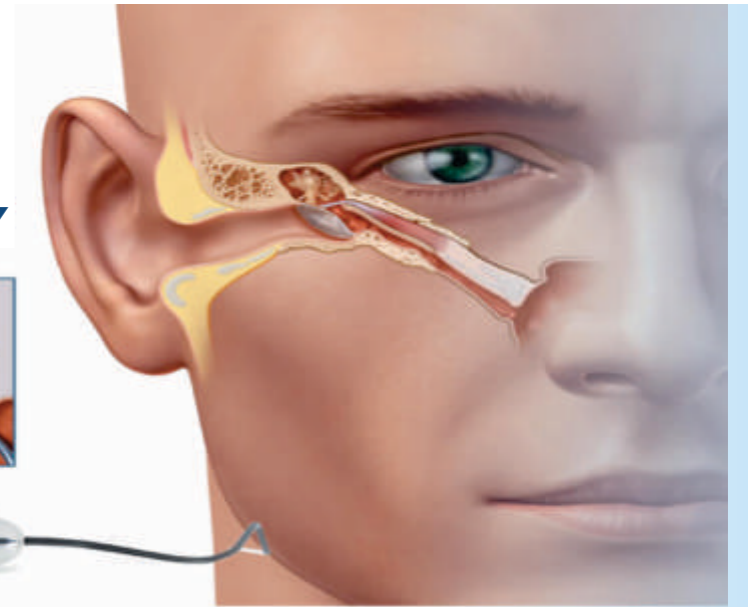
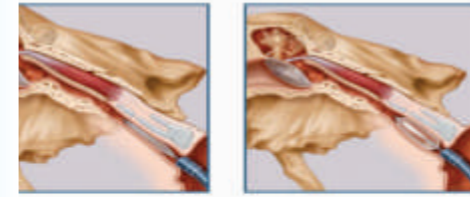


# TUBAVENT BALLOON EUSTACHIAN TUBOPLASTY



## 2019 Update for Balloon Dilatation of the Eustachian Tube



minimally invasive • safe • fast



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Spiggle & These devices are sold by or used on the order of a Physician only.



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The information is provided to assist you with what NEOMEDICAL understands to be the current status with regard to Balloon Dilatation of the Eustachian Tube. It is intended to assist in submitting patient Funder motivation and for potential Funder authorization reimbursement for Balloon Dilatation of the Eustachian Tube procedures. It is not intended to increase or maximize reimbursement by any Funder. All Funders have different Schemes, each Scheme has its own rules with regard to covering a patient for any healthcare procedures. The information contained in this document is provided for information purposes only and represents no statement, promise or guarantee by NEOMEDICAL concerning levels of reimbursement, payment or charge. Similarly, all surgical procedure codes are supplied for information purposes only and represent no guarantee by NEOMEDICAL that these codes will be appropriate or that Funder reimbursement will be made. The third-party trademarks used herein are trademarks of their respective owners. Please contact the NEOMEDICAL at 021-447-0881, solutions@neomedical.co.za if we be of any further assistance.

## 1. INTRODUCTION.

With an incidence of approximately 1% in the adult population alone, Eustachian Tube dysfunction places a significant burden on the health system<sup>1</sup>. Eustachian tube balloon dilatation is an evolving clinical application. Patient selection criteria, clinical indications, surgical techniques and management protocols are constantly being updated, changed and improved upon. We at Neomedical are keen to partner the ENT fraternity in keeping you abreast of current international trends, and we hope this brochure will be a small step in that direction.

