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

Part 3:

**Connection devices and reamer diameter
measurements**

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

Partie 3: Dispositifs de connexion et mesurage du diamètre des alésoirs

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Published in Switzerland

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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 15142-3 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.

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 3: Connection devices and reamer diameter measurements

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 other requirements and dimensions for the devices used to insert, remove or both insert and remove intramedullary nails. It also provides a means of measuring reamer diameter. It is applicable to all metal intramedullary fixation devices used for temporary fixation of long bones in the human body, except drive connections for locking elements.

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

ISO 15142-2, *Implants for surgery — Metal intramedullary nailing systems — Part 2: Locking components*

3 Terms and definitions

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

3.1

connection element

integral part of the nail intended to connect the nail to the locking component or insertion/removal device

EXAMPLE Hole, window, bore, slot or thread.

[ISO 15142-1:2003, 3.5]

3.2

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.

[ISO 15142-1:2003, 3.10]

4 Classification and designation

Insertion/removal devices shall be classified as either those containing

- a) hooks, or
- b) parallel external threads.

5 Insertion/removal device requirements

5.1 All intramedullary nails shall have features (connection elements) which permit the attachment of instruments which aid in their insertion and removal. Such insertion/removal devices shall connect temporarily to the nail during surgery via the connection element.

5.2 The dimensions of hook connection elements for insertion/removal devices shall be in accordance with Annex A.

5.3 The dimensions of parallel external threads for insertion/removal devices should be as specified in ISO 8319 designations M4 to M12.

NOTE Many existing insertion/removal devices utilize parallel external threadforms conforming to ANSI B1.1 designations 1/4-28, 5/16-24, 3/8-24, 7/16-20 and 9/16-18. Parallel external threadforms conforming to these designations can also be used. These designations are given in Annex B for information.

6 Measurement of reamer diameter

The diameter of a reamer intended for use with an intramedullary nailing system shall be measured by use of a ring gauge through which the reamer will pass. The marking on the reamer shall correspond to the gauge diameter.

NOTE Considerable confusion has arisen in the past because reamers were described either by their actual diameter, as measured by a ring gauge, or by the diameter of the hole produced in bone or by the diameter of the nail for which they are intended.

7 Drive connections for insertion and removal of locking components

See ISO 15142-2.

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Annex A
(normative)

Hook connection element dimensions

See Figure A.1 and Tables A.1 and A.2.

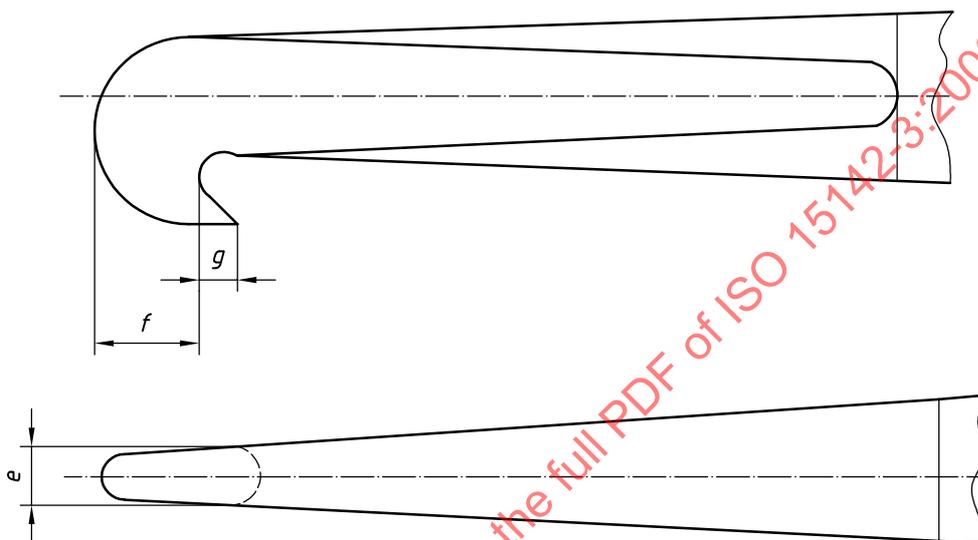


Figure A.1 — Hooks

Table A.1 — Dimensions for hooks in cloverleaf nails

Dimensions in millimetres

Diameter range	Dimension ^a		
	e	f	g
6 to 9	$2,1^{0}_{-0,3}$	7 to 8,7	≥ 2
10 to 16	$\leq 3,15$		

^a See Figure A.1.

Table A.2 — Dimensions for hooks in V-shaped nails

Dimensions in millimetres

Diameter range	Dimension ^a		
	$e^{0}_{-0,1}$	f	g
4 to 5	1,2	5 to 5,8	≥ 2
5,5 to 11	1,8		

^a See Figure A.1.