



MEDORAH® BIOPSY FORCEPS

Instructions for Use

Medorah Meditek Pvt. Ltd.

www.medorah.com

MEDORAH® Biopsy Forceps

Intended Use / Indications for use

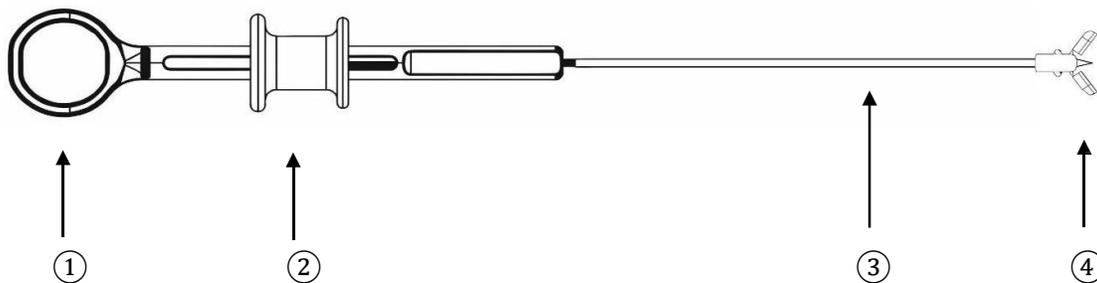
Intended use- MEDORAH® Biopsy Forceps is intended to be used for endoscopic histological sampling of various tissue sites within the gastrointestinal tracts via the operating channel of endoscopic instruments.

MEDORAH® Biopsy Forceps is supplied sterile and is intended for single use only.

Device Description

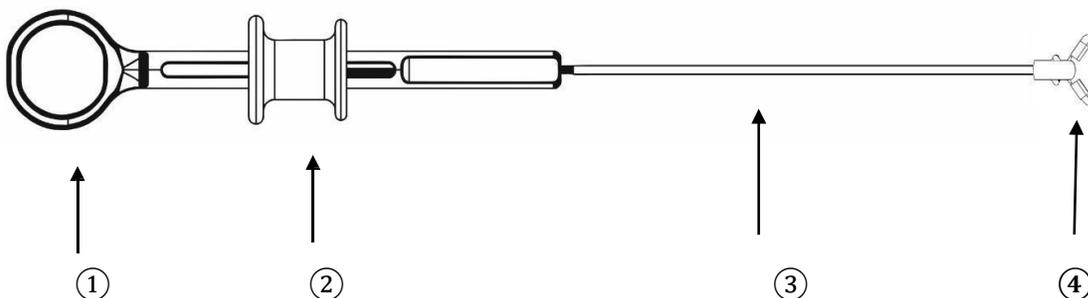
The MEDORAH® Biopsy Forceps consist of a flexible sheath with distal grasping cups controlled by a proximal control handle with a slider. Biopsy forceps are designed for insertion through a predetermined diameter Biopsy channel.

- **Oval Cup Fenestrated with Spike**



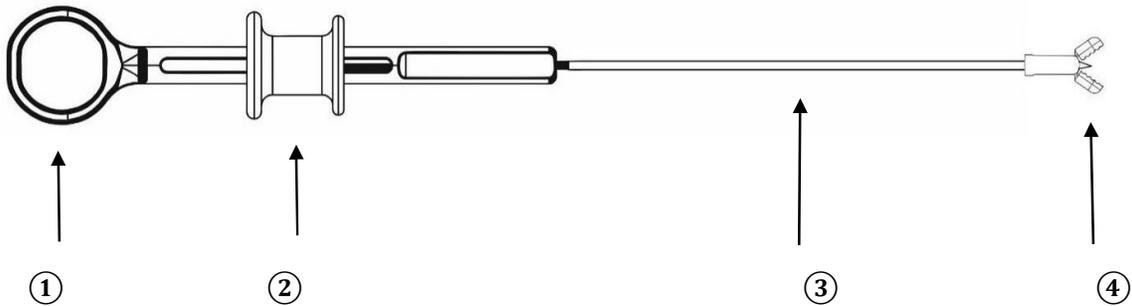
①	Handle
②	Slider
③	Metallic tube/Outer Sheath
④	Oval Cup With Spike

