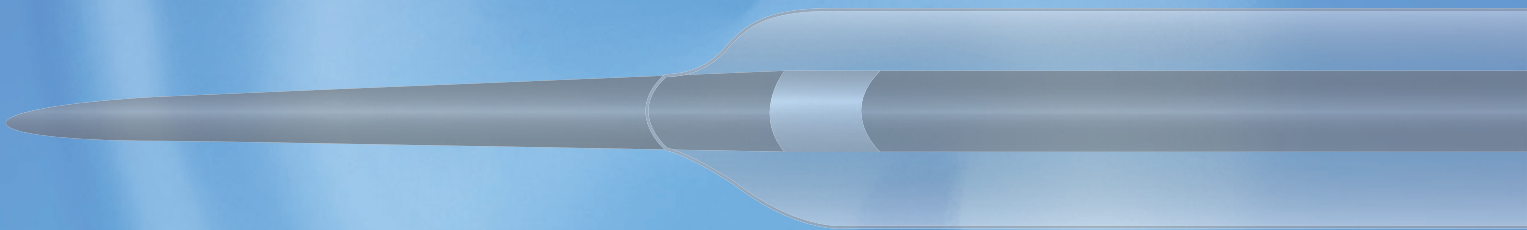




SPIGGLE & THEIS
Medizintechnik

C2 C3
C1 C4



Bielefeld

✓ **BALLOON CATHETER**

The new causative treatment
for chronic tube malfunction

A new therapy concept for the treatment of chronic tube dysfunction

Obstructive tube dysfunction often involves a chronic functional defect in which the regular aeration and ventilation as well as the self-cleaning capability of the middle ear are limited. The consequences of this malfunction include the development of chronic otitis media which, in the worst case, may lead to the destruction of the middle ear structures, resulting in subsequent hearing loss.

"The introduction of microsurgical and endoscopic techniques revolutionized medicine and is still state of the art today.

The development of balloon catheters used, for example, in the dilatation of coronary arteries led to revolutionary treatment concepts, previously deemed unthinkable.

Transferring this technology to the dilatation of the Eustachian tube enables conservative causative treatment of chronic middle ear inflammation for the first time ever and paves the way for further treatment options, particularly for chronic tube malfunction and established middle ear pathologies."



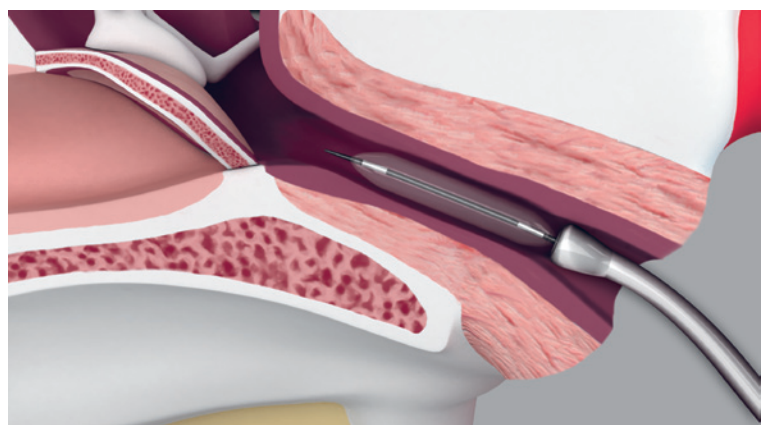
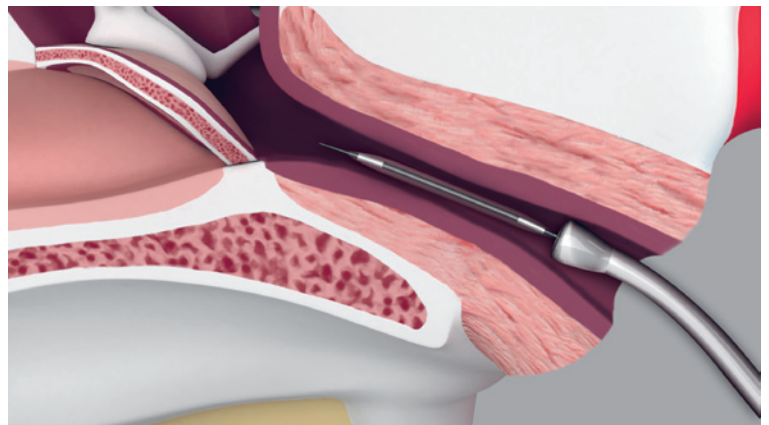
Prof. Dr. Holger Sudhoff, M.D.,
head physician, ENT clinic, Bielefeld

In a practical clinical study, Professor Holger Sudhoff has proved that the Eustachian tube can be treated by means of a modified PTA catheter which is introduced into the tube with the aid of a special microendoscope specifically developed for this purpose. The microendoscope is constructed in such a way that the catheter may be advanced into the tube in a carefully controlled manner without injuring any critical structures. This minimally invasive procedure is extremely gentle on the patient.

