



# SPIGGLE & THEIS

Medizintechnik

Burghof 14

51491 Overath / Germany

Tel.: + 49 (0) 2206 9081-0

Fax: + 49 (0) 2206 9081-13

[www.spiggle-theis.com](http://www.spiggle-theis.com)

[info@spiggle-theis.com](mailto:info@spiggle-theis.com)

EN

**Instructions for use**

**TubaVent® Balloon Dilatation System**

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## **Indication for Use**

The TubaVent<sup>®</sup> balloon dilatation system is intended to dilate the cartilaginous portion of the Eustachian tube to treat persistent obstructive Eustachian tube dysfunction in adults 18 years and older.

**NOTE:** Failure to comply with the indications for use constitutes misuse for which SPIGGLE & THEIS assumes no liability.

## **Compatibility**

The components of the TubaVent<sup>®</sup> balloon dilatation system are compatible with each other. Refer to the appropriate instructions for use when using with compatible devices. The TubaVent<sup>®</sup> components are intended to be used with the whole system and not with other devices from a different company.

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

## **1 Product description**

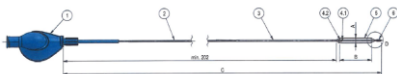
The TubaVent<sup>®</sup> balloon dilatation system includes the following three components:

TubaVent<sup>®</sup> short or short wide balloon catheter (hereinafter referred to as TubaVent<sup>®</sup>), the TubalInsert<sup>®</sup> ONE insertion device (hereinafter referred to as TubalInsert<sup>®</sup> ONE), and the inflation device. The components of the system are provided individually.

**NOTE:** The components of the TubaVent® balloon dilatation system are compatible with each other. They are intended to be used with the whole system and not with other devices from a different company.

### 1.1 TubaVent® short/short wide balloon catheter

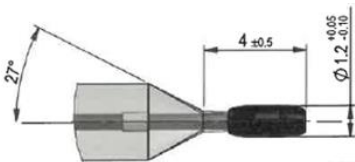
TubaVent® is a balloon dilatation catheter with an inflatable balloon near the distal tip.



**Figure 1: Schematic presentation of the TubaVent® balloon catheter.**

**Table 1: Explanation of Figure 1.**

Position Number	Description
1	Proximal Part TubaVent® short/short wide
2	Intermediate shaft
3	Balloon Shaft Tube
4.1	Guide Wire Tubing
4.2	Marker Band
5	Balloon
6	Tip
A	Balloon diameter: TubaVent® short=3.0 mm; TubaVent® short wide=4.5 mm
B	Balloon length: 20 mm
C	Working length: 236 mm
D	Indicating tip



**Figure 2: Detail of the TubaVent® distal end (from Figure 1) with dimensions.**

The product is available in two sizes: TubaVent® short and TubaVent® short wide which differ only in their balloon diameter (3.0 and 4.5 mm). The flexible distal section of the balloon catheter has a coaxial design. The outer lumen is used to expand the balloon. The proximal catheter section is a single-lumen stainless steel hypotube.

The Luer- Lock connector, located at the proximal end, allows access to the inflation lumen and is thus used to inflate/deflate the balloon. The balloon diameter specifications are listed on the external packaging (secondary packaging) and the products sterile packaging (primary packaging). The diameter is also marked on the Luer-Lock connector with the LOT number of the device.

The product is designed for single-patient use only.

It is not intended to be used for pressure measurements.

