Instruction for Use – Polypectomy Snares 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.

Descriptions/Variants
The polypectomy snares offered by ENDO-FLEX consist of a plastic handle, a plastic tube from 1.8 to 2.35 mm Ø and a stainless steel polypectomy snares located in the tube. The handle is equipped with a finger slide with HF connection, which allows the user to extend the loop distally out of the tube. ENDO-FLEX offers the user snares of oval, asymmetrical and hexagonal shape with different opening widths (15, 20, 25 and 35 mm) in braided and monofilament wire versions. The total lengths result from the endoscopes used between 180 and 280 cm.

Products
This user manual is valid for the products listed below:
(N)OE3xxx-x / (N)OE3x22xx(M)-x

The products mentioned here have been tested for electrical safety according to the standards IEC 60601-2-2:2017 including sub-clauses 201.8.8.3.103 and 201.8.8.3.104 and meet all requirements for safe operation. The ERBE-ICC 200 HF generator and HF connection cable (item no. 640300 and 640500) were used for the application tests.

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 indicated by this symbol. Patients, users or third parties may suffer serious injury as a result of the improper use of the products.

Content and Packaging
Polypectomy Snares SU are offered in packaging units of 5 pieces:
- 1 outer box
- 5 Polypectomy Snares SU (**S**ingle **U**se) individually sterile packed
- 1 Instructions 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
The Polypectomy Snares are intended to be used uninterrupted for a period of less than 60 minutes under normal conditions. (MDD 93/42 EEC)

3. Purpose
Polypectomy snares are used in conjunction with high-frequency current to remove polyps or tissue from the gastrointestinal tract.
Indication
- Polyps that could develop into a malignancy
- Prevention of cancer
- Clinical symptoms (bleeding, occlusion)

Contraindication
- Application to the central cardiovascular system is contraindicated.
- Serious co-morbidities (heart failure, coronary artery disease, cirrhosis of the liver)
- Ileus, peritonitis, florid inflammatory bowel conditions
- Clotting disorders, haemorrhagic diathesis
- Limited life expectancy (malignant disease)

4. Risks and Side Effects
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 when using polypectomy snare:
- Injuries to the mucosa or tissue, especially altered tissue!
- Bleeding secondary to injuries!
- Gastrointestinal perforation due to excessive tissue coagulation - this can still occur several days later!
- Bleeding due to inadequate coagulation of the incised surface - this can still occur several days later!
- Bleeding in patients with poor blood clotting!
- Perforation of vessels, gastrointestinal tract or other organs!
- Burns on the handle due to poor HF plug connection!
- Risk of explosion from endogenous gases, especially in the colon!
- Risk of explosion from the introduction of explosive gases!
- Allergies can occur in very rare cases!

Appropriate preparations for complications that may arise must be made prior to use!
The use of high-frequency generators with an Endo-Cut function is recommended.

5. Materials
The products are made from high quality stainless steel and plastics.

6. 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!
- Check instrument and active cord for cracks and/or damage to the insulation!
- Avoid contact between live handle components, e.g. the push rod when high-frequency current is applied! Contact may cause electrical burns and shocks.
- In any case, the plug connections of the Active cord and HF device must be checked for compatibility!

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.

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.

7. 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.

8. Function Test
The medical devices must be checked with regard to the following aspects prior to use:

Instruction for Use – Polypectomy Snares SU

- 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. Handling

Inserting into the Endoscope

Polypectomy snares are introduced into the endoscope's working channel with the snare retracted in a plastic tube. The relevant tube and working channel diameters must be taken into consideration (see article label).

Establishing the HF Connection

The plastic coil on the handle is equipped with a HF connection jack for the HF cable.

Pay attention to the design of the HF connection!

Performing Polyp Removal

1. Once the HF connection with the HF device has been established, the polypectomy procedure can begin.
   Comply with the HF generator's instructions for use!
2. Position the distal end of the plastic tube just in front of the polyps being removed in the patient's body.
3. By advancing the plastic coil, fully expand the snare and capture the polyps with it.
4. Push the plastic coil back far enough for the snare to lie tightly around the root of the polyps.
5. Apply HF current to the snare (note the HF device manufacturer's instructions).
6. Remove the polyps by retracting the snare fully back into the tube.
7. Interrupt the HF current supply and remove the polypectomy snare from the endoscope.

Do not touch any adjacent tissue with the snare while it is in HF mode! This can cause perforations, which could possibly immediately endanger the patient's health.

Performing Tissue Resection

1. To recognize the lesion more effectively, it should be marked with coagulation markers at its outer edge and physiological saline solution and adrenaline injected into its base.
2. Once the HF connection with the HF device has been established, the tissue resection procedure can begin.
   Comply with the HF generator's instructions for use!
3. Position the distal end of the plastic tube just in front of the tissue being resected in the patient's body.
4. Advance the plastic coil to expand the snare fully, place it over the lesion and press on the tissue.
5. Push the plastic coil back far enough for the snare to lie tightly against the tissue.
6. Resect the tissue using HF current; the snare is retracted fully back into the tube.
7. Interrupt the HF current supply and remove the polypectomy snare from the endoscope.

Do not touch any adjacent tissue with the snare while it is in HF mode! This can cause perforations, which could possibly immediately endanger the patient's health.

10. Combination Products

Polypectomy Snares are only used in conjunction with HF equipment, active cords and endoscope.
The HF working voltage to be set (Forced-CUT) is max. 2.300 Vp.
DO NOT use higher-frequency peak voltage.

Warning!
DO NOT use a higher voltage.

A voltage peak of up to 4.000 Vpeak can occur when the HF generator is switched off.

Check the output power of the high-frequency generator before using the instrument. If the output power of the instrument is incorrectly set, perforations, bleeding or mucous membrane injury may occur. The maximum power consumption of this product is 200 W.

Safety Precautions: Make sure that the safety instructions in the operating manual of the RF generator used have been observed and understood.
The choice and use of the HF generator is the responsibility of the treating specialist personnel.

Attention!
The use of HF generators with Endo-Cut function is recommended.

11. 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.

12. Shelf Life of Products

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

13. 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.

14. 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!

15. 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.

16. Symbols used

REF — Symbol for “Item Number”

LOT — Symbol for “Batch code”

Symbol for “Manufacturer”

Symbol for “Date of manufacture”

Symbol for “Observe instructions for use”

STERILE EO — 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”

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