INTERNATIONAL STANDARD

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Implants for surgery — Malleable wires for use as sutures and other surgical applications

Implants chirurgicaux — Fils malléables pour sutures et autres applications chirurgicales

Reference number
ISO 10334:1994(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.

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Implants for surgery — Malleable wires for use as sutures and other surgical applications

1 Scope

This International Standard specifies the dimensions and mechanical properties of malleable wires for use as sutures and other forms of tissue and implant fixation in surgery, and gives test methods. The mechanical properties specified are tensile strength, elongation, and resistance to damage in bending and in torsion.

Surface finish is not covered by this International Standard.

NOTES

1 For such surgical applications, it is essential that the wire can be twisted or knotted without fracturing or developing cracks or crevices in its surface.

2 Malleable wires may be used in close relationship to other implants. In these circumstances, it is important that stainless steel wire of compositions D and E (see ISO 5832-1) should only be used in relation to implants made of corresponding stainless steel, and wires made of high-nitrogen stainless steel should only be used in relation to implants of high-nitrogen stainless steel. This will reduce the possibility of galvanic corrosion occurring between the wires and implant.

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 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 5832-5:1993, *Implants for surgery — Metallic materials — Part 5: Wrought cobalt-chromium-tungsten-nickel alloy.*

ISO 5832-9:1992, *Implants for surgery — Metallic materials — Part 9: Wrought high nitrogen stainless steel.*

ISO 6018:1987, *Orthopaedic implants — General requirements for marking, packaging and labelling.*

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

ISO 7800:1984, *Metallic materials — Wire — Simple torsion test.*

ISO 7801:1984, *Metallic materials — Wire — Reverse bend test.*

ASTM F 86-91, *Standard Practice for Surface Preparation and Marking of Metallic Surgical Implants.*

3 Materials

Malleable wire shall be made from wrought stainless steel of composition D or E complying with ISO 5832-1, from unalloyed titanium complying with ISO 5832-2, from wrought high-nitrogen stainless steel complying with ISO 5832-9, or from wrought cobalt-chromium-tungsten-nickel alloy complying with ISO 5832-5.

4 Surface preparation

The wire may be subjected to a passivation process if requested by the customer. Such passivation process shall be performed in accordance with ASTM F 86.

5 Dimensions

The nominal diameter of the wire shall be stated by the manufacturer (see clause 8). The actual diameter of the wire shall equal the nominal diameter within the relevant tolerances given in table 1, 2, 3 or 4.

6 Mechanical properties

6.1 Tensile test

The tensile properties of the wire, determined as specified in clause 8, shall be in accordance with table 1, 2, 3 or 4.

6.2 Reverse bend test

Where applicable, the wire shall be tested as specified in ISO 7801, and in accordance with the bending angles and number of cycles laid down in table 5. The wire shall not fracture and no cracks shall be visible on the surface.

6.3 Torsion test

Where applicable, the wire shall be tested as specified in ISO 7800, and in accordance with the number of cycles laid down in table 5. The wire shall not fracture.

No cracks should be visible on the surface.

Table 1 — Dimensions and mechanical properties of wires made of stainless steel complying with ISO 5832-1

Wire diameter mm		Maximum tensile strength	Minimum elongation
nom.	tol.	MPa	%
0,1 to 0,199	± 0,005	895	30
0,2 to 0,299	± 0,007 5	860	30
0,3 to 0,599	± 0,01	825	30
0,6 to 0,799	± 0,013	790	35
0,8 to 1,099	± 0,02	760	35
1,1 to 1,6	± 0,025	690	40

Table 2 — Dimensions and mechanical properties of wires made of unalloyed titanium complying with ISO 5832-2

Grade	Wire diameter mm		Maximum tensile strength	Minimum elongation
	nom.	tol.	MPa	%
1	0,125 to 0,249 0,25 to 0,749 0,75 to 1,6	± 0,013 ± 0,025 ± 0,05	400	10 10 12
2	0,125 to 0,249 0,25 to 0,749 0,75 to 1,6	± 0,013 ± 0,025 ± 0,05	490	8 8 10
3	0,125 to 0,249 0,25 to 0,749 0,75 to 1,6	± 0,013 ± 0,025 ± 0,05	580	6 6 8
4	0,125 to 0,249 0,25 to 0,749 0,75 to 1,6	± 0,013 ± 0,025 ± 0,05	680	4 4 6

Table 3 — Dimensions and mechanical properties of wire made of cobalt-based alloy complying with ISO 5832-5

Wire diameter mm		Maximum tensile strength	Minimum elongation
nom.	tol.	MPa	%
0,1 to 0,199	± 0,005	1 450	35
0,2 to 0,299	± 0,007 5	1 380	40
0,3 to 0,599	± 0,01	1 310	40
0,6 to 0,799	± 0,013	1 240	45
0,8 to 1,099	± 0,02	1 170	45
1,1 to 1,6	± 0,025	1 140	45

Table 4 — Dimensions and mechanical properties of wires made of high-nitrogen stainless steel complying with ISO 5832-9

Wire diameter mm		Maximum tensile strength	Minimum elongation
nom.	tol.	MPa	%
0,1 to 0,199	± 0,005	1 370	15
0,2 to 0,299	± 0,007 5	1 300	20
0,3 to 0,599	± 0,01	1 230	20
0,6 to 0,799	± 0,013	1 160	25
0,8 to 1,099	± 0,02	1 100	25
1,1 to 1,6	± 0,025	1 070	25

Table 5 — Conditions for tests for resistance to bending and torsion

Wire diameter nom. mm	Angular deflection from zero position[1)]	Number of bending cycles	Number of torsion cycles
0,15 to 0,299	40°	20	10
0,3 to 0,799	40°	15	7,5
0,8 to 1,099	30°	12	6
1,1 to 1,6	30°	4	2

1) Applies to reverse bending test only.

7 Packaging and marking

Malleable wire shall be packaged and marked as specified in ISO 6018.

The material and nominal diameter of the wire shall be stated.

The packaging shall protect the wire from damage and contamination.

If the wire is packaged in a coiled configuration, the wire should lie flat and not adopt substantial corkscrew set.

8 Test methods

The test methods to be used in determining compliance with the requirements of this specification shall be those given in table 6.

Representative test pieces for the determination of mechanical properties shall be prepared in accordance with the provisions of ISO 6892.

Table 6 — Test methods

Requirements	Relevant subclause	Test methods
Méchanical properties Ultaminate tensile strength Elongation	6.1	 ISO 6892 ISO 6892
Reverse bend test	6.2	ISO 7801
Torsion test	6.3	ISO 7800