## Article list: TubaVent® balloon catheter

Art. No.	Description
2080-1236320-US	TubaVent® balloon dilatation system, TubaVent® short balloon catheter, WL 236 mm, balloon 3x20 mm, sterile
2080-12364520-US	TubaVent® balloon dilatation system, TubaVent® short wide balloon catheter, WL 236 mm, balloon 4.5x20 mm, sterile

### **Material**

Catheter: Polyamide (PA); Stainless steel

Balloon: Polyamide (PA)

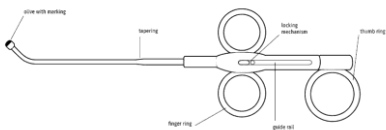
Luer-Lock connector: Polycarbonate (PC)

### **Performance features:**

The proximal catheter section is a single-lumen hypotube made of stainless steel, which decreases flexibility in this section and ensures that the catheter shaft has good shear strength. The balloon provides controlled compliance, i.e., at a given pressure, it expands to its defined dimensions, as shown in Table 1 or 2. The expanding property of the semi-compliant balloon enables the inflation of the catheter with high elasticity and flexibility. The maximum insertion depth of the catheter is limited, encouraged by the accurate fit between the insertion device TubaInsert® ONE and the TubaVent® catheter. The olive-shaped tip of the TubaVent® enables an atraumatic insertion of the catheter into the Eustachian tube. The Luer-Lock connector at the proximal end provides a stable connection between the inflation device and the catheter.

## 1.2 TubalInsert® ONE insertion device

Art. No.	Description
2080-3045-US	TubaVent® balloon dilatation system, TubalInsert® ONE – Type 45°, insertion device, sterile, 10 pieces



**Figure 3: TubalInsert® ONE Type 45°**

### Material:

Tube: Stainless steel 304.

Handle: ABS (blue)

## 1.3 Inflation device

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

**Material:**

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

**NOTE:** Please also refer to the inflation device instructions for use.

**2. Eustachian tube dysfunction**

The cause of the tube dysfunction lies within the course of the Eustachian tube, i.e., the lumen is not wide enough, or its ability to open is restricted. Obstructive tubal dysfunction is often a chronic functional disorder in which the middle ear's ability to ventilate and clean itself regularly is restricted. The consequences of this disorder include the development of chronic otitis media, which in the worst-case scenario, can lead to the destruction of the middle ear structures and, thus, to hearing loss.

**2.1 Intended user**

The TubaVent® balloon dilatation system should only be used by experienced medical professionals (e.g., a qualified otolaryngologist/ENT physician) trained on the product. The accompanying information, such as the instructions for use, is not a substitute for basic medical and technical skills. Such skills must be acquired by the user through specialized training, if necessary. The acquisition of medical

skills and their diagnostic and therapeutic consequences are the sole responsibility of the product user.

When using the catheter, the respective instructions for use of the inflation device must also be consulted.

## **2.2 Intended use environment**

The intended places of use include the operating theatre, aseptic area, or ENT practices under general or local anesthesia. The use of the TubaVent® balloon dilatation system under local anesthesia has not been studied in a controlled randomized trial. Evidence of its use under topical/local anesthesia, sedation, and analgesia for adults is available in the literature (see section 6.2 Special Directions).<sup>1</sup>

The use of local anesthesia is evident in adults with appropriate patient preparation which may include supplemental medication for patient management.

## **3. Contraindication**

The TubaVent® balloon dilatation system is contraindicated for use in Eustachian tube with an ipsilateral carotid artery that is dehiscant into the Eustachian Tube lumen or near the lumen, or history of ipsilateral patulous Eustachian tube.

In addition, the device is contraindicated for use in patients with the following diseases:

- Atresia of the tubal ostium (congenital or acquired, e.g., following adenotomy)
- Presence of an obstruction whose cause lies in the epipharynx, e.g.,

adenoid vegetations or tumors, exclusion by means of a preoperative diagnosis, e.g., by an endoscopic transnasal epipharyngeal examination

- Gaping or open tube (Tuba aperta), dilatation may increase existing symptoms
- Vascular abnormalities of the internal carotid artery
- Basal skull fracture/traumatic brain injury

**NOTE:** Always use preoperative examinations like imaging procedures to safely exclude any contraindications prior to use of the TubaVent® balloon dilatation system.

