



## Instructions for Use

### AD-Ducer™

## Steerable Introducer Sheath

### Description:

The Steerable introducer sheath set consists of a Catheter sheath and Dilator. The Catheter sheath is composed of a handle, single-handle tee, a side port with extension, and the sheath tube. The introducer handle includes a rotating knob to enable clockwise and counterclockwise tip deflection up to 90°. The side port has a three-way stopcock attached for air or blood aspiration, fluid infusion, blood sampling, and pressure monitoring. The sheath has a radiopaque marker at the distal tip. The dilator has a tapered tip to reduce insertion force.

### Indications for Use:

ALSPL's Steerable Introducer Sheaths are intended to introduce catheters and other similar devices in cardiac vessels and chambers or peripheral vessels.

### Contraindications:

- As the Steerable Introducer Sheath is only an accessory for intervention procedures, the contraindications are limited to the contraindications for the respective procedures. Some known contraindications for the procedures include patients with active peptic ulcers, and patients who do not tolerate anticoagulant therapy
- The physician must decide when percutaneous vessel entry is unsuitable

### Warnings and Precautions:

1. Please read all packaging insert warnings, precautions, and instructions before use. Failure to do so may result in severe patient injury or death.
2. Warning: Sterile by EO, Single Use: Do not reuse, reprocess or re-sterilize under any circumstance. Blood and other foreign material can collect in the inner parts of the product which cannot be removed; therefore, products are for single use only.
3. Warning: Do not use if the packaging is damaged or opened unintentionally before use. This will lead to loss of sterility.
4. Warning: Rx Only. The device must be used by trained physicians
5. Precaution: Aseptic techniques must be used wherever possible, especially during removal from packaging.
6. Warning: During insertion or removal of a balloon catheter, the balloon must be completely deflated to safely and easily pass through the introducer.
7. Warning: Do not advance introducer sheath or guidewire if there is a great amount of resistance
8. Precaution: Aseptic techniques must be used wherever possible, especially during removal from packaging.
9. Precaution: The device must be used under the guidance of fluoroscopy
10. Precaution: The size of the vessel should be known before selecting the appropriate size introducer sheath
11. Precaution: Connections to the side port should only be made with devices compliant to ISO 80369-7
12. Precaution: Do not bend the sheath or the dilator before use
13. Warning: Store in a cool, dark, dry place
14. Warning: Any infusion through the side port must be done after removal of all air from the system

### Instructions for Use:

Preparation: The device requires a guidewire, introducer needle, scalpel blade, syringe for infusion and sterile heparinized saline solution, which are not supplied along with the device.

1. Use aseptic technique to take the steerable sheath out of the package, rinse the components of the steerable sheath with the heparinized saline solution to remove the air in the catheter sheath (including the extension hose), and insert the dilator into the catheter sheath for assembly.
2. Use aseptic technique to insert the puncture needle into the blood vessel, insert the flexible end of the guidewire into the blood vessel through the puncture needle and slowly push it to the designated position.
3. After fixing the guidewire, withdraw the puncture needle, use a scalpel to puncture the puncture point (if necessary), and slowly insert the steerable sheath along the guidewire into the blood vessel.
4. When the steerable sheath comes near the target position, draw back the dilator by about 80 mm, rotate the Extension range of catheter sheath 4 steering knob on the handle to bend the distal end of the sheath, and manipulate the steerable sheath to find the target position. To avoid damaging the blood vessel, wait until the catheter sheath fully enters the blood vessel before withdrawing the dilator.
5. Fix the catheter sheath, and slowly withdraw the guidewire and dilator.
6. To take out the catheter sheath, first rotate the steering knob on the handle to restore the angle of the catheter sheath head to its original state, compress the blood vessels at the puncture site, and slowly withdraw the catheter sheath.

**Disposal:**

7. The device can be a biological hazard if disposed incorrectly. They should be disposed using recognised medical procedures and industry best practices. Local laws and regulations should be taken into account during disposal

**Potential Complications / Adverse Effects**




The device is an accessory used in interventional medical procedures. The potential complications or adverse effects caused during use are dependent on the procedure being performed, and other device used.









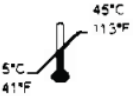








**Warranty and Limitations**


Steerable Introducer Sheath are sold in ‘as is’ condition. The entire risk as to the quality and performance of the product is with the buyer. ALSPL disclaims all warranties, expressed or implied, with respect to its products, including but not limited to, any implied warranty of merchantability or fitness for a particular purpose. ALSPL shall not be liable to any person for any medical expenses or any direct or consequential damages resulting from the use of any product or caused by any defect, failure, or malfunction of any product, whether a claim for such damages is based upon warranty, contract, tort, or otherwise. No person has any authority to bind ALSPL to any representation or warranty with respect to its products.

**Notice:** Any serious incident which occurs in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

**Symbols Glossary**

	Caution, Consult Indications for Use
	Date of Manufacture
	Do not re-use

	Do not use if package is damaged
	Sterilized using ethylene oxide
	Keep away from sunlight
	Batch code
	Catalogue Number
	Manufacturer
	Use-by date
	Keep dry
	Temperature Limit (5-45°C)
	Non-Pyrogenic
	Prescription use only
	Medical device
	Do not re-sterilize
	Single Sterile Barrier System
	Single Sterile barrier system with protective packing outside
	Double Sterile Barrier System
	Single sterile barrier system with protective packing inside

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