A preoperative tubomanometry (TMM) is performed on the patients for a detailed assessment of tube function and in order to decide whether dilatation should be performed.

The treatment principle is similar to that of balloon dilation in vascular stenosis and has recently also been established in the treatment of chronic obstructive sinusitis. Studies on balloon sinuplasty have shown it to be a safe and reliable treatment procedure.

This study had to be divided into an experimental and a subsequent clinical stage so that a precise assessment of the feasibility and effects of tube dilation could be assessed.

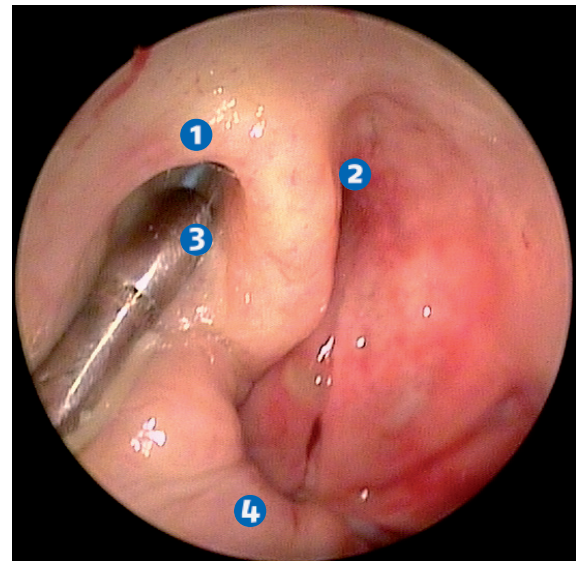


Balloon catheter – schematic illustration

An experimental investigation was initially performed on cadavers to develop and test the technical procedures of such an intervention. Thereafter, histological examinations were performed on the petrosal bone to record the direct effects that balloon dilation has on the Eustachian tube and its surrounding structures.

During the clinical part of the study, balloon dilation was performed on subjects with obstructive tube dysfunction. The functional outcome was statistically analysed. A clinical prospective study concept was developed and put into practice.

First of all, under transnasal endoscopic vision of the lateral wall of the epipharynx, a suitably modified catheter is placed adjacent to the pharyngeal ostium of the Eustachian tube. This catheter, with a balloon at its distal tip, is pushed through the working channel of the microendoscope and carefully advanced into the tube while avoiding any resistance. Once the balloon is positioned inside the tube, a saline solution is used to apply the dilation up to a pressure of 10 bar. Pressure is maintained for 2 minutes. Then the solution is aspirated from the balloon and the catheter is carefully removed with the endoscope to complete the procedure.



Legend:

- 1) Tube opening
- 2) Rosenmüller's fossa
- 3) Balloon catheter at the pharyngeal ostium of the Eustachian tube
- 4) Velum

In order to investigate the functional changes of Eustachian tube dilation by balloon catheter, the intervention was performed on a total of eight patients (aged 20 and above) treating a total of 13 ears. Pre and post-operative results were compared using a specially developed Eustachian tube score (ETS) of subjective and objective parameters. Follow-up examinations were performed after one, two and eight weeks. Only patients with chronic obstructive Eustachian tube dysfunction were included in the study. The Eustachian tube score showed a significant improvement in tube function in the clinical part of the study. There were no intra or post-operative complications.

The success of other treatment procedures was mainly assessed using examination methods that only allowed indirect conclusions regarding tube function. This study, however, used tubomanometry as a method of directly measuring tube function by assessing the tube's gas transfer capability. Two months after the treatment, ten cases showed evidence of tube opening in all three TMM measurements (30, 40, 50 millibar). Three cases showed tube opening in two of the three measurements. There was not a single case where tube opening did not occur in one of the three measurements.

The results of this study show that dilation of the Eustachian tube is a safe and uncomplicated procedure. It appears to be a good treatment option to improve obstructive tube dysfunction.

