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**Implants for surgery — Metal  
intramedullary nailing systems —**

**Part 1:  
Intramedullary nails**

*Implants chirurgicaux — Systèmes d'enclouage intramédullaire en  
métal —*

*Partie 1: Clous intramédullaires*



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## Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 15142-1 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 5, *Osteosynthesis and spinal devices*.

ISO 15142 consists of the following parts, under the general title *Implants for surgery — Metal intramedullary nailing systems*:

- *Part 1: Intramedullary nails*
- *Part 2: Locking components*
- *Part 3: Connection devices and reamer diameter measurements*

## Introduction

Intramedullary nailing is a method of fixation for temporary stabilization of long bones with reduced strength due to fractures or disease or both. Because of the wide variety of the devices, some illustrations are provided in this part of ISO 15142. Medical and engineering considerations influence the design of the different devices and the choice of a device for a particular clinical situation.

Nails are often, but not always, removed when they have completed their intended purpose of temporary stabilization.

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# Implants for surgery — Metal intramedullary nailing systems —

## Part 1: Intramedullary nails

### 1 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.

### 2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 965-1, *ISO general-purpose metric screw threads — Tolerances — Part 1: Principles and basic data*

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*

ISO 5832 (all parts), *Implants for surgery — Metallic materials*

ISO 14602, *Non-active surgical implants — Implants for osteosynthesis — Particular requirements*

ISO 14630, *Non-active surgical implants — General requirements*

ISO 15142-3, *Implants for surgery — Metal intramedullary nailing systems — Part 3: Connection devices and reamer diameter measurements*

### 3 Terms and definitions

For the purposes of this document, the following terms and definitions apply. See Figures 1 to 4 for examples of various intramedullary nail types defined here.

#### 3.1

##### **angulated nail**

nail whose longitudinal axis is angulated

#### 3.2 Bundle nails

##### 3.2.1

##### **united bundle nail**

nail made of a bundle of parallel rods that are fused to each other at one or more locations along the implant length