INTERNATIONAL STANDARD

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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

Reference number
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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.

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

3.2.2
un-united bundle nail
nail intended for use in parallel groups so that more than one nail is usually inserted in the intramedullary cavity

NOTE The individual nails are not joined to each other but may be in contact.

3.3
cannulated nail
intramedullary nail that has a hole along the longitudinal axis over its full length

NOTE The inner or outer contour of a hollow nail, or both contours, can be circular, polygonal, cloverleaf, star-shaped, etc.

3.4
closed-section nail
cannulated nail whose cross-sections perpendicular to the nail's longitudinal axis have no discontinuities along the outer wall, other than for connection elements to accommodate locking components or insertion/removal devices

3.5
connection element
integral part of the nail intended to connect the nail to a locking component or insertion/removal device

EXAMPLE Hole, window, bore, slot (see Figure 5) or thread.

3.6
cross-arm
auxiliary component which is used for fixation into the femoral head or metaphysis and is intended to provide additional stability across a fracture

3.7
cross-arm intramedullary nail
intramedullary nail whose function is dependent on the use of a cross-arm

3.8
curved nail
nail whose longitudinal axis is curved over at least a part of its length

3.9 Diameters

3.9.1
inner diameter
diameter of the largest circle which is enveloped by the contour of the cross-section of a hollow nail

See Figure 4.

NOTE The site of measurement is indicated if the nail is not of uniform diameter throughout its length.

3.9.2
minimum inner diameter
maximum possible diameter of a guidewire of circular diameter over which the nail, which may be of variable diameter, can be passed

3.9.3
outer diameter
diameter of the smallest circle that will envelop the outer cross-section of the nail

See Figure 4.

NOTE The site of measurement is indicated if the nail is not of uniform diameter throughout its length.

3.10
insertion/removal device
device external to the nail which connects temporarily to the nail through the nail's connection element(s) in order to assist the insertion and/or removal of the nail

EXAMPLE Driving handle, drill guide, extractor bolt or hook.

3.11 Lengths

3.11.1
effective length
length of the nail as measured by the shortest distance between the two ends

3.11.2
overall length
length of the nail as measured along the centreline of the nail from end to end

3.12
lockable intramedullary nail
intramedullary nail that has provisions for the application of locking elements to improve temporary fixation in bone

See Figures 1, 2 and 3.

NOTE These auxiliary components are not always used.

3.13
locking component
device or component which controls or minimizes relative motion between the intramedullary nail and bone and which is designed to fit into the connection elements of the appropriate nail

EXAMPLE Screw, blade, bolt or cross-arm.

3.14
multiple component nail system
nail system which consists of more than one major temporary fixation component, such as a cross-arm configurations or bundle nails

3.15
open-section nail
cannulated nail whose cross-sections perpendicular to the nail's longitudinal axis have one or more discontinuities along the outer wall

3.16
single-component nail system
nail system that consists of one major temporary fixation component, except for locking components such as bolts/screws

3.17
solid nail
nail with a solid cross-section over its entire length except for connection elements

NOTE The contour can be circular, polygonal, cloverleaf, star-shaped, etc.

3.18
straight nail
nail whose longitudinal axis is straight over its length

3.19
unlockable nail
nail which does not have provisions for locking components

See Figure 4.

4 Materials

The metallic materials used for an intramedullary nail shall be chosen in accordance with ISO 14602 and the appropriate part of ISO 5832.

5 Surface requirements

The surface finish shall not adversely affect the biocompatibility of the metal used. The effect of surface finish on biocompatibility shall be considered in the risk analysis for the device (see ISO 14602).

NOTE The surface finish of the implant is normally selected so that it will not encourage surface bone ongrowth which might make removal of the implant difficult or impossible.

6 Marking

The implant shall be marked on its surface in accordance with ISO 14630. In the case of anatomical shaping or orientation (left or right) of the device, there shall be a unique marking to avoid wrong positioning.

7 Product label

The package shall be labelled in accordance with ISO 14630. The label shall include, as a minimum, nail-specific information such as length and diameter.

8 Design requirements for insertion and removal

The nail design shall reflect the insertion/removal technique.

Slots shall comply with Figure 5, and accept the hooks as defined in ISO 15142-3.

Standard threads in the nail should conform to metric dimensions in accordance with ISO 965-1 and ISO 965-2.

NOTE Many existing nail designs utilize threadforms conforming to ANSI B1.1 designations 1/4-28, 5/16-24, 3/8-24, 7/16-20 and 9/16-18. Threadforms conforming to these designations can also be used. These designations are given in Annex A for information.

