Doc: MHD02(25920)WC

#### **BUREAU OF INDIAN STANDARDS**

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### भारतीय मानक मसौदा

### सर्जरी के लिए प्रत्यारोपण - कॉर्टिकल अस्थि मॉडल के रूप में उपयोग के लिए सामग्री की परीक्षण विधियाँ

#### Draft Indian Standard

# Implants for surgery — Test methods of material for use as a cortical bone model

ICS 11.040.40

Orthopaedic Instruments, Implants and Accessories Sectional Committee, MHD 02

Last date for comments: 20 July 2024

#### NATIONAL FOREWORD

(Adoption clause will be added later)

The text of ISO Standard has been approved as suitable for publication as an Indian Standard without deviations. Certain terminologies and conventions are, however, not identical to those used in Indian Standards. Attention is particularly drawn to the following:

- a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'.
- b) Comma (,) has been used as a decimal marker, while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards, which are to be substituted in their places, are listed below along with their degree of equivalence for the editions indicated:

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		Degree of
International Standard	Corresponding Indian Standard	Equivalence
ISO 179-1:2023 Plastics — Determination of Charpy impact properties — Part 1: Non- instrumented impact test	IS 13360 (Part 5/Sec 5): 2017 ISO 179-1: 2010 Plastics - Methods of testing: Part 5 mechanical properties section 5 determination of charpy impact properties - Non - Instrumented impact test (First Revision)	Identical
ISO 180 Plastics — Determination of Izod impact strength	IS 13360 (Part 5/Sec 4): 2021 Plastics - Methods of Testing Part 5: Mechanical Properties Sec 4 Determination of Izod Impact Strength	Identical
ISO 527-1:2019 Plastics — Determination of tensile properties — Part 1: General principles	IS 13360 (Part 5/Sec 1): 2021 ISO 527-1: 2019 Plastics - Methods of testing: Part 5 Mechanical properties Section 1 Determination of tensile properties - General requirements Second Revision	Identical
ISO 527-2:2012 Plastics — Determination of tensile properties — Part 2: Test conditions for moulding and extrusion plastics	IS 13360 (Part 5/Sec 2): 2017 ISO 527-2: 2012 Plastics - Methods of testing: Part 5 mechanical properties section 2 determination of tensile properties - Test conditions for moulding and extrusion plastics (First Revision)	Identical
ISO 527-3:2018 Plastics — Determination of tensile properties — Part 3: Test conditions for films and sheets	IS 13360 (Part 5/Sec 3): 2022 ISO 527-3: 2018 Plastics Method Of Testing Part 5 Mechanical Properties Section 3 Determination Of Tensile Properties Test Conditions For Films And Sheets	Identical
ISO 527-4:2023 Plastics — Determination of tensile properties — Part 4: Test conditions for isotropic and orthotropic fibre-reinforced plastic composites	IS 13360 (Part 5/Sec 25): 2004 ISO 527-4 Plastics - Methods of testing: Part 5 mechanical properties section 25 determination of tensile properties - Test conditions for isotropic and orthotropic fibre - Reinforced plastic composites	Identical
ISO 527-5:2021 Plastics — Determination of tensile properties — Part 5: Test conditions for unidirectional fibre-reinforced plastic	IS 13360 (Part 5/Sec 26): 2023 ISO 527-5: 2021 Plastics Methods Of Testing Part 5 Mechanical Properties Section 26 Determination Of Tensile	Identical

composites	Properties Test Conditions For Unidirectional Fibre-Reinforced	
	Plastic Composites	
ISO 604 Plastics —	IS 13360 (Part 5/Sec 8): 2013	Identical
Determination of compressive	ISO 604 : 2002 Plastics - Methods	
properties	of testing: Part 5 mechanical	
	properties section 8 determination	
	of compressive properties (First	
	Revision)	
ISO 7500-1, Metallic materials —	IS 1828 (Part 1): 2022	Identical
Calibration and verification of	ISO 7500-1 : 2018 Metallic	
static uniaxial testing machines —	Materials - Calibration And	
Part 1: Tension/compression	Verification Of Static Uniaxial	
testing machine — Calibration	Testing Machines - Part 1:	
and verification of the force-	Tension/Compression Testing	
measuring system	Machines - Calibration And	
	Verification Of The Force-	
	Measuring System	

The technical committee responsible for the preparation of this standard has reviewed the provisions of following mentioned International Standards and has decide that they are acceptable for use in conjunction with this standard:

International Standard/	Title
Other Publication	
ISO 179-2:2020	Plastics — Determination of Charpy impact properties — Part
	2: Instrumented impact test
ISO 291	Plastics — Standard atmospheres for conditioning and testing
ISO 2039-2	Plastics — Determination of hardness — Part 2: Rockwell
	hardness
ISO 2602	Statistical interpretation of test results — Estimation of the
	mean — Confidence interval
ISO 18397	Dentistry — Powered scaler
ASTM D256	Standard Test Methods for Determining the Izod Pendulum
	Impact Resistance of Plastics
ASTM D638	Standard Test Method for Tensile Properties of Plastics
ASTM D695	Standard Test Method for Compressive Properties of Rigid
	Plastics
ASTM F543-07	Standard Specification and Test Methods for Metallic Medical
	Bone Screws
JIS T 5750	Dentistry — Dental Handpieces — Ultrasonic Instruments
	And Tips For Multi-purpose Treatment

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)'.

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**Note:** The technical content of the document has not been included as it is identical with the corresponding ISO standard. For details, please refer to ISO 19213: 2017 or kindly contact:

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#### **SCOPE**

This document specifies mechanical test methods for characterizing cortical bone model materials for use as a standard model for performing mechanical tests for devices or instruments used in orthopaedic surgery, plastic surgery, neurosurgery, and oral and maxillofacial surgery.

The document specifies static mechanical test and properties. Dynamic and viscoelastic/poroelastic tests and properties are not included in the scope of this document.