Balloon Eustachian Tuboplasty – BET –

BET-Catheter

The new treatment for chronic tube dysfunction
Balloon Eustachian Tuboplasty

A new 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 damage to the middle ear structures, resulting in loss of hearing.

A pre-operative tubomanometry (TMM) is performed on the patients for a detailed assessment of tube functions in order to decide whether dilation is necessary. The treatment principle is similar to that of balloon dilation in vascular stenosis. It has also recently been established in the treatment of chronic obstructive sinusitis. Studies on balloon sinuplasty have proved 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.

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 a micro endoscope and carefully introduced into the tube, avoiding resistance.

Using the combined insertion instrument (Art.No. 80-806-90 / 80-806-91) and a rigid endoscope (4mm/30°), is an alternative to a micro endoscope. Once the balloon within the catheter is in position, a saline solution is injected at a pressure of up to 10 bar, causing dilation. The pressure is maintained for two minutes. The saline solution is then aspirated from the balloon. 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.
Pre-operative Diagnostics and Preparation

Pre-operative diagnostics:
- Thorough recording of the medical history; Valsalva
- Inspection and endoscopic examination of the nose and throat area
- CT / DVT of the petrosal bone
- Tympanometry
- Audiometry
- Eustachian tube manometry according to Estève

Pre-operative preparation includes:
- Decongestant nasal drops
- Endoscopic examination using a monitor with camera and documentation system
- Corresponding optics and a Xenon light source

Additional Instruments:
- Nasal specula
- Suction device
- Bayonet dressing forceps
- Mouth gag for pharyngeal access, if required

Application

Connect one of the three different distally angled attachments to the insertion instrument using the ring nut.

Take a sufficient amount of physiological saline solution into the piston of the inflation pump. Make sure that the pump’s reservoir contains virtually no air bubbles.

Lock the pump using the switch.

Carefully remove the balloon catheter from its protective tube. Remove the stabilising wire and the protective cap from the distal catheter part. Introduce the catheter into the insertion instrument making sure that the white shrink tube has been inserted completely. This way it is guaranteed that the balloon can only be inserted into the Eustachian tube to the defined length and does not damage the mucous membrane at the front, as it is completely contained in the instrument. During the operation, the balloon catheter is pushed forward within the insertion instrument.

Connect the inflation pump to the catheter – either prior to or during the operation.
Operating Procedures

Contra lateral Access

Insert the endoscopic camera into the nose just like a normal nose examination and localise the tubal ostium on the opposite side.

Now introduce the insertion instrument with the balloon catheter on the side to be treated, placing it within the ostium of the Eustachian tube.

Avoid entering the Rosenmüller's fossa.

Make sure that the distal part of the instrument is not inserted too far to avoid the catheter being pushed through to the bony part.

Now push the balloon catheter forward smoothly.

Connect the inflation pump with or without extension to the catheter. Now fill the catheter up to a pressure of 10 bar by performing a screwing movement on the inflation pump.

The balloon catheter will dilate the compromised area of the Eustachian tube. Maintain the pressure constant for 2 minutes.

Release the quick lock, relieve the pressure of the pump, and aspirate. The Eustachian tube will be diluted.

Remove the insertion instrument and catheter from the Eustachian tube.

Ipsilateral Access

With ipsilateral access, both the endoscopic camera and the balloon catheter are inserted through the same nostril. It should be noted here that the anatomical conditions should not be suited to such a procedure.

After positioning the catheter within the tubal ostium, the subsequent steps of dilatation are identical with the method of the contralateral access.

Pharyngeal Access

With pharyngeal access, the endoscopic camera is inserted through the oral cavity. Using this method, the tubal openings of both sides are well visible.

The balloon catheter is inserted endonasally on the side to be treated using the insertion instrument.

This access method has many advantages when there are difficult anatomical conditions within the nose.

After positioning the catheter correctly, the actual dilatation procedure is identical with the methods above.
The instruments for balloon dilatation of the Eustachian tube comprise a number of different components:

**Balloon Catheter**  
Art. No. 2080-1300320

- Balloon dilatation catheter with an inflatable balloon near the distal tip
- Single-use only
- Two x-ray contrast markers show the cylindrical part of the balloon on x-rays
- Luer-Lock adapter for inflation and deflation

**Inflation Pump**  
Art. No. 2080-9030020

- Inflation pump with extension tube for the inflation of catheter balloons
- Single-use only
- 20 ml 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 balloon catheter
- 100 cm extension tube
Combined Insertion Instrument  
Art. No. 80-806-90
- For the insertion of catheters into the Eustachian tube
- Includes three colour-coded distally angled attachments (30°, 45°, 70°)
- Advance indicator with brake to prevent the catheter from entering the tympanum

Combined Insertion Instrument  
Art. No. 80-806-91
- For the insertion of catheters into the Eustachian tube
- Includes three colour-coded distally angled tapered attachments (30°, 45°, 70°)
- Advance indicator with brake to prevent the catheter from entering the tympanum

Sterilization Basket  
Art. No. 80-850-10
- For combined insertion instrument and attachments
- Special rinsing module for cleaning of inner lumina
- Lid, bands and segmentations
- Dimensions: 24.4 cm x 24.4 cm
- Material: Stainless steel