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भारतीय मानक मसौदा

ओटोलॉजी ड्रिल

Draft Indian Standard

Otology Drill

[ICS 11.040.99]

Ear, Nose, Throat and Head & Neck Surgery Instruments, Sectional Committee (MHD 04)	Last date for comments: **11 Aug 2024**

FOREWORD

(Formal clause will be added later)

This Indian Standard outlines the fundamental functional criteria for an 'Otology drill'. It is engineered for the purpose of delicately drilling and reshaping bone within the ear region through the high-speed rotation of a specialized bur using straight or angled hand piece attachments during ENT surgical procedures.

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.

Indian Standard

OTOLOGY DRILL

1 SCOPE

This Indian Standard provides general functional requirements of an otology drill system. The otology drill is a powered handheld device that can be used to work on bone at various speeds. It applies to otology drill hand engines capable of accommodating straight or angled hand piece attachment, which fixes burs of various sizes and materials for each application.

The speed, torque, and direction is controlled by the power console with a variable foot control unit. The otology drill power console device can support an irrigation system to reduce thermal damages to the bones (thermal necrosis).

2 REFERENCES

The standards given below contain provisions, which, through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of these standards.

IS No./ Other Publication	***Title***
IS 13450 (Part 1): 2018 /IEC 60601-1 2012	Medical Electrical Equipment: (Part 1) General Requirements for Basic Safety and Essential Performance *(second revision)*
IS 13450 (Part 1/Sec 2): 2018 / IEC 60601-1-2: 2014	Medical Electrical Equipment: (Part 1) General Requirements for the Basic Safety and Essential Performance Section 2 Collateral standard: Electromagnetic disturbances — Requirements and tests *(first revision)*
IS 62366 : (Part 1) : 2015/IEC 62366-1:2015	Medical devices — Part 1: Application of usability engineering to medical devices
IS/ISO 14971:2019	Medical devices — Application of risk management to medical devices
IS 15223 : (Part 1) : 2016/ ISO 15223-1: 2021	Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied — (Part 1): General requirements
IS/ISO 10993 : Part 1 : 2009/ISO 10993-1:2018	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process

3 TERMS AND DEFINITIONS: -

For the purpose of this standard, the following terms and definitions shall apply

3.1 Micro motor Hand Engine: It is a powered handheld device that operates at high speed up to 80,000 rpm in forward/reverse directions and can be used to drill bones during ENT surgeries.

3.2 Power Console: It provides power to the attached otology drill/micro motor hand engine (3.1) to drive various rotating burs (3.5).

3.3 Foot Control Unit: It is used to control the speed of the otology drill/micro motor hand engine (3.1) also, the direction can be controlled.

3.4 Hand piece: It is used as the bridge between the otology drill/micro motor hands engines (3.1) used to operate a bur (3.5) at variable speed. There are two types of hand pieces, Straight and Contra (Angled) hand pieces.

3.5 Burs: The rotary Bone Undercutting Reamer (BUR) is used with a continuous rotation in a hand piece (3.4) attachment. It is used for drilling and reshaping bone within the ear region during surgical procedures.

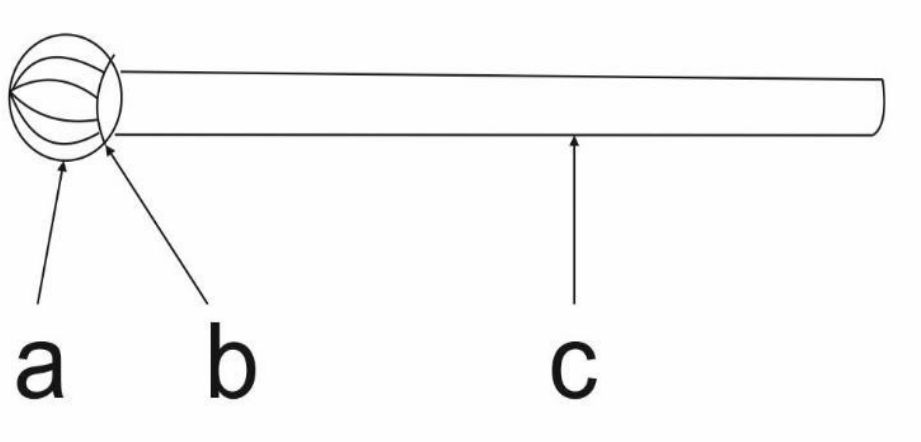

Figure 1. — Designation of bur parts

Key

a) working part

b) neck

c) shank

It consists of working part, neck (if applicable) and shank (3.6), which is constructed to fit into a handpiece (3.4)

Note 1 to entry: This includes continuous rotary bur.

