE DESCRIPTION

The SureFlex Steerable Guiding Sheath kit consists of three components: a sheath, a dilator, and a J-tipped Mechanical Guidewire.
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.
The J-tipped Mechanical Guidewire, hereafter referred to as the "guidewire", comprises a stainless-steel core with a flexible, spiral shaped PTFE coated steel coil along the full length of the device. The sheath shaft and guidewire are coated in their entirety with a hydrophobic lubricious coating for smoother device manipulation. No pre-conditioning is required for these coatings.

II. 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.

III. WARNINGS

- Laboratory staff and patients can undergo significant x-ray exposure during interventional procedures due to the continuous usage 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. The use of echocardiography is recommended.
- The SureFlex Steerable Guiding Sheath kit is intended for single patient use only. Do not attempt to sterilize and reuse the SureFlex Steerable Guiding Sheath kit. Reuse can cause the patient injury and/or the communication of infectious disease(s) from one patient to another.
- Care should be taken to ensure that all air is removed from the sheath before infusing through the side port.
- Care should be taken when inserting or removing accessory devices from the sheath. For example, if removing the dilator, any devices through the dilator shall be removed as well.
- Do not attempt direct percutaneous insertion of the sheath without the dilator as this may cause vessel injury.
- Damage to guidewire may result if withdrawn through a metal needle cannula.
- Maintain continuous hemodynamic monitoring throughout procedure
- Provide continuous heparinized saline infusion while the introducer remains in vessel.
- To minimize vacuum effects during withdrawal, remove components/aspirate slowly. Refrain from aspiration if a wire is directly through the valve.
- Avoid contact with liquids other than blood, isopropyl alcohol, contrast solution or saline.
- Prior to steerable sheath's delivery and removal, ensure distal section is as straight as possible.
- Do not kink, stretch or severely bend steerable sheath.
- Do not use surgical instruments to handle sheath.
- The sheath device shaft in its entirety is coated with a hydrophobic lubricious coating for smoother device manipulation. The following warning must be considered:
  - Excessive wiping and/or wiping with a dry gauze may damage the coating.
- The guidewire is coated with a lubricious coating. The following warnings must be considered:
  - Use with incompatible introducers or dilators may affect device performance and integrity, including coating integrity.
  - Excessive manual bending and/or shaping of the device may affect the coating integrity.
- DO NOT attempt to insert or retract the guidewire through a metal cannula or a percutaneous needle, which may damage the guidewire and may cause patient injury.

IV. PRECAUTIONS

- Careful manipulation must be performed to avoid cardiac damage, or tamponade. Sheath, dilator and guidewire advancement should be done under fluoroscopic guidance. Echocardiographic guidance is also recommended. If resistance is encountered, DO NOT use excessive force to advance or withdraw the device.
- The SureFlex Steerable Guiding Sheath kit is supplied STERILE using an ethylene oxide process.
- 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.
- Do not reshape distal tip or curve of the guidewire. Excessive bending or kinking of the distal curve may damage the integrity of the wire or coating and lead to patient injury.
- Only use compatible tip straighteners with the guidewire.
- Do not attempt to insert the proximal end of the guidewire as the distal end.
- Confirm ancillary devices are compatible with the dilator and guidewire diameters before use.
- Individual patient anatomy and physician technique may require procedural variations.
- Do not attempt to use the guidewire with electrocautery tools.
- Avoid guidewire contact with liquids other than blood, isopropyl alcohol, contrast solution or saline.

V. CONTRAINDICATIONS

There are no known contraindications for this device.

VI. SPECIAL STORAGE AND/OR HANDLING INSTRUCTIONS

Keep away from sunlight.

VII. ADVERSE EVENTS

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

Infection	Air embolus
Local nerve damage	Vasovagal reaction
Dissection	Vessel spasm
AV fistula formation	Atrial septal defect
Pseudoaneurysm	Aortic puncture
Arrhythmias	Perforation and/or tamponade
Hematoma	Hemorrhage
Catheter entrapment	Embolic events
Stroke	Valve damage
Myocardial infarction	Pericardial/pleural effusion
Pacemaker/defibrillator lead displacement	
Pulmonary edema	Coronary artery spasm and/or damage
Vessel trauma	

VIII. INSPECTION PRIOR TO USE

Prior to use of the SureFlex Steerable Guiding Sheath kit, the individual components should be carefully examined for damage or defects, as should all equipment used in the procedure. Do not use defective equipment. Do not reuse the device.