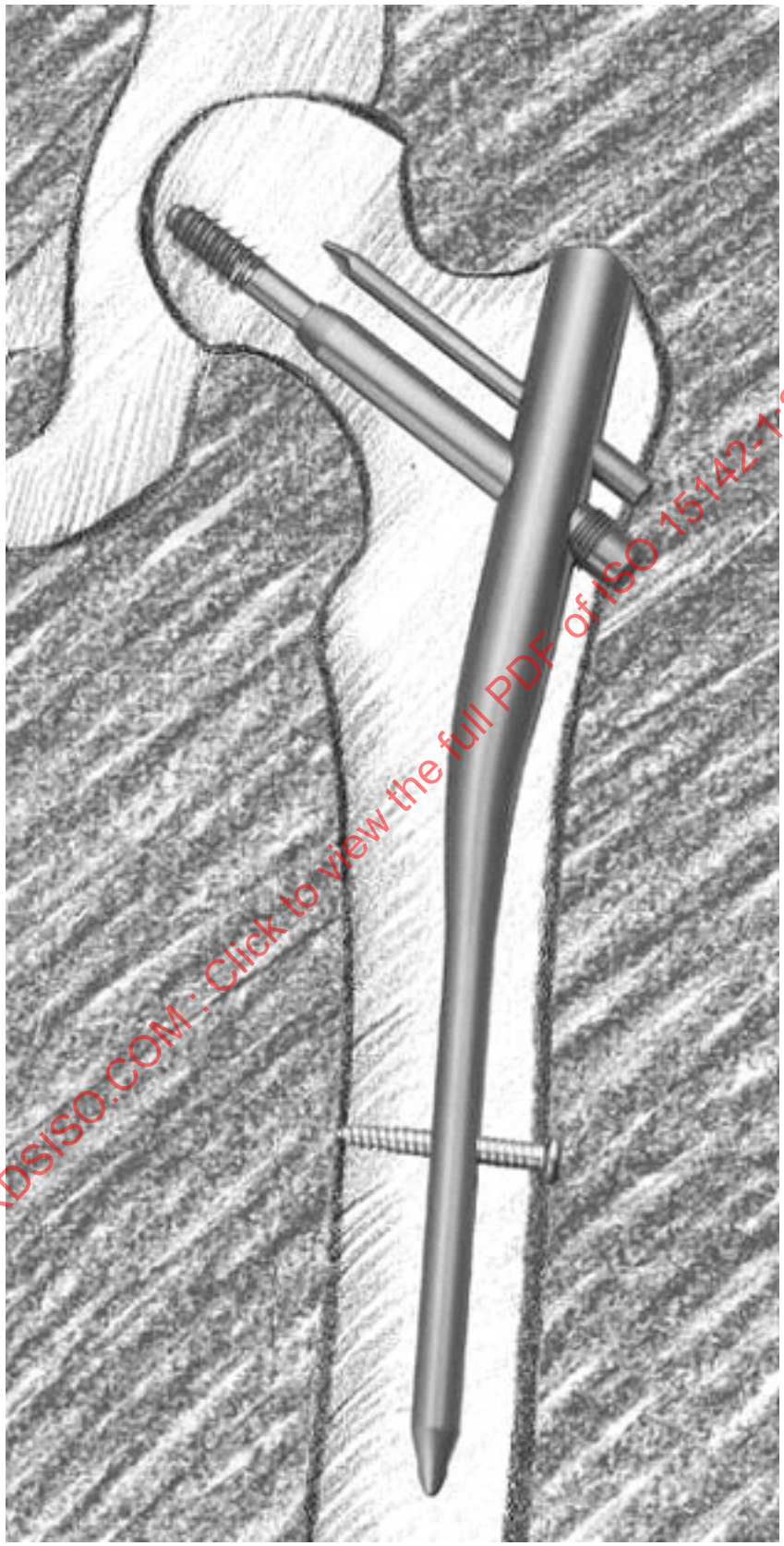

Figure 1 — Example of lockable, hollow nail with cross-arm for proximal femur fractures

