Doc: MHD02 (28424) WC
August 2025

BUREAU OF INDIAN STANDARDS

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भारतीय मानक मसौदा

सर्जरी के लिए प्रत्यारोपण — विस्तारित समय अवधि में धातु प्रत्यारोपण योग्य सामग्रियों और चिकित्सा उपकरणों के संक्षारण व्यवहार का आकलन करने के लिए ओपन-सर्किट क्षमता का मापन

Draft Indian Standard

Implants for Surgery — Measurements of Open-circuit Potential to Assess Corrosion Behaviour of Metallic Implantable Materials and Medical Devices Over Extended Time Periods

ICS 11.040.40

Orthopaedic Instruments, Implants and Accessories Sectional Committee, MHD 02

Last date for comments: **05 September 2025**

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:

International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*
ISO 16428 Implants for surgery — Test solution and environmental conditions for static and dynamic corrosion and wear tests on implantable materials and medical devices	MHD 02 (28423) / ISO 16428 : 2005 Implants for surgery — Test solution and environmental conditions for static and dynamic corrosion and wear tests on implantable materials and medical devices	Identical

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 3696	Water for analytical laboratory use — Specification and test methods

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 16429: 2004 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 International Standard specifies a test method for measurements over extended time periods of the open-circuit potential of implant materials and surgically implantable devices immersed in a test environment related to body fluid, using a standard corrosion test cell to study the electrochemical corrosion properties of the devices.

This method of monitoring the open-circuit potential can also be combined with mechanical static or dynamic loading tests.

This International Standard is applicable in particular to metallic materials which form passive layers with protective properties against corrosion, as typical for surgical implant materials.

This test method is intended for the investigation of single metallic materials or alloys. It is not applicable to dissimilar material combinations, which require particular considerations in measuring and interpreting the results.