

Bielefeld

BALLOON CATHETER

The new 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 where both the regular aeration and ventilation as well as the self-cleaning capability of the middle ear are restricted. The consequences of which include the development of chronic otitis media which, in the worst case, may lead to destruction of the middle ear structures, resulting in loss of hearing.

“The introduction of microsurgical and endoscopic techniques revolutionized medicine and are still state of the art today. The development of balloon catheters being 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 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.”

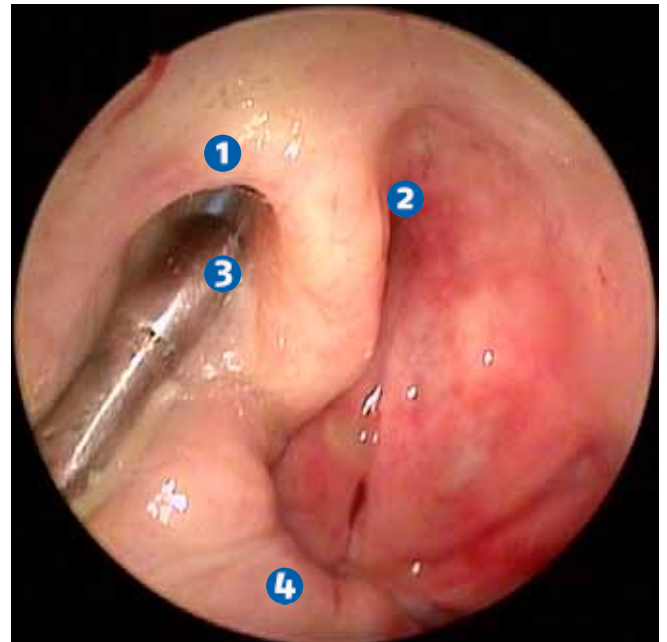


Prof. Dr. Holger Sudhoff, M.D.,
head physician, ENT clinic, Bielefeld

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

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

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



Legend:

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

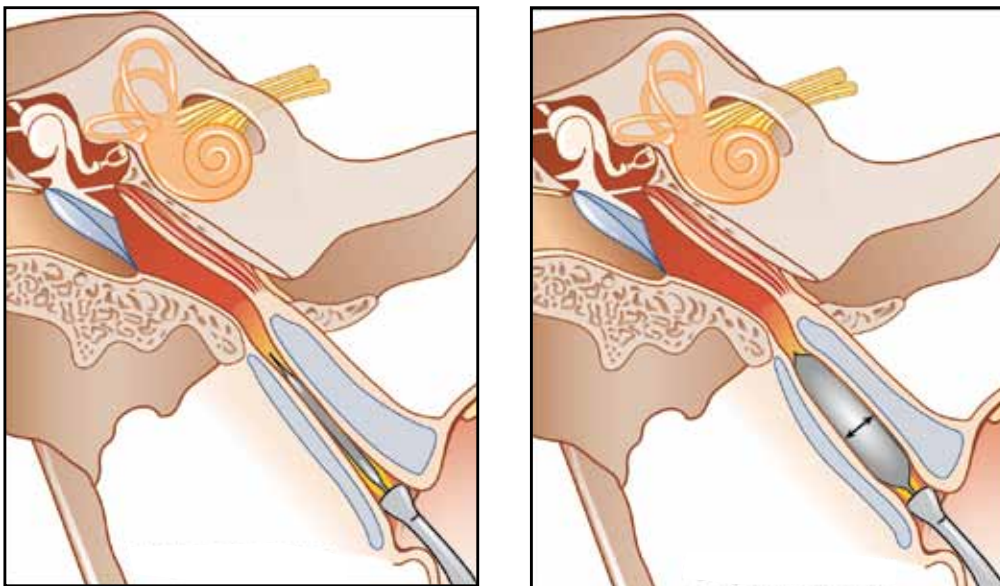
The Bielefeld Balloon Catheter

The catheter is placed adjacent to the pharyngeal ostium of the Eustachian tube while the lateral wall of the epipharynx is endoscopically observed. The catheter is inserted via the working channel of the micro endoscope (Art. No. 80-806-30) and carefully introduced into the tube, avoiding resistance.

An alternative to the micro endoscope is the use of the combined insertion instrument (Art. No. 80-806-90) and a rigid endoscope, 4 mm / 30°.

Once the balloon within the catheter is in position, a saline solution is injected at a pressure of up to 10 bar, causing the dilation. The pressure is maintained for two minutes. The saline solution is then aspirated from the balloon. The removal of the catheter and endoscope completes the procedure.

