MEDORAH MEDITEK

HELICON®

HEMOSTATIC GRASPER

Instructions for Use

Medorah Meditek Pvt. Ltd.

www.medorah.com

HELICON® Hemostatic Grasper

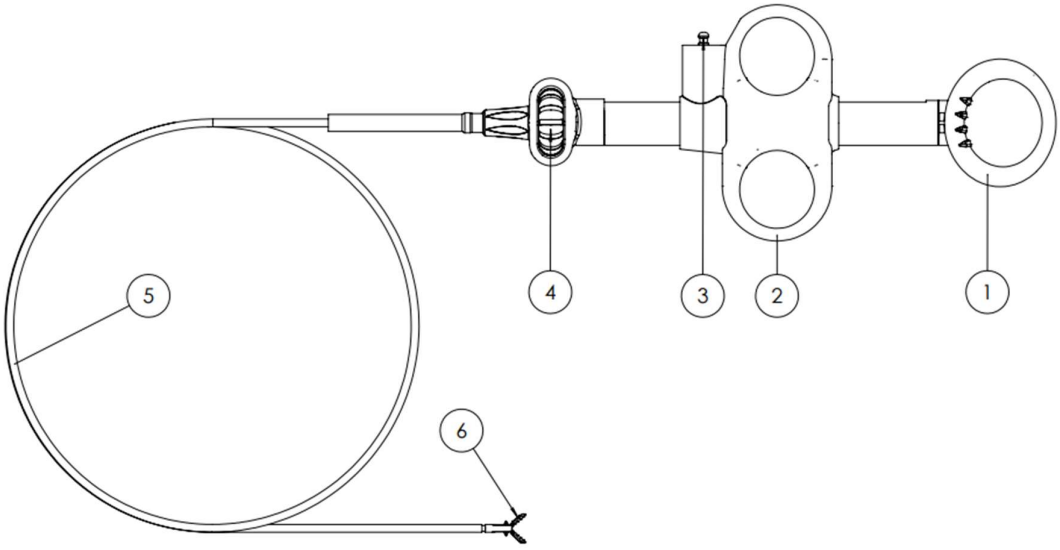
Intended Use

HELICON® Hemostatic Grasper is intended to be used to capture tissue, cauterize, coagulate, and perform hemostasis using high-frequency current within the digestive tract.

HELICON® Hemostatic Grasper is sterile and intended for single use only.

Device Descriptions

HELICON® Hemostatic Grasper is a single-use, endoscopic device designed for hemostasis during endoscopic procedures. It consists of a flexible catheter with distal grasping jaws that are operated by a proximal control handle. The device incorporates an electrosurgical connector at the handle, enabling use with an electrosurgical unit to facilitate coagulation while providing mechanical grasping of target tissue.



①	Handle
②	Hub
③	Cautery Port
④	Rotator
⑤	Catheter
⑥	Forceps

Contraindications

Contraindications include but are not limited to: coagulopathy and those specific to the primary endoscopic procedure.

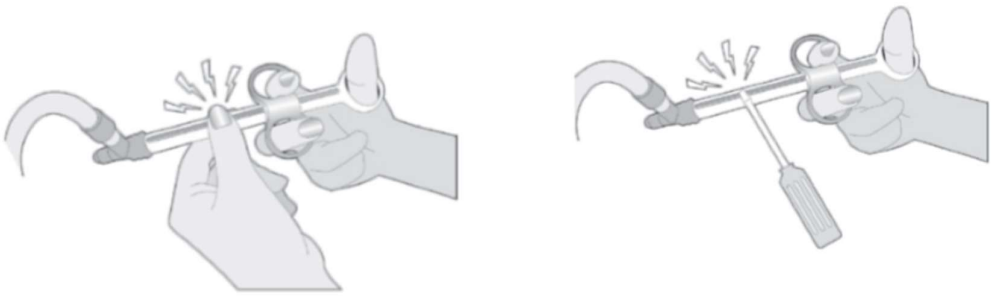
Potential Complications

Possible complications include, but are not limited to:

