INTERNATIONAL STANDARD

ISO 15142-2

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Implants for surgery — Metal intramedullary nailing systems —

Part 2: Locking components

Implants chirurgicaux — Systèmes d'enclouage intramédullaire en métal —

Partie 2: Éléments de fixation

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 15142-2 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. Medical and engineering considerations influence the design of the different devices and the choice of a device for a particular clinical situation.

This part of ISO 15142 addresses the locking components used for lockable metal intramedullary nails. Because of the wide variety of the devices, classification of the locking components is provided.

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 2: Locking components

1 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.

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 5835 (all parts), *Implants for surgery — Metal bone screws — Dimensions*

ISO 8319 (all parts), *Orthopaedic instruments — Drive connections*

ISO 10993 (all parts), *Biological evaluation of medical devices*

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

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

ISO 14971-1, *Medical devices — Risk management — Part 1: Application of risk analysis*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
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.

[ISO 15142-1:2003, 3.13]

4 Classification and designation

Locking components shall be classified into one of the following:

a) bolts/screws;

b) wires;

c) expanding elements;

d) other (claws, hooks, etc.).

5 Materials

Locking components shall be manufactured from the same material as the intramedullary nail, or, if another material or condition or both is chosen, the biocompatibility shall be demonstrated in accordance with ISO 10993. A risk assessment in accordance with ISO 14971-1 shall be performed in order to determine that the level of risk of corrosion is appropriate.

If another metal is chosen then the effects of galvanic corrosion should be taken into account.

6 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 of 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.

7 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.

8 Product labelling

The package shall be labelled in accordance with ISO 14602. The label shall include, as a minimum, specific information such as length and diameter.

If the locking component is required to be used with an intramedullary nail of a specific metallic composition, then its metallic composition should be stated.

9 Drive connections for insertion and removal of locking components

Screw and bolt locking components should be inserted or removed with screwdrivers in accordance with ISO 8319, using a recess in accordance with ISO 5835.

NOTE Many existing locking components are designed to be inserted or removed with screwdrivers in accordance with ASTM F116 using recesses in accordance with ASTM F543-02. Drive connections conforming to those standards can also be used.

Bibliography

[1] ASTM[1)] F116, *Standard Specification for Medical Screwdriver Bits*

[2] ASTM F543-02, *Standard Specification and Test Methods for Metallic Medical Bone Screws*

1) American Society for Testing and Materials