Note 2. to entry: See Figure 1.

3.6 Shank: part of the shaft of a bur (3.5) used in ENT which is designed to fit into the chuck of a hand piece (3.4) or a hand piece for laboratory use

3.7 Irrigation Pump: It is used as a coolant to reduce the heat of the burning tissues or bone when the burs are rotating at very high speed.

3.8 Irrigation Nozzle: It is used to flow the saline on the bur (3.5)

4 GENERAL REQUIREMENT

4.1 The Otology Drill shall be used by the trained ENT Surgeons in a suitable healthcare facility environment.

4.2 General Requirements for Basic Safety and Essential Performance of the otology drill shall be compliant to IS 13450 (Part 1).

4.3 Each part of the otology drill shall be made from materials of suitable strength and shall be suitably finished.

4.4 Coating and plating on each part shall be durable to resist discoloration, wear and corrosion,

4.5 The otology drill should be compatible with both straight and angled hand piece attachments, allowing flexibility in its use.

4.6 The burs shall be sterilizable.

4.7 The device shall be user-friendly in shape, size and weight ensuring it is easy to handle and carry for user convenience.

4.8 User instructions with warnings, precautions and notes shall be provided

5 Functional requirement:

The essential parts of the device shall meet the following requirements:

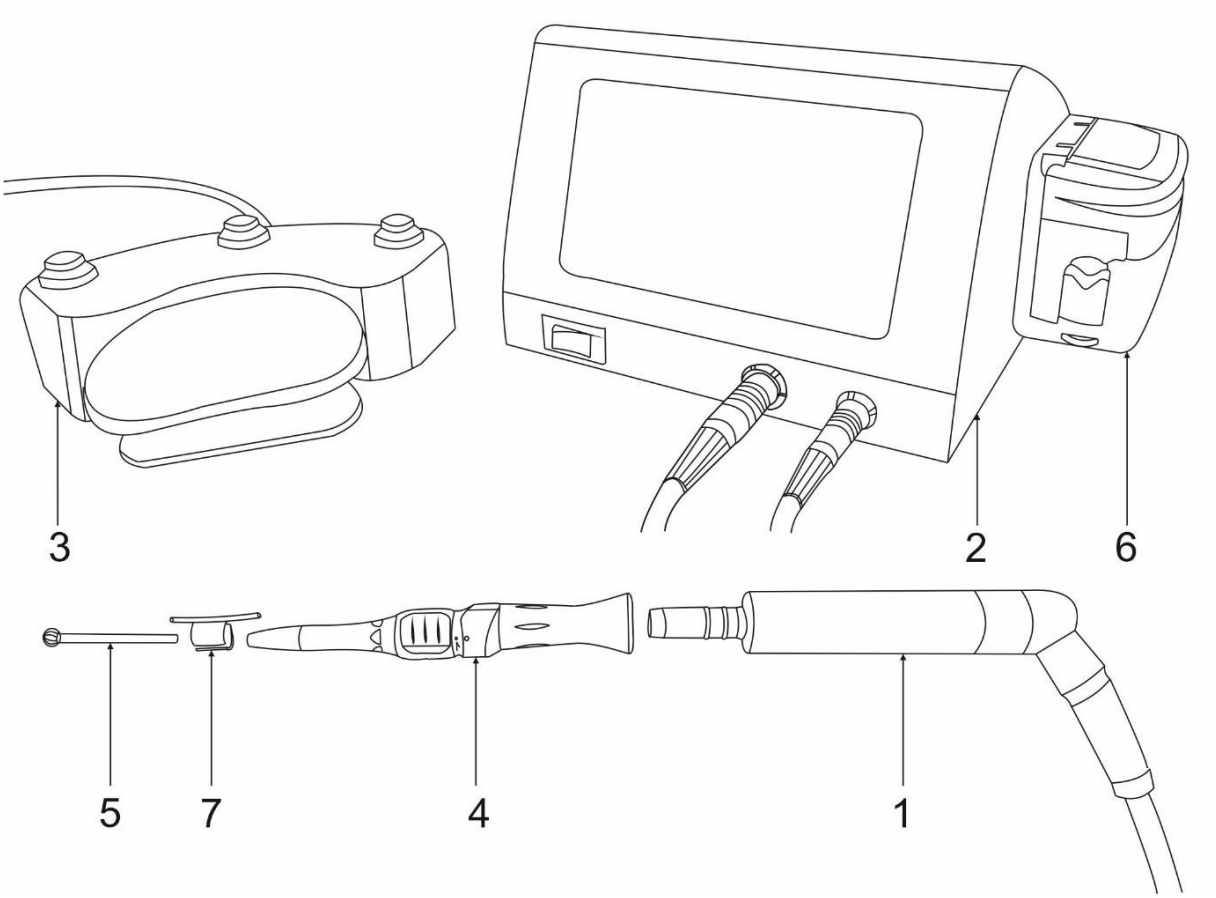

Figure 2. — Illustrative sketch of Otology Drill System

Key

1	Micro motor Hand Engine	5	Bur
2	Power Console	6	Irrigation Pump
3	Foot Control Unit	7	Irrigation Nozzle
4	Hand Engine Attachment		

5.1 Micro motor Hand Engine:

The powered hand engine body shall have a rigid enclosure to house the motor and wires.

5.1.1 The hand engine shall be convenient to hold and use to give adequate comfort and grip to the surgeon.

5.1.2 It shall have the provision to attach the straight/angled hand piece attachment.

5.1.3 The hand piece attachments shall lock properly with the hand engine

5.1.4 The materials of the hand engine shall not get rusted and to be cleaned easily.

5.1.5 The diameter of the hand engine shall be between 10mm to 18mm

5.1.6 The length of the hand engine shall not be too long, to avoid hitting the microscope

5.1.7 The cable length of the hand engine should not be less than 2.5 Meters and shall be easily detachable from the console.

5.2 Power Console:

5.2.1 The device shall comply with the general and electromagnetic compatibility requirements of IS 13450 (part 1) / IEC 60601-1 and IS 13450 (part 1 / Sec 2)/ IEC 60601-1-2.

5.2.2 It should have an equipotential connector to avoid electric shock to the patient or its User/Surgeon.

5.2.3 The power console shall have a universal power input.

5.2.4 The power console shall have a user interface to set the desired speed and direction.

