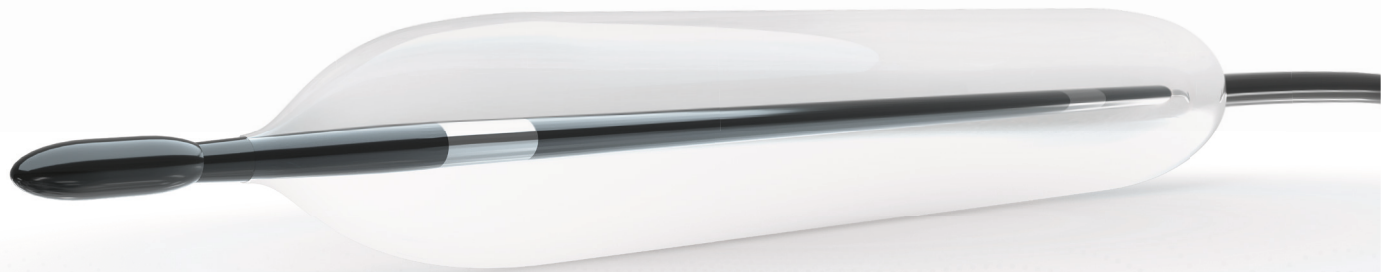


TubaVent Balloon Dilatation System

Causal therapy for Eustachian tube dysfunction



Quality

Made in
Germany

Quality you can rely on

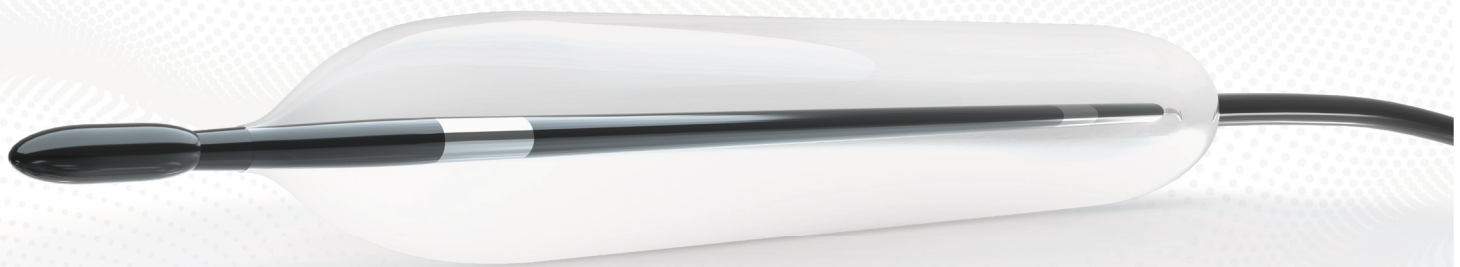
A close-up photograph of two surgeons in an operating room. They are wearing blue surgical caps and light blue surgical masks. The surgeon on the right is looking directly at the camera with a focused expression, while the surgeon on the left is looking down and to the right. The background is dark and out of focus, with a bright light source visible in the upper right corner.

Eustachian Tube Dilatation

TubaVent Balloon Dilatation System

As the first of its kind, the **TubaVent** balloon dilatation system was developed to treat dysfunctions of the Eustachian tube through a gentle and persistently controlled dilatation.

Our dilatation catheter has had over **125,000** applications worldwide since its market introduction in 2010. This treatment method has been firmly established in practice thanks to the high level of patient satisfaction and the **significant improvement of Eustachian tube function**, which can be achieved with our system.



safe & effective



TubaVent Balloon Dilatation System

For more than **10 years**, we have been the **pioneer** and **market leader** in Europe in Eustachian tube dilatation. Our system offers solutions that fulfill all requirements for a patient-friendly treatment of Eustachian tube dysfunction.

