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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
	Use-by date
	Keep away from sunlight
	GS1 Data Matrix
	Temperature limit (fom 0 to 40°C)
STERILIZE	Do not resterilize
UDI	Unique-device identifier
QTY	Number of Pieces

Instruction For Use
TubaVent balloon dilatation system

Indication for Use
The TubaVent 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 balloon dilatation system are compatible with each other. Refer to the appropriate instructions for use when using with compatible devices. The TubaVent 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 balloon dilatation system includes the following three components: TubaVent short or short wide balloon catheter (hereinafter referred to as TubaVent), the TubaInsert insertion device (hereinafter referred to as TubaInsert), 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.

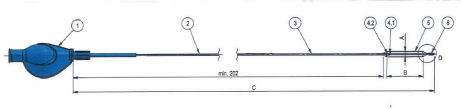

Figure 1: Schematic presentation of the TubaVent balloon catheter.

Table 1: Explanation of Figure 1.	
Position Number	Description
1	Proximal Part TubaVent short/short wide
2	Intermediate
3	Balloon Shaft Tube
4.1	Guide Wire Tubing
4.2	Marker Band
5	Balloon
6	Tip Tubing
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

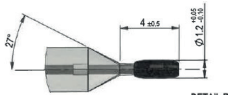

Figure 2: Detail of the TubaVent distal end (from Figure 1) with dimensions.

The product is available in two variants: 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. It is not suitable 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 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 TubaInsert insertion device

Art. No.	Description
2080-2045-US	TubaVent balloon dilatation system, TubaInsert – Type 45°, insertion device, sterile, 10 pieces

Figure 3: TubaInsert Type 45°

Material:
Tube: Stainless steel 1.4301.
Handle: Polypropylene HP671T, PP (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:

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)

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

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 is available in the literature (see section 6.2 Special Directions).1 The use of local anesthesia is evident 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 dehiscent into the ET lumen or near the ET 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 manoever 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 with each other. They are intended to be used with the whole system. Do not use the components of the TubaVent dilatation system with other devices from a different company since these are incompatible with it, and the dilatation procedure cannot be carried out as a result. The patient may be injured.
- 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 structures there (see also the reference to different balloon diameters under 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 area! 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.

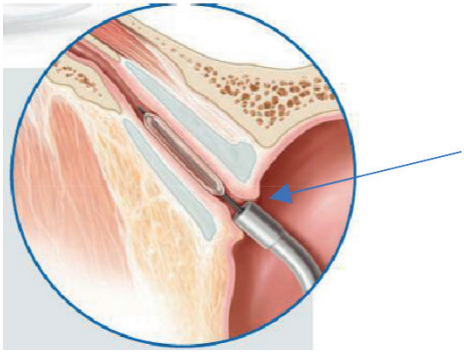

Figure 4: Correct placement of the insertion instrument at the orifice of the Eustachian tube

- 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 a life-threatening situation for the patient.
- 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).

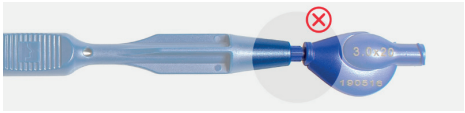

Figure 5: TubaVent is wrongly seated in the TubaInsert

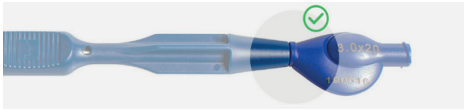

Figure 6: TubaVent is correctly seated in the TubaInsert

- DO NOT inflate the TubaVent until the balloon has exited the TubaInsert device.
- 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 and the compatible inflation device of the system.

6.2. Special directions

- The attending physician determines the choice of catheter (balloon diameter 3 or 4,5 mm).
- The catheter should only be used under endoscopic control.
- 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 danger to the patient! See Section 5. Warnings and precautions, and 6.6 Inflate the balloon.
- Failure to follow the instructions for use can result in defective products which in turn 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. 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 with appropriate patient preparation, which may include supplemental medication for patient management. 1

6.3. Preparing the TubaVent balloon dilatation system

- Before opening the sterile package of TubaVent, TubaInsert, 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 TubaInsert and the inflation device from the package accordingly.
- 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, please use an appropriate 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 Integrating the TubaVent catheter, inflation device, and TubaInsert

- 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 TubaInsert and advance it until the tip of the balloon appears at the distal opening of the TubaInsert.

6.5 Accessing the Eustachian Tube

- Place the endoscope through the nose into the nasal cavity until the Eustachian tube orifice is well visualized.
- Hold the insertion instrument with the TubaVent by the proximal hub. Under endoscopic visualization, gently insert the insertion instrument through the nose on the side to be treated until the tip of the TubaInsert is positioned proximal to the Eustachian tube orifice.

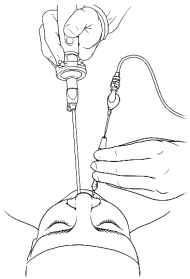

Figure 7: The endoscope is placed through the nose. The insertion instrument with the catheter is inserted through the nose on the side to be treated.