- Pain
- Transmural burns
- Thermal injury to the patient or explosion
- Septicemia/infection
- Coagulation disorders

Warnings

- DO NOT use it if the pouch is opened or damaged.
- For single use only. 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.
- It is suggested that the operator and the assistant wear protective gloves to prevent accidental burns. Universal precautions should be used in all cases.
- 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.
- DO NOT USE in patients who have electronic implants such as cardiac pacemakers without first consulting a qualified professional (e.g., cardiologist). A possible hazard exists because interference with the action of the electronic implant may occur, or the implant may be damaged.
- Do not use this instrument for any purpose other than its intended use.
- The product is intended for adult populations.
- DO NOT USE in the presence of flammable anesthetics or oxidizing gases (such as nitrous oxide (N2O) and oxygen) or in close proximity to volatile solvents (such as ether or alcohol), as explosion may occur. When using this product with active electrosurgical current, do not touch the wire as shown in picture (a).
- When using this product with active electrosurgical current, do not touch the wire with any metal part, as shown in picture (b).



(a) (b)

- PATIENT leads should be positioned in such a way that contact with the PATIENT or other leads is avoided.
- When not using, place ACTIVE ELECTRODES in a clean, dry, highly visible area not in contact with the patient. Inadvertent contact with the patient may result in burns.
- The intensity should be set as low as is necessary to achieve the desired effect.
- ASPIRATE fluid from the area before activating the instrument. Conductive fluids (e.g., blood or saline) in direct contact with or in close proximity to an active electrode may carry electrical current or heat away from target tissues, which may cause unintended burns to the patient.
- DO NOT USE with hybrid trocar systems, i.e., a combination of metal and plastic, when using monopolar active components. This may result in alternate site burns due to capacitive coupling. Use only all-metal or all-plastic trocar systems.
- The instrument is monopolar. The high-frequency electrosurgical unit should be used with a neutral electrode to prevent burns/injury to the patient.
- To ensure the correct use of applicable electrosurgical units and neutral electrodes, please refer to the electrosurgical unit and neutral electrode user manuals for additional instructions.
- DO NOT place instruments near or in contact with flammable materials (such as gauze or surgical drapes). Instruments that are activated or hot from use may cause a fire.
- Please check if the compatible generator has a CQM. If it does not have a CQM, please be noted that the loss of safe contact between the neutral electrode and the patient will not result in an alarm unless a compatible monitoring neutral electrode is used.

Procedure

- Ensure that the device and all necessary surgical tools are sterilized and intact prior to use.
- Connect the electrosurgical unit to the grasper, ensuring that the proper energy mode is selected based on the surgeon's preference and the specific procedure.
- Verify that grounding pads are applied correctly in the case of a monopolar system.
- Introduce the endoscope to the target site under direct visualization.
- Advance the grasper through the accessory channel of a compatible endoscope with the jaws closed.
- Position the distal jaws adjacent to the target tissue or bleeding site.
- Open the jaws using the proximal handle and securely grasp the target tissue.

- Once tissue is engaged, activate the electrosurgical generator to cauterize the blood vessels and stop bleeding. Ensure that the energy setting is appropriate for the tissue type and bleeding severity.
- Monitor the tissue closely to ensure that proper hemostasis is achieved without damaging surrounding structure.
- If necessary, reposition and repeat the procedure until hemostasis is achieved.
- After achieving hemostasis, release the tissue or proceed to remove it, depending on the surgical goals.
- Once the procedure is complete, inspect the surgical site to ensure that all bleeding has been controlled and no tissue damage is evident.
- Fully close the jaws, extract the hemostatic grasper and other surgical tools carefully from the surgical site.
- Dispose of the device after use according to institutional protocols for biohazardous waste.

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.

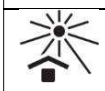
Disposal of a used device

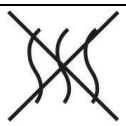
The used device must be disposed of according to hospital, local and country regulations. Disposal is the responsibility of the user.

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

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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