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Implants for surgery — Fixation devices for use in the ends of the femur in adults

*Implants chirurgicaux — Implants de fixation à utiliser dans les
extrémités du fémur chez les adultes*



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Contents

	Page
1 Scope	1
2 Normative references	1
3 Materials	2
4 Types of nails and fixation screws	2
5 Dimensions	2
6 Ancillary components for assembly of fixation devices of multi-piece construction	4
7 Surface finish	4
8 Packaging	4
9 Marking	4

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.

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.

International Standard ISO 8615 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Sub-Committee SC 5, *Osteosynthesis*.

Introduction

Fixation devices for use in the upper and lower ends of the femur may be made in a variety of configurations, according to the design of the originator or the individual manufacturer. However, certain dimensions are critical and may not be exceeded without risk of damage to the bone when the device is inserted. Other than specifying this limited number of features, the main object of this International Standard is to ensure uniformity in designating and describing the size of the device in order that devices of different origin but of the same nominal size will not differ significantly in their critical dimensions. It is required that these dimensions be stated on the packaging and marked on the device; it is also required that the packaging carry other information useful to the surgeon, such as details of instruments and ancillary devices necessary at the implantation of the device.

Implants for surgery — Fixation devices for use in the ends of the femur in adults

1 Scope

This International Standard specifies the materials, dimensions, surface finish, and packaging and marking of metal surgical implants used for the fixation of fractures and osteotomies of the upper and lower ends of the femur in adults. The types of devices covered are as follows:

- a) nails and screws intended to be used alone;
- b) nail plates and blade plates of one-piece construction;
- c) fixation devices of multi-piece construction having either a fixed or an adjustable angle;
- d) fixation devices of multi-piece construction with sliding nail or screw, with or without a compression device.

NOTE 1 Figures 1 to 7 are intended to illustrate nomenclature and designation of dimensions, but the representation of the components does not otherwise form part of the requirements specified in this International Standard.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 261:1973, *ISO general-purpose metric screw threads — General plan*.

ISO 272:1982, *Fasteners — Hexagon products — Widths across flats*.

ISO 965-2:1980, *ISO general purpose metric screw threads — Tolerances — Part 2: Limits of sizes for general purpose bolt and nut threads — Medium quality*.

ISO 5832-1:1987, *Implants for surgery — Metallic materials — Part 1: Wrought stainless steel*.

ISO 5832-2:1978, *Implants for surgery — Metallic materials — Part 2: Unalloyed titanium*.

ISO 5832-3:1990, *Implants for surgery — Metallic materials — Part 3: Wrought titanium 6-aluminium 4-vanadium alloy*.

ISO 5832-4:1978, *Implants for surgery — Metallic materials — Part 4: Cobalt-chromium-molybdenum casting alloy*.

ISO 5832-5:1978, *Implants for surgery — Metallic materials — Part 5: Wrought cobalt-chromium-tungsten-nickel alloy*.

ISO 5832-6:1980, *Implants for surgery — Metallic materials — Part 6: Wrought cobalt-nickel-chromium-molybdenum alloy*.

ISO 5832-7:1984, *Implants for surgery — Metallic materials — Part 7: Forgeable and cold-formed cobalt-chromium-nickel-molybdenum-iron alloy*.

ISO 5832-8:1987, *Implants for surgery — Metallic materials — Part 8: Wrought cobalt-nickel-chromium-molybdenum-tungsten-iron alloy*.

ISO 5835:1991, *Implants for surgery — Metal bone screws with hexagonal drive connection, spherical under-surface of head, asymmetrical thread — Dimensions*.

ISO 5836:1988, *Implants for surgery — Metal bone plates — Holes corresponding to screws with asymmetrical thread and spherical under-surface*.

ISO 6018:1987, *Orthopaedic implants — General requirements for marking, packaging and labelling*.

ISO 9268:1988, *Implants for surgery — Metal bone screws with conical under-surface of head — Dimensions*.

ISO 9269:1988, *Implants for surgery — Metal bone plates — Holes and slots corresponding to screws with conical under-surface*.

3 Materials

3.1 Metallic materials used shall be in accordance with ISO 5832, parts 1 to 8.

3.2 Locking bushes and inserts shall be made from plastics materials. These materials shall not be used for any other part of any of the devices.

The plastics materials should be biocompatible and of sufficient strength to provide permanent locking, e.g. by swelling. At present only polyamide homopolymer type 66 (nylon 66) is known to be suitable.

4 Types of nails and fixation screws

Nails and fixation screws may be divided into three types:

- Type A nails of rectangular cross-section;
- Type B nails and fixation screws designed to be inserted without preparation of the femoral neck and head;
- Type C nails and fixation screws designed to be inserted only after drilling or other preparation of the femoral neck and head.

NOTE 2 The use of a nail or screw of too large a cross-sectional dimension might result in bursting of the femoral neck during insertion of the device.

5 Dimensions

5.1 General

5.1.1 The expression of sizes of plates, nails and fixation screws shall be as given in table 1.

5.1.2 The nomenclature of dimensions shall be as shown in figures 1 to 7.

The most important dimension for the surgeon is the effective length of nails and fixation screws.

5.2 Cross-sectional dimensions of types A and B nails and fixation screws

5.2.1 Type A nails shall have a maximum width of 16 mm and a maximum depth of 6,5 mm (see dimensions *b* and *d* respectively in figures 1 and 2).

5.2.2 In type B implants, the effective length of the nail or fixation screws, as designated in figures 1 to 7, shall be able to pass through a circle of 13 mm diameter.

NOTE 3 Nails and fixation screws of type C are intended for use only where prior drilling or other preparation of the femoral neck is undertaken before implantation. Incorrect preparation of the femur or the use of a nail or screw of too large a cross-sectional dimension can result in bursting of the femoral neck during insertion.

5.3 Effective length of nails and fixation screws

The range of effective lengths of nails and fixation screws shall be from 50 mm to 150 mm.

The preferred increment between lengths is 5 mm.

5.4 Cannula of nail or fixation screw

5.4.1 The cannulation hole, if present, shall be one of the following sizes:

- a) nominal diameter of 2,8 mm and a minimum actual diameter of 2,80 mm; or
- b) nominal diameter of 2,2 mm and a minimum actual diameter of 2,20 mm; or
- c) nominal diameter of 2,0 mm and a minimum actual diameter of 2,00 mm.

NOTE 4 The 2,8 mm nominal diameter hole is suitable for use with guide wires 2,5 mm in diameter; the 2,2 mm nominal diameter hole is suitable for use with guide wires 1,6 mm and 2,0 mm diameter; the 2,0 mm nominal diameter hole is suitable for use with guide wires 1,5 mm in diameter.

5.4.2 The minimum wall thickness of cannula of nail or fixation screw shall be as specified in table 2.