Please be aware that so far there has not been sufficient experience in the treatment of patients under 20 years of age.

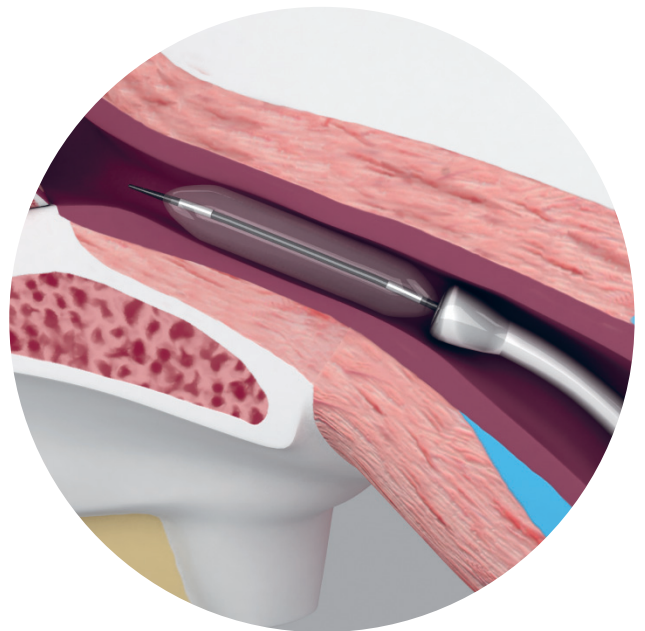


Bielefeld Balloon Catheter

Art. No. 2080-1300320



- Balloon dilatation catheter with an inflatable balloon near the distal tip
- For single use only
- Two X-ray visible markers to indicate the cylindrical part of the balloon during radiography
- Luer lock adapter for inflation and deflation
- Material:
 - Catheter: Polyamide (PA)/Pebax®;
 - Stainless steel/PTFE.
 - Balloon: Polyamide (PA).
 - Luer connection: Polycarbonate (PC)
 - X-ray marker: Platinum / Iridium (90% / 10%)



Intelligent innovations
for new surgical procedures.

The catheter has an overall length of 400 mm with a working length of 355 mm from the Luer lock connection to the distal tip. This size of the balloon is 3 x 20 mm.

The flexible distal part of the catheter has a coaxial structure. The outer lumen is used for inflating the balloon. The proximal part of the catheter is a single lumen hypotube made of stainless steel. It is therefore less flexible in this section, ensuring good pushability. The balloon offers controlled compliance, i.e. with a preset pressure application it expands to its defined dimensions (6 bar = 3.00 mm, 10 bar = 3.28 mm balloon diameter).

Tube dilation by means of a Bielefeld balloon catheter offers a new option for causal treatment of Eustachian tube dysfunction: **minimally invasive – safe and reliable – fast.**