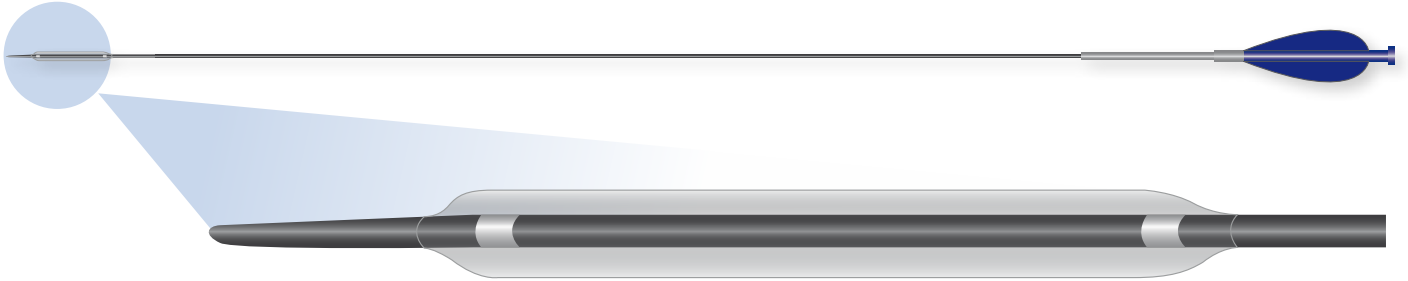
Please note that to date there is no extensive experience in the treatment of patients under the age of twenty.



Illustrations: © 2011 Dr. med.Carsten Dalchow

Bielefeld Balloon Catheter

Art. No. 2080-1300320



- Balloon dilatation catheter with balloon near the distal tip
- Single use only
- Two X-ray visible markers indicate the cylindrical part of the balloon during radiography
- Luer lock adapter for inflation and deflation

Intelligent innovations
for new surgical procedures

Inflation Pump

Art. No. 2080-9030020

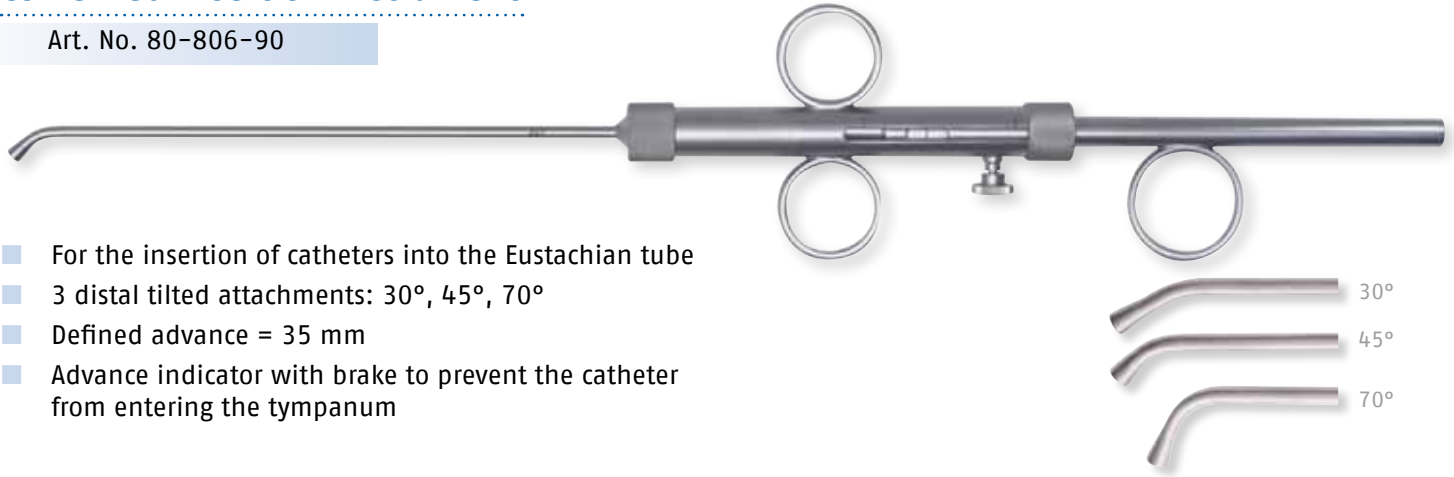
- Pump with extension tube for the inflation of catheter balloons
- Single use only
- 20cc syringe with control switch to release the plunger, rotating handle, pressure gauge and high pressure connection with Luer lock rotary adapter
- PSI scale ranging from 0 - 30 atm (= bar)
- 100 cm extension tube



Intelligent ergonomics for
comfortable and safe handling

Combined Insertion Instrument

Art. No. 80-806-90



- For the insertion of catheters into the Eustachian tube
- 3 distal tilted attachments: 30°, 45°, 70°
- Defined advance = 35 mm
- Advance indicator with brake to prevent the catheter from entering the tympanum

