SPIGGLE & THEIS
Medizintechnik

TubaVent® Balloon Dilation System

Restoring Natural Eustachian Tube Function at its Core

Quality you can rely on

Gentle and Patient-Friendly

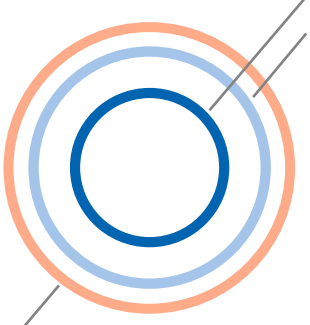
Approximately 4.6% of the adult population in the U.S. suffers from Eustachian Tube Dysfunction (ETD).[1] Balloon Eustachian Tuboplasty (BET) is a proven interventional treatment that directly addresses the underlying cause of ETD. Recognized as a safe and effective method, BET has been widely studied and validated.

Multiple studies have demonstrated that the **TubaVent® Balloon Catheter** successfully restores normal ear function, leading to high patient satisfaction rates.[2,3] Since its launch in 2010 in Europe, TubaVent® has been used in over **125,000 cases** worldwide, solidifying its role as a trusted solution for ETD treatment.

Reliably treat persistent obstructive Eustachian tube dysfunction with the gentle and patient-friendly TubaVent® Balloon Dilation System by SPIGGLE & THEIS.

Specifically designed to treat persistent obstructive Eustachian tube dysfunction

- Available balloon sizes in diameter and length: 3.28 x 20 mm and 4.94 x 20 mm at 10 bar (~9.87 atm)
- Flexible balloon allows for precise placement
- Enhanced protection of the mucosa thanks to the olive-shaped tip



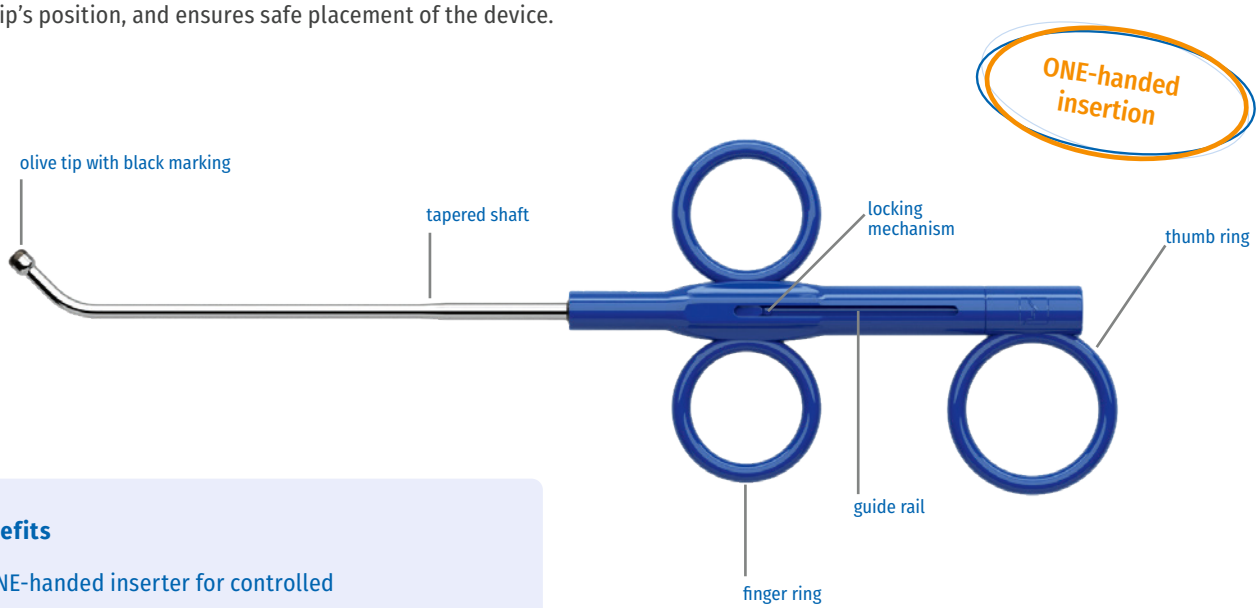
TubaVent® Balloon by SPIGGLE & THEIS Medizintechnik
with a diameter of 3.28 mm (45 % smaller than conventional balloons)
with a diameter of 4.94 mm (18 % smaller than conventional balloons)

Conventional balloon
with a diameter of 6 mm

According to Hubbell et al., BET caused patulous ETD symptoms in ca. 7 % of dilated Eustachian tubes in a 182-patient study with increased risk for younger patients and those with severe inflammation. Over 90 % of the balloons used had a diameter of 6 mm![4]

TubaInsert® ONE

The **TubaInsert® ONE** allows ONE-handed operation, features a black safety marking for precise visual control of the tip's position, and ensures safe placement of the device.



Benefits

- ONE-handed inserter for controlled catheter advancement
- Excellent tactile feedback during catheter insertion
- Black marking for enhanced safety during catheter insertion
- Designed for bilateral use

Inflation Device

- Pressure gauge 0 to 30 atm
- 30 cc syringe with 30 cm tube, lockable plunger, and Luer-Lock connector
- 50 cm extension tube
- Single-patient use

Product Number	Item	Technical Details
2080-1236320-US	TubaVent® Short Balloon Catheter	Working length 236 mm, balloon 3.0 x 20 mm at 6 bar (~5.92 atm)*
2080-12364520-US	TubaVent® Short Wide Balloon Catheter	Working length 236 mm, balloon 4.5 x 20 mm at 6 bar (~5.92 atm)*
2080-3045-US	TubaInsert® ONE	Angled tip 45°
2080-9030040-US	Inflation Device	With 50 cm extension tube, syringe volume 30 cc

** at nominal pressure*

References

1. Shan A, Ward BK, Goman A.M., et al. (2019) Prevalence of Eustachian Tube Dysfunction in Adults in the United States JAMA Otoaryngology Head Neck Surgery 145, no. 10: 974-975.
2. Schröder S, Lehmann M, Ebmeyer J, Upile T, Sudhoff H. Balloon Eustachian tuboplasty: a retrospective cohort study. Clin Otolaryngol. 2015 Dec;40(6):629-38. doi: 10.1111/coa.12429. PMID: 25867023.
3. Clinical Affairs SPIGGLE & THEIS Medizintechnik GmbH: 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
4. Hubbell RD, Toivonen J, Kawai K, Kim HJ, Nieman CL, Ward BK, Poe DS. Patulous Eustachian Tube Dysfunction Symptoms Following Balloon Dilation. Laryngoscope. 2023 Nov;133(11):3152-3157. doi: 10.1002/lary.30659. Epub 2023 Mar 17. PMID: 36929856.

Compatibility: The components of the TubaVent® Balloon Dilation 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 Dilation 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: U.S. federal law restricts this device to sale by or on the order of a physician

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