#### **4. Side effects**

Complications cannot be ruled out during dilatation. The following overview does not claim to be complete.

##### **4.1. Primarily concerning tubal dilatation**

- Further stenosing processes due to dissolution of intratubal mucosal adhesions
- Minimal damage to the mucosa due to bursting of cartilaginous and bony structures during balloon dilatation (in individual cases)
- Inner ear trauma
- Explosion trauma (barotrauma)
- Dizziness
- Hearing loss through to deafness or sensorineural hearing loss
- Tinnitus
- Worsening of existing tinnitus
- Dislocation/destruction of the ossicles

- Perforation/rupture of the eardrum (tympanic membrane; serious adverse event)
- Rupture of the round window membrane (This serious adverse event can occur if patients perform the Valsalva manoeuvre before the end of the second postoperative day.)
- Stroke
- Carotid artery injury
- Dissection of the internal artery aorta wall
- Epistaxis, severe bleeding
- A feeling of pressure on the ears and earache
- Skin, soft tissue, or nerve damage with sensitization disorders
- Nerve lesion through to facial nerve paralysis
- Inflammations through to inflammation of the middle ear
- Tuba aperta
- Emphysema

#### **4.2. General**

- Infections
- Bleeding, hematoma
- Material-related intolerance reactions

### **5. Warnings and Precautions**

#### **5.1 Warnings**

- The components of the TubaVent® balloon dilatation system are compatible when used as directed and are intended to be used as a system. Do not use the components of the TubaVent® dilatation system with any other devices as patient injury may occur.

- The system is intended for single-patient use. Do not sterilize and /or reuse, as it may result in compromised device performance and risk of improper sterilization and cross-contamination.
- Do not use the system if the integrity of the sterile packaging has been compromised or if a component appears damaged.
- Do not use it if the device becomes damaged or touches a non-sterile object outside the operating field.
- Do not exceed the recommended maximum balloon inflation pressure of 10 atmospheres (atm).
- If there is a suspicion of acute or previous diseases of the petrous bone or skull, a preoperative examination of the structures using computer tomography (CT), digital volume tomography (DVT), or magnetic resonance imaging (MRI) is indicated to exclude these.
- Never advance or retract the catheter against unknown resistance. Difficult access to the entrance to the Eustachian tube, difficult advancement of the catheter in the Eustachian tube, or a blocked entrance to the Eustachian tube may result in mucosal injury or damage to the product.
- In the rare case of small anatomical conditions, there is a possibility that the catheter may go too far into the middle ear and damage the associated structures (see also the reference to different balloon diameters under section 1. Product description, 6.2. Special directions, and 6.3 Preparing the catheter). A preoperative CT

scan can be used to determine the individual size of the Eustachian tube.

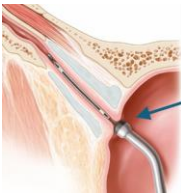
- Patients with a history of skull base surgery, skull fracture, or anatomic abnormalities may have an elevated risk of complications and should be radiographically screened before treatment.
- Take special care during acute and chronic infections of the ear, nose, and throat. If possible, wait for an inflammation-free period before application, as inflammation can lead to pressure changes and, thus, to an increased pressure load on the membrane of the middle and inner ear during the procedure. Paracentesis should be considered before dilating to relieve pressure if this is not possible.
- The materials used in the product may cause intolerance reactions in the patient (see section 1 Material and 4.2 General side effects).
- During catheter insertion, if the fossa of Rosenmüller is confused with the tubal ostium, the mucosa may be injured.
- Use only sterile isotonic saline NaCl 0.9% for inflation.

**NOTE:** Preoperative examinations using imaging procedures can exclude a vascular anomaly of the internal carotid artery (internal carotid aneurysm) and/or a glomus tumor.

