Traxcess™ Docking Wire
Instructions for Use
For Use with the Traxcess™ Guidewire

For further instructions and information, refer to the Instructions for Use that accompanies the Traxcess Guidewire.

DEVICE DESCRIPTION

The Traxcess Docking Wire is a 0.014" diameter guidewire attachment consisting of stainless steel and nitinol. The shaft is coated with polytetrafluoroethylene (PTFE) for lubricity. The Traxcess Docking Wire is compatible with the Traxcess guidewire with an extendable proximal end. The Traxcess Docking Wire is used to extend the guidewire for facilitating catheter replacement.

CONTENTS

One docking wire.

INDICATIONS FOR USE/ INTENDED PURPOSE

The Traxcess Docking Wire is intended for general intravascular use, including the neuro and peripheral vasculature. The Traxcess Docking Wire can be used with Traxcess guidewires to facilitate the 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 Traxcess Docking Wire 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 Traxcess Docking Wire is provided sterile and non-pyrogenic unless the unit package is opened or damaged. Do not use if package is opened or damaged.

The Traxcess Docking Wire 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 Traxcess Docking Wire prior to use for any irregularities or damage and discard if noted.

The Traxcess Docking Wire cannot be used alone and must be used with the guidewire securely connected.

Attachment and detachment to and from the guidewire should be done while confirming the position of the guidewire tip and catheter under high resolution fluoroscopy. The unintentional advancement of the wire may result in perforation or damage to the vasculature or other devices.

Do not bend the Traxcess Docking Wire repeatedly at the same point. This may result in deformation, breakage, or separation of the Traxcess Docking Wire.

Do not torque or manipulate the Traxcess Docking Wire once it is attached. This may cause the Traxcess Docking Wire to detach from the guidewire.

Do not insert the Traxcess Docking Wire into the patient (body). This may result in disconnection or breakage of the Traxcess Docking Wire or damage to the vessel.

PRECAUTIONS

Verify Traxcess Docking Wire compatibility when using other ancillary devices commonly used in intravascular procedure. The physician must be familiar with percutaneous, intravascular technique and possible complications associated with the procedure.

Exercise care in handling the Traxcess Docking Wire to reduce the chance of accidental damage. Do not expose the Traxcess Docking Wire surface to organic solvents such as alcohol or medications, which may damage the coating and/or cause loss of lubricity.

Verify that the inner diameter of any diagnostic or therapeutic catheter to be used with the Traxcess Docking Wire is compatible with the outer diameter prior to use.

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

To prevent damage to the Traxcess Docking Wire, gently remove the wire clip that holds the wire in place in the protective dispenser tube. Gently remove the Traxcess Docking Wire by pulling it from the dispenser tube. Inspect the Traxcess Docking Wire thoroughly to ensure it is not damaged.

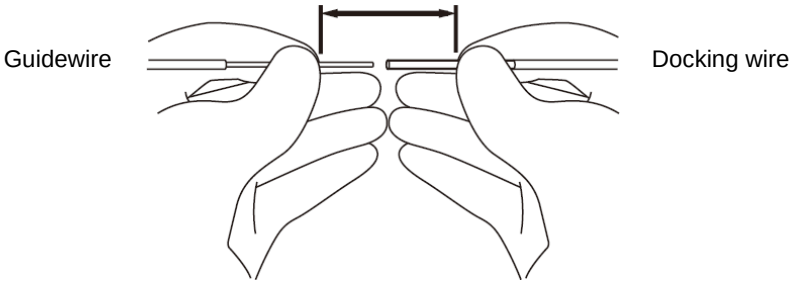
DIRECTIONS FOR USE

Remove any devices, such as a torque device, attached from proximal end of the Traxcess guidewire.

Carefully insert the proximal end of the Traxcess guidewire into the distal end of the Traxcess Docking Wire.

To avoid damage to the Traxcess Docking Wire and guidewire, grip as close to the ends of the wires as possible (Figure 1).

Figure 1



Check for secure attachment by pulling gently both the Traxcess Docking Wire and the Traxcess guidewire on each side of the connection.

Gently open the hemostatic Y-connector attached on the proximal end of the inserted catheter. Withdraw the catheter over the connected wires while maintaining the guidewire tip position.

Introduce the replacement catheter over the proximal end of the Traxcess Docking Wire. Advance the catheter while maintaining the guidewire tip position.

After placement of the catheter, carefully detach the Traxcess Docking Wire from the Traxcess guidewire by first grasping both the Traxcess Docking Wire and the Traxcess guidewire, and then pulling the Traxcess Docking Wire away from the Traxcess guidewire.

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 Traxcess Docking Wire 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		Attention: Refer to Instructions For use
CONTENTS	Contents		Use by Date
STERILE EO	Sterilized Using Ethylene Oxide		Importer
CE	CE Mark		Manufacturer
EC REP	Authorized European Representative		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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