Selection of angled attachments provide precise handling to suit diverse anatomic scenarios

Sterilization Basket for Combined Insertion Instrument

Art. No. 80-850-10

- Lid, band and segmentation
- Special rinsing module for cleaning of inner lumina
- Dimensions: 24.4 cm x 24.4 cm
- Material: stainless steel



Efficient cleaning and sterilizing – safe storage

Micro Endoscope

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 intervention via monitor

Insertion Instrument

Art. No. 80-806-99

- For inserting catheters into the Eustachian tube
- Defined advance = 35 mm
- Advance indicator with brake to prevent the catheter from entering the tympanum
- Compatible with micro endoscope (Art. No. 80-806-30) and insertion handle (Art. No. 80-806-50)



Precise instruments for exact positioning of the catheter

Insertion Handle

Art. No. 80-806-50

- For insertion of tube catheters into the Eustachian tube
- Rigid, 30° downward bend
- 3 mm outer diameter
- Total length: 170 mm
- Working channel: 1.2 mm
- Irrigation channel: 0.7 mm



Safe guidance and exact positioning of the balloon catheter

Sterilization Basket for Micro Endoscope, Insertion Handle and -Instrument

Art. No. 80-850-00

- Lid, band and segmentation
- Special rinsing module for cleaning of inner lumina
- Dimensions: 24.4 cm x 24.4 cm
- Material: stainless steel



Safety and stability during cleaning and storage

Tubomanometer

Art. No. TMM – including notebook (see next page)

System for examining the pressure equalization function of the Eustachian tube

With the application of excess pressure to 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 aim is to build up sufficient pressure in the nose and rhinopharynx which enables the tubomanometer to assess the delay between the pressure application and the opening of the Eustachian tube.

Deviations from standard values can be shown.

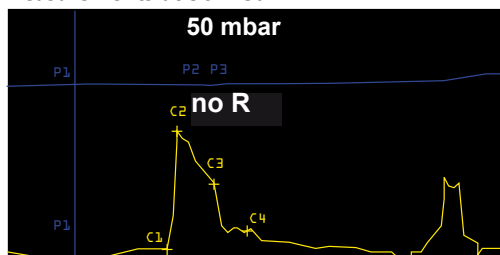


Preoperative tubomanometry

No pressure increase in the ear

$R = 0$ (obstructive tube dysfunction)

Measurements at 50 mbar



1

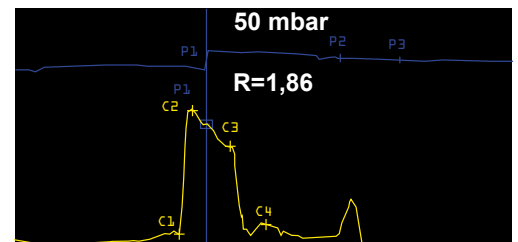
- 1) Ear measurement curve
- 2) Nasopharynx measurement curve

2

Postoperative tubomanometry

$R > 1$, normal increase in pressure with a slight delay, 2 months after tube dilation

Measurements at 50 mbar



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 at 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

Equipment Trolley

Art. No. 80-806-43

- Equipment trolley for tubomanometer and accessories
- Width 43 cm, height 107 cm
- 1 drawer
- 2 shelves
- Power distribution
- Central switch



State of delivery

Highest quality coupled with elegant design and sophisticated features

Tubomanometer (Art. No. TMM) consisting of:

- Tubomanometer, standard version
- High definition notebook with OS and software*
- 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)



*) Please contact our instrument sales team for details



Ear Plugs for Impedance Measurements

- For tubomanometry and tympanometry

Art. No.	Size	Diameter	Colour	Package size
0S01	1	6 mm	Purple	10 pieces / box
0S02	2	7 mm	Yellow	10 pieces / box
0S03	3	9 mm	Green	10 pieces / box
0S04	4	10 mm	Blue	10 pieces / box
0S05	5	11 mm	White	10 pieces / box
0S06	6	13 mm	Yellow	10 pieces / box
0S07	7	15 mm	Green	10 pieces / box
0S08	8	18 mm	Blue	10 pieces / box



Scale 1:2

Cleaning Brush

Art. No. 80-844-30

- With ring handle, working length 30 cm
- Brush \varnothing 2.0 mm, brush head length 10 mm for working channels up to 1.5 mm
- 10 pieces / box



Spiral Brush

Art. No. 80-844-40

- Tip 90 mm (without edging)
- Rounded ends, total length 45 cm
- Length of edging 7-9 mm, brush \varnothing 1.0 mm
- 10 pieces / box



We will gladly compile complete units to meet your specific requirements.
Please don't hesitate to contact us for further details.

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