



Instructions for Use

AD-VALVE™

Insertion Tool

Description:

ALSPL Insertion Tools are disposable intervention accessories which allow easy access for guidewires during procedures. The product is a needle with a blunt tip to allow access through hemostasis valves which may be found on connectors, or introducer sheaths.

Indications for Use:

ALSPL's Insertion Tools are intended to facilitate the introduction of guidewires through hemostasis valves or catheters during interventional procedures.

Contraindications:

- No specific contraindications known
- As Insertion Tools are only an accessory for procedures, the contraindications are limited to the contraindications for the respective procedures

Warnings and Precautions:

1. Please read all packaging insert warnings, precautions, and instructions before use. Failure to do so may result in loss of blood and delay to the procedure.
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.
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 products must be used by trained physicians
5. Precaution: Aseptic techniques must be used wherever possible, especially during removal from packaging.
6. Precaution: Check products carefully to ensure there is no entrapped air which can lead to an embolism

Instructions for Use:

1. Open the Insertion Tool aseptically from the packaging
2. Flush the device with saline using the end port.
3. Gently insert the device in the hemostasis valve. When the device is inserted into the valve, there is a risk of air embolization and back bleeding. Keep the proximal end of the device covered with your thumb
4. Insert the guidewire through the insertion tool.
5. After completion of the procedure, gently remove the insertion tool after the guidewire has been removed.

Disposal:

6. Insertion Tools 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


Insertion Tools are accessories used in various medical procedures. The potential complications or adverse effects caused during use are limited to the procedure being performed.

Warranty and Limitations

Insertion Tools 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.

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

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