



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(25947)

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 (25947) WC

Title of the document : Wear of Implant Materials - Polymer and Metal Wear Particles - Isolation and Characterization

Document Type : New Indian Standard

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

- 1) This International Standard specifies methods for sampling wear particles generated by joint replacement implants in humans and in joint simulators. It specifies the apparatus, reagents and test methods to isolate and characterize both polymer and metal wear particles from samples of tissues excised from around the joint replacement implant, obtained at revision surgery or post mortem, and from samples of joint simulator test fluids. Some of these procedures could certainly be adapted for isolation and characterization of particles from human biological fluids (e.g. synovial fluid).*
- 2) The methods given in this International Standard do not quantify the level of wear the implant produces; neither do they determine the amount of wear from any particular surface. This International Standard does not cover the biological effects of wear particles or provide a method for evaluation of biological safety.*

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(25947)

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 (25947) 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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