MEDORAH MEDITEK

JAQUAR™ ERCP Guidewire

Instructions for Use

Medorah Meditek Pvt. Ltd.

www.medorah.com

JAQUAR™ ERCP Guidewire

Intended Use
JAQUAR™ Guidewire is intended to be used in natural or surgically invasive orifices as a guidance for introduction and placement of diagnostic or therapeutic devices in hollow organs of the human body during endoscopic or interventional procedures.

Indications for use: JAQUAR™ Guidewire is indicated for use to assist cannulation of the biliary and the pancreatic ducts and to aid in bridging strictures during ERCP.

Contraindications
Contraindications those specific to ERCP.

Complications

- Injury to the mucous membrane or tissue, particularly in the case of mutatedtissue
- Bleeding due to injuries
- Perforation of blood vessels, stomach or intestinal wall or other organs
- Ulcers in or necrosis of injected tissue
- Stricture formation
- Allergic reaction
- Vessel spasm
- Vascular thrombosis
- Hematoma at puncture site
- Air embolism
- Stroke
- Death or serious injury related to device use or anesthesia required for theprocedure.
- Plaque dislodgment infection
- Emboli

Target Population

The target patient population is identified based on the indication determined by the treating physician responsible for diagnostic or therapeutic interventions during endoscopic procedures, which are the primary procedures in question, in accordance with the intended use of the medical device. No specific limitations are known to apply to either the patient population or the designated target group.

Use of the product on minors-

The product may be utilized on minors if the physiological and anatomical conditions of the patient allow for the appropriate use of the product.

Use of the product on women who are pregnant or breastfeeding-
The user is required to refine the indication for using the product on pregnant or breastfeeding women, taking into consideration the specific physiological and anatomical conditions of each individual patient.

Shelf Life of Product
The shelf life of the product is typically 3 years after the date of manufacture under normal conditions.

Warnings

- If not used correctly guide wires can lead to perforation of tissue. The damages caused by perforation may be serious and can lead to death of the patient. Tissue perforation primarily occurs due to kinking of the guide wire.
- During the use of guide wires an insertion technique must be used that avoids kinking of the guide wire. An insertion guide has to be used. Furthermore, there have been cases of over insertion of guide wires; this is generally considered a serious risk.
- Over insertion of guide wires can lead to injury and/or perforation of the vessel / lumen being treated.
- JAQUAR™ guidewire is coated (e.g. catheter), special attention has to be paid to an appropriate combination to avoid damages to the integrity of the coating.
- The user is responsible for taking adequate measures to prevent thrombosis during the application of the guidewire. The guide wire should be manipulated slowly and carefully.
- The guide wire must be held in position when changing or withdrawing the catheter in order to prevent injury to the patient.
- The measuring results should be confirmed. If any resistance is felt during use, the manipulation of the guide wire and/or the combination device used such as catheter or endoscope must be stopped immediately and the cause for the resistance must be determined by use of various visual methods. Otherwise, overexpansion, kinking, breaks or partial detachment of the outer polymer jacket or the coating material of the guide wire can occur.
- Remove, if required, the guide wire and the combination devices used as a complete unit to avoid complications.
- Never insert, advance and/or withdraw the guide wire through a metal cannula or needle or other sharp-edged devices. This may damage the guide wire and may lead to destruction and/or detachment, in particular of the outer polymer jacket or the coating, and therefore may require subsequent retrieval of the fragments.
- Sterile only if packaging is undamaged or unopened!
- For single use only! Do not reuse, reprocess or sterilize several times. Reuse, reprocessing or repeated sterilization of the instrument may affect its structural integrity and cause malfunction, resulting in contamination, infection and serious injury.
- If the instrument accidentally becomes dirty before treatment, it must be disposed of immediately!
- No cleaning agents may be applied.
- Do not use after the “use by date”
- All components should be carefully checked for compatibility and integrity before use.
- Do not use defective instruments! If defects occur, dispose of the instrument and replace it with a new one.

- Never use the product outside the recommended technical specifications.
- Never tamper with the structural conditions of the instrument, avoid kinks and other damage, and immediately discontinue use in the event of a malfunction!
- A guidewire is a delicate instrument and must not be advanced, withdrawn, or torqued if resistance is met. Guidewire manipulations must always be observed under fluoroscopy.
- If the wire is removed and not immediately reinserted, store the wire in a bowl of sterile saline in order to avoid particulate adhering to the activated hydrophilic coating of the guidewire.
- Guidewires contain magnetizable materials and must therefore not be used with MRI, as heating and movement of the guidewire can occur due to the existing residual magnetism, which may lead to severe 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.

Precautions

- The compatibility between guide wire and interventional medical devices must be verified before use.
- Always inspect the guidewire carefully for bends, kinks or other damage.
- Do not use damaged guidewire.
- This device should be used by trained physician.
- Read the IFU carefully prior to use.
- For clinical use only.
- Do not use if package is opened.
- Do not expose to organic solvents.
- Do not autoclave.

Procedure

Prior to removing guidewire from dispenser, flush with sterile water.
Flush endoscope's accessory channel and / or lumen of device with sterile water, then insert the guidewire's floppy end first.
Note: For best results, guide wire should be kept wet.
Fluoroscopically monitor guide wire's advancement in ductal system.
Proceed with exchange of compatible wire-guided accessories over the guidewire.

Storage Conditions

Store the device under normal temperature and avoid direct sunlight. Follow the first in first out rules and do not use the device beyond its use by date.

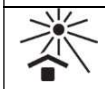
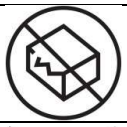
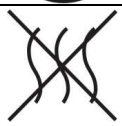
Disposal of a used device

The used device must be disposed of according to hospital, local and country regulations. Disposal is the responsibility of user.

Goods Return Policy

Refer to the company's return good policy. Please contact the branch office or customer service at info@medorah.com or call +91 124-4712471.

Symbols used on product label

	Date of Manufacture		Use By Date
	Catalogue Number		Do Not Reuse
	Consult Instructions for use		Caution
	Keep away from sunlight		Batch Code
	Do not use if package is damaged		Manufactured By
	Non-Pyrogenic		Keep dry
	Do Not Resterilize		Sterilized using Ethylene Oxide

Warranty

Medorah Meditek Pvt. Ltd. warrants that this product has been manufactured by the appropriate procedures. This warranty is in lieu of and excludes all other warranties not expressly set forth herein which are beyond Medorah Meditek Pvt. Ltd. control such as warranties implied to the application of law, sales or specially purpose suitability after handling over, storage, cleaning and sterilization of this product as well as matters related to the patient, diagnosis, treatment, surgical procedures, and any other details. Medorah Meditek Pvt. Ltd. shall not be liable for any incidental, or consequential loss, damage or expense directly or indirectly arising from the use of this product other than the replacement of it. Medorah Meditek Pvt. Ltd. shall neither take any additional responsibility nor authorize such responsibility or duty to other person related to this product.

MEDORAH MEDITEK

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