Instruction for Use – Foreign Body Retrievers SU / Polyp Retrievers 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 3-arms or 4-arms sharp grabs for the extraction of foreign bodies in the digestive tract, depending on the type and shape of the foreign bodies. Furthermore, foreign body retrievers with Teflon-coated stainless steel spiral with different shapes of cups.
In addition, polyp grabs were developed which are equipped with blunt grabs in order not to unnecessarily damage separated polyps during extraction, so that these can be supplied to subsequent histological examinations as far as possible unaltered.

Products
Foreign Body Retrievers SU (**S**ingle **U**se)
- NE1222-G3
- NE1222-G4
- NEX0622-C
- NEX0822-C
- NEX0822-G
- NEX1418-A
- NEX1418-C
- NEX1422-C
- NEX1422-G
- NEXSET01

Polyp Retrievers SU (**S**ingle **U**se)
- NE1322-G3
- NE1322-G4

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.

Content and Packaging
Foreign Body Retrievers SU (NE1222-Gx):
- 1 outer box
- 5 Foreign Body Retrievers individually sterile packed
- 1 Instruction for use

Foreign Body Retrievers SU (NEX0x22-C):
- 1 outer box
- 10 Foreign Body Retrievers individually sterile packed
- 1 Instruction for use

Foreign Body Retriever Set SU (NEXSET01):
- 1 outer box
- 3x NEX0622-C + 3x NEX0822-C + 4x NEX1422-C individually sterile packed
- 1 Instruction for use

Polyp Retrievers SU (NE1322-Gx):
- 1 outer box
- 5 Polyp Retrievers individually sterile packed
- 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 must only be used by physicians with appropriate specialist training in gastroenterology. 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 familiarize themselves with the instruments before the user makes use of them.

2. Application Period
These instruments are intended to be used uninterrupted for a period of less than 60 minutes under normal conditions. (MDD 93/42 EEC)

3. Intended Use
Foreign Body Retrievers and Polyp Retrievers are used for gripping and removing foreign bodies, removed polyps and tissue, mostly in gastroscopy.
Indications
- Endoscopic recovery of foreign objects
- Endoscopic recovery of separated polyps for histological examinations
- Detection of lesions, tumours, carcinomas, Crohn's disease etc.

Contraindications
- 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.
Possible injuries in connection with endoscopic examinations can be: perforations, bleeding, infections such as acute pancreatitis.

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!

6. Liability and Warranty
As the manufacturer here, ENDO-FLEX shall not be liable for any damage or consequential damage arising from improper use or handling. This shall in particular apply to any use not in line with the defined purpose or failure to observe the preparation and sterilisation instructions and warnings. This shall also apply to repairs or modifications to the product made by individuals who are not authorised to do so by the manufacturer.

7. Compatibility
Not specified.

8. 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.

9. Preparation / Application
- Check the instrument for reliable function and irregularities before the procedure.
- Test the smooth movement of the instrument by carefully moving the finger slide forwards and backwards.
- **If you notice any irregularities, replace the instrument with a new one!**

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- Inserting into the working channel is carried out with the grab retracted into the tube or closed forceps cups. The corresponding working channel and tube diameters must be observed.

Foreign Body Retrievers:

- Position the foreign body retriever just in front of the object to be removed.
- Pull the grab completely out of the tube or open the cups by carefully pushing the finger slide on the handle and grasp the object.
- Carefully retract the finger slide on the handle to retract the grab / close the cups, as far as the object allows, and remove it by carefully removing the endoscope.
- Hold the finger slide in the position so as not to lose the captured foreign body from the grab.
- Dispose of the instrument immediately after use.

Polyp Retrievers:

- Position the polyp retriever just in front of the polyps to be recovered.
- Pull the grab completely out of the tube by carefully pushing the finger slide on the handle and grip the polyp.
- Carefully retract the finger slide on the handle, if the polyp permits, and remove the grab by carefully removing the endoscope.
- Hold the finger slide in the position so as not to lose the trapped polyp from the gripper.
- Dispose of the instrument immediately after use.

10. 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.

11. Shelf Life of Products

The shelf life of the product is typically 3 years after the date of manufacture under normal conditions.

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

The products, packaging materials and accessories must all be disposed of in accordance with the nationally applicable regulations and laws. No specific instructions regarding this are given by the manufacturer.

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”