Doc: MHD02(25942)WC
July 2024

BUREAU OF INDIAN STANDARDS

DRAFT IN WIDE CIRCULATION FOR COMMENTS ONLY
(*Not to be reproduced without permission of BIS or used as standard*)

भारतीय मानक मसौदा

सर्जरी के लिए प्रत्यारोपण - अवशोषक धात्विक प्रत्यारोपण के मूल्यांकन के लिए सामान्य दिशानिर्देश और आवश्यकताएं

Draft Indian Standard

Implants for Surgery — General Guidelines and Requirements for Assessment of Absorbable Metallic Implants

ICS 11.040.40

Orthopaedic Instruments, Implants and Accessories Sectional Committee, MHD 02

Last date for comments: **22 August 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.

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/ Other Publication	*Title*
ISO/TS 37137-1	Biological evaluation of medical devices — Part 1: Guidance for absorbable implants
ASTM F3160	Standard guide for metallurgical characterization of absorbable

International Standard/ Other Publication	*Title*
	metallic materials for surgical implants
ASTM F3268	Standard guide for in vitro degradation testing of absorbable metals

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)'.

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/TS 20721: 2020 or kindly contact:

Head (MHD)
Bureau of Indian Standards
Manak Bhawan
9 Bahadur Shah Zafar Marg
New Delhi 110002
Email: hmhd@bis.gov.in; mhd@bis.gov.in

SCOPE

This document established the currently recognized approaches and special considerations needed when evaluating the in vitro and in vivo performance of absorbable metals and implants fabricated, in whole or in part, from them. This document describes how the evaluation of these metals can differ from those utilized for permanent non-absorbable implantable implants (or subcomponents), in that absorbable metal implants (or subcomponents) are — by design — intended to be absorbed in their entirety by the host.

This document provides guidance regarding the materials considerations, in vitro degradation/fatigue characterization, and biological evaluation of medical implants made of absorbable metals. The provided content is intended to deliver added clarity to the evaluation of these materials and implants to increase awareness of critical factors and reduce potential for generation of erroneous or misleading test results.

While this document and the herein described referenced standards contain many suggested alterations or modifications to currently practiced procedures or specifications, the provided content is intended to complement, and not replace, current conventions regarding the assessment of implantable implants.

This document covers the evaluation of absorbable metal specific attributes in general and is not intended to cover application or implant specific considerations. Thus, it is important to consult relevant implant and/or application specific standards.

This document does not apply to non-absorbable or non-metallic components (e.g. polymeric coatings, pharmaceuticals, non-absorbable metals) used in conjunction with absorbable metal implants.