INSTRUCTIONS FOR USE

Guide Wires

Guide Wires

Intended Use

Guide Wires are intended to be placed invasive in the human body through a natural or artificially produced body orifice or surgical invasive in blood vessels and/or central circulatory system in combination with a cannula, to be guided by controllable distal and proximal ends to a certain area of the human body to be used as a guide for catheters or other medical devices, which are intended to be used in the certain area of the body.

Indications

Urology, Angioplasty, Percutaneous Dilatationstracheotomy (PDT), Percutaneous endoscopic Gastrojejunostomy (PEG/J), Chronical Total Occlusion (CTO), Stent Implantation, Carotid Entarterectomy (CEA), Carotid Artery Stenting (CAS)

Contraindications

Contraindications for guide wires > 0.014“ (0.35 mm) can be Chronical Total Occlusionen (CTOs).

Application

General

The interventional combination device has to be prepared according to the instructions of the manufacturer of the device. The guide wire lumen of the combination device has to be flushed before insertion of the guide wire.

Guide Wires with hydrophil Coating

Prior the extraction of hydrophil guide wires out of the dispenser, physiological saline solution has to be injected in the dispenser to wetting the complete hydrophil surface of the guide wire. After the injection of the saline solution the guide wire has to be extracted carefully out of the dispenser. If the guide wire cannot be extracted easily out of the dispenser further saline solution has to be injected into the dispenser.

After extraction of the guide wire may not be introduced into the dispenser again.

Warning Notices

If not used correctly guide wires can lead to arterial perforation. The damages caused by arterial perforation are almost serious and can lead to death of the patient. According to published literature arterial perfora- tion often occurs due to kinking of the guide wire. During the use of guide wires it has to paid special attention to the insertion technique, to avoid a kinking of the wire guide. An insertion guide has to be used.

Further literature sources refer to risks occurring due to overinsertion of the guide wire, which also can lead to serious damages likewise traumatisation and/or perforation of the treated vessel.

Guide wires containing magnetising materials such as high-grade steel and may therefore not be used under MR conditions, as heating and movement of the guide wire can occur, which may lead to catastrophic complications.

Certain cases of entrapped or breakdown guidewires are reported as well as possible techniques to retrieve the entrapped or broken parts. The user should have knowledge in such techniques in order to prevent serious consequences related to such events.

If coated guidewires are used special attention has to be paid to the combination product (e.g. catheter) to avoid damages to the integrity of the coating. Malposition of the catheterizing guidewire may lead to serious complications.

Like almost every product that is introduced into blood vessels guidewires may lead to thrombosis. The user is responsible to apply adequate measures to prevent thrombosis during the application of the guidewire.

Preventive Measures

- Guide wires are sensible devices which should be used very care- fully. Before and, if possible, during the use the guide wire should be checked visually regarding damages, misalignment, knicks and other deformations. Damaged, misaligned, knicked and other de- formed guides wire may not be used due to the risk of potential risks inherited.
- The combination ability between the guide wire and interventional medical device must be verified before the use.
- Due to the possible damaging of the PTFE-coating and / or shearing of the guide wire the withdrawing of the guide wire back through a metal needle must be avoided. The cannula should be replaced as soon as possible after the insertion of the guide wire into the vessel by a catheter, introducer sheath or vessel dilator.
- Ultrasound confirmation of guidewire position may eliminate acci- dental arterial dilation during application of guidewires.

ATTENTION: The guidewires may not be used in MR fields!

Reprocessing and Sterilization

Guide wires are delivered in sterile condition. Due to the design of the devices reprocessing is not possible as body fluids are migrated into the inner part of the wire and cannot be removed afterwards. Used once the guide wire has to be scraped.

The devices remain sterile if packaging is not damaged or has been opened and the use by date is not exceeded. In case of damaged sterile packaging or exceeded use-by date must be discarded.

Sizes

ACSFC-190-.014/SOFT	Guidewire PTCA	Lenght-guidewire dieameter
ACSFC-190-.014/MEDIUM	Guidewire PTCA	Lenght-guidewire dieameter
ACSFC-190-.014/EXTRA	Guidewire PTCA	Lenght-guidewire dieameter
ACSFC-300-.014/SOFT	Guidewire PTCA	Lenght-guidewire dieameter
ACSFC-300-.014/MEDIUM	Guidewire PTCA	Lenght-guidewire dieameter
ACSFC-300-.014/EXTRA	Guidewire PTCA	Lenght-guidewire dieameter

ACJ3-FC-150-.035	Guidewire	Lenght-guidewire dieameter
ACJ3-FC-260-.035	Guidewire	Lenght-guidewire dieameter
ACJ3-FC-080-.035	Guidewire	Lenght-guidewire dieameter

Annotation

Symbols used on the labelling of these devices do have following meanings:

Graphical Symbols for Medical Device Labeling

 Sterilized using ethylene oxide	 Lot number Batch number	 Manufacturer	 Contents
 Use-by date[1]	 Keep dry	 Keep away from sunlight	 Do not re-use
 Caution, attend accompanying documents	 MR unsafe Do not use this device in MR fields	 Do not useif package is damaged	 Consult instructions for use

[1] The symbol is accompanied by a date to indicate that the device may not be used after the end of the year, month, or day shown.

Manufacturer

EPflex Feinwerktechnik GmbH
Im Schwoellbogen 24
72581 Dettingen
Germany

Distributor

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