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BUREAU OF INDIAN STANDARDS

DRAFT IN WIDE CIRCULATION FOR COMMENTS ONLY

भारतीय मानक मसौदा

सर्जरी के लिए प्रत्यारोपण — धातु इंट्रामेडुलरी नेलिंग सिस्टम

भाग 2 लॉकिंग घटक

(ISO 15142-2 : 2003; संशोधित)

Draft Indian Standard

Implants for Surgery — Metal Intramedullary Nailing Systems

Part 2 Locking Components

(ISO 15142-2 : 2003; MOD)

ICS 11.040.40

Orthopaedic Instruments, Implants and Accessories Sectional Committee, MHD 02	Last date for comments: **31 October 2025**

NATIONAL FOREWORD

(*Adoption clause will be added later*)

This standard is published in several parts. The other parts in this series are:

Part 1 Intramedullary Nails

Part 3 Connection Devices and Reamer Diameter Measurements

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 5835 (all parts), Implants for surgery — Metal bone screws — Dimensions	IS 9829 (Part 1) : 1996, Implants for surgery - Metal bone screws Part 1 with hexagonal drive connection, spherical under surface of head, asymmetrical thread - Dimensions (First Revision)	Identical
ISO 8319 (all parts), Orthopaedic instruments — Drive connections	IS 6801 (Part 1) : 1999, Orthopaedic instruments - Drive connections Part 1 keys for use with screws with hexagon socket heads (Second Revision)	Identical
	IS 6801 (Part 2) : 1987, Specification for drive connections for orthopaedic instruments Part 2 Screw drivers for single slot head screws, screws with cruciate slot and cross-recessed head screws (First Revision)	Identical
ISO 10993 (all parts), Biological evaluation of medical devices	IS 17932 (Part 1) : 2023, Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process	Modified
	IS/ISO 10993 (Part 2) : 2006 Biological Evaluation of Medical Devices Part 2 Animal Welfare Requirements (First Revision)	Identical
	IS/ISO 10993 (Part 3) : 2014, Biological evaluation of medical devices Part 3 Tests for Genotoxicity, Carcinogenicity and Reproductive toxicity (First Revision)	Identical
	IS/ISO 10993 (Part 4) : 2017, Biological evaluation of medical devices Part 4 Selection of tests for interactions with blood	Identical

	IS/ISO 10993 (Part 5) : 2009, Biological evaluation of medical devices Part 5 Tests for in vitro cytotoxicity	Identical
	IS/ISO 10993 (Part 6) : 2016, Biological evaluation of medical devices Part 6 Tests for local effects after implantation	Identical
	IS 17932 (Part 7) : 2024, Biological Evaluation of Medical Devices Part 7 Tests for irritation ISO 10993-23:2021	Modified
	IS 17932 (Part 2) : 2024, Biological Evaluation of Medical Devices Part 2 Framework for identification and quantification of potential degradation products	Modified
	IS 17932 (Part 6) : 2023, Biological Evaluation of Medical Devices Part 6 Tests for skin sensitization (ISO 10993-10 : 2021, MOD)	Modified
	IS/ISO 10993 (Part 11) : 2017, Biological evaluation of medical devices Part 11 Tests for systemic toxicity	Identical
	IS/ISO 10993 (Part 12) : 2021, Biological Evaluation of Medical Devices Part 12 Sample Preparation and Reference Materials	Identical
	IS/ISO 10993 (Part 13) :2010, Biological evaluation of medical devices Part 13 Identification and quantification of degradation products from polymeric medical devices	Identical
	IS/ISO 10993 (Part 14) : 2001, Biological evaluation of medical devices Part 14 Identification and quantification of degradation products from ceramics	Identical
	IS 17932 (Part 3) : 2024, Biological Evaluation of Medical Devices Part 3 Identification and quantification of degradation products from metals and alloys	Modified
	IS/ISO 10993 (Part 16) : 2017, Biological Evaluation of Medical Devices Part 16 Toxicokinetic	Identical

	Study Design for Degradation Products and Leachables	
	IS/ISO 10993 (Part 17) : 2002, Biological Evaluation of Medical Devices Part 17 Establishment of Allowable Limits for Leachable Substances	Identical
	IS/ISO 10993 (Part 18) : 2020, Biological evaluation of medical devices Part 18 Chemical characterization of medical device materials within a risk management process	Identical
	IS 17932 (Part 4) : 2024 / IS/IEC/TS 10993 : Part 19 : 2006, Biological Evaluation of Medical Devices Part 4 Physico-chemical morphological and topographical characterization of materials	Modified
	IS/ISO/TS 10993 (Part 20) : 2006 / ISO/TS 10993-20:2006, Biological evaluation of medical devices Part 20 Principles and methods for immunotoxicology testing of medical devices	Identical
	IS/ISO/TR 10993 (Part 22) : 2017 / ISO/TR 10993-22 : 2017, Biological Evaluation of Medical Devices Part 22 Guidance on Nanomaterials	Identical
	IS 17932 (Part 7) : 2024, Biological Evaluation of Medical Devices Part 7 Tests for irritation	Identical
ISO 14602, Non-active surgical implants — Implants for osteosynthesis — Particular requirements	MHD02 (28422), Non-active surgical implants — Implants for osteosynthesis — Particular requirements	Identical
ISO 14630, Non-active surgical implants — General requirements	MHD02 (28550), Non-active surgical implants - General requirements	Identical
ISO 14971-1, Medical devices — Risk management — Part 1: Application of risk analysis	IS/ISO 14971 : 2019, Medical devices - Application of risk management to medical devices First Revision	Identical

IS 17932 (Part 1) : 2023 is modified adoption of ISO 10993-1 : 2018 which outlines the principles and requirements for biologically evaluating medical devices that contact the patient or user, focusing on risk-based assessment of safety, data gaps, and hazards from device changes, while excluding risks from infectious agents.

IS 17932 (Part 7) : 2024 is modified adoption of ISO 10993-23 : 2021 which outlines procedures, including in silico, in vitro, and in vivo methods, to assess and classify the irritation potential of medical devices and their materials based on ISO 10993-1 and ISO 10993-2.

IS 17932 (Part 2) : 2024 is modified adoption of ISO 10993-9 : 2019 which outlines principles for evaluating in vitro degradation of medical devices for biological assessment, excluding purely mechanical degradation, non-degradation leachables, and non-body-contacting devices.

IS 17932 (Part 6) : 2023 is modified adoption of ISO 10993-10 : 2021 which outlines procedures and interpretation factors for assessing the skin sensitization potential of medical devices and materials

IS 17932 (Part 3) : 2024 is modified adoption of ISO 10993-15 : 2019 which specifies general requirements for designing in vitro tests to identify and quantify chemical degradation products from metallic medical devices, excluding mechanical degradation and biological effects.

IS 17932 (Part 4) : 2024 is modified adoption of ISO 10993-19 : 2020 which outlines parameters and test methods for assessing the physico-chemical, morphological, and topographical properties of medical device materials relevant to biological evaluation, excluding degradation products and chemical characterization.

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 15142-2: 2003 or kindly contact:

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SCOPE

This part of ISO 15142 specifies metallic medical devices used for the temporary intramedullary stabilization of long bones by surgical implantation, classifying and giving requirements for the locking components of intramedullary nails. It is applicable to all metal intramedullary fixation devices used for temporary fixation of long bones in the human body, except unlockable nails.