**It is up to the attending physician's discretion to decide whether and how to perform a safe dilatation or, if necessary, not to perform the treatment based on the results of the preoperative examinations.**

## 5.2 Precautions

- Radiographic assessment of the targeted Eustachian tube is recommended prior to any procedure involving balloon tuboplasty.
- **NEVER USE AIR FOR BALLOON DILATATION**  
The performance of the balloon can be influenced by the solution used for filling. The balloon should, therefore, always be inflated with a sterile isotonic saline solution NaCl 0.9%.
- The distal part of the insertion instrument must only be guided up to the tubal ostium to ensure the optimal insertion length.



The distal part of TubalInsert ONE® is in the correct position, the balloon of the TubaVent® catheter has been advanced correctly into the cartilaginous part of the Eustachian tube.

### **Figure 4: Correct placement of the insertion instrument at the orifice of the Eustachian tube**

- When placing the TubalInsert® ONE against the lateral epipharyngeal wall in front of the pharyngeal tubal ostium, the black marking on the olive of the TubalInsert® ONE must be visible.
- **ONLY** guide the distal part of the insertion instrument up to the tubal ostium to ensure the optimal insertion length. The insertion instrument **MUST** remain outside of the Eustachian tube. If the insertion device is

penetrated too deep into the tube during catheter insertion, as well as during the entire procedure, it may lead to dilatation of the osseous part due to the then extended insertion length of the catheter. Injury to the *internal carotid artery* during dilatation of the osseous part of the Eustachian tube can lead to serious injury.

- Shortening the insertion length of the catheter may cause the balloon to remain in the introducer and damage the balloon. The catheter connector must therefore be firmly seated in the introducer during dilatation to ensure the ideal insertion length (see Figures 5 and 6).



**Figure 5: TubaVent® is wrongly seated in the TubalInsert® ONE**



**Figure 6: TubaVent® is correctly seated in the TubalInsert® ONE**

- DO NOT inflate the TubaVent® until the balloon has exited the TubalInsert® ONE.
- DO NOT fill the catheter balloon beyond the defined burst pressure (rated burst pressure; see Table 1 and Table 2). In the event of a balloon rupture (rapid loss of pressure in the inflation device), deflate the balloon and remove it carefully.
- Always inflate the balloon under control using the inflation device and read just the pressure if necessary. Slow balloon inflation is recommended for optimal pressure equalization of the tissue being treated. If an extension tube is used, this may accelerate the pressure drop in the balloon. Due to the design, there may be a slight pressure drop in the balloon during dilatation.
- If paracentesis and the placement of a ventilation tube is planned in the same procedure, this should be done before the tubal dilatation to further minimize the risk of possible membrane damage to the middle ear due to the dilatation.
- Exercise particular caution in patients with granulomatosis. Here, the pre-damaged mucosa can lead to increased bleeding during dilatation as well as to the formation of air emphysema during post-operative Valsalva maneuvers.
- The Valsalva or similar maneuvers to equalize the pressure should only be performed from the 2nd day postoperatively and should be performed 3-5 times a day (before this, there may be a risk of emphysema formation and membrane damage).

## **6. Instructions for Use**

### **6.1 General**

Use endoscopy for visualization during catheter access, balloon inflation, and removal.

**NOTE:** TubaVent® MUST only be used with the compatible TubaInsert® ONE and the compatible inflation device of the system.

### **6.2. Special directions**

- The attending physician should determine the choice of catheter (balloon diameter 3 or 4.5 mm) based on patient anatomy.
- The catheter should only be used under endoscopic visualization.
- Avoid pulling/stretching the catheter when removing it from the protective packaging, removing the transport protection tube and the mandrel, or when inserting the catheter. Improper handling can lead to a change in the specific insert length. This may result in damage to the product and/or risk to the patient. See Section 5. Warnings and precautions, and 6.6 Inflate the balloon.
- Failure to follow the instructions for use can pose risks to the patient.

