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BUREAU OF INDIAN STANDARDS

DRAFT FOR COMMENTS ONLY

भारतीय मानक मसौदा

ग्रोमेट – विशिष्टि

Draft Indian Standard

Grommet – Specification

[ICS 11.040.30]

Ear, Nose and Throat Surgery Instruments Sectional Committee, MHD 04

Last date for comments: 21 November, 2023

FOREWORD

(Formal clause will be added later)

The standard provides requirements for Grommet used in Ear surgery. Grommets or myringotomy tubes work with formation of a conduit channel between the middle ear and the external auditory canal through the axial lumen of the device and help in ventilation of the middle ear in pathologies where the inherent ventilatory mechanism of ear is hampered. The standard applies to various types of Grommets including Shah, Shepard, Mini Shah, T-Tube (Long 12 mm).

For the purpose of deciding whether a particular requirement of this standard is complied with the final value, observed or calculated, expressing the result of a test or analysis shall be rounded off in accordance with IS 2: 2022 ‘Rules for rounding off numerical values (*second revision*)’. The number of significant places retained in the rounded off value should be same as that of the specified value in this standard.

1 SCOPE

The standard specifies the requirements for Grommet used in ear surgeries primarily for Otitis media with effusion. The Grommet can also be used in acute otitis media and early stages of adhesive otitis media.

2 REFERENCES

No standards are referred in this text.

3 TERMS & DEFINITIONS

3.1 Grommet

Grommet, also known as myringotomy tube, is primarily a device with an axial lumen two flanges on both sides to hold it onto the tympanic membrane.

4 REQUIREMENTS

4.1 General

The Grommet shall have smooth contours. The colour should be White or Blue, distinct from natural ear pathology, for optimum contrast and visibility.

4.2 Material

The material shall be Fluoroplastic or silicone elastomer. It shall be resistant to bacterial or fungal growth.

4.3 Performance Evaluation

4.3.1 Shall be chemically inert, biocompatible, and free from latex or phthalate (DEHP).

4.3.2 Should be introduced and removed using standard surgical instruments.

4.3.3 T-Tube options may be easily shortened by scissors or scalpel blade if required.

5 PACKAGING

5.1 Shall be supplied sterile in a moulded plastic cassette, and single-wrapped in a peel pouch.

5.2 Accompanying documents, if any may be provided.

6 MARKING

6.1 The product shall be marked with the manufacturer’s name, initials or registered trade-mark.

6.2 BIS Certification Marking

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the *Bureau of Indian Standards Act, 2016* and the Rules and Regulations framed thereunder, and the product(s) may be marked with the Standard Mark.