# Traxcess™ Guidewire
## Instructions for Use

### DEVICE DESCRIPTION

Traxcess Guidewire is a 0.014” diameter steerable guidewire consisting of a 0.012” diameter distal coil constructed of radiopaque platinum and stainless steel. The coil section is coated with a hydrophilic material for lubricity. The distal 14 mm of the coil tip is shapeable. The distal core wire consists of nitinol, and the proximal section is stainless steel. The proximal shaft section is coated with polytetrafluoroethylene (PTFE).

### CONTENTS

One Hydrophilic Guidewire with Torque Device, Insertion Tool, and Shaping Mandrel.

### INDICATIONS FOR USE / INTENDED PURPOSE

Traxcess Guidewire is intended for general intravascular use, including the neuro and peripheral vasculature. The guidewire can be steered to facilitate the selective placement of diagnostic or therapeutic catheters. This device is not intended for use in coronary arteries.

There are no known contraindications.

**CAUTION:** Federal law (USA) restricts this device to sale by or on the order of a physician.

### WARNINGS

The device should only be used by physicians who are familiar with angiographic and interventional procedures. It is important to follow the instructions for use prior to using this product.

The guidewire is provided sterile and non-pyrogenic unless the unit package is opened or damaged.

The guidewire is intended for single use only. Do not resterilize and/or reuse the device. After use, dispose in accordance with hospital and/or local government policy. Do not use if the packaging is breached or damaged.

Inspect the guidewire prior to use for any irregularities or damage and discard if noted.

The guidewire should be manipulated under fluoroscopic guidance. Do not advance or withdraw the guidewire when excessive resistance is met until the cause of resistance is determined. Observe the tip response when turning the guidewire and avoid turning in the same direction more than three times when the tip is stationary. Avoid kinking the tip of the guidewire, as damage to the guidewire might occur.

### PRECAUTIONS

Verify guidewire compatibility when using other ancillary devices commonly used in intravascular procedure. Physician must be familiar with percutaneous, intravascular technique and possible complications associated with the procedure.

The guidewire has a lubricious surface and distal platinum coil section should be hydrated prior to use.

Exercise care in handling the guidewire to reduce the chance of accidental damage. Do not expose the guidewire surface to organic solvents such as alcohol or medications, which might damage the guidewire coatings and/or cause the guidewire to lose lubricity.

Verify that the inner diameter of any diagnostic or therapeutic catheter to be used with the guidewire is compatible with the outer diameter of the guidewire prior to use.
Avoid repeated bending at the same point in order to avoid damage or separation of the guidewire.

Take precaution when manipulating the guidewire in tortuous vasculature to avoid damage to the guidewire.

## POTENTIAL COMPLICATIONS

Potential complications include, but are not limited to: vessel or aneurysm perforation, vasospasm, hematoma at the site of entry, embolism, ischemia, intracerebral/intracranial hemorrhage, pseudoaneurysm, seizure, stroke, infection, death, thrombus formation, additional procedure/treatment required, and inability to treat or diagnose patient.

This device requires the use with fluoroscopy. Potential complications related to angiographic and fluoroscopic X-ray radiation doses include, but are not limited to, alopecia, burns ranging in severity from skin reddening to ulcers, cataracts, and delayed neoplasia.

Users and/or patients should report any serious incidents to the manufacturer and the Competent Authority of the Member State or Local Health Authority in which the user and/or patient is established.

## PREPARATION FOR USE

Before removing the guidewire, hydrate the hydrophilic segment by flushing heparinized saline through the dispenser tube using a syringe attached to the dispenser tube hub (see Figure 1).

To prevent damage to the guidewire, gently remove the wire clip that holds the wire in place in the protective racetrack. Gently remove the guidewire by pulling it from the dispenser tube. If resistance is met, repeat the flushing procedure until the guidewire can be easily removed from the dispenser tube. Inspect the guidewire thoroughly to ensure it is not damaged.

If tip shaping is desired, gently bend the distal tip using fingers or by winding the tip round the shaping mandrel as shown (Figure 2) until the desired shape is achieved.

