

INTERNATIONAL STANDARD

**ISO
8615**

First edition
1991-11-01

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

iTeh STANDARD PREVIEW
*Implants chirurgicaux — Implants de fixation à utiliser dans les
extrémités du fémur chez les adultes*
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ISO 8615:1991

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Reference number
ISO 8615:1991(E)

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International Organization for Standardization
Case Postale 56 • CH-1211 Genève 20 • Switzerland

Printed in Switzerland

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*.

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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.

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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.

Table 1 — Expression of sizes of plates, nails and fixation screws

Type of device (see clause 5)	Plates	Nails		Rectangular section nail	Fixation screws
		Types (e.g. tri-fin) where point length is less than effective length	Types (e.g. V-shaped) where point length equals effective length		
One-piece nail plates Nails and fixation screws for use alone Fixed angle non-sliding plates, nails and screws of multi-piece construction	Effective length/number of screw holes Angle, θ , β , between plate and nail or fixation screw(s), in degrees	Cross-sectional dimension(s) of point Shaft diameter Point length Effective length Overall length Diameter of cannula (if present)	Cross-sectional dimension(s) of point Effective length Overall length Diameter of cannula (if present)	Cross-sectional dimensions d and h (see figures 1 and 2) Effective length Overall length	Thread diameter Shaft diameter Thread length Effective length Overall length Diameter of cannula
Adjustable angle plates of multi-piece devices	Effective length/number of screw holes Minimum and maximum angle, θ between plate and nail or fixation screw, in degrees	---	---	---	---
Sliding nail and screw plates	Barrel length Effective length/number of screw holes Angle, θ , between plate and nail or fixation screw, in degrees	Cross-sectional dimension(s) of point Shaft diameter Point length Effective length	Cross-sectional dimension(s) of point Shaft diameter Effective length		Thread diameter Shaft diameter Thread length Effective length

NOTES

- 1 Linear dimensions shall be expressed in millimetres.
- 2 The terms given in this table are illustrated in figures 1 to 7.
- 3 The most important dimension for the surgeon is the effective length of nails and fixation screws.

Table 2 — Minimum wall thickness of cannulation holes

Dimensions in millimetres

Material of screw or nail	Minimum wall thickness of cannulae for cannulation holes having minimum actual diameters of	
	2	2,8
Stainless steel	1	1,35
Cast cobalt-based alloys	0,79	0,79
Wrought cobalt-based alloys	0,79	0,79
Wrought titanium alloy	1	1,29

5.5 Heads of non-sliding nails and fixation screws

5.5.1 The effective screw thread depth of the recess for introducer in head of nail shall be not less than 8 mm.

5.5.2 The length of the protruding screw-threaded spigot of male-type heads shall not exceed 20 mm.

5.5.3 The screw threads for introducer recesses and protruding screw-threaded spigots shall be either M6 or M8 × 1 or M7 or M10 × 1 in accordance with ISO 261, of tolerance class 6H/6g in accordance with ISO 965-2.

5.6 Angle between femoral plate and nail or fixation screw

5.6.1 In the case of plates in which there is no provision for adjusting the angle between the plate and the nail or fixation screw, the angle between the plate and the nail or fixation screw shall not differ from the nominal value stated by the manufacturer by more than 2°.

5.6.2 If there is provision for adjusting the angle between the plate and the nail or fixation screw, the minimum and maximum angles shall not differ from the nominal values stated by the manufacturer by more than 2°.

NOTE 5 In both cases, the stress borne by the implant is maximal at the shoulder between the nail and the plate; this zone needs therefore to be particularly strong. Test methods are under consideration.

5.7 Screw holes

Screw holes shall be in accordance with either ISO 5836 or ISO 9269.

NOTE 6 The type of hole is dependent upon the type of bone screw with which the plate is intended to be used.

5.8 Clearance between barrel and nail or fixation screw

5.8.1 In the case of sliding nails and screws, the clearance between the outside surface of the nail or fixation screw and the inside surface of the barrel, excluding working surfaces of devices that control rotary or sliding motion, shall be 1 mm $\begin{matrix} 0 \\ -0,25 \end{matrix}$ mm.