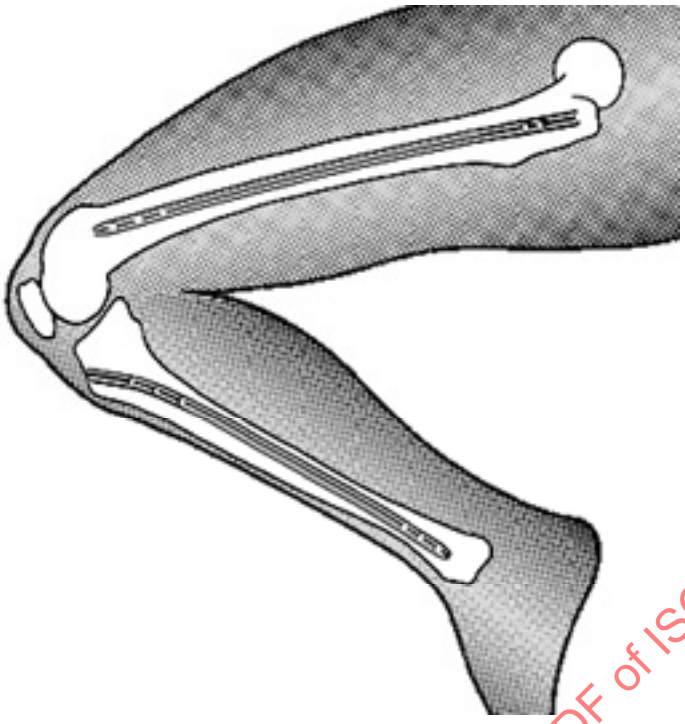

Figure 2 — Example of lockable nail, tibia and femur, solid, angulated

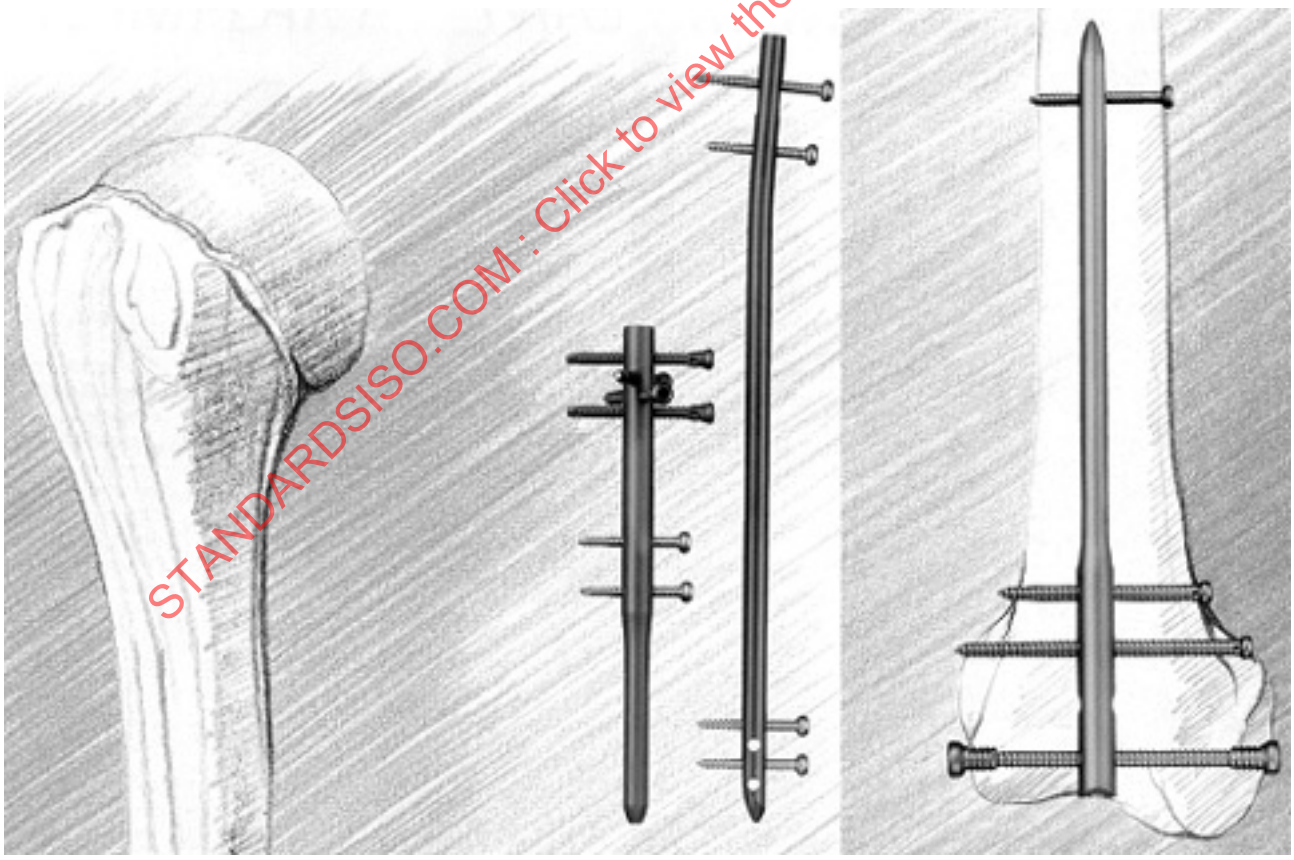

Figure 3 — Example of lockable nail, humerus and distal femur, solid, straight