MEDORAH MEDITEK

# MEDORAH®

# TRIPLE LUMEN NEEDLE KNIFE

## Instructions for Use

**Medorah Meditek Pvt. Ltd.**

**www.medorah.com**

# MEDORAH® Triple Lumen Needle Knife

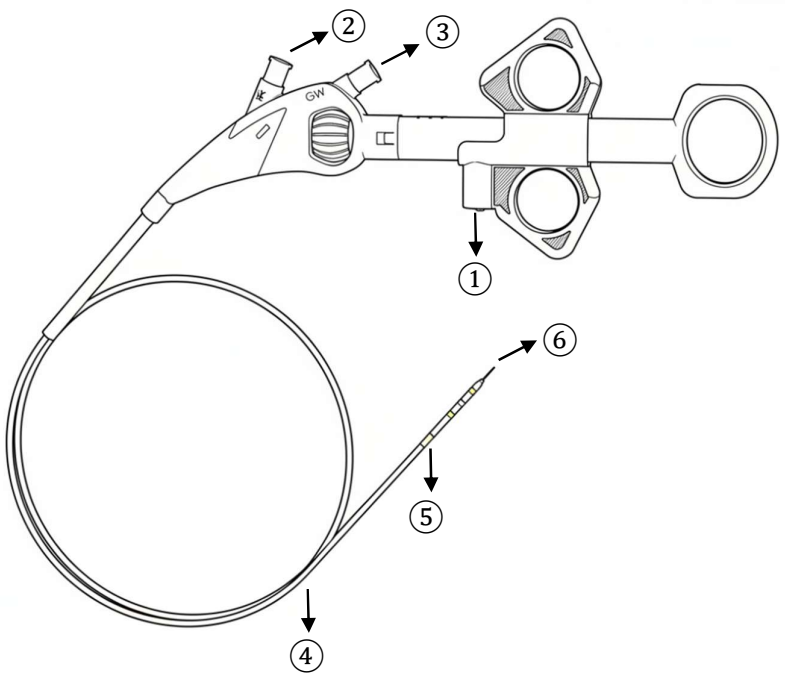
## Intended Use

**MEDORAH®** Triple Lumen Needle Knife is intended to be used for accessing the common bile duct when standard methods for cannulation have been exhausted and for incision of papilla of Vater prior to ERCP. Its triple lumen design facilitates cannulation after incision without the need to exchange the catheter.

**MEDORAH®** Triple Lumen Needle Knife is supplied sterile and intended for single use only.

## Device Descriptions

MEDORAH® Triple Lumen Needle Knife is designed with three distinct lumens. The first lumen is for guidewire insertion. The second lumen is for cutting knife/needle, which is controlled by a proximal slider and delivers electrocautery current for precise tissue incision. The third lumen is intended for the injection of contrast medium. Endoscopic markers are incorporated on the catheter to enhance visibility, and the tapered tip design facilitates smooth insertion into the papilla.



| | |
|---|---|
| ① | Electrocautery Port |
| ② | Injection Port |
| ③ | Guidewire |
| ④ | Catheter |
| ⑤ | Endoscopic markers |
| ⑥ | Cutting knife |

**Contraindications**

Contraindications those specific to ERCP and any procedure to be performed in conjunction with papillotomy.

Contradictions to papillotomy include but not limited to: Coagulopathy.

**Potential Complications:**

Possible complications associated with ERCP.

- Bleeding
- Pancreatitis
- Cholangitis
- Perforation of hollow organs (duodenum, bile duct, GI tract)
- Infection, including abscess or sepsis
- Adjacent organ injury (pancreas, vessels)
- Electrosurgical burns to patient

**Warnings**

- DO NOT use if pouch is opened or damaged.
- Do not reuse, reprocess or re-sterilize
- Reuse, reprocessing or re-sterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death.
- Reuse, reprocessing or re-sterilization may also create a risk of contamination of the device and/or cause patient infection or cross infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another.
- Contamination of the device may lead to injury, illness or death of the patient. After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.
- It is suggested that the operator and assistant wear protective gloves to prevent accidental burns. Universal precautions should be used in all cases.
- 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.

- Avoid contact between live handle components, e.g. the push rod when high frequency current is applied! Contact may cause electrical burns and shocks.

**Precautions**

- These devices are compatible with an endoscope accessory channel of 2.8 mm or larger.
- The guidewire diameter and the inner lumen of the wire guided device must be compatible.
- Injection of contrast media during ERCP must be monitored fluoroscopically. Overfilling of the pancreatic duct may cause pancreatitis.

**Procedure**

- Prior to the procedure, inspect device packaging. Do not use it if compromised.
- Examine the device smoothness by slowly sliding the slider forward and backward.
- Inspect the cutting knife/needle carefully for any kinks, bends, or damage.
- Introduce the endoscope into the patient and identify the target site.
- Advance the Needle Knife through the accessory channel of the endoscope until the distal tip becomes visible under endoscopic view.
- If any resistance is encountered while passing through the angulated or tilted portion of the scope, gently rotate and adjust the insertion angle to minimize stress on the working channel.
- Once the knife tip is visualized, carefully position it against the target site, usually at the papilla or selected incision area, as indicated for pre-cut or controlled sphincterotomy/papillotomy.
- Use fluoroscopic guidance if required, to confirm the proper positioning before cutting.
- Using the appropriate active cord, connect the electrosurgical generator cable to the finger slider's HF socket.
- Activate the generator by pressing the foot pedal to deliver short, controlled bursts of cutting current. At the same time, carefully advance or retract the needle knife using the slider to achieve the intended depth and length of incision.
- Always keep the knife tip under visual control, ensuring the active cutting portion does not contact the endoscope or its components to prevent short-circuit damage.
- Upon completion of the needle knife incision and/or sphincterotomy, switch off the electrosurgical generator and disconnect the active cable.
- Withdraw the needle knife from the working channel with slow, gentle pressure, ensuring that the needle is fully retracted during removal to prevent scope channel damage.

**Change of Performance**

If a device's performance is changed or the intended purpose is lost, further actions shall be taken according to the medical specialist's decision considering the clinical condition of patients.

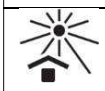
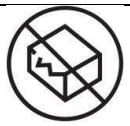
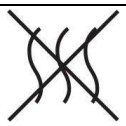
**Disposal of a used device**

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

**Storage**

Keep the device under normal room temperature and avoid direct sunlight. Follow the first in-first-out rules and do not use the device out of expiry date.

**Symbols used on product label**

| | | | |
|---|---|---|---|
|  | Date of Manufacture |  | Use-By Date |
|  | Catalogue Number |  | Do not re-use |
|  | Consult instructions for use |  | Caution |
|  | Keep away from sunlight |  | Batch Code |
|  | Do not use if package is damaged |  | Manufacturer |
|  | Non-Pyrogenic |  | Keep dry |
|  | Do not resterilize |  | Sterilized using Ethylene Oxide |
|  | Medical device | | |

## 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 persons related to this product.

MEDORAH MEDITEK

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