Instruction for Use
Colon Decompression Probes 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
A one-lumen catheter made of plastic with radiopaque material included. On the distal part over a length of 180 mm, we have six side openings that allow the air to escape from the colon. On the proximal part is a funnel connector adapted.
The Colon Decompression Probe SU accepts a .052" guide wire.

Products
This user manual is valid for the products listed below:
- 291140
- 291160
- 291180

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 indicated by this symbol. Patients, users or third parties may suffer serious injury as a result of the improper use of the products.

Content and Packaging
Colon Decompression Probes SU are offered in packaging units of 1 piece:
- 1 outer box
- 1 Colon Decompression Probe SU (**S**ingle **U**se) incl. individually packed
- 1 Instructions 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
The Colon Decompression Probes SU are intended to be used uninterrupted for a period of less than 60 minutes under normal conditions (MDD 93/42 EEC).

3. Intended Use
The Colon Decompression Probes SU are used for decompression to channel air out of the colon.
Indications
- Non-toxic mega-colon
- Pseudo obstruction
- Remaining air from previous colonoscopy

Contraindications
The endoscopic decompression is contraindicated in the presence of bowel ischemia, bowel gangrene and perforation. Colorectal cancer patients being treated or considered for treatment with anti-angiogenic therapy.

4. Risks and Side Effects
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.
Potential complications with colonic decompression include, but are not limited to perforation.

Appropriate preparations for complications that may arise must be made prior to use!

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

6. 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 product safety cannot be ensured. Dispose of these products accordingly, or please return them to the manufacturer.

7. Application
General
- Advance the colonoscope into the colon as much as possible or until it has reached cecum.
- Observe the location of colonoscope tip fluoroscopically or macroscopically.
- Insert a guide wire into working channel of colonoscope until it exits the tip.
- Carefully remove the colonoscope from the colon and keep the guide wire in place. The position can be controlled by fluoroscopic monitoring.
- Flush colon decompression probe with sterile water or lubricate with water-soluble lubricant.
- Advance the colon decompression probe over pre-positioned guide wire and check the correct position fluoroscopically.
- As soon as the colon decompression probe is in place, remove the guide wire.
- Make sure that the funnel connector on proximal part stays outside the body.

8. Reprocessing and Sterilisation
Colon decompression probes are delivered in non-sterile condition and **CANNOT EFFECTIVELY** be cleaned, disinfected and sterilised after single use on account of the design. Colon decompression probes must be disposed of after single use.
Products whose packaging is damaged or whose shelf life has expired must be discarded.

9. 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 colon decompression probes are disposable products and must not be reprocessed and resterilized, as damage to the materials and the coatings cannot be ruled out.

10. 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.

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. 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!

ENDO-FLEX GmbH ° Alte Hünxer Str. 115 ° D-46562 Voerde ° Germany ° ☎ (0049) - (0)281 – 9 44 00 – 0 ° FAX: (0049) - (0)281 – 9 44 00 – 11
Email: sales@endo-flex.de ° www.endo-flex.de

Instruction for Use
Colon Decompression Probes SU

14. 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 “Non sterile”


Symbol for “non-reuse”


Symbol für “nicht erneut sterilisieren”


Symbol for “Do not use if packaging is damaged”


Symbol for “Expiry Date”


Symbol for “keep dry”


Symbol for “protect from sunlight”