Instruction for Use – Suction Polyp Trap 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
Suction Polyp Traps are aspiration containers for collecting separated polyps and those intended for further histological examination. They consist of a transparent plastic and are equipped with 4 polyp collection chambers inside. The flexible, tight-closing lid is equipped with two nozzles, on each of which one suction hose is attached.

Products
This user manual is valid for the products listed below:
- 900334H

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
Suction Polyp Traps SU are offered in packaging units of 6 pieces:
- 1 outer box
- 6 Suction Polyp Traps SU (**S**ingle **U**se) nonsterile packed separately
- 1 Instruction for use

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
Suction polyp traps are aspiration containers for collecting separated polyps and those intended for further histological examination during an endoscopy. They are applied via the instrumentation channel of an endoscope and a suction system.
Indications
- Endoscopic extraction of separated polyps

Contraindications
- Not known

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:
- For single use only! Do not reuse, reprocess or sterilize several times. Reuse, reprocessing or 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!

6. Compatibility
Endoscope / Suction System

7. Service Life of Products
The service life of the product is typically 5 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.

9. Preparation / Components / Application
- Check the instrument for reliable function and irregularities before the procedure.
- **! If you notice any irregularities, replace the instrument with a new one.**

Components
The Polyp Suction Collector consists of:
- A jar with four filtered collectors (labelled with 1, 2, 3 and 4) to collect polyps, and four open areas (labelled 0) for direct suction.
- A lid with 2 tubes: one for connecting the device to a suction system (including connector) and one tube for connecting it to an endoscope.

Procedure
1. Connect the tube situated in the center of the lid to the port of the suction system (Fig. 1).
2. Connect the outer tube with the endoscope (Fig. 1).

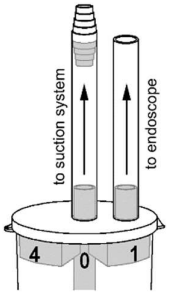
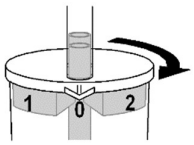


Fig. 1

3. For normal suction, rotate the jar until the arrow of the lid points at an open area (“0”) (Fig.2).



Fif. 2

4. To absorb the first polyp, rotate jar until the lid’s arrow points at the number “1” (Fig. 3).

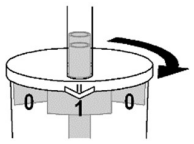


Fig. 3

5. After trapping the polyp, repeat step 3 for normal suction as needed.
6. Repeat step 4 for positions 2, 3 and 4 for each additional polyp to be trapped (same patient only).
7. Disconnect the tubes from endoscope and suction system.
8. Fill the Suction Polyp Collector with a fixing agent by using either the middle port by removing the lid completely. Reattach the lid when the filling is complete.

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9. Connect both tubes with the connector (Fig. 4). The Suction Polyp Collector is now sealed

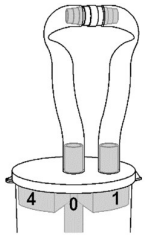

Fig. 4

10. The device can now be taken to the laboratory.

10. Reprocessing and Sterilisation
These instruments are delivered in non-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.

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!
- Do not store near aggressive chemicals.

16. Symbols used

REF	Symbol for “Item Number”
LOT	Symbol for “Batch code”
	Symbol for “Manufacturer”
	Symbol for “Date of manufacture”
	Symbol for “Observe instructions for use”
NON STERILE	Symbol for “non-sterile”
	Symbol for “non-reuse”
STERILIZE	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”

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