Historically, previous generations of otolaryngologists<sup>1</sup> abandoned the idea of eustachian tube surgery due to its inherent risks and ineffectiveness, but at present, three significant developments have occurred that has changed the clinical landscape;

- < the first is that the understanding of the pathophysiology of the eustachian tube has evolved i.e. research suggesting that the nasopharyngeal end of the eustachian tube, not the proximal bony segment, is the site of the obstruction. Also, the revised concept of the middle ear as a "5th sinus"<sup>2</sup>, with the cartilaginous eustachian tube acting as a "valve"<sup>2</sup>.
- < secondly, in the modern era new endoscopic technology has allowed unprecedented optical appreciation of the Eustachian Tube
- < and thirdly, new tools for safely enlarging the eustachian tube opening have come to the fore—initially lasers and microdebriders (with limited results), and now success with micro balloon catheters for dilation of the cartilaginous portion of the incompetent Eustachian Tube.

Having been associated with Spiggle and Theis for more than 20 years, we have noted with encouragement the ongoing success and positive outcomes of balloon dilatation studies globally<sup>3,4,5,6,7</sup>. We have taken even more encouragement in the beneficial impact this is having on the quality of life of patients suffering with Eustachian Tube dysfunction, and the ability of the ENT Surgeon to achieve this.

With this in mind, we are making every effort to keep in contact with leading international clinicians and researchers in the field of BDET, and are hoping to partner with you in the future in bringing key opinion leaders in the field of Eustachian Tube dysfunction to South Africa, for future instructional courses and academic meetings.

We have also included in this brochure some practical guidelines we hope will help with the administrative issues relating to ETBD. Insurance industries and funders worldwide are awaiting final multicenter review input before issuing formal ICD-10 coding, as is the case with all new technologies. As the domestic funding industry tends to follow international guidelines, notably that of the managed care rulings in the United States, it is pertinent that the American Medical Association has stated that formal CPT coding is only scheduled for December 2020 / January 2021 for Eustachian Tube Balloon Dilatation.

1. Van Rompaey, V. et al. Value and discriminative power of the seven-item eustachian tube dysfunction questionnaire: Value and Discrimination. *The Laryngoscope*. April 2015. DOI: 10.1002/lary.25316
2. Poe, D.S. Revised Concepts Of Eustachian Tube Function (a presentation). AAO-HNS Annual Meeting & OTO Experience 2019. 123rd AAO-HNS Annual Meeting & OTO Experience. Date: 9/15/2019 - 9/18/2019. Venue: Ernest N. Morial Convention Center, New Orleans LA, United States.
3. Poe, D.S. Revised Concepts Of Eustachian Tube Function (a presentation). AAO-HNS Annual Meeting & OTO Experience 2019. 123rd AAO-HNS Annual Meeting & OTO Experience. Date: 9/15/2019 - 9/18/2019. Venue: Ernest N. Morial Convention Center, New Orleans LA, United States.
4. Poe, D.S. (Harvard ENT Dept), et al. Balloon Dilatation of the Eustachian Tube for Dilatory Dysfunction: A Randomized Controlled Trial. *Laryngoscope*. 2017, 00
5. Poe, D.S. (Harvard ENT Dept), et al. Balloon Dilatation of the Eustachian Tube: 12-Month Follow-up of the Randomized Controlled Trial Treatment Group *Otolaryngology—Head and Neck Surgery* 2019, 160 (4): 687-694
6. A. Leichtle, et al. Balloon Eustachian Tuboplasty in children. *European Archives of Oto-Rhino-Laryngology*. June 2017, Volume 274, Issue 6, pp 2411–2419.
7. Tisch, M. et al. Balloon dilation of the Eustachian tube: clinical experience in the management of 126 children. *ACTA OTORHINOLARYNGOLOGICA ITALICA* 2017;37:509-512; doi: 10.14639/0392-100X-1690

## 2. CLINICAL CONSENSUS STATEMENT: BALLOON DILATATION OF THE EUSTACHIAN TUBE

The American Academy of Otolaryngology and Neck Surgery recently published a set of clinical statements under indications for and appropriate use of Balloon Dilatation of the Eustachian Tube [BDET] for patients with obstructive eustachian tube dysfunction. Published on June 4th 2019 in the *Otolaryngology- Head and Neck Surgery Journal*<sup>8</sup> by a panel of experts in response to the increasing rate of use of this technology for eustachian tube dysfunction by otolaryngologists. The statement was intended to bring to attention the current state of the literature as interpreted by experts in the field.

