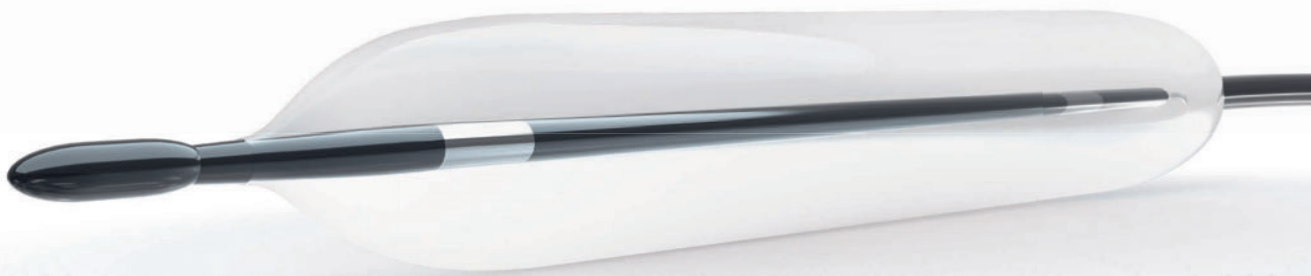


TubaVent[®] Family

Causal therapy for tube dysfunction



Quality you can rely on



Eustachian Tube Dilatation

TubaVent® Family

As the first of its kind, the **TubaVent®** System was developed to treat dysfunctions of the Eustachian Tube by means of a special gentle and persistently controlled dilatation.

Our dilatation catheter has had over **100,000** applications worldwide since its market introduction in 2010. Thanks to the high levels of patient satisfaction and the **significant improvement of the Eustachian Tube function**, which can be achieved with our systems, this treatment method has become firmly established in practice.



minimally invasive · safe · fast



For more than **10 years**, we have been the **pioneers** and **market leaders** in the field of Eustachian tube dilatation. With our systems, we offer solutions which fulfill all requirements for a patient-friendly Eustachian Tube dilatation.

The **Eustachian tube** in adults is a 3.5 cm long, 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 balance of pressure between the middle ear and throat possible, 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 speciality field.

To be able to reliably treat ventilation issues and dysfunctions of the Eustachian tube, we have developed our system, which has become a recognized treatment method in the field of medicine. More than **100,000 placements** worldwide speak for our success.

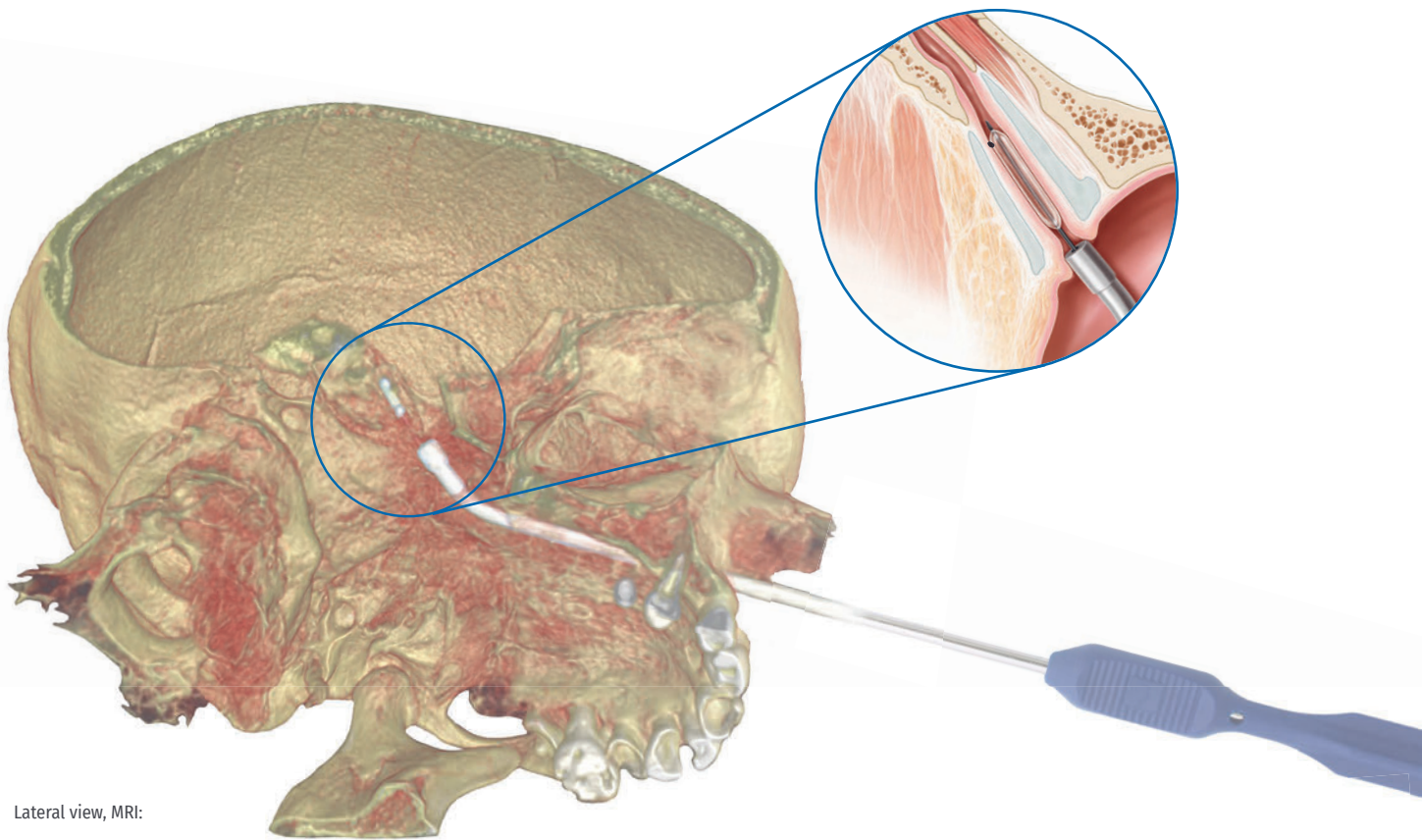
Further development of our catheters was liked with a rising demand and adapted to the market requirements. After the successful introduction of the **TubaVent®** and **TubaVent® short** we now have additional balloon sizes available, the **TubaVent® wide** and **TubaVent® short wide**.



