

VESSEL DILATOR INSTRUCTIONS FOR USE

INTENDED USE:

Short-term use for entry into a vessel.

INDICATIONS:

The Medcomp® vessel dilators are designed for percutaneous entry into a vessel in order to enlarge the opening of the vessel for the placement of a catheter in a vein or artery.

POTENTIAL COMPLICATIONS:

- Bleeding
- Embolism
- Infection
- Perforation/Trauma to Vessel

WARNINGS:

- Product is sterile in unopened, undamaged package. STERILIZED BY ETHYLENE OXIDE

STERILE	EO
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- For single use only. **DO NOT RE-USE.** Re-use may lead to infection or illness/injury. 
- Do not use if package is damaged. 
- Federal (USA) law restricts this device to sale by or on the order of a physician.
- Do not resterilize. 
- Caution when using this device. Be aware of sharps.
- Do not use if components are damaged, deformed or missing.
- Do not overtighten. Do not proceed if resistance is felt or interaction between components is failing.

Medcomp® vessel dilators are designed for use with maximum diameter guidewires. The maximum diameter of guidewire to be used is specified on individual vessel dilator labels. The use of guidewires has been associated with greater incidence of thrombus. Optimal guidewire size and judicious use are recommended.

Medcomp® dilators are designed for one time use only. **DO NOT RESTERILIZE.** Resterilization could change the physical characteristics of the material and should not be attempted. Variations in individual patient anatomy may preclude the utilization of the percutaneous technique.

PRECAUTIONS:

The percutaneous technique should be undertaken only by an experienced angiographer. Vessel dilators are supplied sterile and non-pyrogenic. Do not use if package is opened or damaged. Employ aseptic technique during removal from the package and during use. Do not autoclave. To avoid damage and crimping of the dilators during removal from the package, grasp the hub and slowly withdraw from the package. Care should be taken during placement and withdrawal of dilator in order to prevent possible tissue damage.

Note: Discard biohazard according to facility protocol.

ADVERSE REACTIONS:

Anytime an angiography procedure is performed the possibility exists for arterial wall damage, thrombus formation, emboli formation and plaque dislodgment which could result in myocardial infarction, cardiac arrhythmias, stroke or death. The physician should be familiar with the current literature concerning the complication of angiography.

STORAGE:

Handle with care. Do not store in excessive heat. Prolonged exposure to ultraviolet light may cause discoloration and changes in the physical characteristics of the dilator material.

HOW SUPPLIED:

Individually packaged in units of 10 dilators per carton. Also supplied with certain Medcomp Hemodialysis kits.

INSTRUCTIONS FOR USE:

1. Puncture vessel with needle.
2. Insert flexible (distal end) of guidewire through the needle cannula.
3. Remove needle cannula leaving guidewire in position.
4. Pass dilator over guidewire to dilate tissue in vessel. Remove dilator and insert catheter over guidewire.
5. Remove guidewire leaving catheter in position.
6. Examine the device after it is removed from the patient to ensure no foreign material remains inside the patient.

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.**

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 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 in accordance with all relevant regulatory requirements.

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