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Medizintechnik

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Instruction For Use
Inflation device

CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

Note: The inflation device is only for use with TubaVent short/short wide and TubaInsert from SPIGGLE & THEIS Medizintechnik GmbH!

Explanation of used symbols

Symbol	Meaning
RxOnly	Federal (USA) law restricts the use of this device to sale by or on the order of a physician
STERILE EO	Sterilized using ethylene oxide
	Date of manufacture
	Consult instructions for use
	Do not re-use
	Manufacturer
LOT	Batch Code
REF	Catalogue number
	Do not use if package is damaged and consult instructions for use

Symbol	Meaning
	Single sterile barrier system
MD	Medical device
	Keep dry
	Use-by date
	Keep away from sunlight
	GS1 Data Matrix
	Temperature limit (fom 0 to 40°C)
2 STERILIZE	Do not resterilize
UDI	Unique device identifier

1. Product description

The inflation device is a component of the SPIGGLE & THEIS TubaVent balloon dilatation system for the Eustachian tube. This medical device is a pump to inflate, deflate and monitor pressure during dilatation therapy of the Eustachian tube in combination with the TubaVent balloon catheter from SPIGGLE &THEIS Medizintechnik GmbH. The product is designed for single patient use. The sterile and single use device is connected to the TubaVent via the Luer Lock connector.

Article list: Inflation Device

Art. No.	Description
2080-9030040-US	TubaVent balloon dilatation system, inflation device w. 50 cm extension tube, syringe volume 30 cc, sterile

The inflation device consists of a 30 cc syringe with a plunger (Figure 1). At the proximal end of the seal is a knob, which can be turned to either increase/inflate or decrease/deflate the pressure of the attached dilatation balloon. The distal end of the inflation device is connected with a tube that ends in a male Luer Lock to connect to the balloon catheter. The pressure gauge is equipped with a display from 0 to 30 atm and includes a PSI-scale to control the pressure when the balloon is inflated and/or deflated.

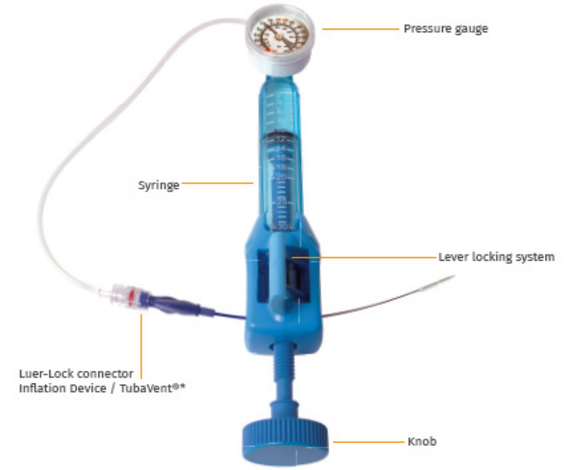

Figure 1: Inflation device

Materials:

Components	Material
Syringe	Polycarbonate
Lever	Polyethylen (PE)
Plunger	Polyethylen (PE)
Tube	Thermoplastic polyurethane (TPU)
Lever shell	Acrylonitrile Butadiene Styrene (ABS)
Extension tube	Thermoplastic polyurethane (TPU)

2. Indications for Use

The TubaVent balloon dilatation system is intended to dilate the cartilagenous portion of the Eustachian tube for treatment of persistent obstructive Eustachian tube dysfunction in adults of 18 years and older.

The inflation device for the Eustachian tube is used to inflate, deflate and monitor pressure in the TubaVent short and TubaVent short wide balloon catheter in Eustachian tube procedures.

2.1 Intended User

This product should only be used by medical professionals (e.g., a qualified otolaryngologist/ENT physician) who have been trained in Eustachian tube dilatation. The accompanying information, such as the instruction for use, is not a substitute for basic medical and technical skills. Such skills must be acquired by the user through specialized training.

2.2 Intended use environment

Operating theatre and/or aseptic area, ENT practices under general or local anaesthesia. Please refer to the IFU TubaVent balloon dilatation system, TubaVent short, TubaInsert.

3. Contraindications

Please refer to the TubaVent balloon catheter used in combination's instructions for use for the contraindications regarding the Eustachian tube dilatation procedure.

