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DRAFT FOR COMMENTS ONLY

भारतीय मानक मसौदा

कर्ण अस्थि पुनर्निर्माण कृत्रिम अंग – सामान्य आवश्यकताएं

Draft Indian Standard

Ossicular Reconstruction Prosthesis- General Requirements

ICS:11.040.30

Ear,Nose and Throat , Head & Neck Surgery Instruments Sectional Committee , MHD 04

Last date for Comment: **10 Aug 2024**

FOREWORD

(Formal clause will be added later)

The standard provides requirements for Partial and Total Ossicular Reconstruction Prosthesis (PORP and TORP). These devices are primarily intended for reconstruction of hearing mechanism. TORP works by forming a bridge between the tympanic membrane and the footplate of stapes to conduct sound waves. PORP works by forming a bridge between the tympanic membrane and the remaining viable part of the ossicular chain to conduct sound waves.

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 Ossicular Reconstruction Prosthesis used in ear surgeries when there exists an ossicular discontinuity or defect due to disease, trauma, any congenital absence or deformity of the ossicles present within the middle ear.

2 REFERENCES

No standards are referred in this text.

3 TERMS & DEFINITIONS

3.1 TORP

TORP or Total ossicular reconstruction prosthesis is a device that forms a replacement ossicle present within the ear in cases where no ossicles are present due to the disease process or had to be removed during the surgery.

3.2 PORP

PORP or Partial Ossicular Reconstruction Prosthesis is a device that forms a replacement ossicle present within the ear in cases where there exists partial loss or destruction of ossicles due to disease or surgical removal.

4 REQUIREMENTS

4.1 General

4.1.1 Should be introduced and removed using standard ear surgery instruments.

4.1.2 A cutter should be provided for resizing the TORP as an integral part.

4.2 Material

4.2.1 Should be chemically inert and biocompatible.

4.2.2 Shall have smooth contours.

4.2.3 Shall be resistant to bacterial or fungal growth.

5 TYPES

5.1 Titanium Fixed length

5.2 Titanium Variable Length

5.3 Malleus Notch Prosthesis

5.4 Malleus Replacement Prosthesis

5.5 Titanium Clip Partial Prosthesis

5.6 Titanium Clip Flexible Prosthesis

5.7 Titanium Angular Prosthesis

5.8 Adjustable Titanium Implants with HAP Cap

5.9 HA Partial incus prosthesis

6 PACKAGING

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

6.2 Accompanying documents, if any may be provided.

7 MARKING

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

7.2 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.