The consensus statement offers 28 specific points of guidance categorized into 3 specific areas;

- i. Patient Criteria,
- ii. Perioperative Considerations,
- iii. Outcomes

In summary the patient criteria<sup>8</sup> was hoped to achieve consensus to achieve an accurate diagnosis of ETD prior to considering balloon dilatation, given the variable and non-specific symptoms that patients may present with. The panel also emphasized the need to be aware of associated pathology such as allergic rhinitis, rhinosinusitis and laryngeal reflux. If any of these co-morbid conditions are found the panel recommended treating them prior to offering balloon dilatation. The panel also emphasized the need for nasal endoscopy prior to balloon dilatation. The importance of tympanometry was also emphasized.

**Table 1 (i) Patient Criteria<sup>8</sup>**

1	A comprehensive history and physical exam, including otoscopy are essential parts of the diagnostic evaluation of a candidate for BDET
2	Nasal endoscopy is an essential part of the diagnostic evaluation prior to BDET
3	BDET is contraindicated for patients diagnosed as having patulous ETD
4	Nasal endoscopy in patients who are candidates for BDET is necessary for assessing ET lumen and assessing the feasibility of transnasal access to nasopharynx
5	A diagnosis of patulous ETD is suggested symptoms of autophony of voice, audible respirations, pulsatile tinnitus
6	The benefit of repeat BDET after a prior ineffective BDET has not been determined
7	Symptoms of obstructive ETD can include aural fullness, aural pressure, hearing loss and otalgia
8	Tympanometry is an essential part of the diagnostic evaluation prior to BDET
9	Establishing a diagnosis of obstructive ETD requires ruling out other causes of aural fullness such as patulous ETD, temporomandibular joint disorders, extrinsic obstruction of ET, superior semicircular canal dehiscence, and endolymphatic hydrops
10	Patient-reported symptom scores alone are insufficient to establish a diagnosis of ETD
11	Nasal endoscopy is necessary to rule out extrinsic causes of ETD
12	Comprehensive audiometry is an essential part of the diagnostic evaluation prior to ETD
13	BDET is appropriate in patients with obstructive ETD who have failed medical therapy for identified treatable causes
14	Common causes of obstructive ETD that benefit from identification and management are allergic rhinitis, rhinosinusitis and laryngopharyngeal reflux
15	Medical management of known pathology that could affect nasal or ET function is appropriate to perform prior to BDET
16	Patients with a history of recurrent barochallenge, defined as uncomfortable pressure in the ear upon exposure to ambient pressure changes that cannot be easily relieved, may improve following BDET
17	There are no scientifically proven or standard medical therapy for ETD
18	Pneumatic otoscopy can identify negative pressure in the middle ear space and can be different between adhesive and nonadhesive retractions of the tympanic membrane

**Abbreviations : BDET – Balloon Dilation of the Eustachian Tube. ET – Eustachian Tube. ETD – Eustachian Tube Dysfunction.**

8. Tucci, D.L., et al. American Academy of Otolaryngology-Head and Neck Surgery FOUNDATION; Clinical Consensus Statement: Balloon Dilatation of the Eustachian Tube. 2019, Vol. 161(1), 6-17.

For the *Perioperative Considerations*<sup>9</sup>, the following points were confirmed:

**Table 2 (ii) Perioperative Consideration<sup>10</sup>.**

19	Patients undergoing BDET concurrent with sinus ostial dilation should meet the same diagnostic criteria for BDET as those undergoing BDET alone
20	Potential risks of BDET that are relevant to patient counseling include bleeding, scarring, infection, development of patulous ETD and/or the need for additional procedures
21	Myringotomy with or without tympanostomy tube replacement is not a mandatory prerequisite for BDET
22	A dehiscent carotid artery identified on imaging is a contraindication to use of a device without a depth marker that demarcates insertion into the cartilaginous Eustachian Tube
23	Patients with a middle ear effusion at the same time of BDET may benefit from concurrent myringotomy with or without tympanostomy tube replacement
24	BDET is an alternative to tympanostomy tube replacement for obstructive ETD
25	Failure to relieve symptoms despite a functioning myringotomy or tympanostomy tube suggests a diagnosis other than obstructive ETD

