Operating Instructions – Cysto-Gastro-Sets SU

Attention:
This medical device may only be purchased by specialists, doc-tors and medical personnel and may only be used in accordance with these instructions for use and the defined area of application.

Description/Variants
ENDO-FLEX GmbH offers two types of Cysto-Gastro-Sets in Fr. 8.5 and Fr. 10 and one Cystotome in Fr. 6.
The Cysto-Gastro-Set (Fr. 8.5 or optionally Fr. 10) consists of 2 set components:
- an outer tube with a length of 180 cm, equipped with a metal tip at its distal end and a lateral HF- connector at its proximal end.
- an inner catheter 210 cm long, equipped with a puncture needle at its distal end and a Luer-Lock connector and a HF-connector at its proximal end.

The inner catheter is pushed into the outer one in its full length and fixated by a LL-connector.
The Cystotome (Fr. 6) consists of:
- an outer tube with a length of 180 cm, equipped with a metal tip at its distal end and a lateral HF- connector at its proximal end.

Products
This user manual is valid for the products listed below:
E30006345; E30008341; E30010340

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
- 1 outer box
- 1 Cysto-Gastro-Set 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
Cysto-Gastro-Sets are intended to be used uninterrupted for a period of less than 60 minutes under normal conditions (MDD 93/42 EEC).

3. Intended Use
Cysto-Gastro-Sets are used in conjunction with high frequency current to puncture pancreatic cysts or pseudo-cysts endoscopically as an alternative to surgical or percutaneous treatments. During the procedure the cyst is punctured by a needle and finally dilated to a diameter of 8.5 or 10 Fr. (depending on which set is used).
Indications
- Cysts that could develop into a malignancy
- Prevention of cancer
- Clinical symptoms (bleeding, occlusion)

Contraindications
The Cysto-Gastro-Set must not be used if therapeutic endoscopic procedures, especially pancreatic interventions, are contraindicated.
Specific contraindications are portal hypertension and pseudo-aneurysms of regional vessels.
- 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.
- Pancreatitis
- Cholangitis
- Abdominal pain
- Infection, also systemic infection
- Abscess
- Gastric or duodenal perforation
- 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!

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

6. Precautionary Measures and Warnings
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:
- 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. Compatibility
Cysto-Gastro-Sets are only used in conjunction with HF equipment, active cords and endoscope and are compatible with ERBE and OLYMPUS generators. They can be connected to these HF devices without restriction using the active cords (***ENDO-FLEX part numbers 640300 and 640500***).
For performance data and use of the recommended HF generators (ERBE E and T series; ERBE ICC; OLYMPUS HF 120/130), please refer to the respective manufacturer's manual. If HF generators from other manufacturers are used, check their compatibility and follow their instructions.
- **max. power: 300 W**
- **max. HF voltage: 1600 Vpeak**

The use of high-frequency generators with an Endo-Cut function is recommended.

10. Handling
Insertion Cysto-Gastro-Set (Fr. 8.5 and 10) into the Endoscope
Ensure that both components are assembled and fixed at the Luer-Lock connection.
Please note: The inner catheter is approx. 20 cm longer than the outer Teflon tube.
Cysto-Gastro-Sets require an endoscope´s working channel of at least 3.7 mm Ø.

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HF Cable Connection
Both components are supplied with HF-connectors fitting to active cords.

Procedure of Cystotomy
After the size and position of the cyst or pseudo-cyst is determined by endosonography, the Cysto-Gastro-Set is inserted into the endoscope´s operating channel.

Procedure Fr. 8.5 and Fr. 10
1. Connect the active cord to the HF–connector at the proximal end of the inner catheter and the HF generator, respectively
2. Carefully move out the puncture needle of the inner catheter.
3. Puncture the stomach wall and the cyst with the puncture needle by using electric current.
4. Disconnect the electric current and remove the active cord from the inner catheter.
5. Open the HF- connector and remove the puncture needle from the inner catheter.
6. Inject contrast through the lateral Luer-Lock adapter at the proximal end of the inner catheter if needed and place a guide wire **(Fr. 8.5 → .025" / Fr. 10 → .035")** through the inner catheter and into the cyst.
7. Connect the active cord to the lateral connector at the outer tube and to the HF generator.
8. Loosen the Luer-Lock fixation between inner catheter and outer tube. Push forward the outer tube by using the inner catheter as a guiding catheter until the distal metal tip reaches the stomach wall.
9. Apply HF current and enlarge the opening in the cyst by advancing the metal tip carefully.
10. Disconnect the active cord and remove the Cysto-Gastro-Set from the endoscope by leaving the guide wire in place.

Procedure Fr. 6
1. Connect the active cord to the HF–connector at the handle.
2. Bring the Cysto-Gastro-Set to the stomach wall, apply HF current and enlarge the opening in the stomach wall and the cyst by advancing the metal tip carefully.
3. Disconnect the active cord.
4. Place a guide wire .035" through the sealing cap, advance it through the Cysto-Gastro-Set into the cyst and close the sealing cap.
5. The lateral Luer-Lock adaptor at the handle facilitates as contrast injection or vacuum port.
6. Remove the Cysto-Gastro-Set from the endoscope by leaving the guide wire in place.

Do not touch other tissue areas with the tip when using HF electricity (danger of perforation)! During HF-electricity usage no contrast fluids can be injected!

After cystostomy the cyst can be drained by placing a suitable stent.

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

13. Preparation
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.
However, if the product is reprocessed and resterilized, then the user shall assume responsibility for doing so!

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!

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 "Caution"