INTERNATIONAL STANDARD

ISO 5838-1

Second edition
1995-11-15

Implants for surgery — Skeletal pins and wires —

Part 1:
Material and mechanical requirements

Implants chirurgicaux — Fils et broches pour os —

Partie 1: Matériaux et propriétés mécaniques

Reference number
ISO 5838-1:1995(E)

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

This second edition cancels and replaces the first edition (ISO 5838-1:1983), of which it constitutes a technical revision.

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

— *Part 1: Material and mechanical requirements*

— *Part 2: Steinmann skeletal pins — Dimensions*

— *Part 3: Kirschner skeletal wires*

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Case Postale 56 • CH-1211 Genève 20 • Switzerland
Printed in Switzerland

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Implants for surgery — Skeletal pins and wires —

Part 1:
Material and mechanical requirements

1 Scope

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

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 5838. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 5838 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 5832-1:1987, *Implants for surgery — Metallic materials — Part 1: Wrought stainless steel.*

ISO 5832-2:1993, *Implants for surgery — Metallic materials — Part 2: Unalloyed titanium.*

ISO 5832-3:—[1], *Implants for surgery — Metallic materials — Part 3: Wrought titanium 6-aluminium 4-vanadium alloy.*

ISO 5832-5:1993, *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 5832-7:1994, *Implants for surgery — Metallic materials — Part 7: Forgeable and cold-formed cobalt-chromium-nickel-molybdenum-iron alloy.*

ISO 5832-8:—[2], *Implants for surgery — Metallic materials — Part 8: Wrought cobalt-nickel-chromium-molybdenum-tungsten-iron alloy.*

ISO 5832-11:1994, *Implants for surgery — Metallic materials — Part 11: Wrought titanium 6-aluminium 7-niobium alloy.*

ISO 6892:1984, *Metallic materials — Tensile testing.*

3 Material

Skeletal pins and wires shall be made of wrought materials in accordance with the appropriate parts of ISO 5832 (see clause 2).

1) To be published. (Revision of ISO 5832-3:1990)

2) To be published. (Revision of ISO 5832-8:1987)

4 Mechanical properties

The mechanical properties, determined as specified in clause 5, shall be in accordance with the requirements given in table 1.

5 Test methods

The test methods to be used in determining compliance with the requirements of this part of ISO 5838 shall be in accordance with ISO 6892.

Table 1 — Mechanical properties

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

1) Gauge length $= 5{,}65\sqrt{S_o}$ where S_o is the original cross-sectional area in square millimetres 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). However, in this case the minimum value of elongation shall be agreed between the interested parties.

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

ICS 11.040.40

Descriptors: medical equipment, surgical implants, surgical pins, wire, specifications, materials specifications, mechanical properties.

Price based on 2 pages