The procedure is usually carried out under general anesthesia. Evidence is emerging in the scientific literature that the procedure can be done under local anesthesia, sedation, and analgesia in adults. Real-world clinical data collected in a pilot feasibility study from 10 patients (5 received bilateral BET) supports the use of the TubaVent® short device under local anesthesia. The use of local anesthesia for this procedure is evident in

adults with appropriate patient preparation, which may include supplemental medication for patient management. <sup>1</sup>

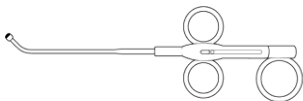
### **6.3. Preparing the TubaVent® balloon dilatation system**

- Before opening the sterile package of TubaVent®, TubalInsert® ONE, and the inflation device, visually inspect the package to ensure that the seals remain intact, the sterile integrity has not been compromised, and no damage has occurred during shipping and handling.
- Remove TubaVent® from the package. Detach the transport protection tube and the rubber sleeve from the end of the Luer-Lock connector, and remove the mandrel and the balloon sleeve from the balloon.

**NOTE:** When pulling the catheter out of the transport protection tube, the rubber sleeve can come off the balloon protection sleeve and remain on the catheter. The rubber sleeve must be removed from the catheter (Luer-Lock connector).

- Remove the TubalInsert® ONE and inflation device from the package accordingly.

**NOTE:** Do not change the preset position of the TubalInsert® ONE of the guide rail (guide rail in the front position). The catheter must be placed in this position in the insertion instrument.



**Figure 7: Preset position of the TubalInsert® ONE of the guide rail.**

- Flush the pump by aspirating sterile isotonic saline solution NaCl 0.9% through the proximal hub (please refer to the instruction for use of the inflation device).

**NOTE:** Never inflate the balloon with air! See also section 5.2 Precautions.

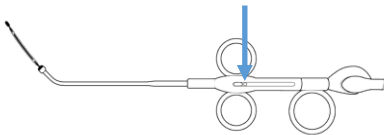
- When using the catheter for tubal dilatation, the respective instructions for use for the products used in combination with this catheter must be observed.
- If you would like to extend the connection between the catheter and the inflation device, use the extension tube enclosed in the packaging of the inflation device. The connection must be tightened firmly.

**NOTE:** Make sure that the inflation device, the tube, and the extension tube is completely vented and that no air enters the system.

#### **6.4 Connecting the TubaVent® catheter, inflation device, and TubalInsert® ONE**

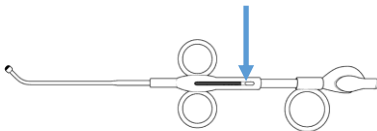
- Connect the tubing of the inflation device to the inflation port on the TubaVent® located on the side of the Luer- Lock.

- Insert the TubaVent® into the TubalInsert® ONE and advance it until the connector of the catheter is seated proximally tightly in the TubalInsert® ONE.



**Figure 8: TubalInsert® ONE with inserted TubaVent® and guide rail in the front position.**

- Pull back the guide rail until the locking mechanism engages.



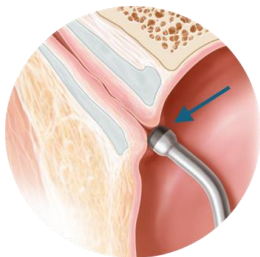
**Figure 9: TubalInsert® ONE with TubaVent® in the locked position.**

### **6.5 Accessing the Eustachian Tube**

- Place the endoscope through the nose into the nasal cavity until the Eustachian tube orifice is well visualized.
- Under endoscopic visualization, gently insert the insertion instrument through the nose on the side to be treated until the tip of the TubalInsert® ONE is positioned proximal to the Eustachian tube orifice. The locking

mechanism is released by applying light pressure on the thumb ring.

- When placing the TubalInsert® ONE against the lateral epipharyngeal wall in front of the pharyngeal tubal ostium, the black marking on the olive of the TubalInsert® ONE must be visible.