IX. EQUIPMENT REQUIRED

Intracardiac puncture procedures should be performed in a sterile environment in a specialized clinical setting equipped with a fluoroscopy unit, radiographic table, echocardiographic imaging (recommended), physiologic recorder, emergency equipment and instrumentation for gaining vascular access.

X. SUGGESTED DIRECTIONS FOR USE

- Carefully read all instructions prior to use. Failure to do so may result in complications.

1. Preparing for Insertion

- Remove sterilized equipment from kit in sterile environment
- Verify proper deflection of steerable sheath by using knob.
- Insert steerable 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 through the vasculature access point 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.
- Enlarge the cutaneous puncture site as necessary.
- Assemble the dilator and sheath until the dilator hub locks into the sheath hub.
- Thread 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 steerable 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. Echocardiographic guidance is also recommended.
- Ensure the sheath is clear of air. To aspirate blood, use the sheath side port.
- Monitor the location of the radiopaque tip frequently under fluoroscopy. Echocardiographic guidance is also recommended.
- Deliver a continuous heparinized solution infusion or aspirate periodically. This may help reduce the risk of thromboembolic complications due to thrombus formation, as there may be a possibility of thrombus development at the distal sheath tip or inside the sheath lumen. Also aspirate when removing the transseptal device or dilator.

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.

XI. CLEANING 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.

XII. DISPOSAL OF WASTE

Treat the used device(s) as biohazardous waste and dispose of in compliance with standard hospital procedures.

XIII. 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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NOTES:

1. In order to return products you must have a return authorization number before shipping the products back to Baylis Medical Company. Product Return Instructions will be provided to you at this time.
2. Ensure that any product being returned to Baylis Medical has been cleaned, decontaminated and/or sterilized as indicated in the Product Return Instruction before returning it for warrantied service. Baylis Medical will not accept any piece of used equipment that has not been properly cleaned or decontaminated as per the Product Return Instructions.

XIV. LABELING AND SYMBOLS

	Manufacturer		Single use – do not reuse
STERILE EO	Sterile using ethylene oxide	LOT	Lot number
	Use by date		Do not re-sterilize
	Caution		Do not use if packaging is damaged
	Keep away from Sunlight		Non-pyrogenic
	Consult instructions for use	REF	Model number
Max Guidewire O.D.	Maximum guidewire outside diameter that can be used with this device		
Rx ONLY	**Caution:** Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.		

XV. LIMITED WARRANTIES – Disposables and Accessories

Baylis Medical Company (BMC) warrants that its products are free from defects in original workmanship and materials. BMC warrants that sterile products will remain sterile for a period of time as shown on the label as long as the original package remains intact. The SureFlex Steerable Guiding Sheath kit is designed for single use only. The SureFlex Steerable Guiding Sheath kit is not designed for reuse. If any BMC product is proved to be defective in original workmanship or original materials, BMC, in its absolute and sole discretion, will replace or repair any such product, less charges for transportation and labour costs incidental to inspection, removal or restocking of product.

This limited warranty applies only to original factory delivered products that have been used for their normal and intended uses. BMC's limited warranty shall NOT apply to BMC products which have been resterilized, repaired, altered, or modified in any way and shall NOT apply to BMC products which have been improperly stored or improperly installed, operated or maintained contrary to BMC's instructions.

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XVII. LIMITATION OF LIABILITY FOR DAMAGES

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This limited warranty applies only to new original factory delivered products that have been used for their normal and intended uses. BMC's Limited Warranty shall not apply to BMC products which have been resterilized, repaired, altered, or modified in any way and shall not apply to BMC products which have been improperly stored or improperly cleaned, installed, operated or maintained contrary to BMC's instructions.

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No agent, employee or representative of Baylis Medical has the authority to bind the Company to any other warranty, affirmation or representation concerning the product.

This warranty is valid only to the original purchaser of Baylis Medical products directly from a Baylis Medical authorized agent. The original purchaser cannot transfer the warranty.

Use of any BMC product shall be deemed acceptance of the terms and conditions herein.

The warranty periods for Baylis Medical products are as follows:

Disposable Products	The shelf life of the product
Accessory Products	90 days from the shipment date