6 Ancillary components for assembly of fixation devices of multi-piece construction

6.1 Nuts and bolt heads

6.1.1 The screw threads of nuts and bolts shall be in accordance with 5.5.3.

6.1.2 The width across flats of hexagonal nuts and bolt heads shall be in accordance with ISO 272.

6.2 Locking bushes and inserts

Locking bushes and inserts shall be made from plastics materials (see 3.2) and, if present, screw threads shall be in accordance with 5.5.3.

When using nuts fitted with nylon locking bushes, care should be taken to ensure that the nut is fully tightened so that the thread of the nail or screw projects beyond the nylon bush.

If for any reason such a nut is removed from the nail or screw during an operation it should be discarded and replaced by a new nut. Similar conditions apply when the components of a nail or screw are fastened together by a bolt fitted with a plastics material locking insert.

7 Surface finish

The external surface finish shall be free from burrs, scratches and other defects visible by normal or corrected vision.

8 Packaging

Packaging shall be in accordance with ISO 6018. Sharp edges shall be capped.

9 Marking

9.1 Marking of devices

Each device or major component or multi-piece device shall be marked in accordance with ISO 6018 and with the appropriate requirements given in table 3 where the size of the component allows.

9.2 Marking of packages

Packages shall be marked in accordance with ISO 6018; the markings relating to size shall be as given in table 3.

The unit package or a leaflet inserted in the package shall also give the following information:

- a) the size and type of drill, spanner, screwdriver and all other preparatory instruments rec-

recommended for use with the device by the manufacturer;

- b) the diameter of the recommended guide wires and guide wire drill;
- c) the size and types of bone screws as specified in ISO 5835 or ISO 9268 with which the device is intended to be used;
- d) recommendations for sterilizing and handling the device including, where appropriate, details of

the procedure and equipment for contouring the device;