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 TubaInsert is placed against the lateral epipharyngeal wall in front of the pharyngeal tubal ostium, the endoscope remaining in the nasal cavity in the same position will be handed over to the nurse or another clinical practitioner.
- Stabilize the position of the TubaInsert under endoscopic control and advance the proximal end of the catheter with the other hand until the Luer-Lock connector is firmly seated with the TubaInsert. The balloon is now passed through the insertion instrument into the cartilaginous portion of the Eustachian tube lumen.

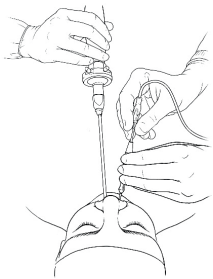

Figure 8: The correct placement of the insertion instrument in front of the tubal ostium has been identified. The endoscope is handed to the nurse so that the surgeon with the free hand can repare the access into the cartilaginous portion of the Eustachian tube.

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. 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 device damage!

6.6 Inflate the balloon

- After the balloon has been placed into the Eustachian tube, the endoscope will be handed back.
- The nurse or another clinical practitioner takes the inflation device filled with sterile isotonic solution saline solution NaCl 0.9% and connects this with the catheter at the proximal end.

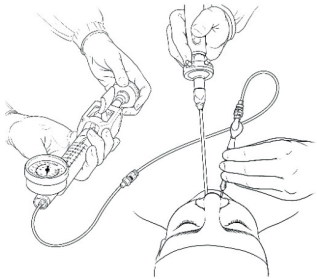

Figure 9: The inflation device is in the hand of a second person. The surgeon has the insertion instrument and the catheter in one hand and the endoscope in the other.

- 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 only inflate the balloon under endoscopic control and with additional control of the pressure monitoring 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 recommended at 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, carefully remove the entire system from the patient under endoscopic control.

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 use 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

Any contamination of the TubaVent balloon dilatation system before use must be avoided. The TubaVent, TubaInsert, 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, the relevant aseptic regulations should be observed.

7.3. Sterilization

The product is EO (ethylene oxide) sterilized in its protective packaging. DO NOT re-sterilize the device if the original packaging was damaged or it may be contaminated for other reasons because it is not intended to be re-sterilized (see section 7.4 Re-sterilization).

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.
The product must 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 a resident.

11. Summary of adverse events

In a retrospective study of 1,076 dilated Eustachian tubes (622 patients) with the TubaVent catheter, zero serious device or procedure related adverse events were observed. In three subjects, surgical emphysema within the parotid region was observed. In all cases, the emphysema reabsorbed under antibiotic cover, and the Eustachian tube healed without permanent damage. The function of the Eustachian tube still improved in these patients. Other observed adverse effects were minor bleeding and a temporary increase in pre-existing tinnitus for two weeks after the procedure. A patulous Eustachian tube never occurred in this study (Schröder et al., 2015).2
Since the initial placement of the TubaVent catheter on the European market in 2010, 1.11% of the sold products were subject to complaints. Only 0.19% of the products sold were quality-related complaints. Quality-related complaints were due to application errors, damaged items, non-functioning items, catheters not correctly seated in the introducer, and processing errors. Only two adverse events concerning injury to the patient were reported to SPIGGLE & THEIS Medizintechnik GmbH. One event described the rupture of the round window membrane hours after the balloon dilatation. This rupture could be traced back to Valsalva training prior to the second post-operative day, which is strongly not recommended in the IFU of TubaVent. The second event was a rupture of the tympanic membrane during balloon dilatation when the balloon of the catheter burst, possibly due to misuse. Post-surgery, the patient showed a minor conductive hearing loss of 30 dB. No other event concerning the rupture of a tympanic membrane has been brought to our attention since 2010. Independently of this situation, the FDA considers the rupture of the tympanic membrane and/or the round window membrane as a serious adverse event.
Most of the quality-related complaints could be traced back to damaged catheter balloons due to not handling them in compliance with the instructions for use.

For the TubaInsert, 1.60% of the sold products have been subject to complaints since the initial placement of the product on the European market in 2016. 0.43% of the sold products were quality-related complaints. These complaints were based on damaged balloons of the TubaVent short catheter. In none of these complaints, deviations of the TubaInsert were detectable and the damaged balloons were traced back to not handling them in compliance

with the instructions for use. Additionally, no patient was harmed during these interventions.

For the inflation device, 0.52% of the sold products have been subject to complaints since the initial placement of the product on the European market 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.

12. Compliance table between inflation pressure and balloon diameter

Table 1: TubaVent short

Inflation pressure		Balloon diameter
bar	kPa	mm
4	400	2.82
6	600	3.00
8	800	3.17
10	1000	3.28
11	1100	3.33
12	1200	3.38
13	1300	3.42
14	1400	3.45
15	1500	3.48
16	1600	3.51
17	1700	3.53
18	1800	3.55

1 atm=1.01325 bar
Nominal pressure = 6 bar;
working pressure = 10 bar;
burst pressure = 16 bar.

Table 2: TubaVent short wide

Inflation pressure		Balloon diameter
bar	kPa	mm
4	400	4.25
6	600	4.50
8	800	4.73
10	1000	4.94
11	1100	5.02
12	1200	5.08
13	1300	5.13
14	1400	5.18
15	1500	5.22
16	1600	5.26
17	1700	5.31
18	1800	5.36

1 atm=1.01325 bar
Nominal pressure = 6 bar;
working pressure = 10 bar;
burst pressure = 14 bar.

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