Instruction for Use – Lithotripsy Baskets and Spirales 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
The lithotripsy baskets offered by ENDO-FLEX consist of a 4m long stainless-steel traction wire equipped proximal with a stainless-steel push tube, a distal multifilament stainless-steel basket and a plastic tube of 2.6 and 2.9mm Ø equipped proximal with lateral Luer-Lock connector as working channel insertion aid. Due to the different dimensions and shapes of the stones to be crushed, the basket is available in variable designs: 4 and 6 wires as basket or dormia type with a stretched length between 30 and 70mm (corresponds in new and extended condition at room temperature to an approximate basket width between 15 and 35mm).
In addition, ENDO-FLEX offers adequate stainless steel Lithotripsy Spirals as a counter-support for force transfer during the lithotripsy procedure.

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

Lithotripsy Spirals:
- E120261
- E120602
- E120604

Lithotripsy Baskets:
- E122264N
- E122265N
- E122266N
- E122267N
- E122336N
- E124263N
- E124264N
- E124265N
- E124266N
- E124267N
- E124335N
- E124337N
- E128336N

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
Lithotripsy Spirals SU:
- 1 outer box
- 5 Lithotripsy Spirals SU (**S**ingle**U**se) individually sterile packed
- 1 Instructions for use

Emergency Lithotripsy Spiral SU:
- 1 outer box
- 1 Lithotripsy Spiral SU (**S**ingle**U**se) individually sterile packed
- 1 Instructions for use

Lithotripsy Baskets SU:
- 1 outer box
- 5 Lithotripsy Baskets 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
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
The Lithotripsy Baskets and spirals are used for crushing stones in the biliary and pancreatic ducts. Contrast medium injection is possible through the lateral Luer-Lock port of the Y-Adapter found of the Teflon tube.
Indication
- Biliary Lithotripsy

Contraindication
- 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. Combination products
Lithotripsy Baskets and -spirals can be used in conjunction with an endoscope (except E120604), and the handle for lithotripsy (120610) only.

7. Shelf Life of Products
The shelf 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.
- **! If you notice any irregularities, replace the instrument with a new one.**

Insertion into the Endoscope
The Lithotripsy Basket has to be drawn back into the Teflon tube completely in order to be introduced into the endoscope's operating channel. Please observe compatibility between the Lithotripsy Basket and the operating channel diameter.

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Catching the Stone
Once the stone is located by usual means do as following:
- Advance the closed catheter and pass the stone. Place the distal tip of the catheter behind the stone.
- Open the basket completely and bring the stone by controlled movement in the center of the basket.

Changing the Teflon tube for the metal spiral
For crushing the stone it is necessary to replace the Teflon tube with a metal spiral fitting to the working. By doing so, a stabile counter-pressure during the crushing procedure is given.
- Loosen the screw cap at the Teflon tube's Y-adapter.
- Remove the Teflon tube completely and gently from the endoscope by sliding it over the traction cable.
- Push the metal spiral over the traction cable with its distal end first and shift it up to the basket with the stone captured inside.

Handle Assembling
The following handle is available for using the Lithotripsy baskets:

- Type III (Order No. 120600) fitting to Spiral E120602 (regulary Lithotripsy) and E120604 (Emergency Lithotripsy).

For instructions as to how to assemble them, please refer to the instruction for use.

Crushing the Stone
Turn the manual wheel at the handle, until the stone is crushed.

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.
Keep the Metal Spiral in alignment with the scope's working channel. Avoid excessive bending or arching of the Metal Spiral during the procedure to reduce the potential of cable breakage.
If necessary to push the basket out of the Metal Spiral, never apply excessive force using the handle. If significant resistance is encountered when attempting to eject the basket out of the metal spiral, either reposition (straighten) the metal spiral / basket combination and retry or retract the spiral /basket assembly out of the endoscope and inspect.

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. 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.

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 "Caution"