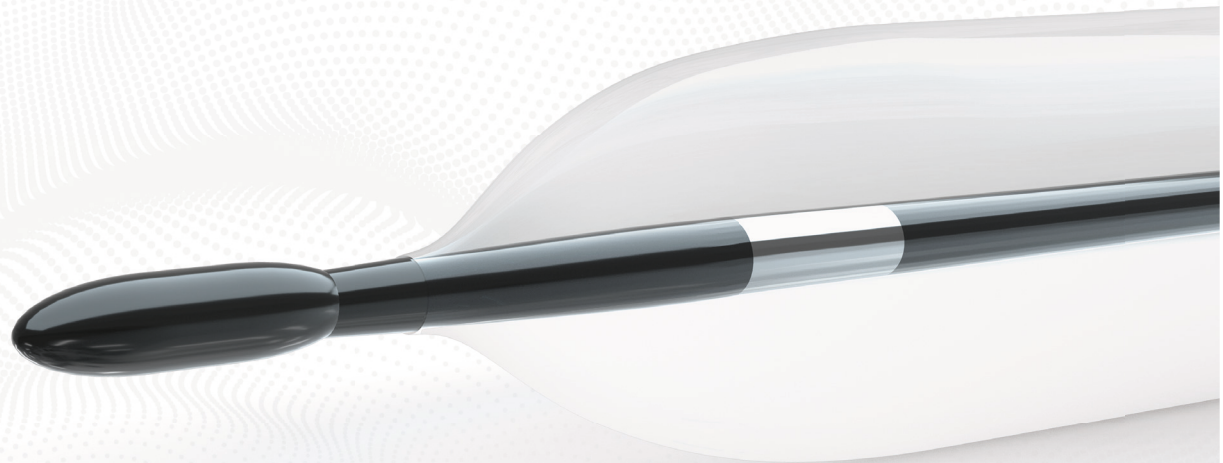
The **Eustachian tube** in adults is a narrow, tube-like connection between the pharynx and the middle ear. It is lined with respiratory epithelial tissue and consists of a long cartilaginous part on the side of the pharynx as well as a short bony part towards the eardrum. The Eustachian tube enables a pressure balance between the middle ear and throat, dissipates secretions from the middle ear to the pharynx, and protects the middle ear from germs that rise up from the throat. A complete understanding of this complex structure in reference to the function and pathological development of diseases has occupied the field of medicine for decades.

