Instruction for Use – Fibrin Application Needles 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
ENDO-FLEX generally offers Fibrin Application Needles in 2 types:
- ***double lumen with a standard needle Ø 0.9mm:***
  The components are combined in a "mixing chamber" before leaving the needle.
- ***double lumen with one coaxial needle Ø 1.2mm:***
  The components combine for the first time in the tissue.

The needle is protected by a Teflon tube. The tube diameter of both variants is 2.6mm. Instrument lengths are available in 160, 180 and 230cm. Proximal Luer-Lock tips are color-marked to match the adhesive components to the correct needle lumen.

Products
This user manual is valid for the products listed below:
- ET272620-B
- ET272620-C
- ET272620-C4
- ET272620-G
- ET272630-B
- ET272630-C
- ET272630-G

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
Fibrin Application Needles SU are offered in packaging units of 1 pieces:

- 1 outer box
- 1 Fibrin Application Needle SU (**S**ingle **U**se) 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
Fibrin Application Needles are used for haemostasis in the gastrointestinal tract (endoscopic Fibrin sealant application) and are only used in conjunction with endoscopes.
Indications
- Endoscopic Fibrin sealant application

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.

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
Not specified.

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

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.**
- When inserting into the working channel, the corresponding working channel and tube diameters must be observed.
- Fibrin Application Needles must be passed through the endoscope´s operating channel with its needle withdrawn into the tube.

Procedure:

1. Fill the system with physiological saline solution.
2. Connect the syringes filled up with the respective components to the Luer-Lock ports as follows:
   RED marked Luer-Lock port: Thrombin
   BLUE marked Luer-Lock port: Fibrinogen
3. Take the double needle completely out of the tube by pushing both Luer-Locks.
4. Inject the components by pressing both plungers of the syringes simultaneously.
5. By inserting physiological saline solution again the remaining amount of tissue glue is being injected into the system completely.

10. 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.

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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.

11. Disposal and Reprocessing

After use, this product may present a biological hazard. Handling and disposal must be carried out according to recognised medical procedures and in accordance with applicable legal requirements. These instruments are disposable products and must not be reprocessed and resterilized, as damage to the materials cannot be ruled out.

12. 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!

13. 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.

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!

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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