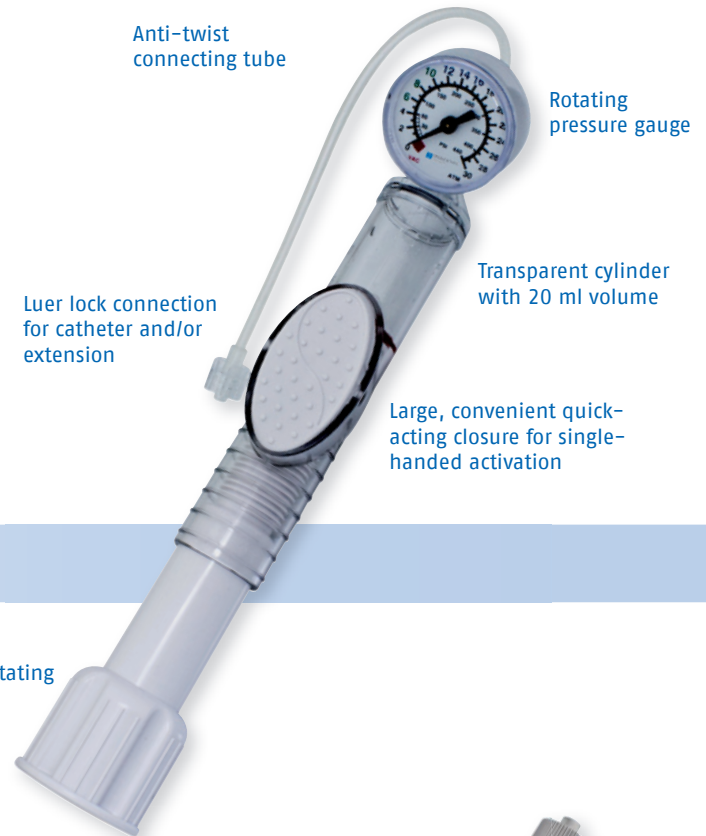


Inflation pump

Art. No. 2080-9030020

- Inflation pump with extension tube for the inflation of catheter balloons
- For single use only
- 20cc syringe with control switch to release the Plunger, rotating handle, pressure gauge and high pressure connection with Luer lock rotary adapter
- PSI scale ranging from 0 to 30 atm (= bar)
- Working pressure marker for Bielefeld balloon catheter
- Including 100cm extension tube

Intelligent ergonomics for
comfortable and safe handling



Insertion Instrument

Art. No. 80-806-99

- For the insertion of catheters into the Eustachian tube
- Maximum advance = 35 mm for tube lengths from 31 to 38 mm
- Advance indicator with stop to prevent the catheter from entering the tympanum
- Compatible with micoro endoscope (Art. No.80-806-30)

Precise instruments for exact
positioning of the catheter





Microendoscope

Art. No. 80-806-30

- For the insertion of the Eustachian tube catheter under vision
- Rigid 30° downward bend
- Line of vision: 0°, field of vision: 70°
- Working length: 90 mm
- Distal length: 7 mm
- Outer diameter: 3 mm
- Length including handle: 170 mm
- Fiberoptic cable: 800 mm
- Digital display: 10 Megapixel
- Suitable for gas and plasma sterilization, autoclavable
- Working channel: 1.2 mm, irrigation channel: 0.7 mm



Top quality fiberoptic endoscope for
minimally invasive interventions via monitor.

Equipment trolley

Art. No. 80-806-43

- Equipment trolley for tubomanometer and accessories
- Width 430 mm, height 1070 mm
- 1 drawer
- 2 shelves
- Power distribution
- Central switch



State of delivery

Highest quality coupled with an
elegant design and sophisticated features

Tubomanometer

Art. No. TMM – delivery includes Notebook „Dell Vostro 3700“ (see next page)

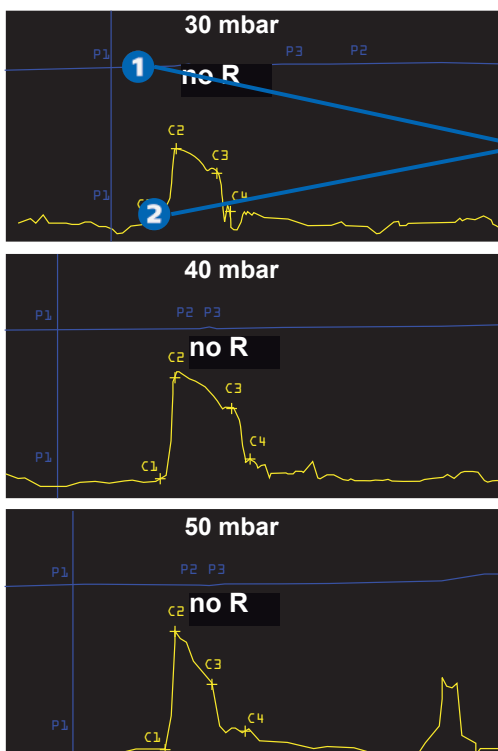
System for examining the pressure equalization function of the Eustachian tube

With the application of excess pressure into the nose and rhinopharynx during swallowing, the tubomanometer can record the opening parameters of the Eustachian tube and the pressure equalization function of the middle ear.