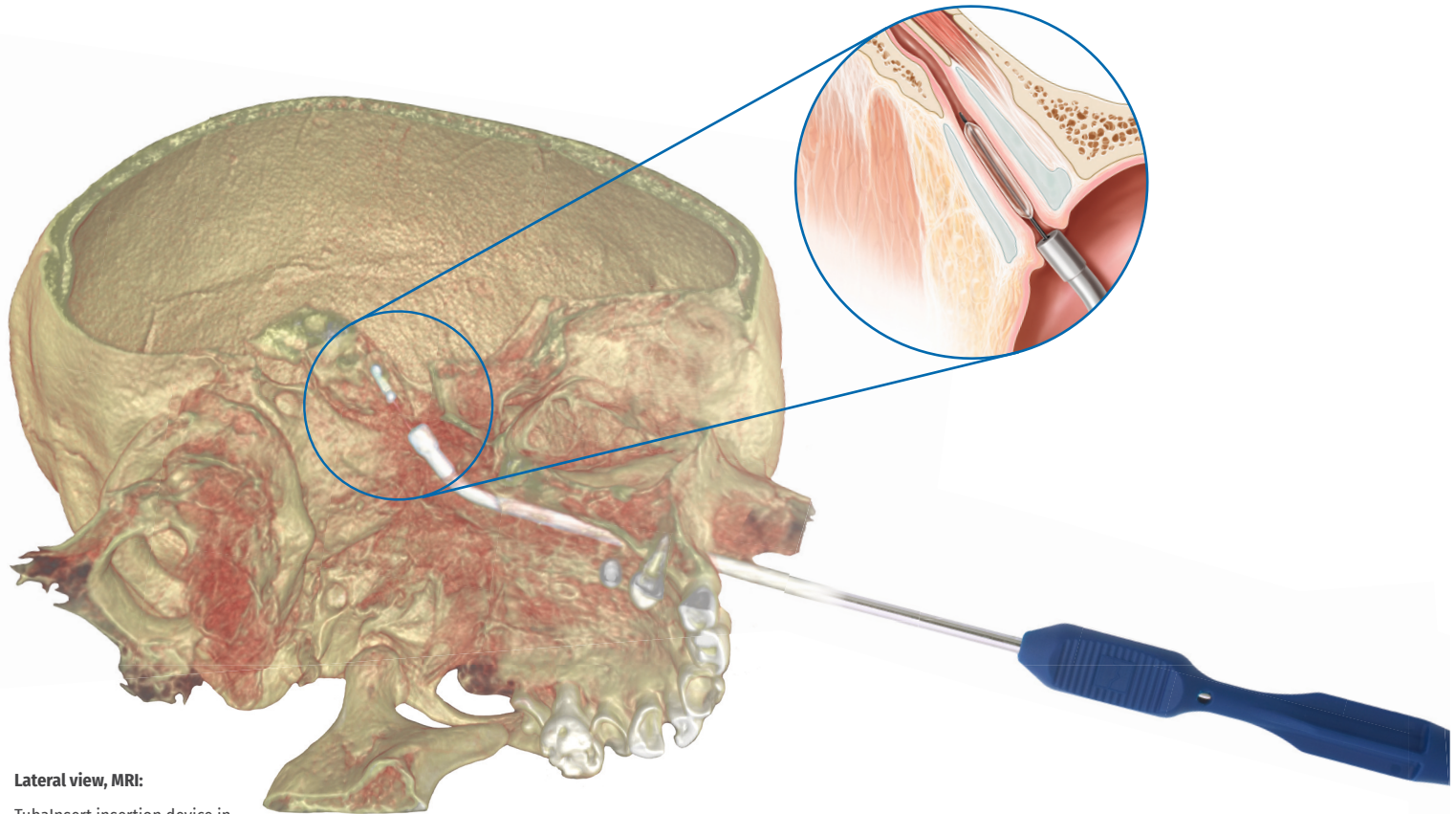
At **SPIGGLE & THEIS Medizintechnik GmbH**, we are proud of our network of experts and our decades-long experience in this specialty field.

To be able to treat ventilation issues and dysfunctions of the Eustachian tube reliably, we have developed our system, which has become a recognized treatment method in the field of medicine. Over **125,000 TubaVent placements** since its international market introduction in 2010 speak for our success.



Scan here for
more product
information





Lateral view, MRI:

TubalInsert insertion device in combination with the TubaVent short catheter



TubaVent short



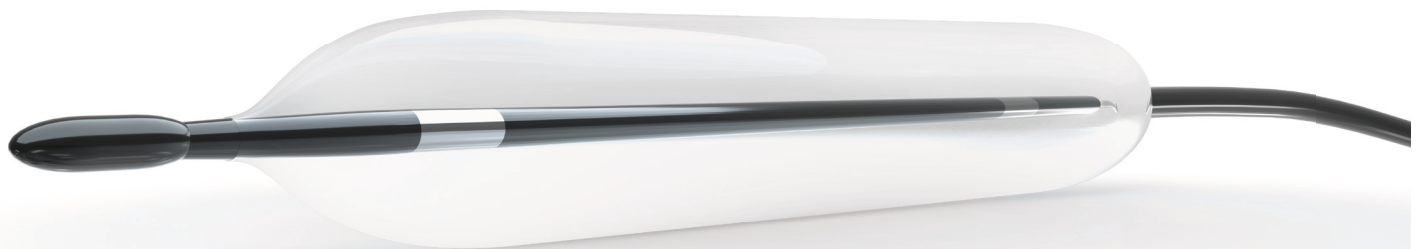
Prof. Dr. med. habil. Matthias Tisch
Honorary Doctorate in Medicine
Jordan University of
Science and Technology (JUST),
Medical Director Clinic and
Polyclinic for Otolaryngology,
Head and Neck Surgery
Bundeswehr Hospital Ulm, Germany

»» The **TubaVent** catheters, in combination with the single-use **TubaInsert** insertion device, provide a comfortable, safe, and reliable application for **successful treatment**. ««

Prof. Dr. med. habil. Matthias Tisch

The **TubaVent short** and the **TubaVent short wide** are Eustachian tube dilatation catheters, which, combined with the **TubaInsert** insertion device, allow a precise and straightforward application.

