GUIDEWIRE INTRODUCER SYRINGE INSTRUCTIONS FOR USE

INDICATION FOR USE:

Used to pass the guidewire into the target vein.

DESCRIPTION:

Valved syringe used for introduction of guidewire with minimal blood loss.

POTENTIAL COMPLICATIONS:

- Air embolism
- Blood loss
- Device dislodgement
- Infection

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 resterilize by any method.
- Re-Use may lead to infection or illness/injury.
- The manufacturer shall not be liable for any damages caused by re-use or resterilization of the device.
- Contents sterile and non-pyrogenic in unopened, undamaged package.
- STERILIZED BY ETHYLENE OXIDE STERILE EO
- Do not use if package is opened, damaged, or deteriorated.
- Do not use if any sign of product damage is visible.
- Do not insert or withdraw the guidewire forcibly from any component. The wire may break or unravel. If the guidewire becomes
 damaged, the introducer needle or sheath/dilator and guidewire must be removed together.

INSTRUCTIONS FOR USE:

- Attach valved syringe to the introducer needle.
- Insert the introducer needle with attached syringe into the target vein.
- Aspirate to assure proper placement.
- Advance guidewire through valved syringe into vessel.
- Hold guidewire in place and remove syringe and needle.
- Proceed with insertion procedure.
- Discard biohazard according to facility protocol.

Medcomp® does not recommend a particular technique for the use of this device. The physician should evaluate the appropriateness of the device 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 TREATEMENT, AND PRODUCT MAINTENANCE MAY EFFECT THE PERFORMANCE OF THIS PRODUCT. USE OF THIS PRODUCT SHOULD BE IN ACCORDANCE WITH THE INSTRUCTIONS PROVIDED AND AS DIRECTED BY THE PRESCRIBING PHYSICIAN.

Because of continuing product improvement, prices, specifications, and model availability are subject to change without notice. Medcomp® reserves the right to modify its products or contents without notice.

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EC REP

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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 STENE	Do Not Resterilize *
5.3.4	Keep Dry *	Rx Only	Prescription Use Only ***
LOT	Batch/Lot Number *	REF	Catalogue Number *
5.2.8	Do Not Use if Package is Damaged *		
5.1.2 EC REP	Authorized Representative in the European Community *		
5.2.3 STERILE EO	Sterilized Using Ethylene Oxide [*]		

^{*} This symbol is in accordance with ISO 15223-1.

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^{***} FDA guidance Use of Symbols in Labeling.