

**INTRODUCER NEEDLE**  
**Instructions for Use**

**Indication for Use:**

- These needles are used for the percutaneous introduction of guidewires.



**Device Description:**

- Introducer Needles are composed of two components: a stainless-steel cannula with over molded hub. The introducer needle provides an access path into the vasculature.

**Potential Complications:**

- Air embolism
- Bleeding
- Device dislodgement
- Needle cannula breakage
- Hemothorax
- Infection
- Pneumothorax
- Thrombosis
- Trauma to vessels

**Warnings:**

- Federal Law (USA) restricts the device to sale by or on the order of a physician.
- This device is for Single Use Only. 
- Do not re-sterilize the needle by any method.
- Re-Use may lead to infection or illness/injury.
- The manufacturer shall not be liable for any damages caused by reuse or re-sterilization of the needle.
- Contents sterile and non-pyrogenic in **unopened, undamaged** package.
- STERILIZED BY ETHYLENE OXIDE 
- Do not use the needle if package is opened or damaged.
- Do not use the needle if any sign of product damage is visible.

**Instructions for Use:**

- Attach syringe to needle hub, if applicable
- Hold skin taut
- Adjust angle of insertion and insert needle tip, bevel of needle up
- Puncture vein;
- Aspirate to assure proper placement

Introduce guidewire per hospital procedure.

**Needle Disposal:**

- The needle should be disposed in accordance with policies and procedures for contaminated sharps disposal.












Medcomp does not recommend a particular technique for the use of this device. The physician should evaluate their appropriateness according to individual patient conditions and his or her medical training and experience.

**WARRANTY**

**Medcomp® WARRANTS THAT THIS PRODUCT WAS MANUFACTURED ACCORDING TO APPLICABLE STANDARDS AND SPECIFICATIONS. PATIENT CONDITION, CLINICAL TREATMENT, AND PRODUCT MAINTENANCE MAY AFFECT THE PERFORMANCE OF THIS PRODUCT. USE OF THIS PRODUCT SHOULD BE IN ACCORDANCE WITH THE INSTRUCTIONS PROVIDED AND AS DIRECTED BY THE PRESCRIBING PHYSICIAN.**

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5.1.1 	Manufacturer *	5.6.3 	Non-pyrogenic *
5.1.4 	Use-by Date *	5.3.2 	Keep Away from Sunlight *
5.4.2 	Do Not Re-use *	5.2.6 	Do Not Resterilize *
5.3.4 	Keep Dry *	Rx Only	Prescription Use Only ***
5.1.5 	Batch/Lot Number *	5.1.6 REF	Catalogue Number *
5.2.8 	Do Not Use if Package is Damaged *		
5.1.2 	Authorized Representative in the European Community *		
5.2.3 	Sterilized Using Ethylene Oxide *		

\* This symbol is in accordance with ISO 15223-1.

\*\*\* FDA guidance Use of Symbols in Labeling.

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