- **Oval Cup Fenestrated Without Spike**



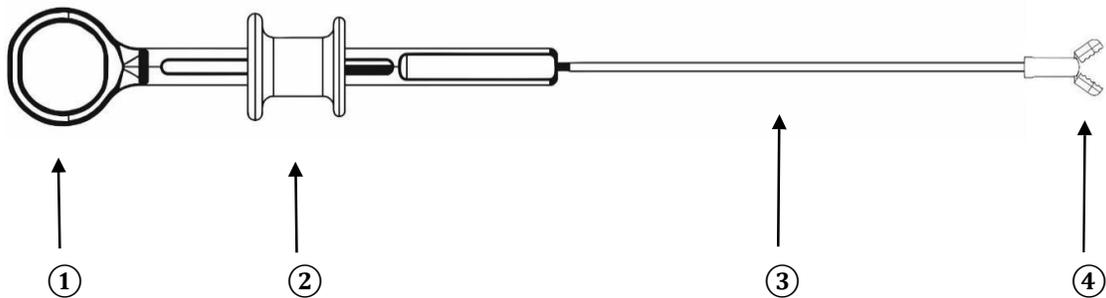
①	Handle
②	Slider
③	Metallic tube/Outer Sheath
④	Oval Cup Without Spike

- Alligator jaws with Spike



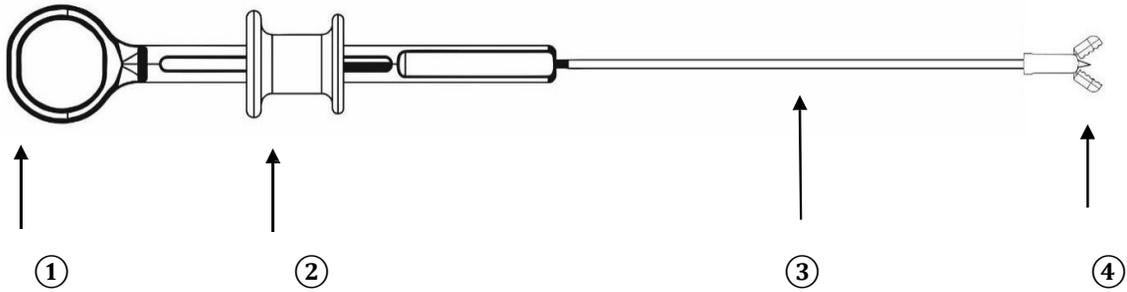
①	Handle
②	Slider
③	Metallic tube/Outer Sheath
④	Alligator Jaws With Spike

- Alligator jaws without Spike



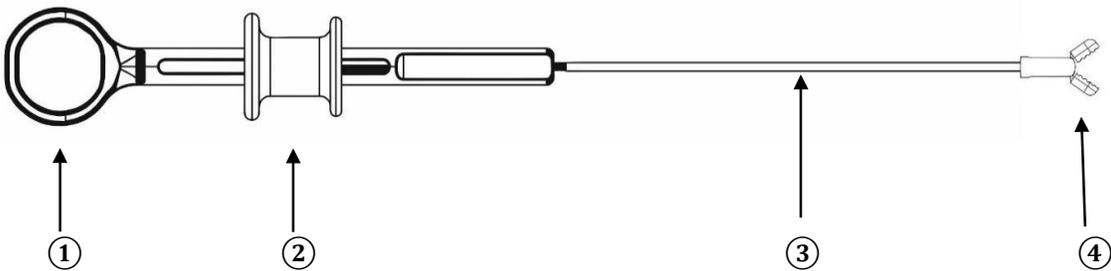
①	Handle
②	Slider
③	Metallic tube/Outer Sheath
④	Alligator Jaws without Spike

- **Serrated Jaws with Spike**



①	Handle
②	Slider
③	Metallic tube/Outer Sheath
④	Serrated Cup with Spike

- **Serrated Jaws without Spike**



①	Handle
②	Slider
③	Metallic tube/Outer Sheath
④	Serrated Cup without Spike

Contradictions

- Coagulopathy
- Tissue samples from vessel injury in ulceration.
- Insufficient prepped bowel
- Primary endoscopy, colonoscopy, rectoscopy
- Application to the central cardiovascular system is contradicted

- Specific contraindications for primary endoscopic procedures to access the desired injection site.
- Not fasting patients
- Fragility of the intestinal wall: e.g. highly florid inflammation of the colon (e.g. ulcerative colitis, diverticulitis, ulcerative colitis, toxic megacolon)
- Peritonitis, acute abdomen, e.g. intestinal perforation, ileus
- Sepsis
- Co-morbidity, e.g. severe cardiopulmonary diseases and decompensation
- Uncontrollable haemorrhagic diatheses
- Recently created gastrointestinal anastomosis
- Pregnancy

Potential Complications

- Sedation during endoscopic exams raises the risk of complications.
- These complications include hypoxemia, hypercapnia, hypotension, arrhythmias, and aspiration.
- The reduced protective reflexes contribute to these risks.
- Even without sedation, hypoxemia can occur during endoscopic procedures
- This is due to the presence of the endoscope itself.

The following complications may occur:

- Fever
- Perforation
- Haemorrhage
- Infection
- Sepsis
- Allergic reaction to contrast or medication
- Hypotension
- Respiratory depression or arrest
- Cardiac arrhythmia or arrest

Warnings

- Endoscope accessory channel less than 2.4 mm can damage the device integrity.
- This product is designed for single use only. Please refrain from reusing, re-sterilizing or reprocessing it
- Reusing, re-sterilizing, or reprocessing a device could weaken its structural integrity and/or cause it to malfunction, which could endanger the health or safety of the patient and even lead to death.