**Figure 10: The olive of TubalInsert® ONE with the black marking at the tubal ostium.**

- After placement of the TubalInsert® ONE, the catheter is inserted into the Eustachian tube by sliding the thumb ring forwards.

**NOTE:** The marking on the olive of the TubalInsert® ONE must be visible on the tubal ostium during the entire application in order to avoid insertion into the Eustachian tube and thus an extended exit length!



**Figure 11: The endoscope is placed through the nose. The insertion instrument with the catheter is inserted through the nose on the side to be treated.**

**NOTE:** Avoid penetration into the fossa of Rosenmüller at all costs; it is located in the immediate vicinity of the tubal ostium.

- Rotate the insertion instrument so that the tip angle is aligned with the trajectory of the Eustachian tube.
- After the alignment of the insertion instrument has been performed and the TubalInsert® ONE is placed against the lateral epipharyngeal wall in front of the pharyngeal tubal ostium.
- The balloon is then passed through the insertion instrument into the cartilaginous portion of the Eustachian tube lumen.

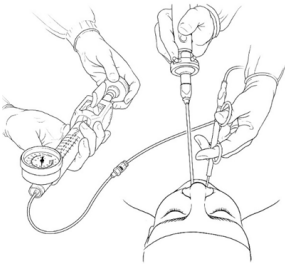


**Figure 12: The correct placement of the insertion instrument in front of the tubal ostium has been identified. The catheter is inserted into the cartilaginous portion of the Eustachian tube by pushing the thumb ring.**

**NOTE:** ONLY guide the distal part of the insertion instrument up to the tubal ostium to ensure the optimal insertion length. The insertion instrument **MUST** remain outside of the Eustachian tube. This can be insured by seeing the marking at the olive of the TubalInsert® ONE. If the insertion device is penetrated too deep into the tube during catheter insertion, as well as during the entire procedure, it may lead to dilatation of the osseous part due to the then extended insertion length of the catheter. Injury to the *internal carotid artery* during dilatation of the osseous part of the Eustachian tube can lead to a life-threatening situation for the patient.

**NOTE:** Never advance the catheter against unknown resistance. This could cause tissue trauma or damage to the device.

## **6.6 Inflate the balloon**



**Figure 13: The inflation device is in the hand of a second person. The surgeon has the insertion instrument with the catheter in one hand and the endoscope in the other.**

- The balloon is inflated per the inflation device instructions for use.
- For dilatation of the Eustachian tube, the balloon is inflated through the inflation device with sterile isotonic saline solution NaCl 0.9% up to a pressure of 10 bar. The inflation time should be held for 2 minutes at 10 bar.
- Always inflate the balloon under endoscopic visualization maintaining control of the pressure with the inflation device, as a slight pressure drop may occur during balloon dilatation due to the balloon's design.
- Slow balloon inflation is recommended for optimal pressure equalization of the tissue being treated.

**NOTE:** The total hold time for dilatation is 2 minutes (10 bar).

**NOTE:** If an extension tube is used, this may accelerate the pressure drop in the balloon.

Do not inflate the balloon above the rated burst pressure (cf. Tab. 1 and Tab. 2).

For these points, see also section 5.2 Precautions.

### **6.7 Deflate and remove the balloon**

- After the dilatation time of 2 minutes (10 bar) has been achieved, deflate the balloon carefully and completely per the inflation device instructions for use.
- Once the balloon is fully deflated, close the shut-off valve on the inflation pump to maintain negative pressure and then carefully remove the entire system from the patient under endoscopic control.
- The catheter does not have to be removed from the insertion instrument after use. Both products can be disposed of together.

### **6.8 Bilateral use of TubaVent®**

After removal of the devices from the patient, carefully retract the balloon into the insertion device. The devices may be used again in the same patient on the other Eustachian tube by repeating steps 6.5 - 6.7.

