TubaVent Family
Causative therapy for tube dysfunction

Quality you can rely on
Eustachian Tube Dilatation
TubaVent Family

With the TubaVent Family from SPIGGLE & THEIS Eustachian Tube Dysfunction can be treated simply and effectively.

This atraumatic method has been successfully used in over 75,000 procedures.

Convince yourself

minimally invasive • safe • fast
Tube dilatation with a balloon catheter is an atraumatic and interventional alternative therapy for persistent obstructive tube dysfunction. This concept of therapy has established itself in modern otolaryngology and allows the treating physician to provide a causal, targeted therapy for his patients. To date, approximately, **75,000 successful dilatations** have been carried out **worldwide** in the last nine years.

It has become possible to treat the base cause of chronic, middle ear infections by dilating the cartilaginous part of the auditory tube. Left untreated, such infections can turn into chronic otitis media, resulting in destruction of the middle ear structures and lead to loss of hearing. Particularly when dealing with chronic tube dysfunction or middle ear pathologies, the **TubaVent** system from **SPIGGLLE & THEIS** provides the means to approach the black box of Eustachian Tube treatment in an extremely effective, yet minimally invasive way.

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**TubaVent**

- The olive-shaped 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 to 3.28 mm *∅*  

**Art. Nr. 2080-1300320**  
WL 355 mm, balloon 3 x 20 mm, sterile

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* at 10 bar
Accessory - combined insertion instrument

Attachments

- To insert the catheter into the Eustachian tube
- three color-coded distal angled attachments: 30°, 45°, 70°
- Insertion instrument

SET - 80-806-90

Attachments, tapered

- To insert the catheter into the Eustachian tube
- three color-coded distal angled tapered attachments: 30°, 45°, 70°
- Insertion instrument

SET - 80-806-91

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
**TubaVent short** is a modified dilatation catheter that can be placed precisely in the Eustachian Tube, when combined with TubaInsert.

The TubaVent System has established itself as a therapy for ventilation disorder, particularly when treating the disorder at an early stage, to prevent middle ear pathologies. With the growing recognition and demand for this concept of treatment, the balloon dilatation system has continued to evolve, meeting the very latest market requirements.

- The olive-shaped tip ensures enhanced protection of the mucosa
- The catheter dimensions were perfectly adapted to the length of the single use insertion instrument (TubaInsert), which defines the process and prevents the catheter from being pushed too far into the Tuba Eustachii
- Controlled dilatation to 3.28 mm Ø *

**Art. Nr. 2080-1236320** WL 236 mm, Ballon 3 x 20 mm, sterile

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* at 10 bar
The new disposable instrument - TubalInsert - 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 comfortable and safe handling
- Compatible in length with TubaVent short only
- The disposable insertion tool eliminates time-consuming preparation processes

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
- 20 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 100 cm - extension tube
- Useable for TubaVent and TubaVent short
- Single use

2080-9030020
**Paths of access**

**Contralateral access**

- Insert Hopkins optic, a 70° for example on the contralateral side
- Localise the tubal ostium
- Carefully Insert the TubaVent or TubaVent short with the appropriate insertion instrument and place at the tubal ostium

**Ipsilateral access**

- Insert Hopkins optic, a 30° for example
- Carefully insert the TubaVent or TubaVent short with the appropriate insertion instrument, parallel to the optic, through the same nostril

**Pharyngeal access**

- Insert Hopkins optic, a 70° for example, through the oral cavity; both tube openings are clearly visible

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**Procedure**

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

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! 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.

! For tight anatomical conditions this access may not be suitable

! Ideal for difficult anatomical conditions
Pre-operative diagnostics

- Thorough medical history examination
- Valsalva
- Inspection and endoscopy of the nasopharynx
- CT/DVT of the petrous bone, if necessary
- Tympanometry
- Audiometry

Pre-operative preparation / equipment

- Nose drops
- Endoscopic work, using a monitor with a camera and documentation system
- Optics, with xenon light source (0°, 30°, 45°, 70°)
- System Screen Basket for combination insertion instrument and attachments
- Combined insertion Instrument (for TubaVent short use TubalInsert)
- Attachments (30°, 45°, 70°) or tapered attachments (30°, 45°, 70°)
- Inflation pump with extension tube
- TubaVent / TubaVent short
  - Water bowl
  - Nasal speculum
  - Frazier suction tube
  - Bayonet forceps
  - ENT-Patties
  - Mouth gag, if necessary, for pharyngeal access
  - Catheter, if necessary, for velotraction for pharyngeal access

Instrument preparation

- Screw the relevant attachment (30°, 45° or 70°) onto the combined insertion instrument
- Fill (aspiration) the inflation pump with physiological saline solution
- Lock the inflation pump
- Remove protection tube, stabilisation wire and distal protective cap of the TubaVent
- Completely insert the catheter into the combined insertion instrument
- Connect the inflation pump (pre- or intra-operative) to the TubaVent
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;

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 month 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 Otolarvngology 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 Dilation 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 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.

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.