Instruction for Use – Progressive Dilation Balloons 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 Progressive Dilation Balloons offered by ENDO-FLEX generally have a distal transparent plastic balloon, a double lumen plastic tube and two proximal Luer-Lock-connectors, one of which serves as a contrast medium and guide wire access and the second of which is equipped with a 2-way stopcock to fill the balloon with the filling medium and then block the filling volume of the balloon during treatment.
Depending on the application, a distinction is made between biliary, esophageal and colonic Dilation Balloons:
Biliary Dilation Balloons: These are placed via endoscope (TTS) using stylet/guide wire. The total length is 200cm with a tube diameter of Fr. 7, a balloon diameter between min. 6mm and max. 15mm and a balloon length of 30mm.
Esophageal/colonic Dilation Balloons: These can be placed either via endoscope (TTS) using stylet/guide wire or without endoscope (OTW) using guide wire. The total length is 230cm with a tube diameter of Fr. 7, a balloon diameter between min. 6mm and max. 20mm and a balloon length of 55mm.

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

Esophageal / colonic:
- 34106PRO
- 34108PRO
- 34110PRO
- 34112PRO
- 34115PRO
- 34118PRO

Biliary:
- 3410630PRO
- 3410830PRO
- 3411030PRO
- 3411230PRO

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
Progressive Dilation Balloons SU are offered in packaging units of 1 piece:
1 outer box
1 Progressive Dilation Balloons 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 60 minutes under normal conditions (MDD 93/42 EEC).

3. Intended Use
The dilation balloon is used to dilate stenosis endoscopically in the alimentary tract. The balloon is equipped with a soft distal tip and is delivered with a preloaded guidewire. Alternatively this guide-wire can be removed to introduce the balloon over a .035 inch guidewire which is already in place. The application is carried out by means of an endoscope.
Indications
- Clinically relevant stenosis in esophagus, ductus choledochus, colon
- Dysphagia of the esophagus

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
Inflation/deflation devices for liquids with manometer, Luer-Lock connection and 2-way stopcock for blocking and unloading.

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
Preparation
- Note any damage/open seal of the packaging.
  If damage or an open seal is detected, sterilization may be compromised and the instrument should be discarded and replaced.
- Check date of sterilization.
  Never use products with non-valid sterilization date.
- Keep an appropriate inflation device with pressure gauge available.
  Check the inflation device for appropriate pressure and volume.
- Keep enough fill liquid (e. g. low viscosity contrast media; sterile, isotonic saline solution; or a mixture of both) available.
- To support application with a guide wire, keep an appropriate guide wire available.
- Open packaging and carefully remove the pouch.
- Inspect catheter to any damages.
  If you note any problems, exchange the balloon for a new one.

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- Connect a syringe to the Luer-Lock marked "BALLOON" and apply a moderate vacuum and remove protective tubing.
- To improve the slide properties inside the endoscope, spray the balloon with silicone.
  Only use silicone, other lubricants may damage the product.

Filling

To remove the air from the balloon, please follow the instruction below:

- Fill a 20 ml syringe or other inflation device with approx. 5 ml filling liquid.
- Connect to the Luer-Lock marked "BALLOON" and hold the catheter tip down.
- Apply vacuum and keep for at least 30 seconds. Slowly release to ambient pressure with syringe still connected to allow the liquid to fill the balloon.
- Change over to a complete filled syringe/inflation device.
- Repeat vacuum procedure, without allowing air to enter the system. Keep vacuum during insertion in the endoscope

REMARK: Essential volume of air in the system may result in inconsistent expansion of the balloon. If this is recognized, repeat filling steps.

Application

Please decide prior to the application if the balloon will be inserted in the endoscope with the preloaded guidewire, or over any .035" guide wire. In case of introducing the balloon over a guidewire which is already in place, the preloaded guidewire must be removed prior to the application.

- Slowly introduce the balloon catheter into the endoscope's working channel.
  Due to different endoscope styles and types, there may be higher resistance when initially inserting the catheter into the endoscope and approx. 2 to 3 cm from the working channel's distal end.
- Forward the balloon under endoscopic control to its end position.
- Fill balloon using an appropriate inflating device. Recommended liquids are sterile, isotonic saline solution; low viscosity contrast media or a mixture of both.

Caution: Never fill the balloon with any gas!

The progressive Dilation Balloon will reach the designated diameters (see lable) by applying the corresponding pressure. The parameters are clearly shown on the label.
Never exceed the given maximum inflation pressure. In case of a balloon burst or a liquid leakage, empty the balloon and remove it carefully together with the endoscope. Don't try to pull burst balloon back into the endoscope. Start with a new balloon again.

- After reaching the indicated balloon diameter adjust the balloon pressure as necessary (do not exceed maximum inflation pressure).
  After the inflator device has been set to working pressure the pressure gauge will indicate slightly decrease of pressure because of pressure equalization in the catheter system. After a few seconds the indication should stabilize.
- Keep pressure till the requested dilation is reached.
  The pressure indication may fluctuate during dilation.
- After dilation deflate the balloon completely.
  This may take approx. 20 to 30 seconds depending on the size and liquid.
- To deflate completely the proximal end of the balloon must be visible in the endoscope during vacuum application.
  Remove catheter only if completely empty.
- Keep the endoscope as straight as possible. Every curve increases wall friction and difficulty to remove the catheter.
- Pull the catheter slowly out of the endoscope.
  If an unusual resistance is recognized, remove endoscope and balloon together to avoid patient injury or damages on the endoscope.
- After use, dispose the entire instrument according to legal requirements and your facility's infection control protocols.

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.
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"