Operating Instructions – Stone Extraction Balloons 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/Variants
The stone extraction balloons offered by the ENDO-FLEX have a distal balloon made of Latex with radiopaque markers, a double or triple lumen plastic tube and three proximal luer-lock-connectors, one of which serves as contrast access, one as guide wire access and a third, with a 2-way cock, as inflation port.
A basic distinction is made between 2 variants:
Single-Stage Extraction Balloons
The tube has a diameter of Fr. 5 to Fr. 7 with a total length of 200 cm. The balloon diameter is between 9 and 18 mm. This instrument comes with a syringe prepared for the maximum filling volume.
Multi-Stage Extraction Balloons
The tube has a diameter of Fr. 7 with a total length of 200 cm. The balloon diameter is between 9 and 16 mm. This instrument comes with three syringes prepared for the maximum filling volume.

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

• **134000**	• **134020**	• **134033**
• **134005**	• **134030**	• **134011A**
• **134010**	• **134031**	• **134010PRO**
• **134011**	• **134032**	• **134030PRO**

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
- 1 Stone Extraction Balloon SU (**S**ingle **U**se) incl. syringe(s), 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
Stone Extraction Balloons are used in conjunction with an ERCP for the extraction of stones in the bile ducts. When necessary, contrast injection is possible through one of the Luer-Lock connectors.
Indication
- Stone extraction during ERCP

Contraindication
- Application to the central cardiovascular system is contraindicated.
- Specific contraindications for primary endoscopic procedures to access the desired injection site
- Severe coagulopathy
- 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 when using Extraction Balloons:
- Injury to the mucous membrane or tissue, particularly in the case of mutated tissue
- Bleeding due to injuries
- Perforation of blood vessels, stomach or intestinal wall or other organs
- Ulcers in or necrosis of injected tissue
- Stricture formation
- Allergic reaction

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

BALLOON CONTAINS LATEX !
The latex and rubber devices cannot be used in sensitive patients with allergic reaction to these substances. In these cases others alternative treatments should be used.

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!

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.

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. 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.

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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.

8. Preparation / Application

Inserting into the endoscope

The Balloon Catheter must be inserted **deflated** into the endoscope operating channel. Please observe compatibility of catheter diameter and the endoscope operating channel diameter (see label).

The use of a guide wire starting from a certain diameter is recommended. In addition, with the 3-lumen version, contrast medium can be injected while the guide wire is inserted.

Stone Extraction

After locating the stone to be removed, proceed as follows:

1. Insert the deflated balloon into the biliary duct until the distal tip is located above the stone to be removed.
2. Pull the plunger of the included syringe and connect it to the transparent stopcock at the proximal end of the catheter.
3. Open the stopcock.
4. Push the plunger of the syringe carefully to inflate the balloon. Air capacity specified for each balloon must be respected to avoid its destruction.
5. Close the stopcock to prevent the air to leak out of the balloon.
6. Gently withdraw the inflated balloon catheter to pull the stones out of the biliary duct and drop them into the duodenum. They can be expelled naturally out of the body through the intestines.
7. Open the stopcock and deflate the balloon.
8. Remove the entire instrument out of the endoscope carefully.

Sharp stones can destroy the balloon and should be removed with an extractor basket or a lithotripsy basket.

9. Combination Products

Stone Extraction Balloons may only be used in conjunction with an endoscope.

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 2 years after the date of manufacture under normal conditions.

12. 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.

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

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 “contains latex”


Symbol for “Caution”