Instruction for Use – HOT Biopsy Forceps SU

(Biopsy Forceps with High Frequency Connector)

Attention:
This medical device may only be purchased by specialists, doctors and medical personnel and may only be used in accordance with these instructions for use and the defined area of application.

Description / Versions
ENDO-FLEX offers the HOT biopsy forceps with plastic-coated stainless-steel-spiral with a diameter of 2.3 mm and a length of 230 cm. It has distal oval fenestrated cups. The handle is equipped with a finger slide including HF connection for receiving the HF cable.

Products
This user manual is valid for the products listed below:
HOT-Biopsy Forceps SU (Single **U**se**):**
- NE6122-G

Important Note
Please ensure you read this user manual carefully before each use and keep it somewhere that is easily accessible for users and/or appropriate specialist staff.
Ensure you carefully read through the warnings. Patients, users or third parties may suffer serious injury as a result of the improper use of the products.

Contain and Packaging
- 1 outer box
- 10 Biopsy Forceps SU (**S**ingle **U**se) individually packed sterile
- 1 Instruction for Use

Patient Population
The patient population or target patient group is derived from the indication determined by the responsible doctor who diagnostically or therapeutically treats the patient as part of an endoscopic procedure (the leading procedure per se) according to the intended use of the medical device.
There are no known restrictions to the patient population or the target patient group.
- **Use of the product on minors:**
  The user can use the product on minors in the case that the physiological and anatomical conditions of the patient permit the use of the product.
- **Use of the product on women who are pregnant or breastfeeding:**
  The indication for the use of the product on women who are pregnant or breastfeeding must be narrowed down by the user based on the respective individual physiological and anatomical conditions of the patient.

Warning
1. According to law, this instrument is intended for use by physicians who have received appropriate training.
2. For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization 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 resterilization 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. ENDO-FLEX assumes no liability with respect to instruments reused, reprocessed or resterilized.
3. The instrument, when applied to a patient with a pacemaker implanted, may cause malfunction or failure of the pacemaker, seriously affecting the patient. Always confirm that it is safe to proceed with a cardiologist or the manufacturer of the pacemaker before proceeding.
4. When using the instrument in the vicinity of the heart, be sure to use it with the minimum necessary output. Spark discharge during operation may affect the heart.
5. When using an electrocardiograph or other physiological monitoring equipment simultaneously with the instrument, any monitoring electrodes should be placed as far away as possible from the electrodes used with the electrodes unit. Needle monitoring electrodes should not be used. Physiological monitoring equipment incorporating high-frequency current limiting devices is recommended.
6. When the endoscopes are used with the device, the patient leakage currents may be additive.
7. Prepare monitoring equipment and rescue equipment to control unpredictable risks.
8. Before use, please check the insertion patients body parts, ensure that no sharp edge.
9. No modification of this equipment is allowed.
10. Humidity applicable range 20% - 85%, pressure applicable range 80Kpa - 106Kpa, temperature applicable range 0°C - 60°C.
11. In the use of high frequency endoscopic accessories area, should avoid high explosive gas exist, in case of explosion hazard.
12. This product in the process of the electricity, hands cannot touch the chute of handle acc. Fig. 1.
13. This product in the process of the electricity, Shall not make external conductive objects in contact with the handle acc. Fig. 2.

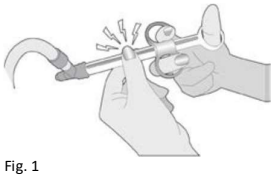

Fig. 1

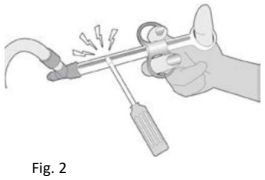

Fig. 2

14. The product is intended for adult and adolescent populations.

Caution
1. Before using this instrument, the operator must have received sufficient training in endoscopic manipulation and been aware of the related risks of the operation.
2. This instrument has been designed to be used with endoscopes to sampling and/or removal of polyps using high-frequency current within the digestive tract. Do not use this instrument for any purpose other than its intended use.
3. Please read this instruction manual entirely before use.

Structure
The hot biopsy forceps consists of jaws, a tube, a plug and a handle (See Fig. 3).

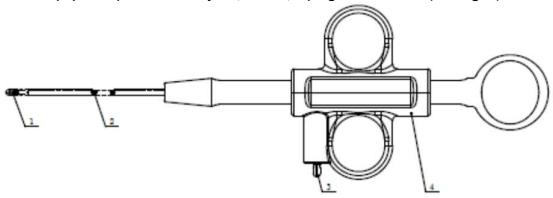

Fig. 3

1. Jaws / 2. Tube / 3. Plug / 4. Handle

Note:
Electrode of 1&2 parts are defined as applied part.

Specifications
REF-No.: NE6122-G
Shape: oval Jaws without spike
Material of outer tube: FEP
Jaw open area: 1: 6,7mm
Diameter of closed jaws: 2.3mm
Effective length of Forceps: 2300mm

Rated High-frequency Voltage:
CUT: 1600Vp (3200Vp-p)
DO NOT use higher repeated peak voltage

Compatible Electrosurgical Unit:
ERBOTOM ICC 200 high frequency electrosurgical apparatus.
If use the other Electrosurgical Unit, it must be used within product parameter.
(With electrodes are used together operation cable type is ERBOTOM High frequency output line 20192-117)

Compatible Working Channel:
The working channel diameter of those endoscopes refers to the information on the indication.

