
Hydrophilic Guidewire



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Hydrophilic Guidewire

70081-001 Rev. 10/05

Instructions for Use

International Symbols Glossary

	Attention, See instructions for use
	Use by
	Lot Number
	Do Not Reuse
	Catalogue Number
	Sterile (Ethylene Oxide)
	Date of Manufacture
	The product is placed on the market in conformity with Directive 93/42/EEC relating to medical devices
	Contents of Package

Glosario de símbolos internacionales










	Atención. Ver las instrucciones de uso
	Fecha de caducidad
	Número de lote
	No volver a utilizar
	Número de catálogo
	Estéril (óxido de etileno)
	Fecha de fabricación
	Este producto se comercializa en conformidad con la normativa 93/42/EEC sobre dispositivos médicos
	Contenidos del paquete

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Glossario de simboli internazionali

	Attenzione: leggere le istruzioni per l'uso.
	Data di scadenza
	Numero di lotto
	Non riutilizzare.
	Numero di catalogo
	Sterile (ossido di etilene)
	Data di fabbricazione
	Questo prodotto è commercializzato in conformità alla direttiva 93/42/CEE relativa ai dispositivi medici.
	Contenuto della confezione

Symboles internationaux

	Attention. Consulter le mode d'emploi
	Utiliser avant
	N° du lot
	Ne pas réutiliser
	Numéro de catalogue
	Stérile (oxyde d'éthylène)
	Date de fabrication
	Ce produit est commercialisé conformément aux dispositions de la directive 93/42/CEE relative aux dispositifs et appareils médicaux
	Contenu de l'emballage

Hydrophilic Guidewire

INSTRUCTIONS FOR USE

CAUTION

- Federal (USA) law restricts this device to use by or under the direction of a physician.
- This device should be used only by physicians with a thorough understanding of angiography and percutaneous interventional radiologic procedures.



It is important to read the instructions for use with careful attention to cautions, notes and warnings prior to using this product.



STERILE: This device is sterile and non-pyrogenic.



This device is intended for SINGLE USE ONLY. **DO NOT RESTERILIZE AND/OR REUSE.**

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CONTENTS: One (1) sterile, hydrophilic guidewire with torque device and guidewire introducer.

DESCRIPTION

The MTI Hydrophilic Guidewire is a stainless steel guidewire with a radiopaque, platinum distal coil. The guidewire is hydrophilically coated on the distal portion, and is available in lengths ranging from 145-300 cm. The proximal portion of the 300 cm guidewire is coated with polytetrafluoroethylene (PTFE). The 300 cm guidewire facilitates the exchange of one interventional device for another, while maintaining guidewire position in the anatomy. Included within the sterile pouch is a torque device to assist in guidewire manipulation and a guidewire introducer to ease the introduction of the guidewire into the catheter hub and/or hemostasis valve.

INDICATIONS FOR USE

The MTI Hydrophilic Guidewire is indicated for general intravascular use to aid in the selective placement of catheters in the peripheral, visceral and cerebral vasculature during diagnostic and/or therapeutic procedures.

CONTRAINDICATIONS

The MTI Hydrophilic Guidewire is not indicated for use in the coronary vessels.

WARNINGS

This device is intended for single use only. Discard the product after use. Structural integrity and/or function may be impaired through reuse or cleaning.

Never advance or withdraw the guidewire against resistance until the cause of the resistance is determined by fluoroscopy. Do not attempt to move the guidewire without observing the resultant tip response.

PRECAUTIONS

Prior to use, carefully examine the guidewire and its packaging to verify no damage has occurred during shipment. Do not use if pouch is open or damaged.

Inspect the guidewire for any surface irregularities, bends or kinks. Any guidewire damage may decrease the desired performance characteristics.

The hydrophilic coating bonded to the guidewire is an extremely lubricious surface when properly hydrated. Ensure proper hydration by allowing entire guidewire to become wet for at least 30 seconds prior to use.

Neither the guidewire introducer or the torque device are intended to enter the body.

To prevent damage to the guidewire coating, manipulate the guidewire using the torque device at proximal end of the guidewire.

STORAGE

This device should be stored in a dry place at between 50°F (10°C) and 90°F (32°C).

POTENTIAL COMPLICATIONS

Procedures requiring percutaneous catheter introduction should not be attempted by physicians unfamiliar with the possible complications, which may occur during or after the procedure.

Possible complications include, but are not limited to the following:

- Perforation of vessel or arterial wall
- Puncture site hematoma
- Infection
- Thrombus formation
- Vasospasm
- Ischemia

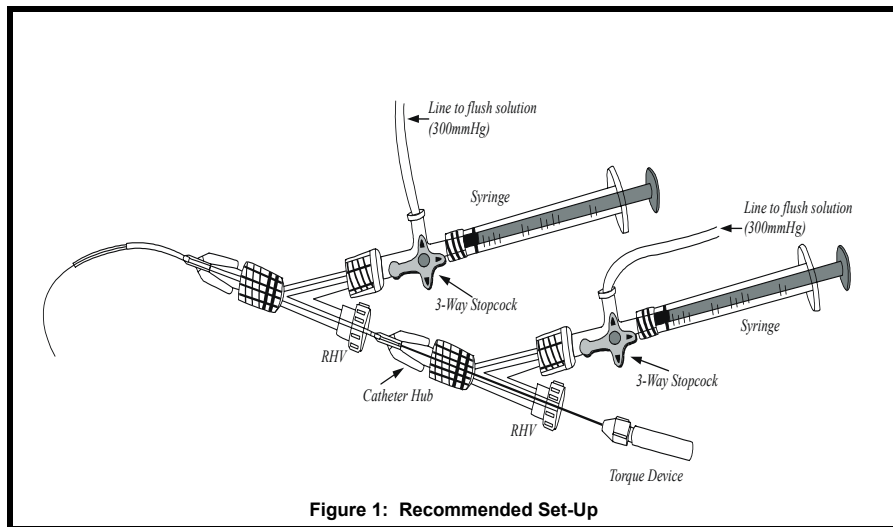
COMPATIBILITY

The guidewire is compatible with other ancillary products used in intravascular procedures. Any over-the-wire style of micro catheter used with the guidewire should have at least 0.004" (0.1 mm) clearance between the lumen of catheter and the guidewire.

PREPARATIONS FOR USE

1. Before removing the guidewire from the protective coil, use a 20 cc syringe to fill the coil with saline and allow the guidewire to hydrate for at least 30 seconds.
2. Carefully remove the guidewire from the protective coil.
3. Inspect the guidewire thoroughly to make certain that it is not kinked or otherwise damaged.
4. Prior to inserting the guidewire into the catheter, flush the catheter lumen with saline to provide smooth movement of the guidewire within the catheter.
5. If desired, the distal coil of the guidewire can be carefully shaped to the desired tip configuration. Gentle shaping may increase the flexibility of the tip of the guidewire.

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DIRECTIONS FOR USE

1. When introducing the guidewire into the catheter and introducer sheath, ensure that at least 5 centimeters of guidewire extends from the most proximal hub. This will keep the guidewire from slipping down inside the catheter. Refer to Figure 1 for illustration of catheter/guidewire set-up.
2. To aid in the selective placement of the catheter into a particular vessel, gently rotate the proximal end of the guidewire as it is advanced forward.
3. Between uses, place the guidewire in a basin of saline, or fill the packaging coil with saline and replace the guidewire between uses. Avoid wiping down with damp cloths, particulate from the cloth can adhere to the surface of the guidewire.

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