



Instruction for Use – Nasal Biliary Drainage Sets 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

Nasal biliary drainage probes are available in 3 basic shapes in the sizes 5 Fr., 7 Fr. and 10 Fr. each:

- probe with loop and tapered standard tip ("classic")
- probe with loop and tapered pigtail tip ("classic & pigtail")
- probe without loop with tapered pigtail tip ("pigtail")

The set consists of:

- a respective probe,
- a nasal tube,
- a drainage connection tube and
- a Luer Lock connector.

The length of the probes is 250cm.

Products

This user manual is valid for the products listed below:

„classic“	„classic & pigtail“	„pigtail“
• 206185	• 207185	• 208185
• 206225	• 207225	• 208225
• 206305	• 207305	• 208305

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
- 1 Nasal Biliary Drainage Set 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 10 Days under normal conditions (MDD 93/42 EEC).

3. Intended Use

Nasal Biliary Drainage Probes are used for a temporarily extracorporeal diversion of the biliary and pancreatic ducts. They provide an effective drainage and thereby reduce the risk of cholangitis. Nasal Biliary Drainage Probes for aspiration of biliary or pancreatic fluids. It can be used for the injection of any medical substances and contrast media in the biliary tree. Nasal Biliary Drainage Sets are mostly used as a preoperative preparation.

Indications

- Inoperable extra hepatic occlusion by malignant stenosis in the area of the papilla duodeni, the common bile duct and the ductus hepaticus, often caused by pancreas-, gallbladder- or bile duct- carcinomas or liver metastasis.
- Benign and postoperative stenosis. Preoperative exculpation in operable stenosis.

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
- General blood coagulation and wound healing perturbances
- Symptomless stenosis without icterus
- The use of Nasal Biliary Drainage Probe is contraindicated if ERCP is generally contraindicated.

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!

Warning on general risks and complications related to ERCP

- Post-ERCP bleeding
- Post-ERCP pancreatitis (PEP)
- Risk of cholangitis and cholecystitis
- Perforation
- Splenic injury
- Long term consequences of sphincterotomy
- Air embolism
- Risk and death
- Include abnormal reaction to sedatives
- Including respiratory and cardiac problems or tissue damage due to radiation exposure (higher on pediatric patients)
- Infection due to improper reprocessing of the endoscope, instruments and accessories.

6. Compatibility

- Duodenoscopes
- Guide wires .025" / .035" / .045"

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, 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 instrument for reliable function and irregularities before the procedure.
- **! If you notice any irregularities, replace the instrument with a new one.**





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- When inserting into the working channel, the corresponding working channel and tube diameters must be observed.

Procedure

The insertion of the Nasal Biliary Drainage Set is done via the working channel of a duodenoscope. The usage of a guide wire (not included) during the insertion is necessary.

Attention: Probes of size 5 Fr. are to be placed with a guide wire of max. .025".

The application proceeds as follows:

- Place the distal end of the duodenoscope in front of the papilla.
- Pass the guide wire through the duodenoscope's working channel into the biliary duct, up to the common hepatic duct.
- Slide the Nasal Biliary Probe over the guide wire with its distal tip straightened.
- Place the Nasal Biliary Probe into the common hepatic duct (under fluoroscopic control).
- Carefully remove the duodenoscope and ascertain that the Nasal Biliary Drainage Probe was left in place (under fluoroscopic control).
- Gently remove the guide wire from the probe.
- Insert the Nasal Catheter through the patient's nose and direct it into the pharynx.
- Grasp the Nasal Catheter's end with a foreign body forceps and remove it through the patient's mouth.
- The proximal end of the Biliary Drainage Probe, which is protruding from the patient's mouth, is led out of the nose via the Nasal Catheter.
- Remove the Nasal Catheter.
- Connect the enclosed Luer-Lock Connector to the proximal end of the Biliary Drainage Probe.
- Fix the end of the Drainage Probe on the patient's cheek and forehead applying adhesive bandage.
- The probe can now be connected to a receptacle (using the drainage connection tube).

Note: The removal of the drainage set should always be conducted under endoscopic view to assure a proper extraction of the tube. After removal of the drainage system the tubing should be checked on any damages.

9. 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.

10. Service Life of Products

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

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. Return transport

Defective or non-conforming products must have gone through the entire reprocessing procedure prior to be sent back for repair/servicing. Please ensure you label the products accordingly with the note "hygienically safe" or "not decontaminated".

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"