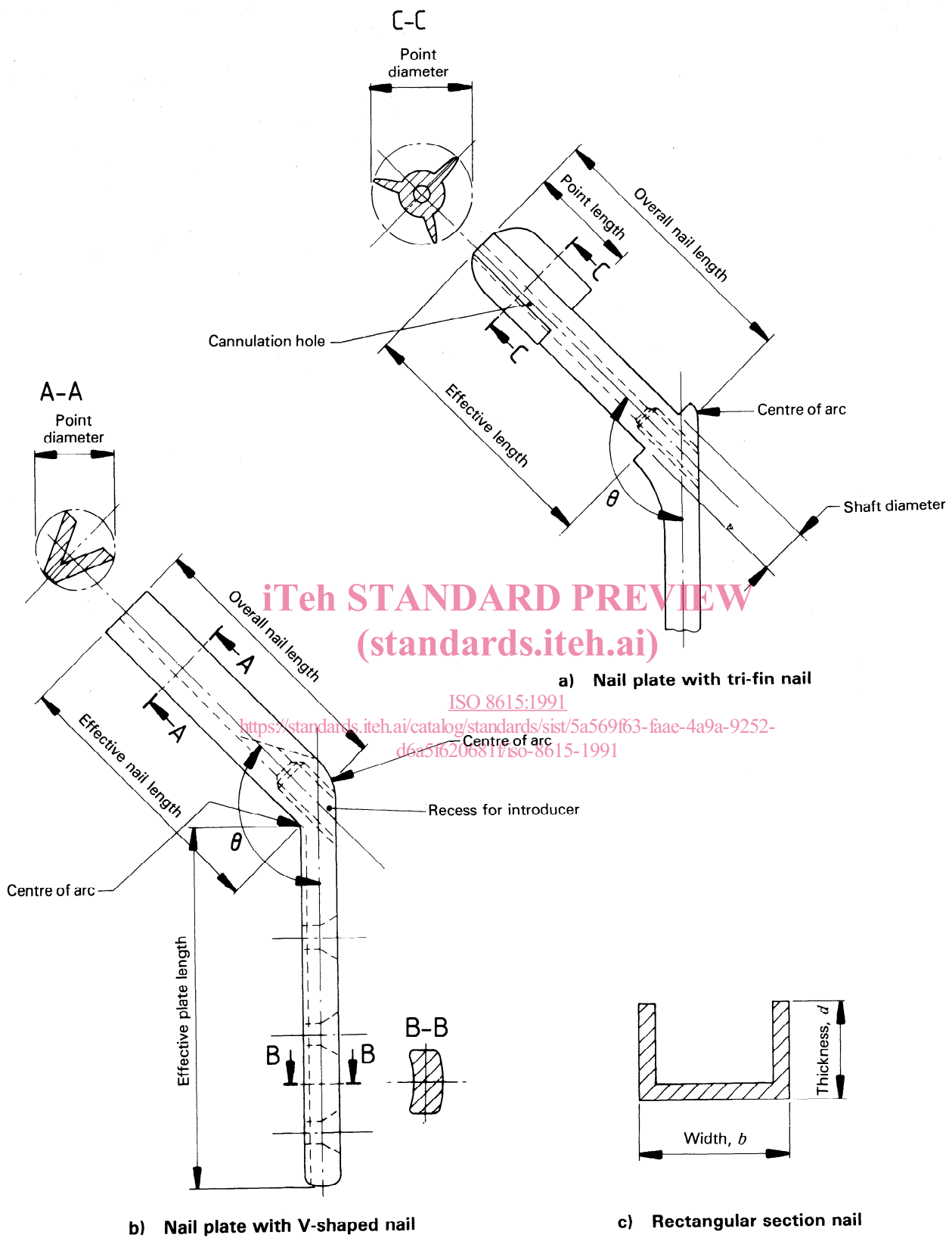
- e) for nails of non-rectangular cross-section and for fixation screws, the type (B or C of the device) shall be specified: recommendations and warning about the correct implantation techniques to minimize the risk of damaging the femoral neck should be stated (see note in 5.2.2).

For nails of rectangular cross-section, the type A of the device shall be specified: recommendations and warning about the implantation techniques should be stated.