4. Side effects

There are no known side effects when the inflation device is used correctly. Please follow also the instructions for use of TubaVent and TubaInsert to avoid possible complications during balloon dilatation.

5. Warnings and Precautions

5.1. Warnings

- Use the inflation device only in combination with TubaVent short/short wide and TubaInsert. DO NOT USE the inflation device with other ET balloon catheters or ET insertion devices from other manufacturers.
- The inflation device is delivered sterile, sterilized with ethylene oxide gas.
- The package should be checked before using the device. If unsealing, gas leakage and breakage are found, it should not be used.
- Intended for single patient use only. DO NOT REUSE.
- The inflation device must be used before the expiry date.
- For qualified physicians use only.
- Do not use air or a gas medium to inflate the balloon, eliminate any air out of the system before use.
- When using the inflation device, the respective instructions for use for TubaVent used in combination with the inflation device must be consulted.
- Do not use force if it is difficult to lock/unlock the lever (locking system) as this may damage the plunger.
- Any possible pressure loss can be compensated by turning the knob of the inflation device clockwise. The lever must be in the center position.
- When the extension tube is used, the pressure drop in the balloon may be accelerated! Further compensation of the pressure drop can be needed.
- Do not exceed the recommended maximum inflation pressure of the TubaVent balloon being used.
- Before any inflation make sure that the indicator of the pressure gauge is at the position zero +/- 1 atm!

5.2 Precautions

- Do not use if package is damaged or unsealed.
- Prior to interventional procedure, all equipment to be used, including interventional devices, should be examined carefully for defects. Do not use any defective equipment.

6. Instruction for Use

6.1 General

Unlock the plunger by moving the lever to the left position. The plunger can be pulled and pushed if the inflation device is unlocked (see figure 2). The plunger is free to move for aspiration or injection procedure.

Figure 2: The plunger is unlocked by moving the lever in the left position.

To fix/lock the plunger in place the lever is moved to the center position (see figure 3). In the locked position, the plunger can be moved in small increments by rotating the knob clockwise or counterclockwise.

Figure 3: The plunger is locked by moving the lever to the center position.

6.2 Special directions

To use the inflation device, sterile isotonic saline solution NaCl 0.9% must be used to inflate the balloon.

NOTE: Never use air/gas medium to inflate the balloon! Eliminate any air/gas from the system before inflation!

6.3 Preparing the inflation device

- Prepare the sterile isotonic saline solution NaCl 0.9% in a sterile bowl.
- If the 50 cm extension tube is needed, please connect the extension tube to the tubing via the Luer lock connector.
- Place the end of the connecting tube into the solution.
- Unlock the inflation device (see figure 2) and pull the plunger back (figure 4) completely to aspirate the fluid into the syringe.

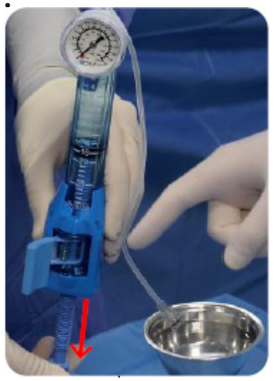

Figure 4: The plunger is unlocked and can be pulled down to draw up the saline solution into the syringe.

- Completely bleed the inflation device and the connection tube by pushing the plunger forward.
- Aspirate additional fluid into syringe and bleed until the syringe and the tubing are filled with fluid.

NOTE: Fill the inflation device only up to the maximum filling quantity of the syringe (30 cc). The optimum filling quantity of the inflation device after bleeding is approx. 20-25 cc l. If you want to use the extension tube, it must be connected to the connection tube of the inflation device and bled. After complete bleeding, lock the plunger by pushing the lever in the center position.

NOTE: Inspect the tip of the syringe and tubing to ensure they contain no air!

- After complete bleeding, lock the plunger by pushing the lever in the center position (see figure 5 below).

Figure 5: Lever is turned to the center position

6.4 Inflation of the TubaVent balloon catheter

- Connect the inflation device to the TubaVent balloon catheter. Make sure that the connection between the Luer Lock connector of the inflation device and (if used) the extension tube is tightly sealed (see figure 6).