**Abbreviations : BDET – Balloon Dilation of the Eustachian Tube. ET – Eustachian Tube. ETD – Eustachian Tube Dysfunction.**

9. Tucci, D.L., et al. American Academy of Otolaryngology-Head and Neck Surgery FOUNDATION; Clinical Consensus Statement: Balloon Dilatation of the Eustachian Tube. 2019, Vol. 161(1), 6-17.

10. Statements are ordered according to mean value for the 9-point Likert scale of agreement with the statement obtaining the highest amount of agreement listed first.

11. The TubaVent device from Spiggle & Theis is collaborated for safety; the length of delivery of the micro balloon inflation catheter into the ET is restricted both by the length of the actual catheter and by the design of the inserter instrument. Both these checks, under normal anatomical conditions, prevent the catheter from approaching the isthmus of the ET.

Concluding with reached consensus on *Outcomes*<sup>12, 13</sup>:

**Table 3 (iii) Outcomes.**

26	Patient-reported symptoms scores are useful in assessing baseline ETD symptoms and treatment outcomes
27	The ability to perform a modified Valsalva is appropriate for assessing outcomes after BDET
28	Change in patient -reported symptom scores is appropriate for assessing outcome following BDET

**Abbreviations : BDET – Balloon Dilation of the Eustachian Tube. ET – Eustachian Tube. ETD – Eustachian Tube Dysfunction.**

12. Statements are ordered according to mean value for the 9-point Likert scale of agreement with the statement obtaining the highest amount of agreement listed first.

13. Tucci, D.L., et al. American Academy of Otolaryngology-Head and Neck Surgery FOUNDATION; Clinical Consensus Statement: Balloon Dilatation of the Eustachian Tube. 2019, Vol. 161(1), 6-17.

## 3. CLINICAL INDICATIONS FOR BDET<sup>14</sup>

- Chronic (>3months) OME
- Atelectatic changes on otoscopy- except adherent atelectasis
- Type B or C tympanometry
- Eustachian tube pathology noted on dynamic endoscopic examination
- Flight or scuba diving discomfort / barochallenge

## 4. POST OPERATIVE INSTRUCTIONS<sup>14</sup>

- No nose blowing for 1 week
- Start modified Valsalva at 1 week- to do hourly while
  - a. Occluding nostrils
  - b. Gently blowing nose
  - c. If unable to perform modified Valsalva, to try a strong swallow while gently blowing nose
- Keep nose humidified as desired
- Continue medical management as indicated; a) Allergy, b) Sinusitis, c) Reflux

14. Poe, D.S. Revised Concepts Of Eustachian Tube Function (a presentation). AAO-HNS Annual Meeting & OTO Experience 2019. 123rd AAO-HNS Annual Meeting & OTO Experience. Date: 9/15/2019 - 9/18/2019. Venue: Ernest N. Morial Convention Center, New Orleans LA, United States.

\* Should you wish to read the complete article, please contact NEOMEDICAL 021-447-0881, we will provide you with a copy.

## 5. SOUTH AFRICAN ENT SOCIETY CPT BILLING GUIDE FOR BDET<sup>15</sup>

As an example of a private healthcare funder, Discovery has agreed to 99 units for Eustachian Tube Dilatation (ETD) with the following guidelines. Note that some funds may not recognise ETD: code 1105 plus 1052 (with 0069) with rule C may be used in these circumstances.

