INTERNATIONAL STANDARD

ISO 10334

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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.

International Standard ISO 10334 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 5, *Osteosynthesis*.

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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.