Product video

Balloon dilatation of the Eustachian tubes

Look for yourself



Lateral view, MRI:
TubalInsert® in combination with
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® short** combines with the **TubalInsert®** insertion instrument, the advantages of the dilatation catheter, and the single-use instrumentation. ««

The **TubaVent® short** is a modified dilatation catheter, which in combination with the **TubalInsert®** insertion instrument allows for a precise and simple application.

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



TubaVent® short and TubaVent® short wide

- The olive-shaped tip ensures enhanced protection of the mucosa
- The catheter dimensions are perfectly adapted to the length of the single use insertion instrument (**TubalInsert®**), which defines the process and prevents the catheter from being pushed too far into the Tuba Eustachii
- Controlled dilatation

Art. No. 2080-1236320 WL 236 mm, Ballon 3.28 x 20 mm*, sterile

Art. No. 2080-12364520 WL 236 mm, Ballon 4.94 x 20 mm*, sterile

NEW



* at 10 bar

The disposable instrument - **TubaInsert®** - combines the reliability of a reusable introducer with the convenience and safety of modern disposable instruments.



Single use insertion instrument, sterile

- Shorter insertion path and easier handling in confined anatomical conditions
- Three different geometries available
- Optimal ergonomics and a serrated grip allows easier handling
- Compatible in length with **TubaVent® short** only
- No time-consuming preparation process required



60° type Ulm, 10 pieces / box

2080-2010



45°, short bending, 10 pieces / box

2080-2045



70°, 10 pieces / box

2080-2070



Inflation pump

- Inflation pump with extension tube
- 30 ml syringe with detachable plunger using command switch, twist grip, pressure gauge and high-pressure connection using Luer-Lock rotary adapter
- Division from 0 to 30 atm, PSI scale
- Includes 50 cm - extension tube
- Useable for all **TubaVent®** catheter
- Single use

2080-9030040





Prof. Dr. med. Dr. rer. nat.
Holger Sudhoff, FRCS (Lon), FRCPath
Chief physician
of the Bielefeld clinic (ENT, head
and neck surgery clinic), Germany

» With the **dilatation of the Eustachian Tube**, the possibility to treat the cause of chronic middle ear infections was offered for the first time. «

The multi-use combination instrument enables Eustachian Tube Dysfunctions to be easily treated.

The entry angles which are available make it possible to fulfill all anatomical conditions.



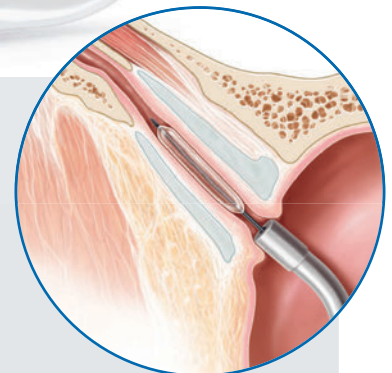
TubaVent® and TubaVent® wide

- The catheter tip allows for easy advancement of the catheter while providing optimal protection for the mucous membrane cleaning system
- Optimum length guarantees complete dilatation of the cartilaginous part
- Controlled dilatation