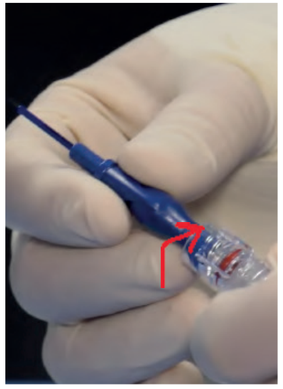

Figure 6: The Luer lock connector of TubaVent is attached with the Luer lock connector of the tubing of the inflation device.

NOTE: Before starting the inflation, make sure that the indicator of the pressure gauge shows on the scale 0/zero +/- atm.

NOTE: Follow the instructions for use of the TubaVent balloon catheter used in combination regarding the warnings of the TubaVent and the maximum pressure to set the pressure in the catheter correctly.

- After the inflation device has been locked (lever in the center position), turn the knob of the plunger slowly and steadily clockwise to increase the pressure in the balloon catheter.

NOTE: Always inflate the balloon under control with the gauge of the inflation device. Any possible pressure loss can be compensated by turning the knob of the inflation device clockwise.

- Inflate the balloon up to 10 bar.
- Maintain 10 bar for 2 minutes.

NOTE: When the extension tube is used the pressure drop in the balloon may be accelerated. Further compensation of the pressure drop can be needed.

Due to the resilience of the plastic parts, the change in volume of the dispensed liquids may not be accurately displayed if the pressure changes.

NOTE: Do not fill the balloon beyond the defined burst pressure. This can cause a balloon rupture. A rapid loss of pressure in the inflation device can be an indication that the balloon has ruptured.

6.5 Deflation of the TubaVent

Deflate the balloon by turning the knob anti-clockwise until the indicator of the gauge shows 0 atm on the display.

Once the balloon is fully deflated, turn the lever to the left position. The plunger is unlocked.

Carefully remove the entire system (TubaInsert with TubaVent, inflation device) from the patient under endoscopic control.

6.6 Discard devices after use

After use, the inflation device may be a potential biohazard. Handle and dispose of in accordance with accepted facility procedures.

7. Handling of sterile single use products

It is very important to avoid product contamination. The product must be stored in its sealed protective packaging. The packaging must not show any signs of damage. The protective packaging should only be opened just before removing the product. Before opening the package, it should be checked for damage and whether it is properly sealed, since its sterility may be compromised. In addition, the product must be inspected for any visible or functional damage insofar as possible.

7.1 Packaging and sterility

The product packaging consists of:

Primary packaging/sterile barrier system
Secondary packaging/protective packaging

The packaging complies with the standards in force. When intact, the packaging protects the product from external influences and ensures product sterility during storage.

7.2 Handling of sterile packaging

When removing the product from the packaging, the relevant aseptic regulations should be observed.

7.3 Sterilization

The product is EO (ethylene oxide) sterilized in its protective packaging.

7.4 Re-sterilization

The inflation device cannot be re-sterilized. The processing of single-use products is inconsistent with patient welfare. It is impossible to determine whether cleaning and sterilization will result in defects such as kinks, tears and material changes, microorganisms, endotoxins, chemical residues, and therefore changes in functionality.
The user bears full responsibility for reprocessing and reusing the product.

8. Storage

The product must be stored protected from dust, moisture and contamination. Direct sunlight must be avoided during storage. The product may no longer be used after the expiry date.

9. Disposal

Care should be taken to prevent the risk of injury and infection when disposing of the product. Contaminated products should be placed in a hazardous waste container and handled in such a way as to eliminate the risk of contaminating third parties.

10. Obligations to report

Any serious incidents that occur in conjunction with the product must be reported to the manufacturer and the competent local health authority where the user and/or patient is resident.

11. Summary of adverse events

With respect to the inflation device, 0.52% of the sold products have been subject to complaints since the initial launch of the product in Europe in 2017. 0.01% of the sold products were quality-related complaints. These complaints were based on a deviation in the production process, damage to the packaging due to transport, and malfunction of the product itself. No patient was harmed due to these complaints. The deviation in the production process was addressed and the malfunction due to this deviation never occurred again. The damage to the packaging and the general malfunction of the product was reported only once and therefore was seen as an isolated incident.

Revisions and typographical errors reserved.