

Instruction for Use – Stone Extraction Baskets 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

For the extraction of gallstones, ENDO-FLEX offers (partly suitable for guide wires) Stone Extraction Baskets drawn into a teflon tube with shapes of Basket Type and Dormia Type, in different basket sizes and basket constructions and in tube diameters of 1.8 mm, 2.35 mm and 2.6 mm.

Products

This user manual is valid for the products listed below:

- | | | |
|---------------|---------------|-----------------|
| • E141225 | • E152227GW | • E161225-280 |
| • E141226 | • E153226GW | • E161225GW |
| • E151185 | • E161182 | • E161225GW-280 |
| • E151185-120 | • E161184-070 | • E161226 |
| • E151186 | • E161222GW | • E161226GW |
| • E152224GW | • E161223GW | • E161227 |
| • E152225 | • E161224 | • E162225 |
| • E152225GW | • E161224GW | • E162226 |
| • E152227-300 | • E161225 | |

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

Stone Extraction Baskets SU are offered in packaging units of 5 pieces:

- 1 outer box
- 5 Stone Extraction Baskets SU (Single Use) 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 Stone Extraction Baskets are intended to be used uninterrupted for a period of less than 60 minutes under normal conditions (MDD 93/42 EEC).

3. Intended Use

Stone Extraction Baskets are used for catching and removing stones from the biliary ducts of the human body. Contrast injection is possible through the lateral Luer-Lock connector. The use is carried out by means of an endoscope.

Indikationen

- Endoscopic retrieval of gallstones and concretions

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. Compatibility

Not specified.

7. Service Life of Products

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

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, 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.**
- The insertion into the working channel takes place with the basket retracted into the tube and can be carried out with instruments with the article number suffix "-GW" via a guide wire. The corresponding working channel and tube diameters must be observed.

Extraction of Stone

Once the stone is located by usual means do as following:

- Place the Extraction Basket's distal tip approx. on the desired position.
- Push the basket completely out of the tube and bring the stone in the basket center.
- Pull the handle back until the stone is fixed in the basket and pull the Extraction Basket out of the endoscope until the basket touches the distal tip of the endoscope.



Excessive traction should be avoided to prevent damage the endoscope.

- By carefully taking out the endoscope and Extraction Basket the stone will be removed from the biliary duct. Keep the handle of the Extraction Basket in position of fixing the stone.

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Emergency Lithotripsy

If the stone (because of its dimension) cannot be removed and it cannot be loosened out of the basket, then it is possible, with the aid of a Emergency Lithotripsy Set to crush the stone.



Emergency lithotripsy is not possible with the following Stone Extraction Baskets:

- E141225
- E152225GW
- E161222GW
- E161225GW
- E141226
- E152227GW
- E161223GW
- E161225GW-280
- E152224GW
- E153226GW
- E161224GW
- E161226GW

The procedure is described in the Operating Instructions of the Emergency Lithotripsy Set.



Rotate the handle crank in 360° increments (one revolution) at a time. Pause for 5 to 10 seconds to allow the energy to transfer from the handle to the Basket wires.

During the procedure, make sure that the metal spiral is ideally in a straight line to the basket. Avoid excessive bending or arching of the metal spiral during the procedure to reduce the potential of cable breakage.



Important Warning:

A lithotripsy cannot be guaranteed! If the stone to be crushed is too hard the basket might break due to the force being applied on it. In this case the stone along with the torn basket should be removed surgically. The lithotripsy should be interrupted immediately if it is being realised that the stone crushing cannot be achieved.

10. Reprocessing and Sterilisation

These instruments are delivered in sterile condition and **CANNOT EFFECTIVELY** be cleaned, disinfected and sterilised after single use on account of the design which can no longer be removed and must be disposed of after single use.

The products are only sterile if the packaging is undamaged and unopened and if the shelf life is not exceeded. Products whose packaging is damaged or whose shelf life has expired must be discarded.

11. Disposal and Reprocessing

After use, this product may present a biological hazard. Handling and disposal must be carried out according to recognised medical procedures and in accordance with applicable legal requirements. These instruments are disposable products and must not be reprocessed and resterilized, as damage to the materials cannot be ruled out.

12. 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!

13. 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.

14. 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.

15. 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!

16. 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 "Caution"



Symbol for "Medical Device"



Symbol for "simple sterile barrier system"



Symbol for "simple sterile barrier system with outer protective packaging"