Instructions for Use
Reprocessed SureFlex Steerable Guiding Sheath

Reprocessed Device for Single Use

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

DEVICE DESCRIPTION

The Reprocessed SureFlex Steerable Guiding Sheath consists of three components: a reprocessed sheath, a reprocessed dilator and a J-tipped Mechanical Guidewire.

The Reprocessed 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 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 dilator shaft, sheath shaft, and guidewire are coated in their entirety with a hydrophobic lubricious coating for smoother device manipulation. No pre-conditioning is required for this coating.

INDICATIONS FOR USE

The Reprocessed SureFlex Steerable Guiding Sheath is indicated for introducing various cardiovascular catheters to the heart, including the left side of the heart through the interatrial septum.

CONTRAINDICATIONS

There are no known contraindications for this device.

WARNINGS

- Tactile feedback of reprocessed device may vary during use.
- 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 comatic and genetic effects. Therefore, adequate measures must be taken to minimize this exposure.
- The SureFlex Steerable Guiding Sheath is intended for single patient use only. Do not attempt to sterilize and reuse the SureFlex Steerable Guiding Sheath. Reuse can cause the patient injury and/or the communication of infectious disease(s) from one patient to another. Failure to follow this instruction may result in patient complications.
- 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 no attempt direct percutaneous insertion of the sheath without the dilator as this may case 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 is 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 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.
- The dilator shaft and sheath in their entirety are coated with a hydrophobic lubricious coating for smoother device manipulation. The following warnings must be considered:
- Excessive wiping and/or wiping with a dry gauze may damage the coating.
- Excessive manual bending and/or shaping of the device may affect the coating integrity.

PRECAUTIONS

- Careful manipulation must be performed to avoid cardiac damage, or tamponade. Sheath, dilator and guidewire advancement should be done under fluoroscopic guidance. If resistance is encountered, DO NOT use excessive force to advance or withdraw the device.
- The Reprocessed SureFlex Steerable Guiding Sheath 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 Reprocessed SureFlex Steerable Guiding Sheath before thoroughly reading the accompanying Instructions for Use.
- Only physicians thoroughly trained in aseptic techniques 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.

ADVERSE REACTIONS

Adverse events that may occur while using the Reprocessed 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
Pulmonary edema	Pacemaker/defibrillator lead displacement
Vessel trauma	Coronary artery spasm and/or damage

INSPECTION PRIOR TO USE

Prior to use of the Reprocessed SureFlex Steerable Sheath, 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.

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.

DIRECTIONS

- The package label is detachable and may be affixed to the medical record of the patient.
- Inspect the device and packaging before opening. The contents of the package are sterile unless the package is opened or damaged. If the device is damaged or if the package is compromised, do not use the device. Return the device and packaging to Innovative Health. Do not attempt to resterilize.
- Carefully read all instructions prior to use. Failure to do so may result in complications.

1. **Preparing for Insertion**
   - Remove the device from the package and place it in a sterile work area using aseptic technique.
   - 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 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.
   - 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.
   - 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.
   - Upon use, please return the device per Innovative Health's Instructions.

EXPLANATION OF SYMBOLS

Rx only	Federal Law in the USA restricts this device to sale by or on the order of a physician
STERILE EO	Sterilized by Ethylene Oxide Gas
REF	Catalog Number
SN	Serial Number
LOT	Lot Number
	Use by Date
	Do Not Reuse
	Do Not Resterilize
	Consult Instructions for Use
	Do Not Use if Package is Damaged
	Keep Product Dry
	Keep Away from Sunlight and Radioactive Sources
	Non-pyrogenic
	Manufacturer

As the reprocessor, Innovative Health is solely responsible for this device. All Original Manufacturer (OM) information is provided for device identification and may contain trademarks from third parties that do not sponsor this device.

Sterilization: This product and its packaging have been sterilized with Ethylene Oxide (EO) gas. Even though the product is processed in compliance with all applicable laws and regulations relating to EO exposure, Proposition 65, a State of California voter initiative, requires the following notice:

Warning: This product and its packaging have been sterilized with EO. The packaging may expose you to EO, a chemical known to the State of California to cause cancer or birth defects or other reproductive harm.

Please refer to www.innovative-health.com for product warranty.