**NOTE:** DO NOT reuse the device on a different patient.

### **6.9 Discard devices after use**

After use, all components of the TubaVent® Eustachian tube balloon dilatation system may be

a potential biohazard. Handle and dispose of in accordance with accepted facility procedures.

## **7. Handling of sterile single-use products**

Avoid any contamination of the TubaVent<sup>®</sup> balloon dilatation system before use. The TubaVent<sup>®</sup>, TubalInsert<sup>®</sup> ONE, and inflation device must be stored in their original sealed protective packaging. The packaging must not show any signs of damage. Do not open the protective packaging until just before removing the products. Before opening the package, it should be checked for damage and whether it is properly sealed since its sterility may be compromised. The product must also be inspected for any visible or functional damage.

### **7.1 Packaging and sterility**

The product packaging consists of the following:

- Product protective packaging inside the primary packaging (including transport carrier, transport tube with rubber sleeve, balloon sleeve, and mandrel/transport wire)
- Primary packaging/sterile barrier system
- Secondary packaging/ outer packaging

The packaging complies with enforced standards. 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, use aseptic technique.

### **7.3. Sterilization**

The product is EO (ethylene oxide) sterilized in its protective packaging. DO NOT re-sterilize the device if the original packaging is damaged.

### **7.4. Re-sterilization**

The user bears full responsibility for reprocessing and reusing the system. The components of the system cannot be re-sterilized. The cleaning process and re-sterilization can also adversely affect the product's material properties.

Manufacturers and distributors accept no liability for products that the user has 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, material changes, microorganisms, endotoxins, chemical residues and therefore changes in functionality.

### **8. Storage**

The TubaVent® balloon dilatation system must be stored and protected from dust, moisture and contamination. Direct sunlight must be avoided during storage.

Avoid exposure to organic solvents (e.g., alcohol) or ionizing radiation.

Do not use the product 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 a resident.

## 11. Explanation of used symbols



Manufacturer

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Date of manufacture

---



Use-by date

---



Batch code

---



Catalogue number

---



Sterilized using ethylene oxide

---



Do Not resterilize

---



Do not use if package is damaged and consult instructions for use

---



Single sterile barrier system

---



Keep away from sunlight

---



Keep dry

---



Do not re-use



Consult instructions for use



Unique device Identifier



Number of Pieces



GS1 Data Matrix



Federal (USA) law restricts this device to sale by or on the order of a physician

## 12. Compliance table between inflation pressure and balloon diameter

<b>Table 1:</b> TubaVent® short		
Inflation pressure		Balloon diameter
<b>bar</b>	<b>kPa</b>	<b>mm</b>
<b>4</b>	400	2.82
<b>6</b>	600	3.00
<b>8</b>	800	3.17
<b>10</b>	1000	3.28
<b>11</b>	1100	3.33
<b>12</b>	1200	3.38
<b>13</b>	1300	3.42
<b>14</b>	1400	3.45

<b>Table 2:</b> TubaVent® short wide		
Inflation pressure		Balloon diameter
<b>bar</b>	<b>kPa</b>	<b>mm</b>
<b>4</b>	400	4.25
<b>6</b>	600	4.50
<b>8</b>	800	4.73
<b>10</b>	1000	4.94
<b>11</b>	1100	5.02
<b>12</b>	1200	5.08
<b>13</b>	1300	5.13
<b>14</b>	1400	5.18

<b>15</b>	1500	3.48
<b>16</b>	1600	3.51
<b>17</b>	1700	3.53
<b>18</b>	1800	3.55
1 atm=1.01325 bar Nominal pressure = 6 bar; working pressure = 10 bar; burst pressure = 16 bar.		

<b>15</b>	1500	5.22
<b>16</b>	1600	5.26
<b>17</b>	1700	5.31
<b>18</b>	1800	5.36
1 atm=1.01325 bar Nominal pressure = 6 bar; working pressure = 10 bar; burst pressure = 14 bar.		

Revisions and typographical errors reserved.

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### References:

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