Instruction for Use – transbronchial Aspiration 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/Variants
The transbronchial aspiration needles offered by the ENDO-FLEX consist of a distal stainless steel needle with a lateral opening, which is connected proximally to a Luer-Lock connector via an internal plastic tube. This Luer-Lock connector is movable and is connected to the proximal handle on the outer tube to extend the distal needle out of the outer tube in the distal direction to stabilize the needle during treatment. Outer tube diameters of 1.8, 1.9 and 2.3 mm are available. The stainless steel needles vary in length (12 mm and 15 mm) and diameter (0.7 mm to 0.9 mm) depending on application. The total length of the needles is 120 cm.
A basic distinction is made between plastic and stainless steel outer tubes:
Plastic outer tube: Luer-Lock connector is connected to the handle by means of a Luer-Lock connection.
Metal outer tube: Luer-Lock connector is connected to the handle by means of a latching mechanism. In addition, the instrument is supplied with a suitable syringe incl. 2-way stopcock.

Products
This user manual is valid for the products listed below:
(M)EB2xxx-xx

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.

Contain and Packaging
- 1 outer box
- 5 Aspiration Needles SU (**S**ingle **U**se) individually packed sterile
- 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 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 Aspiration needles are intended to be used uninterrupted for a period of up to 60 min under normal conditions.

3. Intended Use
The aspiration needles are used in conjunction with an endoscope for tissue sampling for the diagnosis and depiction of bronchial diseases, including mediastinal and peripheral pathologies, subcarinal and peribronchial lumps and parenchymal abnormalities.
Indication
- Primarily in the diagnosis and staging of bronchial carcinoma as well as for the diagnosis of mediastinal malignant lymphoma or granuloma-like diseases.

Contraindication
- Application to the central cardiovascular system is contraindicated.
- This method should not be used for patients whose general medical condition and extent of respiratory insufficiency do not facilitate a bronchoscopy and/or surgery.
- Severe coagulation disorders
- Uncooperative patients

4. Complications / Side Effects / Cross-reactions
The following complications may occur in the bronchoscopy when using aspiration needles:
- Fever
- Transient bacteremia
- Pneumothorax
- Mediastinal infection
- Haemomediastinum
- Pneumomediastinum
- Small bleeding

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!

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.

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

7. Compatibility
Endoscopes

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

9. 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.

10. Preparation / Application
Inserting into the endoscope
Aspiration needles may only be inserted into the working channel of the endoscope using the needle entered into the tube. The corresponding working channel diameters of the aspiration needles must therefore be observed (see article label).
Aspiration needles must not be bent!
Appropriate imaging processes, such as ultrasonography, must be taken into account during use.

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Procedure

1. Position the distal end of the aspiration needle in front of the tissue region intended to be sampled. Place an injection syringe onto the Luer Lock connector.
2. Remove the locking ring and pull the needle completely out of the tube by slowing pushing the Luer Lock connector forward. Lock the needle by
   a. turning the Luer-Lock connector (EB version with plastic outer tube)
   b. engaging the Luer-Lock connector (MEB version with metal outer tube)
3. Insert the needle into the tissue and, using the syringe, extract the air from inside the needle so that a tissue sample is drawn into the needle.
4. Once the tissue has been successfully removed, fully retract the needle again and lock the needle again using the locking ring.

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

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 warnings. This shall also apply to repairs or modifications to the product made by individuals who are not autorized 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. 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.

17. 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”