



भारतीय मानक ब्यूरो

(उपभोक्ता मामले, खाद्य एवं सार्वजनिक वितरण मंत्रालय, भारत सरकार)

BUREAU OF INDIAN STANDARDS

(Ministry of Consumer Affairs, Food & Public Distribution, Govt. of India)

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DRAFT INDIAN STANDARD IN WIDE CIRCULATION

Reference : MHD02(25942)

Date : 23 July 2024

TECHNICAL COMMITTEE : Orthopedic Instruments, Implants and Accessories, MHD 02

To,

All concerned

Dear Madam/Sir,

The following document has been prepared by the Orthopedic Instruments, Implants and Accessories Sectional Committee, MHD 02. Please [click here](#) to view the document.

Document Number : MHD 02 (25942) WC

Title of the document : Implants for surgery General guidelines and requirements for assessment of absorbable metallic implants

Document Type : New Indian Standard

This document has following salient features which may require specific attention for your valuable comments:

- 1) 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.*
- 2) 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.*
- 3) 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.

4) 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.

5) 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.

Please examine the document and share your comments regarding further improvement in the document.

Last date for sharing the comments is : 22 August 2024

The comments should be shared in the prescribed template through this portal only; and the comments so received shall be taken up by the Sectional Committee for necessary action. For any other query, please write an email at mhd@bis.gov.in to the undersigned at Bureau of Indian Standard, Manak Bhawan, 9, Bahadur Shah Zafar Marg, New Delhi.

In case no comments are received, we would presume your approval of the documents. However, in case we receive any comments on the document, the same shall be put up to the Sectional Committee for necessary action.

Thanking You,

**Yours faithfully,
(UNNIKRISHNAN A R)
Head (Medical Equipment and Hospital Planning Department)
Email: mhd@bis.gov.in**



व्यापक परिचालन में मसौदा(दे)

हमारा सन्दर्भ : MHD02(25942)

दिनांक : 23-07-2024

तकनीकी समिति : Orthopedic Instruments, Implants and Accessories Sectional Committee, MHD 02

प्राप्तकर्ता : रूचि रखने वाले सभी निकाय

महोदय/या,

निम्नलिखित मसौदा तैयार किया गया है :

प्रलेख संख्या : MHD 02 (25942) WC

शीर्षक :

कृपया इस/इन मानक(को)/संशोधन(नो) के मसौदे(दो) का अवलोकन करें और अपनी सम्मतियाँ यह बताते हुए भेजें कि यदि ये मानक(को) के संशोधन(नो) के रूप में प्रकाशित हो तो इन पर अमल करने में आपके व्यवसाय अथवा कारोबार में क्या कठिनाइयां आ सकती हैं।

सम्मतियाँ भेजने की अंतिम तिथि : 22 August 2024

सम्मतियाँ, यदि कोई हों तो, कृपया यहाँ क्लिक करके ऑनलाइन पोर्टल के माध्यम से ऊपर दी गयी अंतिम तिथि तक दर्ज कराएं।

यह/ये प्रलेख भारतीय मानक ब्यूरो की वेबसाइट www.bis.gov.in पर भी उपलब्ध है/हैं।

धन्यवाद।

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