### 3213 : Bilateral myringotomy with insertion of bilateral ventilation tube : 65

The normal post-operative aftercare period for the insertion of grommets (items 3211, 3212 and 3213) is 10 days. Modifier 0005 does not apply to items 3211, 3212 and 3213 when performed with tonsillectomy (item 1101) and/or adenoidectomy (item 1105)

### 6999 : Eustachian tube dilatation unilateral or bilateral : 99

Use codes 1105 plus 1052 (with modifier 0069) with Rule C as there is currently no code for this procedure.

The following indications and rules apply:

1. Recurrent Adhesive Otitis Media with failure of appropriate medical and surgical (including Grommets and Adenoidectomy) treatment.
2. Recurrent Mucous Otitis Media after Adenoidectomy (Over 7 years of age).
3. May be performed in combination with grommet insertion following failed previous grommets (Adults and Children older than 7 years).

**NB: funds may require a report detailing indication/s for the procedure \*.**

15. Email from: "ENT Society" admin@entsociety.co.za Subject: Eustachian Tube Dilatation. Date: 20 March 2019 at 15:12:50.\*Please see section '6', for an example of an example draft Patient motivation form.

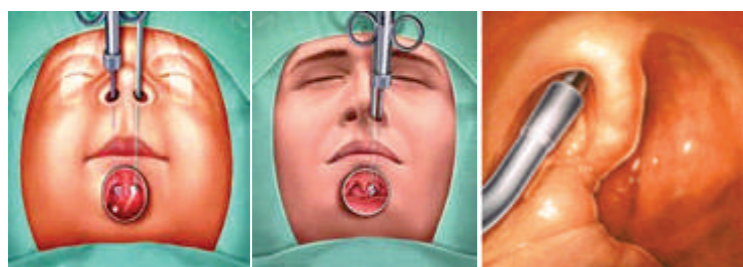
## 6. RECOMMENDED ICD-10 CODES TO BE APPLIED

The table below describes the ICD-10 codes that may apply to Eustachian Tube micro balloon dilation;

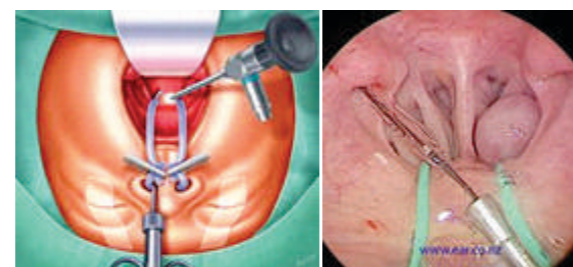
ICD-10 Diagnostic Codes	
ICD-10	
H69.80	Other Specified Disorder of Eustachian Tube, Unspecified Ear
H69.81	Other Specified Disorder of Eustachian Tube, Right Ear
H69.82	Other Specified Disorder of Eustachian Tube, Left Ear
H69.83	Other Specified Disorder of Eustachian Tube, Bilateral

Figure 1 series : Transnasal Endoscopic Approach;

Figure 2 series : Trans Oral Pharyngeal Approach;



1a. Contralateral access. 1b. Ipsilateral access. 1c. Catheter insertion instrument at ET ostia (RH), viewed via pharyngeal access into



2a. Rigid Sinus Scope pharyngeal access superior and catheter instrument transnasal access. 2b. Image shows the catheter inserter instrument with pharyngeal access into the PNS, alternative to that shown in image 2a.

## 7. EUSTACHIAN TUBE DYSFUNCTION QUESTIONNAIRE ( ETDQ-7)

The ETDQ-7 is a disease specific instrument for the assessment of patient reported severity of ETD.

- Scores are reported on a scale from 1-7.
- The higher score indicates more severe symptoms.
- The total score is divided by the number of items (7) to give an overall score ranging from 1-7.
- The difference between preoperative and postoperative scores yields a change score that is used to report outcomes.
- Before the ETDQ-7, the SNOT 22 was used as a comparison measure because of the observed comorbidity of sinonasal disease with ETD<sup>16</sup> ETDQ.

