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BUREAU OF INDIAN STANDARDS

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भारतीय मानक मसौदा

सर्जरी के लिए प्रत्यारोपण — धातु इंट्रामेडुलरी नेलिंग सिस्टम भाग १ इंट्रामेडुलरी कील

(ISO 15142-1 : 2003; संशोधित)

Draft Indian Standard

Implants for Surgery — Metal Intramedullary Nailing Systems

Part 1 Intramedullary Nails

(ISO 15142-1 : 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 supersedes the IS 10729: 1983 Specification for Nail Set, Kuntscher.

The ISO 15142 series specifies the requirements for the material, surface finish, and design of intramedullary nails, including the Kuntscher Nail Sets.

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

Part 2 Locking Components

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

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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 965-1, ISO general-purpose metric screw threads — Tolerances — Part 1: Principles and basic data	IS 14962 (Part 1): 2018, ISO 965-1: 2013, ISO general purpose metric screw threads - Tolerances: Part 1 principles and basic data (First Revision)	Identical
ISO 965-2, ISO general purpose metric screw threads — Tolerances — Part 2: Limits of sizes for general purpose external and internal screw threads — Medium quality	IS 14962 (Part 2): 2001, ISO general purpose metric screw	Identical
ISO 5832 (all parts), Implants for surgery — Metallic materials	IS/ISO 5832 (Part 1): 2016, Implants for surgery - Metallic materials Part 1 Wrought stainless steel	Identical
	IS/ISO 5832 (Part 2): 2018, Implants for surgery - Metallic materials Part 2 Unalloyed titanium (First Revision)	Identical
	IS 18261 (Part 3): 2023, Implants for Surgery - Metallic Materials Part 3 Wrought Titanium 6- Aluminium 4-Vanadium Alloy Second Revision	Identical
	IS/ISO 5832 (Part 4): 2014, Implants for Surgery – Metallic Materials Part 4 Cobalt- Chromium-Molybdenum Casting Alloy	Identical
	IS 18261 (Part 5): 2023, Implants for Surgery - Metallic Materials Part 5 Wrought Cobalt- Chromium-Tungsten Nickel (First Revision)	Identical

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	IS 18261 (Part 6): 2023, Implants for Surgery - Metallic Materials Part 6 Wrought Cobalt-Nickel- Chromium-Molybdenum Alloy First Revision	Identical
	IS/ISO 5832 (Part 7): 2016, Implants for surgery - Metallic materials Part 7 Forgeable and cold-formed Cobalt-Chromium- Nickel-Molybdenum-Iron alloy	Identical
	IS 18261 (Part 9): 2024, Implants for Surgery - Metallic Materials Part 9 Wrought High Nitrogen Stainless Steel First Revision	Identical
	IS/ISO 5832 (Part 11) : 2014, Implants for surgery - Metallic materials Part 11 Wrought Titanium 6-Aluminium 7- Niobium alloy	Identical
	IS 18555 (Part 12) : 2024, Implants for surgery - Metallic Materials Part 12 Wrought cobalt- chromium-molybdenum alloy	Identical
	IS 18555 (Part 14): 2024, Implants for surgery - Metallic Materials Part 14 Wrought titanium 15-molybdenum 5- zirconium 3-aluminium alloy	Identical
ISO 14602, 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 15142-3, Implants for surgery — Metal intramedullary nailing systems — Part 3: Connection devices and reamer diameter measurements	MHD02 (28901), Implants for surgery — Metal intramedullary nailing systems — Part 3: Connection devices and reamer diameter measurements	Modified

MHD02 (28901) is a modified adoption of ISO 15142-3 : 2003 which specifies requirements, classifications, and dimensions for metallic medical devices used in the temporary intramedullary

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stabilization of long bones, including insertion/removal devices and reamer diameter measurement, excluding drive connections for locking elements.

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 15142-1: 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, defining terms and giving requirements for intramedullary nails. It is applicable to all metal intramedullary fixation devices used for temporary fixation of long bones in the human body.