**Figure 1**

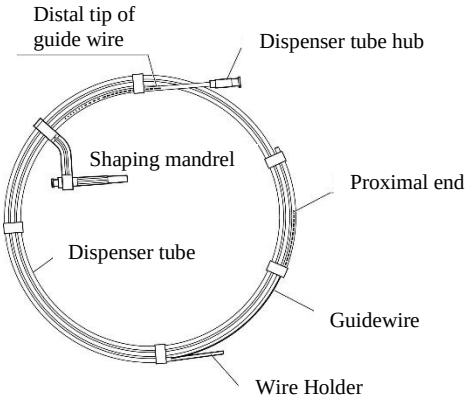
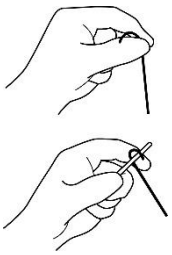



**Figure 2**



## DIRECTIONS FOR USE

Prior to inserting the guidewire into the catheter, flush the catheter lumen with heparinized saline to prime the catheter and provide smooth movement of the guidewire within the catheter. A hemostatic Y-connector may be attached to catheter hub and used to facilitate the flushing process.

Carefully insert the distal section of the guidewire into the catheter and advance. A guidewire Insertion Tool may be used to facilitate insertion of the guidewire distal tip through a Y-adapter and into the catheter hub. Advance the Hydrophilic Guidewire until the distal tip is near the distal end of the catheter. Gently tighten the hemostatic Y-connector to maintain position.

Slip the torque device over the proximal end of the guidewire to the desired location. Secure the torque device in place by tightening the rotating knob. The torque device may be repositioned by loosening and retightening the rotating knob.

During navigation in the vasculature, loosen the hemostatic Y-connector, advance and rotate the guidewire by rotating the torque device in either direction to facilitate vessel selection. To aid in catheter navigation, gently rotate the guidewire as it is advanced.

Between uses, rinse the guidewire in a basin of heparinized saline and wipe it gently with sterile, wet gauze and place in a basin of heparinized saline or a flushed dispenser tube to keep the hydrophilic surface wet until use.

## STORAGE

Keep dry and away from sunlight. See the product label for the device shelf life. Do not use the device beyond the labeled shelf life.

## MATERIALS

The guidewire does not contain latex or PVC materials.

## SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

The Summary of Safety and Clinical Performance (SSCP) for the device will be accessible in the European database on medical devices (EUDAMED: https://ec.europa.eu/tools/eudamed), when available.
The SSCP will be linked to the Basic UDI-DI in the EUDAMED public website.

**SYMBOLS**

| | | | |
|---|---|---|---|
| LOT | Lot Number | | Do Not Reuse |
| REF | Catalog Number | | Use by Date |
| CONTENTS | Contents | | Manufacturer |
| STERILE EO | Sterilized Using Ethylene Oxide | EC REP | Authorized European Representative |
| | Importer | | Attention: Refer to Instructions For use |
| CE | CE Mark | | Non-pyrogenic |
| | Single Sterile barrier system | MD | Medical Device |
| | Do not use if package is damaged | | Country and Date of manufacture |
| | Keep Dry | | Keep Away from Sunlight |
| | Do Not Resterilize | | Consult Instructions for Use |
| Rx ONLY | For Prescription Use Only | UDI | Unique Device Identifier |

**WARRANTY**

MicroVention, Inc. warrants that reasonable care has been used in the design and manufacture of this device. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness. Handling, storage, cleaning and sterilization of the device as well as factors relating to the patient, diagnosis, treatment, surgical procedure and other matters beyond MicroVention's control directly affect the device and the results obtained from its use. MicroVention's obligation under this warranty is limited to the repair or replacement of this device and MicroVention shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this device. MicroVention neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device. MicroVention assumes no liability with respect to devices reused, reprocessed or resterilized and makes no warranties, expressed or implied, including, but not limited to, merchantability or fitness for intended use, with respect to such device.

Prices, specifications and model availability are subject to change without notice.



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MicroVention™
TERUMO

**MicroVention, Inc**.
35 Enterprise
Aliso Viejo, CA 92656, USA
PH: +1.714.247.8000
www.terumoneuro.com

EC REP
**MicroVention Europe SARL**
30 bis, rue du Vieil Abreuvoir
78100 Saint-Germain-en-Laye
France
PH: +33 (0)1 39 21 77 46

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