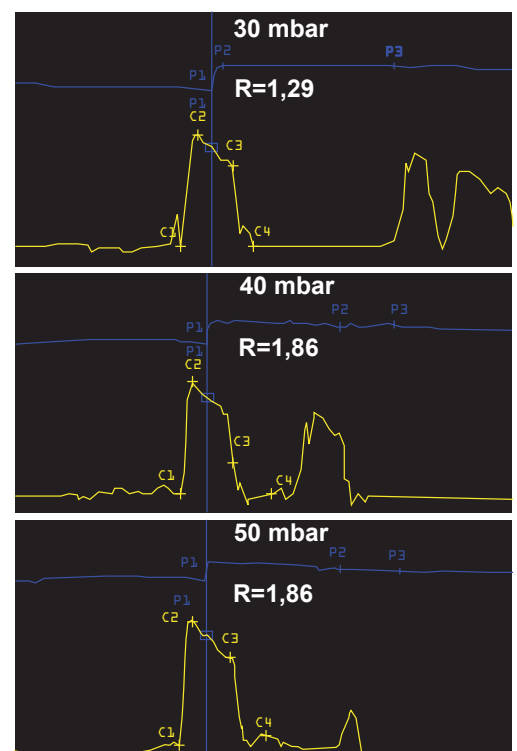
The principle and aim is to build up sufficient pressure in the nose and rhinopharynx that enables the tubomanometer to assess the latency = delay between the pressure application and the opening of the Eustachian tube. Deviations from standard values can be shown. The decisive value is the Opening Latency Index = R

$$R = (P1 - C1) : (C2 - C1)$$


Preoperative tubomanometry
 No pressure increase in the ear
 R = 0 (obstructive tube dysfunction)
 Measurements at 30, 40, 50 millibar



Postoperative tubomanometry
 R > 1, normal increase in pressure with a slight delay, 2 months after tube dilation
 Measurements at 30, 40, 50 millibar



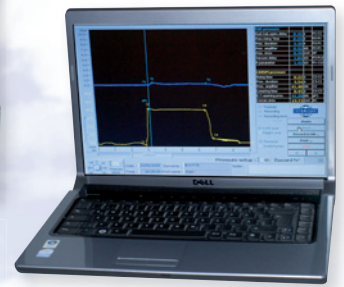
Indication of the various phases of pressure increase in the nasal cavity and velum closure. Indication of insufficient or incomplete velum closure.

Ventilation of the middle ear: Indication of tube reaction and tympanic movement by recording the pressure variations in the outer ear. The recordings indicate the opening pressure and opening latency of the Eustachian tube.

The Tubomanometer – non-invasive and non-traumatic assessment of dysfunctional tube ventilation

Examination kit (Art. No. 80-805-00) consisting of:

- **Tubomanometer** (Art. No. TMM) standard version
- **Notebook Dell® Vostro 3700 professional** with Intel i5 Dual Core processor (2.26 GHz), 4 GB DDR3-RAM, 320 GB hard drive, operating system and software pre-installed for the tubomanometer
- **Nasal adapter for TMM**, small (Art. No. C28F)
- **Nasal adapter for TMM**, medium (Art. No. C28E)
- **Nasal adapter for TMM**, large (Art. No. C28G)
- **Ear plug for TMM**, large, blue, box with 1 pair (Art. No. C34)
- **Ear plug for TMM**, small, yellow, box with 1 pair (Art. No. C35)



C28F



C28E



C28G



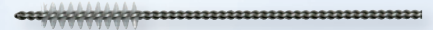
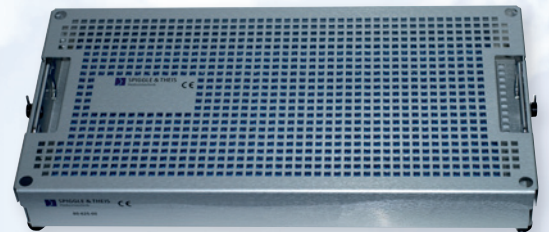
C34



C35

Treatment kit (Art. No. 80-806-00) consisting of:

- **Microendoscope** (Art. No. 80-806-30) for the minimally invasive insertion of a tube catheter into the Eustachian tube
- **Sterilization Container** (Art. No. 80-625-00) For one microendoscope and accessories, consisting of:
 - 1 Instrument box for tough instruments (Art. No. 80-602-20)
 - 1 patterned insert mat (Art. Nr. 80-602-31)
- **Insertion instrument** (Art. No. 80-806-99) For the insertion of catheters into the Eustachian tube, compatible with Art. No. 80-806-30
- **Cleaning brush** (Art. No. 80-844-30) with ring handle, working length 30 cm, brush diameter 2.0 mm, brush head 10 mm, for working channels up to 1.5 mm, 10 pieces per box



SPIGGLE & THEIS

Medizintechnik GmbH
Diepenbroich 15
D-51491 Overath
Fon: +49 (0) 22 06 / 90 81 - 0
Fax: +49 (0) 22 06 / 90 81 - 13
Mail: info@spiggle-theis.de
Web: www.spiggle-theis.com