- 4. Remove the needle, leaving the guidewire in the target vessel.
- A sheath/dilator or catheter can now be passed over the guidewire into the target vessel.
- 6. Carefully remove the guidewire from the sheath/dilator or catheter.
- 7. Discard biohazard according to facility protocol.

Medcomp® does not recommend a particular technique for the use of this device. The steps contained in the preceding directions discuss the Seldinger Technique for percutaneous entry and are for information purposes only. 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 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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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 STEPAZZE	Do Not Resterilize *
5.3.4	Keep Dry	Rx Only	Prescription Use Only ***
LOT	Batch/Lot Number *	REF	Catalogue Number *
5.2.8	bo 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 *		

<sup>\*</sup> This symbol is in accordance with ISO 15223-1.

<sup>\*\*\*</sup> FDA guidance Use of Symbols in Labeling.



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Borngasse 20
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Germany



PN 40659BSI Rev. 3/19B

# GENERAL VASCULAR GUIDEWIRE INSTRUCTIONS FOR USE

#### **CAUTIONS:**

- Federal Law (USA) restricts this device to the sale and use by or on the order
  of a physician.
- Disposable; for single patient use only. Re-Use may lead to infection or illness/injury. Do not resterilize.
- Ethylene oxide (EtO) sterilized; non-pyrogenic. STERILE EO
- Carefully read all instructions prior to use. Observe all warnings and cautions.
- Do not use if package is damaged.
- Do not resterilize.



## **DESCRIPTION:**

Medcomp guidewires are available in a variety of lengths, diameters, tip configurations, and coatings; see product label for guidewire specifications.

#### INDICATIONS:

For general intravascular use, including the peripheral vasculature, to facilitate the selective placement of medical devices in the vessel anatomy.

This device is not intended for coronary or cerebrovascular use.

## **WARNINGS:**

Do not withdraw guidewire through a metal trocar or needle; damage to guidewire and/or coating may result.

Do not advance or withdraw guidewire against resistance until the cause of the resistance has been determined under fluoroscopy. Excessive force against resistance may result in damage to the guidewire or another device, or may cause vessel perforation.

Do not torque a guidewire without observing corresponding movement of the distal guidewire tip; guidewire damage or vessel trauma may result.

Guidewires, by nature of their construction, will collect blood and other foreign matter on the surface. No type of cleaning will completely remove this material. Therefore, they are intended for single use only.

If the guidewire kinks, or if a vascular spasm is suspected, cease manipulating the guidewire and carefully withdraw it from the vessel.

## **INSTRUCTIONS FOR USE:**

- 1. Inspect the guidewire prior to use for tip shape, bends, kinks, or coil separation.
  - If guidewire is damaged, DO NOT USE.
- 2. Using sterile technique, localize and puncture the vessel with a needle.
- 3. Insert the guidewire into the needle and advance the guidewire into the target vessel.