5.2.5 When the motor is running in reverse direction the surgeon should be notified with indication on the console or sound.

5.2.6 The device shall not produce any electrostatic discharge while connected to the power or its accessories**.**

5.3 Foot Control Unit:

5.3.1 The foot control shall have ingress protection of minimum IPX1.

5.3.2 The motor speed can be controlled by variable speed foot control.

5.3.3 The cable length of the foot control unit should not be less than 2.5 Meters.

5.4 Hand piece Attachment – Straight/Angled:

5.4.1 The hand piece which runs above 40,000 rpm shall have an irrigation nozzle provision.

5.4.2 It shall support different sizes and shapes of burs.

5.4.3 Locking and unlocking indication should be clearly mentioned in the attachment

5.5 Bur:

5.5.1 The bur shall be made of high-grade materials like stainless steel, tungsten carbide and diamond

5.5.2 The package of the bur should mention the bur size, description and number of usages.

5.6 Irrigation Pump:

5.6.1 The micro motor hand engine which runs more than 40,000 rpm shall have an inbuilt irrigation pump.

5.6.2 The irrigation pump should have a warning label and hand crush label on or near the irrigation pump. Accessories:

6 TEST

6.1 IS 13450 (Part 1): 2018 / IEC 60601-1 2012**.**

6.2 IS 13450 (Part 1/Sec 2): 2018 / IEC 60601-1-2**:** shall apply.

7 MARKING

7.1 Each Otology Drill system must be labeled with the following information:

a) Manufacturer's name/ trademark,

b) Name and address of the manufacturer,

c) Name and address of the marketer,

d) Month and year of manufacture,

e) Unique Device Identification (UDI) / serial number

7.2 BIS CERTIFICATION MARKING

The product(s) that meet the requirements of this standard can be certified through the conformity assessment schemes under the Bureau of Indian Standards Act, 2016, and the associated Rules and Regulations. Once certified, the product(s) can be marked with the Standard Mark as an indication of compliance.

The marketing of otology drills must be accurate and truthful. It must not make any false or misleading claims about the safety or effectiveness of the drill.

8 PACKING

The device and its accessories must be securely packed within a case or box to ensure that they remain intact and protected during storage and transportation.

9.1 The case for the device should be constructed from a suitable material and designed in a manner that, when the device and accessories are well protected. This ensures that the contents remain secure and protected during storage and transportation.

9.2 Drop Test after packing

The packed device, when subjected to a drop from a height of 1.5 meters onto a hard Surface, should exhibit no signs of damage and continue to operate satisfactorily after the test. This demonstrates its ability to withstand potential impacts during handling and transportation.