The olive-shaped catheter tip ensures enhanced protection of the mucosa and soft anatomical structures.



TubaVent short

Art. No. 2080-1236320-US

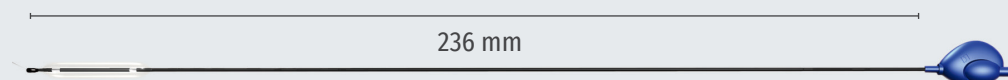
WL 236 mm, balloon 3.28 x 20 mm*, sterile

TubaVent short wide

Art. No. 2080-12364520-US

WL 236 mm, balloon 4.94 x 20 mm*, sterile

- **Two balloon sizes** available in outer diameter of 3.28 mm and 4.94 mm at 10 atm
- **Semi-compliant** balloon allows for fine & precise adjustment
- **Excellent tactile feedback** during insertion of catheter into Eustachian tube
- **Enhanced protection** of the mucosa thanks to olive-shaped tip
- **Proven and trusted system** since 2010, with more than 125,000 TubaVent catheters used globally



*at 10 bar working pressure



Insertion device, sterile

- Short insertion path and easy handling in confined anatomical conditions
- Optimal, ergonomic, and serrated grip enables comfortable handling
- Single patient use



45°, short bending, 10 pieces / box

2080-2045-US



Inflation device, sterile

- 30 ml syringe with lockable plunger and Luer-Lock connector
- Pressure gauge with 0 to 30 atm and PSI scale
- 50 cm extension tube
- Compatible with TubaVent short and TubaVent short wide
- Single-use

2080-9030040-US



Publications

1. Knuth, J. and Warnking, K., Balloon Eustachian Tube Dilatation as the Standard Causal Intervention for Eustachian Tube Dysfunction?! A summary of published clinical research; Whitepaper 2022

The prevalent interventional causal treatment, Balloon Eustachian Tuboplasty, was introduced to clinical practice already in 2009. Although it is not yet the standard treatment of ETD, the current body of knowledge of this surgical, minimally invasive procedure proves it as a safe and effective intervention. This white paper is intended to help the clinician in making their decision whether to recommend Balloon Eustachian tube dilatation to a patient suffering from Eustachian tube dysfunction, and in managing expectations regarding outcomes and success rates. The paper summarizes the relevant scientific literature.



2. Williams, B. et al., Balloon dilation of the eustachian tube: a tympanometric outcomes analysis; Journal of Otolaryngology - Head and Neck Surgery 2016

Documentation of 18 patients, 25 tubes
Period: February 2010 to February 2014
Pre-operative examination: Tympanometry
Post-operative checks after: 2-3, 6-9, 12-15 months

Result: Overall 36 % of ears had improvement in tympanogram type, and 32 % had normalization of tympanogram post-operatively. The Jerger tympanogram type improved significantly following the procedure ($p = 0.04$). Patients also had statistically significant improvement in measured middle ear pressure post-operatively ($P = 0.003$). Eustachian tube balloon dilation is a safe procedure, and produces significant improvement in tympanogram values up to 15 months post-operatively.

3. Xiong, H. et al., Efficacy of balloon dilation in the treatment of symptomatic Eustachian tube dysfunction: One year follow-up study; American Journal of Otolaryngology 2016

Documentation of 40 patients, 58 tubes
Period: April 2013 to November 2014
Pre-operative examination: clinical examination, audiometry, tympanometry, Valsalva, ear microscopy, TMM, ETS
Post-operative checks after: 1 week, 3 and 12 months

Result: A significant effect of treatment was documented when measuring subjective improvement, impedance audiometry, R-value in TMM, ETS and the ability to perform a Valsalva maneuver 1 week, 3 months and 12 months postoperatively. Subjective symptoms were not relieved only in one patient. The overall success rate for all patients was 98%.