Classification:
II b according to COUNCIL DIRECTIVE 93/42/EEC

Shock proof:
Rely on the high frequency apparatus been applied. Refer to related manual.

Intended Use
This device is used endoscopically in conjunction with monopolar electrosurgical current to obtain gastrointestinal mucosal tissue biopsies and for removal of sessile polyps.

Notes
Do not use this device for any purpose other than stated intended use. If the package is opened or damaged when received, do not use. Visually inspect with particular attention to kinks, bends and breaks. If an abnormality is detected that would prohibit proper working condition, do not use. Please notify ENDO-FLEX for return authorization. Store in a dry location, away from temperature extremes.

Contraindications
Contraindications include those specific to the primary endoscopic procedure to be performed in gaining access to the desired biopsy or polypectomy site.
Contraindications to gastrointestinal mucosal biopsy and polypectomy include but are not limited to: coagulopathy and insufficiently prepped bowel.

Potential Complications
Potential complications with endoscopic mucosal biopsy or polypectomy include, but are not limited to: transmural burns, thermal injury to the patient, explosion.

Precautions
Refer to package label for minimum channel size required for this device.
Endoscope must remain as straight as possible when inserting or withdrawing forceps. Forceps cups must remain closed during introduction into, advancement through, and removal from endoscope. If cups are open, damage to forceps and endoscope may occur. Exercising handle while forceps is coiled may result in damage to forceps. Mucosal biopsy and polypectomy should be performed under direct endoscopic visualization. Before using this device, follow recommendations provided by electrosurgical unit manufacturer to ensure patient safety through proper placement and utilization of patient return electrode.

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Ensure a proper path from patient return electrode to electrosurgical unit is maintained throughout the procedure.

Warning
Failure to isolate tissue to be biopsied or polyp to be removed by pulling it away from mucosal wall may result in fulguration of normal mucosa and/or perforation.

Product Inspection
1. Uncoil forceps, open and close cups, verifying smooth handle operation and cup action.
2. With electrosurgical unit off, prepare equipment. Securely connect active cord to handle and electrosurgical unit.

Procedure
1. Endoscopically visualize area to be biopsied or polyp to be removed.
2. With cups closed, insert forceps into accessory channel of endoscope.
3. Advance forceps in 1-2 cm increments until it is visualized exiting endoscope.
4. **Note: Keep end of forceps that is extending from accessory channel straight at all times. Allowing forceps to hang from accessory channel may cause damage to device.**
5. Advance forceps to desired biopsy site or polyp, then open cups and advance into tissue to be biopsied or polyp to be removed.
6. Following electrosurgical unit manufacturer's instructions for settings, verify desired settings and activate electrosurgical unit.
7. Using slight pressure on handle, close forceps around tissue or polyp. Isolate tissue by gently pulling away from mucosal wall.
8. **Caution: When applying current, ensure metal tip of forceps does not come in contact with endoscope. Contact of forceps tip with endoscope may result in grounding, injury to patient and/or operator, as well as damage to endoscope and/or forceps.**
9. Maintain gentle handle pressure to keep cups closed and gently withdraw forceps from site.
10. Continue to apply slight pressure on handle and withdraw forceps from channel. While withdrawing forceps from endoscope, wipe excess secretions from cable.
11. Prepare specimen for examination per institutional guidelines.
12. Upon completion of procedure, turn electrosurgical unit off, disconnect active cord from handle, then dispose of device per institutional guidelines for biohazardous medical waste.
13. Don't touch the wire in the handle.

Sterility
Delivery condition
Disposable medical devices are supplied in an ETO gas-sterilized manner. Renewed preparation and sterilization following use is no longer possible and is prohibited!
The product may only be used once.
Resterilisation should not be performed following expiry of the shelf life, i.e. the product must be disposed of according to clinical provisions.

Shelf Life of Products
The shelf life of the product is typically 4 years after the date of manufacture under normal conditions.

Preparation
Warnings
The properties of raw resources/materials from which the instrument is made may alter in a negative manner as a result of reprocessing and resterilization.

Service
Do not carry out any modifications to the product. If you have any concerns, complaints or comments regarding our products, please get in touch with us.

Transport and Storage Conditions
- Products may only be transported and stored in the packaging provided for this purpose!
- Products must be stored dry and protected from sunlight at room temperature!
- Do not place any objects on the storage packaging and the sterile barrier system!
- Ensure the instruments are not kept near to chemicals, disinfectants or radioactive radiation!

Disposal
After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

Symbols used

Symbol for "Item Number"

Symbol for "Batch code"


Symbol for "Manufacturer"


Symbol for "Date of manufacture"


Symbol for "Observe instructions for use"

Symbol for "Sterilized with ethylene oxide"


Symbol for "non-reuse"

Symbol for "Do not re-sterilize"


Symbol for "Do not use if packaging is damaged"


Symbol for "Expiry Date"


Symbol for "keep dry"


Symbol for "protect from sunlight"


Symbol for "Type BF applied Part"


Symbol for "Caution"

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