BS ISO 5838-1:2013

BSI Standards Publication

Implants for surgery — Metallic skeletal pins and wires

Part 1: General requirements

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National foreword

This British Standard is the UK implementation of ISO 5838-1:2013.

The UK participation in its preparation was entrusted to Technical Committee CH/150/5, Surgical Implants - Osteosynthesis and spinal devices.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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Implants for surgery — Metallic skeletal pins and wires —

Part 1: General requirements

Implants chirurgicaux — Fils et broches pour os —

Partie 1: Matériaux et propriétés mécaniques

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Contents

Page

Foreword ..... **iv**
1 Scope **1**
2 Normative references **1**
3 Material **2**
4 Mechanical properties **2**
5 Method of manufacture **2**
6 Finish **2**
7 Sterilization **2**
8 Packaging **3**
9 Information supplied by the manufacturer **3**
9.1 General 3
9.2 Instructions for use 3
9.3 Marking on implant 3

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.

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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 5838-1 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 5, *Osteosynthesis and spinal devices*.

This third edition cancels and replaces the second edition (ISO 5838-1:1995), which has been technically revised to add to the requirements for finish (Clause 6), to add a reference to ISO 14630 and to introduce new requirements for sterilization (Clause 7), packaging (Clause 8) and information supplied by the manufacturer (Clause 9).

ISO 5838 consists of the following parts, under the general title *Implants for surgery — Metallic skeletal pins and wires*:

— *Part 1: General requirements*

— *Part 2: Steinmann skeletal pins - Dimensions*

— *Part 3: Kirschner skeletal wires*

INTERNATIONAL STANDARD **ISO 5838-1:2013(E)**

Implants for surgery — Metallic skeletal pins and wires —

Part 1: General requirements

1 Scope

This part of ISO 5838 specifies general requirements for metallic skeletal pins and wires for use in bone surgery, excluding wires for binding and twisting.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 3651-2, *Determination of resistance to intergranular corrosion of stainless steels — Part 2: Ferritic,austenitic and ferritic-austenitic (duplex) stainless steels — Corrosion test in media containing sulfuric acid*

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

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

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

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

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

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

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

ISO 5832-9, *Implants for surgery — Metallic materials — Part 9: Wrought high nitrogen stainless steel*

ISO 5832-11, *Implants for surgery — Metallic materials — Part 11: Wrought titanium 6-aluminium 7-niobium alloy*

ISO 5832-12, *Implants for surgery — Metallic materials — Part 12: Wrought cobalt-chromium-molybdenum alloy*

ISO 5832-14, *Implants for surgery — Metallic materials — Part 14: Wrought titanium 15-molybdenum 5-zirconium 3-aluminium alloy*

ISO 6892-1, *Metallic materials — Tensile testing — Part 1: Method of test at room temperature*

ISO 14630:2012, *Non-active surgical implants — General requirements*

3 Material

Skeletal pins and wires shall be made of wrought materials in accordance with ISO 5832-1, ISO 5832-2, ISO 5832-3, ISO 5832-5, ISO 5832-6, ISO 5832-7, ISO 5832-8, ISO 5832-9, ISO 5832-11, ISO 5832-12 and ISO 5832-14.

4 Mechanical properties

The mechanical properties shall be in accordance with the requirements given in Table 1. The test methods in ISO 6892-1 shall be used in determining compliance with the tensile requirements.

Table 1 — Mechanical properties

Type of material	**Diameter**	**Ultimate tensile strength**	**Elongation**[a]
	d	min.	min.
	mm	MPa	%
Wrought stainless steel	$1 < d \leq 2{,}8$ $2{,}8 < d \leq 4$ $4 < d \leq 6$ ≤ 8	1 240 1 100 960 1 400[b]	3 5 5 —
Wrought unalloyed titanium[c]	≤ 3 > 3	730 750	3 5
Wrought titanium alloys	≤ 6	1 030	3
Wrought cobalt-chromium base alloy	≤ 6	1 240	7

[a] Gauge length = $5{,}65\sqrt{S_o}$ where S_o is the original cross-sectional area in mm^2 or equal to 50 mm if possible. If this is not possible, for wires smaller in diameter than 2,5 mm, a gauge length of 100 mm or 200 mm, equal to the total length between the grips, may be used (ISO 6892-1). However, in this case, the minimum value of elongation shall be agreed between the interested parties.

[b] ISO 5832-1 includes an extra-hard classification to accommodate the need for very high strength stainless steels for osteosynthesis devices.

[c] In specific clinical applications, the cross-sectional dimensions of the pin or wire used should correspond to the strength of the material.

5 Method of manufacture

Skeletal pins and wires shall be manufactured by a cold drawing or a cold working process. Welds are not permissible. If local heating is needed for re-shaping points made of stainless steel, this can only be permitted provided that the whole of the final product can be shown to satisfy the intergranular corrosion test according to ISO 3651-2.

6 Finish

The external surface finish shall be free from burs, scratches and other defects visible to the naked eye. The products shall be appropriately treated to provide surface passivation.

Special attention should be paid to screw threads, if applicable.

7 Sterilization

The requirements of ISO 14630:2012, Clause 9, shall apply.

8 Packaging

The requirements of ISO 14630:2012, Clause 10, shall apply.

9 Information supplied by the manufacturer

9.1 General

The requirements of ISO 14630:2012, Clause 11, apply together with the following particular requirement.

9.2 Instructions for use

The requirements of ISO 14630:2012, 11.3, apply, and shall include the following details when relevant:

a) the product name,

b) characteristic sizes,

c) material specification, and

d) the appropriate drill bit dimensional characteristics.

9.3 Marking on implant

The requirements of ISO 14630:2012, 11.5, apply, and shall include the following details when the dimensions permit:

— the manufacturer's name or trademark, and

— the batch code.

Additional markings could include length and diameter or cross-sectional size for skeletal pins.

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