Instruction for Use – Pushers and Guiding Catheters 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
Pushers:
Pushers have the tube diameters Fr. 5 / 7 / 8.5 / 10 and 11.5 in the lengths 180 and 280 cm.
Guiding Catheters:
Guiding Catheters have tube diameters of Fr. 5 and Fr. 6.
Available lengths are 220, 250 and 320 cm. A metal ring has been integrated into the tube in order to be able to monitor the feed radiologically. A Luer-Lock connector is included with the Guiding Catheters for possible injection of contrast medium.

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

Pushers	Guiding Catheters
• E20005001	• E20000325
• E20007001	• E20000326
• E20007001-280	• E20000326-2
• E20008001	• E20000326-220
• E20008001-280	• E20000326-250
• E20010001	
• E20010001M	
• E20011001	

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 the warnings. Patients, users or third parties may suffer serious injury as a result of the improper use of the products.

Content and Packaging
Pushers SU:
- 1 outer box
- 5 Pushers SU (Single Use) individually sterile packed
- 1 Instruction for use

Guiding Catheters SU:
- 1 outer box
- 5 Guiding Catheters SU (Single Use) individually sterile packed
- 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 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
Pushers and Guiding Catheters are designed for placement of biliary and pancreatic polymeric* stents for transpapiliary and transpancreatic drainage through the duodenoscope.
The application is carried out via a guide wire through the working channel of a duodenoscope.
Indications
- Endoscopic implantation of biliary polymeric stents
- Endoscopic implantation of pancreatic polymeric stents (*with E20005001 or E20007001 only)

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.
Appropriate preparations for complications must be made before starting the application!

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
- Guide Wires
- Biliary Polymeric Stents
- Pancreatic polymeric Stents (*with E20005001 or E20007001 only)

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, 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!**

Note: To facilitate the application, an endoscopic sphincterotomy prior to guide wire placement is recommended. (Please observe HF-generator and sphincterotome manufacturer's instructions).

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Procedure

Implantation Stents with flaps (straight, pre-curved type I and II)

Biliary Stents are placed into the biliary duct with a guide wire, a pusher and, when necessary, a guiding catheter. For the application please proceed as follows:

1. Choose type and length of stent to be placed.
2. Steer the tip of the duodenoscope close to the papilla.
3. Insert the guide wire through the operating channel into the biliary duct and past the stenosis.

Note: When implanting stents with a diameter of more than 7 Fr. it is strongly recommended to apply a guiding catheter. Introduce this catheter over the guide wire and position it on top of the stenosis also.

4. Use the included positioning sleeve for easier introduction by sliding it onto the proximal end of the stent (the rear flap should fit back into it).
5. Introduce the Stent (with positioning sleeve) and the pusher over the proximal end of the guide wire (guiding catheter) into the operating channel. The positioning sleeve does not fit into the channel and will stay outside.
6. Place the Stent by using the pusher and carefully pass the stenosis (under constant fluoroscopic control).
7. Pull the guide wire (and guiding catheter) back into the operating channel while maintaining the position of the stent with the help of the pusher. After removing guide wire, guiding catheter and pusher the Stent will return to its original shape.

Note: Injection of contrast medium into the biliary duct is possible via the guiding catheter by using the included Luer-Lock adapter.

Implantation Stents without flaps (Pigtail / Double Pigtail)

The implantation is adequate for stents with flaps. Only the use of a positioning sleeve is not necessary (see points 4 and 5).

Implantation Pancreatic Stents with flaps (pre-curved)

Pancreatic Stents are placed into the pancreatic duct with guide wire and pusher. For the application please proceed as follows:

1. Choose length of stent to be placed.
2. Steer the tip of the duodenoscope close to the papilla.
3. Insert the guide wire through the operating channel into the pancreatic duct and past the stenosis.
4. Use the included positioning sleeve for easier introduction by sliding it onto the proximal end of the stent (the rear flap should fit back into it).
5. Introduce the Stent (with positioning sleeve) and the pusher over the proximal end of the guide wire (guiding catheter) into the operating channel. The positioning sleeve does not fit into the channel and will stay outside.
6. Place the Stent by using the pusher and carefully pass the stenosis (under constant fluoroscopic control).
7. Pull the guide wire back into the operating channel while maintaining the position of the stent with the help of the pusher. After removing guide wire and pusher the Stent will return to its original shape.

Additional Information

- Verification of Stent placement is obtained by multiple magnified fluoroscopic examination. Cholangiograms may be necessary to detect and/or rule out other possible strictures within the affected duct. Multiple Stent placements may be required to assist in draining additional strictures within the duct.
- Stents may remain in the body for up to 29 days. If a Stent becomes occluded over time, it should be replaced with a new Stent.
- Although Stent migration is a rare occurrence, it remains a possibility. Full distal migration occurs when a Stent becomes dislodged from its original position within the duct and moves into the duodenum. If a Stent has fully migrated, it will normally pass via the stool. It is possible that the Stent can cause internal injury to the duodenal wall and may require removal using various instruments used for foreign body retrieval prior to replacing it with a new Stent.

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. 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.

12. Shelf Life of Products

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

13. Service/Repairs

Do not carry out any repairs or modifications to the product. Only staff authorized by the manufacturer shall be responsible and intended to carry out such work. If you have any concerns, complaints or comments regarding our products, please get in touch with us. No liability whatsoever shall be assumed in the event of repairs carried out by individuals not authorized by the manufacturer.

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 “Caution”

Symbol for “Medical Device”


Symbol for “simple sterile barrier system”


Symbol for “simple sterile barrier system with outer protective packaging”

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