

5. 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.

SYMBOL TABLE

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

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

*** FDA guidance Use of Symbols in Labeling.

WARRANTY

Medcomp® WARRANTS THAT THIS PRODUCT WAS MANUFACTURED ACCORDING TO APPLICABLE STANDARDS AND SPECIFICATIONS, PATIENT CONDITION, CLINICAL TREATMENT, 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.

Medcomp® is a registered trademark of Medical Components Inc.

Medical Components, Inc.
1499 Delp Drive
Harleysville, PA 19438 U.S.A.
Tel: 215-256-4201
Fax: 215-256-1787
www.medcompnet.com

MPS Medical Product Service GmbH
Borngasse 20
35619 Braunsfels
Germany

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.
- Do not use if package is damaged.
- Ethylene oxide (EtO) sterilized; non-pyrogenic.
- Carefully read all instructions prior to use. Observe all warnings and cautions.

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.

HYDROPHILIC-COATED GUIDEWIRE PREPARATION:

- a. Remove the hydrophilic-coated guidewire, in its dispenser, from the package.
- b. Using a syringe, completely fill the dispenser with sterile saline through the holder hub.
- c. Remove the hydrophilic-coated guidewire from the dispenser. When removing, make sure that its surface has adequate lubricity and that the guidewire is not damaged. If resistance is felt when removing the guidewire, inject more sterile saline into the dispenser, and then try removing the guidewire again.
- d. Follow "Instructions for use".

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.
4. Remove the needle, leaving the guidewire in the target vessel.