4. Schröder, S. et al., Balloon Eustachian tuboplasty: a retrospective cohort study; Clinical Otolaryngology 2015

Documentation of 622 patients, 1076 tubes
Period: February 2009 to February 2014
Pre-operative examination: clinical examination, audiometry, tympanometry, Valsalva, Toynbee test, TMM, ETDQ score, ETS
Post-operative checks after: 1 year, 2, 3, 4 and 5 years

Result: One year after treatment, the Eustachian Tube Score (ETS) improved from 3.13 (± 2.47) to 5.75 (± 2.75). After two years, the ETS improved for 82% of the patients from 2.65 (± 2.89) to 6.26 (± 3.07). The ETS significantly improved after 5 years. Subjective patient satisfaction is approximately 80%.



5. Dalchow, C. et al., First results of Endonasal dilatation of the Eustachian tube (EET) in patients with chronic obstructive tube dysfunction; Eur Arch Otorhinolaryngol 2015

Documentation of 217 patients, 342 tubes

Period: September 2010 to April 2013

Pre-operative examination: ear microscopy, clinical examination, audiometry, tympanometry, Valsalva, ear microscopy, TMM, ETS

Post-operative checks after: 1 month, 3, 6, 9, 12 months

Result: The Eustachian tube score (ETS) improved after EET from 2.23 (± 1.147 SD) preoperatively to 2.68 (± 1.011 SD) 12 months after surgery. No complications had been observed. EET was technically easy to perform without any intraoperative difficulties. EET presented itself as a safe and successful procedure. In particular, patients after tympanoplasty showed lower score levels and benefited from tube dilatation shown by higher post-treatment tube scores.

6. Bast, F. et al., Balloon Dilatation of the Eustachian Tube: Postoperative Validation of Patient Satisfaction; ORL 2014

Documentation of 30 patients, tubes not specified

Period: September 2011 to September 2012

Pre-operative examination: clinical examination, audiometry, tympanometry, CT, Glasgow Benefit Inventory (GBI)

Post-operative checks after: 1 week, 3 months

Result: An analysis of the GBI results shows a significant improvement in the total score and the subscores 'general health' and 'physical health' following balloon dilatation. This provides evidence that balloon dilatation, with its significant improvement in general and physical health, also leads on the whole to a subjectively improved quality of life.

7. Gürtler, N. et al., Balloon Dilatation of the Eustachian Tube: Early Outcome Analysis; Otolology & Neurotology 2014

Documentation of 217 patients, tubes not specified

Period: not specified

Pre-operative examination: ear microscopy, clinical examination, audiometry, tympanometry, Valsalva, ear microscopy, TMM, ETS

Post-operative checks after: 1 week, 3 months

Result: The Eustachian Tube Score (ETS) including the R-values, tympanogram, and air-bone gap all showed a statistically positive outcome ($p = 0.005$) after Eustachian tube balloon dilation. Subjective improvement was seen in 76%. Normal R-values were achieved in 57%. Retraction processes of the tympanic membrane improved in 18% of patients. Only one minor bleeding complication occurred.

8. Tisch, M. et al., Eustachian tube dilatation using the Bielefeld balloon catheter. Clinical Experience with 320 interventions; HNO 2013

Documentation of 120 patients, 209 tubes

Period: October 2010 to February 2013

Pre-operative examination: clinical examination, Valsalva, Toynbee test, tympanogram, ear microscopy, subjective assessment of patient reported outcomes

Post-operative checks after: not specified

Result: Only 7.2% of the patients were able to perform Valsalva preoperatively. Clinical symptoms improved in 70 % of the patients after balloon dilation and none of the patients reported deterioration of symptoms. 71.4% of the patients reported that the ear symptoms improved or fully regressed.



Notes



Compatibility: 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.

Important Safety Information: TubaVent balloon dilatation system should only be used by experienced medical professionals (e.g., a qualified otolaryngologist/ENT physician) trained on the product. Prior to use, it is important to read the Instructions for Use and to understand the contraindications, warnings, and precautions associated with these devices.

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

In collaboration with:
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Cincinnati, OH 45227, USA



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