The ETDQ-7 questionnaire can be a useful disease specific rating scale for ET dysfunction though we should remain aware that this questionnaire may be unable to accurately discriminate patients suffering from obstructive ET dysfunction, or patulous ET<sup>17</sup>. A complimentary booklet of ETDQ-7 questionnaires has been provided for your convenience.

## Eustachian Tube Dysfunction Questionnaire: (ETDQ-7)

Name: .....

Date: .....

This questionnaire is a validated and reliable symptom score for the diagnosis of adult patients with ETD

Its purpose is to facilitate clinical practice by highlighting the symptoms associated with ETD.

Over the past 1 month, how much has each of the following been a problem for you?	No Problem		Moderate Problem		Severe Problem		
	1	2	3	4	5	6	7
1. Pressure in the ears?	1	2	3	4	5	6	7
2. Pain in the ears?	1	2	3	4	5	6	7
3. A feeling that your ears are clogged or "under water"?	1	2	3	4	5	6	7
4. Ear symptoms when you have a cold or sinusitis?	1	2	3	4	5	6	7
5. Cracking or popping sounds in the ear?	1	2	3	4	5	6	7
6. Ringing in the ears?	1	2	3	4	5	6	7
7. A feeling that your hearing is muffled?	1	2	3	4	5	6	7

16. McCoul, E.D. et al. Eustachian Tube balloon dilation surgery. International Forum of Allergy & Rhinology. Vol 2, 191-198

17. Van Rompaey, V. et al. Value and discriminative power of the seven-item eustachian tube dysfunction questionnaire : Value and discriminative. The Laryngoscope, April 2015 DOI:10.1002/lary.25316

## 8. DRAFT PATIENT MOTIVATION FORM\*

.....SURGICAL PRACTICE LETTER HEAD.....

*Micro Balloon Dilation*

*To Whom it may concern.*

*Date :*

*RE :*

*Date Of Birth :*

*ICD-10 Diagnostic Codes;*

*H69.80 Other Specified Disorder of Eustachian Tube, Unspecified Ear*

*H69.81 Other Specified Disorder of Eustachian Tube, Right Ear*

*H69.82 Other Specified Disorder of Eustachian Tube, Left Ear*

*H69.83 Other Specified Disorder of Eustachian Tube, Bilateral*

*This is to confirm that the above patient has presented to me with ongoing symptoms / signs of chronic Eustachian Tube dysfunction. Conservative therapy has failed to resolve the problem and the patient shows signs of ongoing symptoms / pathology.*

*In the light of this, I have recommended that the patient undergo a Eustachian Tube micro balloon dilatation, which is a non-invasive procedure directed at treating the underlying cause of the clinical problem. I refer you to the publications as listed below. The procedure will include codes 1105, 1052 (with modifier 0069). Rule C applies. The medical device BDET procedure Kit nappi codes of 255219001 or 256903001 may apply.*

*A pre-operative CT scan may be necessary.*

*Related articles;*

*ACTA OTORHINOLARYNGOLOGICA ITALICA 2017;37:509-512; doi: 10.14639/0392-100X-1690*

*Otology*

***Balloon dilation of the Eustachian tube: clinical experience in the management of 126 children***

*M. TISCH, H. MAIER, H. SUDHOFF*

*The Laryngoscope DOI: 10.1002/lary.26827*

*VC 2017 The American Laryngological,*

*Rhinological and Otological Society, Inc.*

***Balloon Dilation of the Eustachian Tube for Dilatory Dysfunction: A Randomized Controlled Trial***

*Dennis Poe, MD, PhD*

*Otolaryngology—Head and Neck Surgery 2019, 160 (4):*

***Balloon Dilation of the Eustachian Tube: 12-Month Follow-up of the Randomized Controlled Trial Treatment Group***

*Dennis Poe (Harvard ENT Dept), et al*

*Sincerely,*

***SPECIALIST ENT SURGEON :***

*Dr..... (ORL) SA*



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\*Please contact Graham clinical@neomedical.co.za for an electronic copy of the example draft patient motivation form for BDET.