- Only biopsy tissue in areas where patients won't be in risk from potential bleeding or hemorrhage when using these single-use biopsy forceps.
- Sufficient protocols for handling possible bleeding or hemorrhaging, together with suitable airway care must be thoroughly established.
- Before using, make sure the endoscopic view is clear.
- An insufficient endoscopic field of view during insertion could result in patient harm such as bleeding, perforation, or damage to mucosal membranes. There's also a chance of endoscope and/or instrument damage.
- Whenever an endoscope is introduced, advanced through or removed, the forceps cups must be closed. The forceps and endoscope could get damaged if the cups are open.
- Following usage, dispose of the product and its packaging in line with administrative, hospital, and/or local government regulations.

Precautions

- Consult the package label to determine the minimum channel size required for using this device.
- Keep the endoscope as straight as possible during the insertion or withdrawal of forceps.
- The forceps handle must be operated with gentle pressure. Over pressurization will make the forceps hard, which could harm the forceps or the endoscope.
- It is not advised to use this product for any operations other than those listed in these instructions.
- Before taking the device out of the tray or holder, enclose it in the sheath.

Procedure

Product Inspection

- Uncoil the forceps carefully, ensuring the cable is not stretched.
- Verify smooth handle operation by opening and closing the cups
- Check for appropriate cup action during this process.
- Familiarize yourself with the necessary handle movement to operate the cups.
- If you notice any irregularities, refrain from use.

Note: Operating the handle while the forceps is coiled could harm its performance characteristics.

1. View the area to be biopsied endoscopically.
2. Insert forceps into the accessory channel while the cups are closed.

Note: Always maintain a straight forceps end extending from the accessory channel. Hanging forceps from accessory channel could break the force.

3. Advance forceps in slight increments till the scope's exit gets viewed endoscopically. **Note:** If you encounter resistance while advancing forceps, gently angle the straight endoscope tip. Avoid exerting excessive force on the forceps through the endoscope. If the endoscope is equipped with an accessory elevator, ensure to close the elevator before advancing the forceps. When resistance is encountered, open the elevator to enable the forceps to pass through. Utilize the elevator to maneuver and position the forceps accordingly.

4. Advance the forceps to the biopsy site, and subsequently, open the cups and advance them into the tissue intended for biopsy.

5. Apply gentle pressure to the handle to close the forceps around the tissue or object.

Note: Excessive pressure is unnecessary to cleanly excise tissue.

Caution: If the forceps fail to close, gently pull the cup against the channel opening. Remove the endoscope and forceps together as a unit, then manually close the cups and withdraw the forceps from the endoscope.

6. Maintain gentle pressure on the handle to keep the cups closed as you delicately withdraw the forceps from the site.

Note: If the endoscope features an elevator, ensure it is opened before withdrawing the forceps. If you encounter resistance while withdrawing the forceps, straighten the endoscope tip. Avoid applying excessive force during the removal of the forceps to prevent potential damage to either the forceps or the endoscope.

7. Continue applying slight pressure on the handle as you withdraw the forceps from the channel.

8. Gently retract the forceps until the object is against the tip of the endoscope. Slowly withdraw the endoscope while monitoring the surrounding area endoscopically. As you withdraw the forceps from the endoscope, wipe any excess secretions from the cable.

9. Follow institutional guidelines to prepare the specimen for examination.

Change of performance

If the 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

After use, this product may be a potential biohazard. It must be disposed of according to hospital, local and country regulations. Disposal is the responsibility of user.

Storage

The product should be stored in a cool, dry, clean, well-ventilated, non-corrosive gas environment. Do not expose the package to organic solvent, ionizing radiation or ultraviolet radiation.

Explanation of Symbols

	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 resterilize		Manufacturer
	Sterilized using Ethylene Oxide		Keep dry
	Non-Pyrogenic		

Warranty

Medorah Meditek Pvt. Ltd. warrants that this product has been manufactured by following appropriate procedures and reasonable care has been applied in designing and manufacturing 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 for a particular purpose. Handling, storage, cleaning and sterilization of this device as well as other factors relating to patient, diagnosis, treatment, surgical procedures, and other matters beyond Medorah Meditek Pvt. Ltd.'s control directly affect the device and the results obtained from its use. Medorah Meditek Pvt. Ltd.'s obligation under this warranty is limited to the repair or replacement of this device and 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 device. Medorah Meditek Pvt. Ltd. neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device. Medorah Meditek Pvt. Ltd. assumes no liability with respect to devices reused, reprocessed or re-sterilized and makes no warranties, expressed or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such devices.



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