Table 3 — Requirements for marking of fixation devices and packages

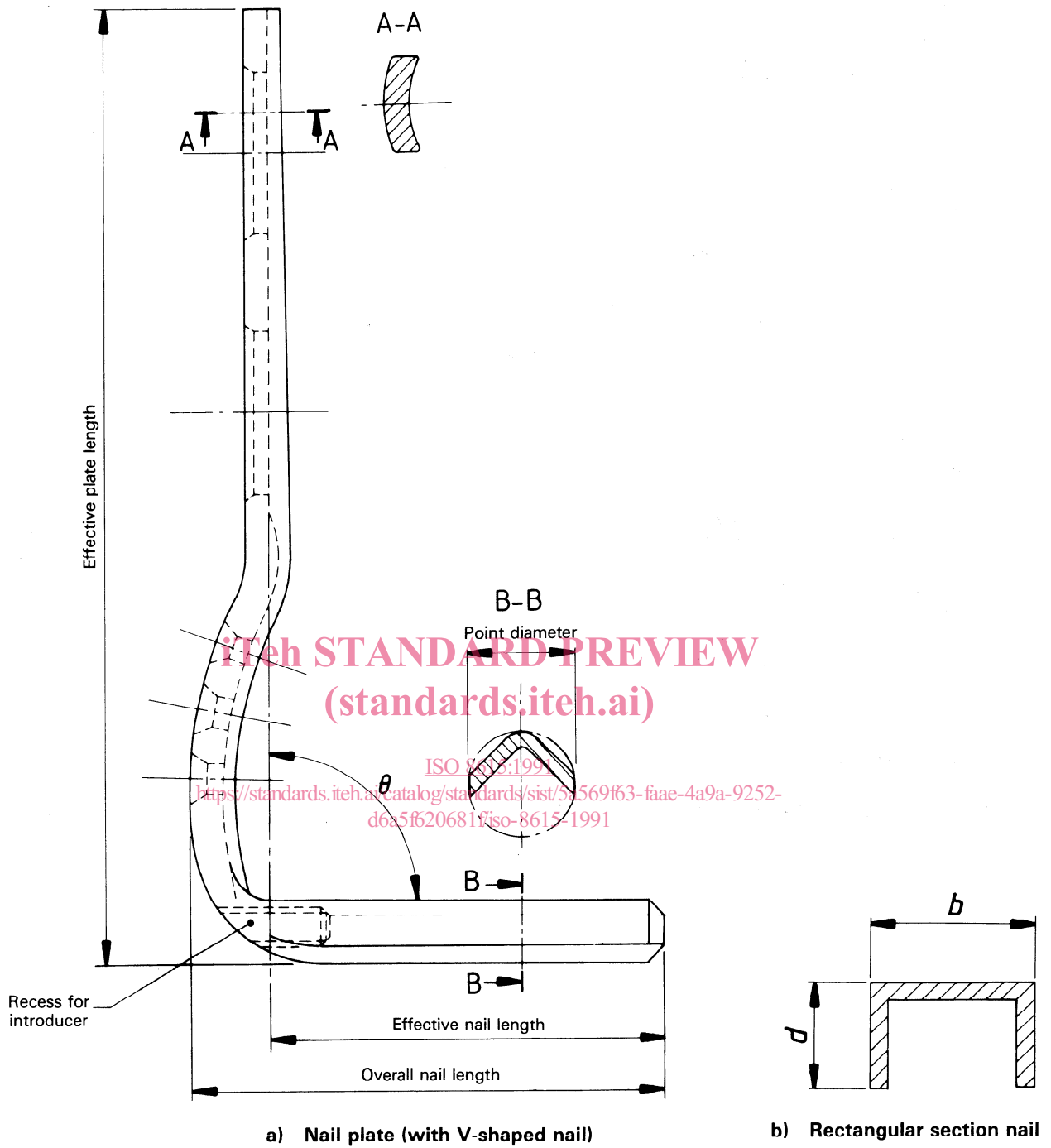
Device or major component of multi-piece device	Marking requirement																				
Fixation devices of one-piece construction	Size of nail and plate, and angle between nail and plate, expressed in accordance with clause 8																				
Nails and fixation screws for use alone	Size expressed in accordance with clause 8																				
<table border="0" style="width: 100%;"> <tr> <td style="width: 20px;"></td> <td style="text-align: center;">fixed angle</td> <td></td> </tr> <tr> <td style="text-align: right;">Plates:</td> <td style="border-top: 1px solid black;">adjustable angle</td> <td></td> </tr> <tr> <td></td> <td style="border-top: 1px solid black;">sliding</td> <td></td> </tr> <tr> <td style="text-align: right;">Nails:</td> <td style="border-top: 1px solid black;">non-sliding</td> <td rowspan="2" style="vertical-align: middle;">Size expressed in accordance with clause 8</td> </tr> <tr> <td></td> <td style="border-top: 1px solid black;">sliding</td> </tr> <tr> <td style="text-align: right;">Fixation screws:</td> <td style="border-top: 1px solid black;">non-sliding</td> <td></td> </tr> <tr> <td></td> <td style="border-top: 1px solid black;">sliding</td> <td></td> </tr> </table>		fixed angle		Plates:	adjustable angle			sliding		Nails:	non-sliding	Size expressed in accordance with clause 8		sliding	Fixation screws:	non-sliding			sliding		
	fixed angle																				
Plates:	adjustable angle																				
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NOTE — See note to clause 1.

Figure 1 — Generalized representation and nomenclature of dimensions of one-piece nail plates for use in the upper end of the femur



NOTE — See note to clause 1.

Figure 2 — Generalized representation and nomenclature of dimensions of one-piece nail plates for use in the lower end of the femur