Art. No. 2080-1300320 WL 355 mm, balloon 3.28 x 20 mm*, sterile

Art. No. 2080-13004520 WL 355 mm, Ballon 4.94 x 20 mm*, sterile

NEW



* at 10 bar

Accessory - combined insertion instrument



Combined Insertion Instrument * for insertion of catheter into Tuba Eustachii

* attachments not included

80-806-92



30°

80-806-93



45°

80-806-94



70°

80-806-95

Combined Insertion Set, 3.0 mm

- three color-coded distal angled attachments: 30°, 45°, 70°
- Combined Insertion instrument

80-806-90



30°

80-806-83



45°

80-806-84



70°

80-806-85

Combined Insertion Set, tapered, 3.0 mm

- three color-coded distal angled tapered attachments: 30°, 45°, 70°
- Combined Insertion instrument

80-806-91



30°

80-807-83



45°

80-807-84



70°

80-807-85

Combined Insertion Set, tapered, 4.5 mm for TubaVent® wide

- three color-coded distal angled tapered attachments: 30°, 45°, 70°
- Combined Insertion instrument

80-807-92

NEW



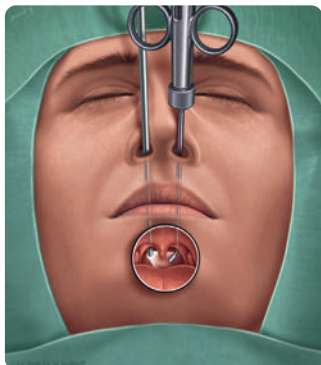
System screen basket for combined insertion instrument

- For combined insertion instrument and attachments
- With cover, retaining strap and silicone strips
- Rinsing module for cleaning the inner lumen
- Material: Stainless steel
- Dimensions: 24.4 cm x 24.4 cm
- Validated Cleaning System

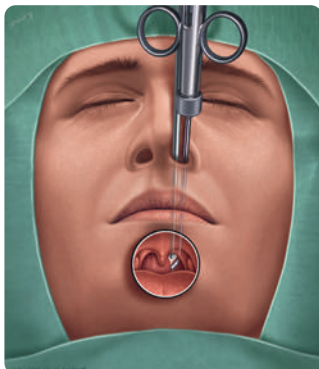
80-850-10



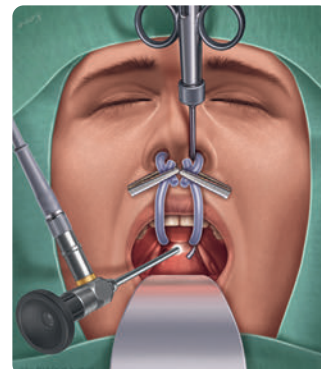
Contralateral access



Ipsilateral access



Pharyngeal access



Procedure

- Insert Hopkins optic (e.g. 70°) on contralateral side
- Localise the tubal ostium
- Carefully insert the **TubaVent®** catheter with the appropriate insertion instrument and place it at the tubal ostium

! For tight anatomical conditions this access may not be suitable

- Insert Hopkins optic (e.g. 30°)
- Carefully insert the **TubaVent®** catheter with the appropriate insertion instrument, parallel to the optic, through the same nostril

! Ideal for difficult anatomical conditions

- Insert Hopkins optic (e.g. 70°) through the oral cavity; both tube openings are clearly visible
- Carefully insert the **TubaVent®** catheter with the appropriate insertion instrument and place it at the tubal ostium

! Avoid penetrating the Rosenmüller recess (recessus pharyngeus); this is in the direct vicinity of the tubal ostium

! Do not insert the instrument too far into the ostium, in order to prevent any dilatation of the bony part

- Advance the catheter without resistance
- Connect the inflation pump
- Inflate the balloon to 10 bar (working pressure)
- Maintain pressure for 2 minutes
- Release pump lock and withdraw balloon
- Carefully remove the deflated catheter with the combined insertion instrument

Publications

M. Tisch, H. Maier, H. Sudhoff, ACTA Otorhinolaryngologica Italica 2017

Clinical experience in the management of children.

Treatment of Eustachian tube dysfunction.

Subjects: 126 children, range 28 months to 13 years.

Preoperative Examination: Clinical Examination, Tympanometry

For the first time worldwide, this procedure was assessed in regard to the treatment of children with Eustachian tube dysfunction, who had previously not responded to other treatments.

No intra- or postoperative complications.

Result: clinical symptoms improved in more than 80% of patients. No patient reported a deterioration. 81.3% of the participating parents were either very satisfied or satisfied with the outcome of the treatment.

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.

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%.

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%.



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.

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.

Gürtler, N. et al., Balloon Dilatation of the Eustachian Tube: Early Outcome Analysis; Otology & 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 dilatation. 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.

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 dilatation and none of the patients reported deterioration of symptoms. 71.4% of the patients reported that the ear symptoms improved or fully regressed.



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