Instruction for Use - Sphincterotomes 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
Sphincterotomes are equipped with different tip shapes and ring markings on the tube for precise positioning. Sphincterotomes are available in 1-lumen, 2-lumen and 3-lumen versions for contrast injection, while a guide wire is placed. The side cutting wire enables a precise cutting process. In addition, a version with semi-insulated cutting wire is available for safe and controlled papillary roof incision. In addition, ENDO-FLEX offers Sphincterotomes for a frontal papillary incision in the form of needle or knife Sphincterotomes and Sphincterotomes of application B-II.
Depending on the type of Sphincterotome, placement may be with a guide wire and/or contrast agent may be injected through a side opening. In addition, Sphincterotomes are used in conjunction with high-frequency electrics.

Products

OE10022xxDL	OE1042230DL-280	OE10518x0GW
OE10022xxTRL	OE10422xxDL-SET01	OE1051825GW11M
OE10022xxTRL-M	OE10422xxTRL	OE11018Nx
OE10222xxDL	OE1042220TRL-3	OE11018N3-280
OE10222xxTRL	OE10422xxTRLC	OE11018N3-DL
OE10318x1	OE10422xxTRL-M	OE11018N4-TRL
OE1031830GW	OE10422xxTRL-SET01	OE11018N-DL
OE10422xxDL	OE10422xxTRL-M-SET01	OE11018N-TRL
OE1042220DL-2	OE1051830	OE11018SPx
OE10422xxDLC	OE10518x1	OE11222FD
OE1042230DLC1	OE10518x1PC	OE11222FD-280

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
- 1 outer box
- 5 Sphincterotomes 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 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
Sphincterotomes are used to probe the bile duct system and to split the duodenal major papilla and the sphincter apparatus.
Indications
- Occlusion of the bile duct and drainage with a transpapillary endoprothesis or nasal biliary drainage.
- Preparation for the extraction or lithotripsy of gallstones from the bile duct.
- Preparation of the implantation of an endoprothesis (stents) into the bile- or pancreatic duct
- Preparation of the extraction of concrements in biliary, acute or chronic pancreatitis.
- Preparation of therapy for the treatment of papilloma.
- Separation of the duodenal minor papilla in pancreas divisum.

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
- Older pacemakers or pacemakers that cannot be set to a fixed frequency due to the parasystolic rhythm
- Hip endoprosthesis or other metal implants
- Pregnancy
- Recently created gastrointestinal anastomosis.

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:
- 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. 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!

6. Compatibility
Sphincterotomes 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**

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.

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
- Check the Sphincterotome 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.**
- Check the active cord for damage.
- **! Never use damaged active cords.**

Papillotomy with lateral cutting wire
- Pull the shaping transport lock distally from the tip of the instrument.
- Insert the Sphincterotome slowly and evenly into the working channel of the endoscope to be used until the tip emerges again at the distal end of the endoscope.
- **! If the Sphincterotome encounters resistance while advancing through the angled part of the endoscope, its angle should be reduced as much as necessary.**
- Move the Sphincterotome to the desired cutting position under endoscopic view.
- **! Make sure that the Sphincterotome is in the bile duct and not in the pancreatic duct. If necessary, check this radiographically.**
- Connect the HF generator to the HF socket of the finger slide using a suitable active cord.
- **! The Sphincterotome can be used in cut or coagulation mode.**
- If necessary, select the corresponding parameters from the instructions and information provided by the manufacturer of the HF generator.
- Use the foot pedal of the generator to apply the cutting current in short jolts, while carefully pulling back the wire is angled on the finger slide until the cutting depth to be achieved has been reached.

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- **! Avoid contact of the cutting wire under HF current with endoscope components. The contact can lead to a short circuit and damage to the instrument.**
- **! Please note that the maximum operating angle of the papilllotoma tip should not exceed 80°.**
- After the papillotomy, switch off the HF generator and remove the active connections.
- After completion of the procedure, the finger slide must be pushed distally to straighten the Sphincterotome tip.
- Slowly pull the Sphincterotome out of the working channel of the endoscope.
- After use, the product should be disposed of.

Needle-Knife-Papillotomy
- Insert the Sphincterotome into the working channel of the endoscope to be used with a knife / needle located in the tube, slowly and with even pushing movements, until the tip emerges again at the distal end of the endoscope.
- **! If the Sphincterotome encounters resistance while advancing through the angled part of the endoscope, its angle should be reduced as much as necessary.**
- Move the Sphincterotome to the desired cutting position under endoscopic view.
- Connect the HF generator to the HF socket of the finger slide using a suitable active cord.
- **! The Sphincterotome can be used in cut or coagulation mode.**
- If necessary, select the corresponding parameters from the instructions and information provided by the manufacturer of the HF generator.
- Move the needle/knife out of the tube into the papilla by advancing the finger slide.
- Use the foot pedal of the generator to apply the cutting current in short jolts, while the knives / needles work their way through the tissue by gently pulling the finger slide forwards and backwards until the opening of the papilla to be achieved is reached.
- **! Avoid contact of the HF-current/needle with endoscope components. The contact can lead to a short circuit and damage to the instrument.**
- After the papillotomy, switch off the HF generator and remove the active connections.
- At the end of the procedure, the finger slide must be pushed proximally to completely retract the needle/knife into the tube.
- Slowly pull the Sphincterotome out of the working channel of the endoscope.
- After use, the product should be disposed of.

B-II Papillotomy
- Insert the Sphincterotome with the cutting wire inside the tube slowly and with even pushing movements into the working channel of the endoscope to be used until the tip emerges again at the distal end of the endoscope.
- **! If the Sphincterotome encounters resistance while advancing through the angled part of the endoscope, its angle should be reduced as much as necessary.**
- Move the Sphincterotome to the desired cutting position under endoscopic view.
- **! Make sure that the Sphincterotome is in the bile duct and not in the pancreatic duct. If necessary, check this radiographically.**
- Connect the HF generator to the HF socket of the finger slide using a suitable Active cord.
- **! The Sphincterotome can be used in cut or coagulation mode.**
- If necessary, select the corresponding parameters from the instructions and information provided by the manufacturer of the HF generator.
- Remove the cutting wire from the tube to the front of the papilla.
- Use the foot pedal of the generator to apply the cutting current in short jolts, while the cutting wire throws a loop by carefully advancing the finger slide until the cutting depth to be achieved is reached.
- **! Avoid contact of the cutting wire under HF current with endoscope components. The contact can lead to a short circuit and damage to the instrument.**
- After the papillotomy, switch off the HF generator and remove the active connections.
- After completion of the operation, the finger slide must be retracted to straighten the cutting wire and pull it into the outer tube.
- Slowly pull the Sphincterotome out of the working channel of the endoscope.
- After use, the product should be disposed of.

9. 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.

10. Shelf Life of Products

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

11. 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.

12. 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.

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

After use, this product may present a biological hazard.
Disposal must comply with national recommendations and must take into account the internal requirements of the medical facility.

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"**