Operating Instructions – Biopsy Forceps SU

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 biopsy forceps with bare or Teflon-coated stainless steel spirals in various diameters (1.8 to 3.0 mm). Models with a spike are available for better local fixation of the forceps. The forceps cups vary between "oval fenestrated" and "alligator" versions. In addition, the total lengths of the biopsy forceps are available for different treatment sites between 120cm, 160cm, 230 and 280cm.

Products
This user manual is valid for the products listed below:

standard
- NE0222-B
- NE0222-C
- NE0222D-B
- NE0222D-C
- NE0222D-G
- NE0222-G
- NE0222-M
- NE0230D-G
- NE0230-G
- NE0418-A
- NE0422D-G
- NE0422-G
- NE0430-G
- NE1618-A
- NE1618-B
- NE1618-C
- NE1618-M

Teflon coated
- NEX0222-B
- NEX0222D-B
- NEX0222D-G
- NEX0222-G
- NEX0230-G
- NEX0422-G
- NEX0430-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.

1. Scope of Application
The products listed above may only be used by suitably trained and qualified staff. The products are intended solely for the medical sector as illustrated below and must therefore be used within an operating environment suitable for this purpose. It is essential that both the user as well as the appropriate specialist staff familiarise themselves with the instruments before the user makes use of them.

2. Application Period
The instruments are intended to be used uninterrupted for a period of up to 60 min under normal conditions.

3. Intended Use
The Single-use Biopsy Forceps are used for endoscopic histological sampling of various tissue sites within the gastrointestinal and bronchial tracts via the operating channel of endoscopic instruments. A thorough understanding of the technical principles, clinical applications, and risks associated with gastrointestinal endoscopy, mucosal biopsy and foreign body retrieval is necessary before using this device. Biopsy forceps should only be used by, or under the supervision of, physicians thoroughly trained in therapeutic endoscopy, mucosal biopsy and foreign body retrieval.
Indication
- Presumption of diagnosis of gastritis
- Suspect clinical sign (coloration of mucosa, mucosa defect, tissue curvature)
- Chronic diarrhea

Contraindication
- Coagulopathy
- Tissue samples from vessel injury in ulceration
- Insuffcient prepped bowel
- Primary endoscopy, coloscopy, rectoscopy
- Application to the central cardiovascular system is contraindicated.
- 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
- Pregnancy
- Recently created gastrointestinal anastomosis

4. Complications / Side Effects / Cross-reactions
Sedation during endoscopic examination increases the risk of hypoxemia, hypercapnia, hypotension, arrhythmias and aspiration due to reduced protective reflexes. Hypoxemia also occurs without sedation during endoscopic examinations due to the feed of the endoscope.

The following complications may occur:
- Perforation,
- hemorrhage,
- infection,
- sepsis,
- allergic reaction to contrast or medication,
- hypotension,
- respiratory depression or arrest,
- cardiac arrhythmia or arrest.

Appropriate preparations for complications that may arise must be made prior to use.

5. Warnings / Precautions
These instructions must be followed, as well as instructions from compatible components and hospital regulations for infection prevention, safe use, cleaning and sterilization. Failure to do so may result in serious injury to the patient and/or the user.
The following applies to the product:
- Sterile only if packaging is undamaged or unopened!
- For single use only! Do not reuse, reprocess or sterilize several times. Reuse, reprocessing or repeated sterilization of the instrument may affect its structural integrity and cause malfunction, resulting in contamination, infection and serious injury.
- If the instrument accidentally becomes dirty before treatment, it must be disposed of immediately! No cleaning agents may be applied.
- Do not use after the expiration date!
- 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.
- Never use the product outside the recommended technical specifications (intended use).
- Never tamper with the structural conditions of the instrument, avoid kinks and other damage, and immediately discontinue use in the event of a malfunction!
- Wear protective clothing (gloves, goggles, gown, etc.) is absolutely necessary!
- Comparison of the technical data of the product with those of the endoscope used. The working channel diameter must be at least 0.2 mm larger than the outer diameter of the instrument.
- Never force instruments into the working channel!
- The compatibility of the diameter of the biopsy forceps and the diameter of the endoscope working channel is essential for obtaining optimal results during the procedure.
- The forceps cups should be closed during introduction into, advancement through, and removal from\advancement through, and removal from the endoscope. If the cups are open, damage to the forceps and endoscope may occur.
- Mucosal biopsy and foreign body retrieval must be performed under direct endoscopic visualization.

Function Impairment
The instrument must be inspected for any damage along with its shelf life prior to use. Only non-damaged and sterile instruments may be used. The instrument may only be used once.

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Operational Conditions
A function test and/or visual inspection should be carried out prior to any use. As a result, we therefore refer to the corresponding sections in this user manual.

6. Function Test
The medical devices must be checked with regard to the following aspects prior to use:
- Expiration date
- Undamaged packaging
- Damage on the product (cracks on tube, bending, deformation)

Inspect products for immaculate surfaces, correct assembly and functionality.
Products that have failed the function test must not be used as their sterility and product safety cannot be ensured. Dispose of these products accordingly, or please return them to the manufacturer.

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7. Preparation / Application
Visually inspect the biopsy forceps with particular attention to bends or breaks. If it appears damaged, do not use the device and contact us.

1. Perform the diagnostic endoscopy and visualize the area to be biopsied.
2. Insert the biopsy forceps with the cups closed into the accessory channel in small increments.
3. Open the cups and advance the device into the tissue to be biopsied.
4. Close the biopsy forceps cups using slight pressure on the handle.
5. Maintain gentle handle pressure to keep the cups closed while gently withdrawing the forceps from the tissue.
6. Withdraw the biopsy forceps from the channel. Continue to apply slight pressure on the handle to hold the cups closed.
7. Prepare the specimen for examination per institutional guidelines.
8. Dispose of for single use only products according to the guidelines for biohazardous medical waste.

8. Combination Products
These instruments may only be used in conjunction with an endoscope.

9. 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.

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

11. 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.

12. 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.

13. 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!

14. 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.

15. 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 “Attention”

Symbol for “Medical Device”


Symbol for “simple sterile barrier system”


Symbol for “simple sterile barrier system with outer protective packaging”