IMPORTANT INFORMATION

Caution: Federal law restricts this device to sale by or on the order of a physician. Read all instructions carefully before use. They contain essential information on using this device safely and effectively. Keep these instructions in a safe, accessible location, as you may need to refer to them again. If you have any questions or comments about any information in these instructions, please contact Micro-Tech.

INTENDED USE

Grasping Forceps device is intended to be used to grasp tissue, retrieve foreign bodies, and remove tissue from within the gastrointestinal tract.

CONTRAINDICATIONS

The contraindications include those specific, but are not limited to the following:

1. Any endoscopic procedures.
2. Endoscopic procedures to remove a foreign body or food bolus.
3. Use of an overtube.
4. Endoscopic procedures performed in conjunction with an overtube.
5. This device has not been designed, nor is it intended to be used with electrosurgical devices or their accessories.

POTENTIAL COMPLICATIONS

1. Perforation
2. Hemorrhage
3. Infection
4. Sepsis
5. Allergic reaction to contrast or medication
6. Hypotension
7. Respiratory depression or arrest
8. Cardiac arrhythmia or arrest
WARNINGS

1. **The product is intended for single use only!** DO NOT re-use, re-sterilize, and/or reprocess. Re-use, re-sterilization or reprocessing 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. Re-use, re-sterilization or reprocessing may also create a risk of contamination of the device and/or cause patient infectious disease(s). Contamination of the device may lead to injury, illness or death of the patient. Micro-Tech assumes no liability with respect to instruments reused, re-sterilized or reprocessed.

2. Do not use this instrument for any purpose other than its intended use.

3. The product is only intended for adult populations.

4. This device is not made with natural rubber latex.

5. Patients should be informed of the potential risks and complications, which may lead to injury, illness or death of the patient.

6. **The instrument is intended for use under the direct supervision of a suitably trained physician only.** A thorough understanding of the technical principles, clinical applications, and associated risks is expected before usage.

7. Confirm that the endoscopy view is clear before use. Do not insert the instrument into the endoscope unless you have a clear endoscopic field of view. Insertion without clear endoscopic field of view could cause patient injury, such as perforation, hemorrhage or mucous membrane damage. Damage to the endoscope and/or the instrument may also occur.

8. Should there occur any irregularities, dispose the instrument and replace it with a new one.

9. Keep traction on the device during retrieval in order for the retrieved object not to become loose, dislodged or, if in the lung, aspirated into the trachea.

10. Do not use excessive force on the handle and do not coil the catheter outside of the endoscope. Excessive force or coiling may damage the device or damage the endoscope; this may result in accidental injury to the patient or clinician.

【 Product Name 】Grasping Forceps  
【 Packaging 】Packed in Pouch  
【 Production Date 】See packaging  
【 Sterilization 】Sterilized by EO (ethylene oxide) gas  
【 Shelf Life 】5 years  
【 Compatible Working Channel 】φ 2.8 mm
PREPARATION

1. Reference the product label and choose the appropriate device.
2. Contents supplied STERILE.
3. Inspect the package before use for any damage. Do not use if package is damaged. Open the package carefully after verifying the shelf life.
4. Carefully remove the device from its packaging and uncoil it. Do NOT use excessive force as this may damage the device and affect performance.
5. Before use, check the clip and the spring tube to ensure that there are no sharp edges.
6. If this device shows any signs of damage, do not use. Do not attempt to repair a nonfunctional or damaged device.

INSTRUCTIONS FOR USE

1. Open the package and remove the device and the tip protector from the device’s distal end.
2. Move the finger ring back and forth to confirm that the Grasping Jaws open and close smoothly.
3. Before inserting the device into the endoscope, ensure that the Grasping Jaws are in the closed position. Place the Grasping Forceps into the endoscope’s working channel, and let it go through the channel slowly into the patient’s canal under the surveillance of the endoscope.
4. Once the object has been identified by the endoscope, place the device down the access channel slowly to avoid bending the catheter.
5. If resistance is encountered while inserting the Grasping Forceps into the endoscope, do not force the device. Reduce the angulation of the endoscope or lower the forceps elevator in the endoscope until the device passes smoothly.
6. Carefully observe the object for retrieval and move the Grasping Jaws to the targeted object.
7. Open the Grasping Jaws and grasp the object gently while maintaining continuous traction. Do not use excessive force on the handle. Do not coil the catheter outside of the endoscope.
8. Keep the distal end of the device endoscopically visible in order to ensure you do not lose sight of the object during removal.
9. Once Grasping Jaws grasp the object, slowly withdraw the object together with the endoscope from the patient.
10. Do not retract the device and the object into the endoscope; this could cause damage to the endoscope and the device.
11. Once the endoscope and the device have been withdrawn from the patient,
open The Grasping Jaws, and remove the object.
12. Remove the device from the endoscope with the Grasping Jaws in the closed position.
13. If removing additional objects from the patient, confirm that the Grasping Jaws open and close smoothly. Repeat steps 4-13 above.

**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.
The product shelf life is 5 years.

**PRODUCT DISPOSAL**

After use, this product may be a potential biohazard. Handle and dispose of in accordance with hospital, local and administrative laws and regulations.

**Limited Warranty and Disclaimers**

1. **Limited Warranty to Buyer.** Micro-Tech USA warrants to Buyer that, for the earlier of one (1) year from the date of purchase, or until the product is used by Buyer, the products will be free from defects in materials and workmanship when stored and used in accordance with the instructions for storage and use provided by Micro-Tech USA and in accordance with applicable regulatory requirements. Descriptions or specifications appearing in Micro-Tech USA’s literature are meant to generally describe the products and do not constitute any express warranties. In the event that Micro-Tech USA gives technical advice with respect to the product, it is agreed that such advice is given without any liability on Micro-Tech USA’s part. Any guarantee of specific properties of or in the products shall only be effective if and to the extent specifically confirmed by Micro-Tech USA in writing. These warranties shall not apply for product failure or deficiency due to improper storage, alteration, or the consequences of uses for which the products were not designed or that adversely affect the products’ integrity, reliability, or performance.
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