International Standard ISO 5838/1

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION•МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ•ORGANISATION INTERNATIONALE DE NORMALISATION

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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

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards institutes (ISO member bodies). The work of developing International Standards is carried out through ISO technical committees. Every member body interested in a subject for which a technical committee has been set up 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.

Draft International Standards adopted by the technical committees are circulated to the member bodies for approval before their acceptance as International Standards by the ISO Council.

International Standard ISO 5838/1 was developed by Technical Committee ISO/TC 150, *Implants for surgery*, and was circulated to the member bodies in May 1982.

It has been approved by the member bodies of the following countries:

Australia	Ireland	Spain
Canada	Korea, Rep. of	Switzerland
China	Mexico	United Kingdom
Egypt, Arab Rep. of	New Zealand	USA
France	Poland	USSR
Germany, F.R.	Romania	
India	South Africa, Rep. of	

The member body of the following country expressed disapproval of the document on technical grounds:

Austria

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Implants for surgery — Skeletal pins and wires — Part 1: Material and mechanical requirements

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1 Scope and field of application

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

2 References

ISO 82, *Steel — Tensile testing.*

ISO 89, *Steel — Tensile testing of wire.*

ISO 5832, *Implants for surgery — Metallic materials*

— *Part 1: Wrought stainless steel.*

— *Part 3: Wrought titanium 6-aluminium 4-vanadium alloy.*

— *Part 5: Wrought cobalt-chromium-tungsten-nickel alloy.*

ASTM E8, *Methods of tension testing of metallic materials.*

NOTE — The above reference will be replaced by a reference to the appropriate International Standard when the latter becomes available.

3 Material

Skeletal pins and wires shall be made of materials in accordance with 3.1, 3.2 and 3.3.

Upon request, the supplier of the pins and wires shall produce evidence that the pins have been manufactured from material complying with the relevant International Standards.

3.1 Austenitic stainless steel

The stainless steel used in making skeletal pins and wires shall be in accordance with ISO 5832/1, composition A or B, and shall meet the requirements of the intergranular corrosion test specified in clause 8 of ISO 5832/1.

3.2 Wrought titanium 6-aluminium 4-vanadium alloy

Wire made of titanium alloy shall be in accordance with the requirements specified for composition in ISO 5832/3, excluding requirements for tensile strength and elongation which are specified in clause 4 of this International Standard.

3.3 Wrought cobalt-chromium-tungsten-nickel alloy

Cobalt-chromium-tungsten-nickel alloy used in making skeletal pins and wires shall be in accordance with ISO 5832/5.

4 Mechanical properties

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

5 Methods of test

The methods of test to be used in determining compliance with the requirements of this International Standard shall be in accordance with ISO 82 or ISO 89 or ASTM E8 depending on the form of the product.

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Table — Mechanical properties

Material	Condition	Diameter d mm	Ultimate tensile strength min. Mpa	Elongation[1] min. %
Stainless steel composition A	Cold worked but may have received stress relieving heat treatment at a temperature not exceeding 450 °C	$1 \leq d \leq 2{,}8$ $2{,}8 < d \leq 4$ $4 < d \leq 6$	1 400	3
			1 325 1 240	5
Stainless steel composition B		$1 \leq d \leq 1{,}5$ $1{,}5 < d \leq 2$ $2 < d \leq 2{,}8$ $2{,}8 < d \leq 4$ $4 < d \leq 6$	1 400 1 350	3
			1 300 1 200 1 100	5
Wrought titanium 6-aluminium 4-vanadium alloy	Cold worked and centreless ground		1 150	3
Wrought cobalt-chromium-tungsten-nickel alloy	Cold worked but may have received stress relieving heat treatment		1 280	7

1) Gauge length $= 5{,}65\sqrt{S_0}$ where S_0 is the original cross-sectional area in square millimetres or 50 mm if possible. If this is not possible, a gauge length of 100 mm or 200 mm should be preferred. However, in this case the minimum value of elongation shall be agreed between the interested parties.

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Norme internationale ISO 5838/1

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Avant-propos

L'ISO (Organisation internationale de normalisation) est une fédération mondiale d'organismes nationaux de normalisation (comités membres de l'ISO). L'élaboration des Normes internationales est confiée aux comités techniques de l'ISO. Chaque comité membre intéressé par une étude a le droit de faire partie du comité technique correspondant. Les organisations internationales, gouvernementales et non gouvernementales, en liaison avec l'ISO, participent également aux travaux.

Les projets de Normes internationales adoptés par les comités techniques sont soumis aux comités membres pour approbation, avant leur acceptation comme Normes internationales par le Conseil de l'ISO.

La Norme internationale ISO 5838/1 a été élaborée par le comité technique ISO/TC 150, *Implants pour la chirurgie*, et a été soumise aux comités membres en mai 1982.

Les comités membres des pays suivants l'ont approuvée :

Afrique du Sud, Rép. d'	Espagne	Roumanie
Allemagne, R.F.	France	Royaume-Uni
Australie	Inde	Suisse
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Chine	Mexique	USA
Corée, Rép. de	Nouvelle-Zélande	
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Le comité membre du pays suivant l'a désapprouvée pour des raisons techniques :

Autriche

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