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Implants for surgery — Requirements for production of forgings

Implants chirurgicaux — Exigences pour la fabrication des pièces forgées



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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 15374 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 1, *Materials*.

Implants for surgery — Requirements for production of forgings

1 Scope

This International Standard specifies requirements for the production of forgings of stainless steel, unalloyed titanium, titanium alloy or cobalt-based alloys intended to be used as semifinished products in the manufacturing of surgical implants.

NOTE An International Standard giving requirements for forgings is under preparation.

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 edition of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 5832-1:1997, *Implants for surgery — Metallic materials — Part 1: Wrought stainless steel.*

ISO 5832-2:1996, *Implants for surgery — Metallic materials — Part 2: Unalloyed titanium.*

ISO 5832-3:1996, *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 5832-6:1997, *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 5832-8:1997, *Implants for surgery — Metallic materials — Part 8: Wrought cobalt-nickel-chromium-molybdenum-tungsten-iron alloy.*

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

ISO 5832-10:1993, *Implants for surgery — Metallic materials — Part 10: Wrought titanium 5-aluminum 2,5-iron alloy.*

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

ISO 5832-12:1996, *Implants for surgery — Metallic materials — Part 12: Wrought cobalt-chromium-molybdenum alloy*.

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

EN 10204:1991, *Metallic products — Types of inspection documents*.

ETTC 2:1995¹⁾, *Microstructural standards for alpha + beta titanium alloy bars*.

NOTE The above reference will be replaced by references to appropriate International Standards when the latter become available.

3 Definitions

For the purposes of this International Standard, the following definitions apply.

3.1 closed-die forging

metallic article formed by pressing or hammering a metal into a closed die

3.2 batch lot

forgings to the same pattern produced from material from the same heat during one production run and, if subsequent heat treatment is required, heat-treated together

3.3 open-die forging

half-finished product shaped by impact or pressure, without a cutting operation

3.4 forging

semifinished product or implant component produced by one or more forging operations

4 Composition of forging stock

Forgings shall be made from forging stock of stainless steel, unalloyed titanium, titanium alloy or cobalt-based alloys that comply with the relevant parts of ISO 5832 (see clause 2).

5 Process control

5.1 Temperature

The heating temperature before forging shall be controlled.

For unalloyed titanium and titanium alloys, heating of the forging shall be carried out in such a manner as to minimize pick-up of hydrogen.

1) Available commercially from Deutsche Titan GmbH, Essen, Germany and Timet UK Ltd., Birmingham, UK. This information is given for the convenience of users of ISO 15374, and does not constitute an endorsement by ISO of these products. These microstructural standards have been prepared by the Technical Committee for European Titanium Products.

5.2 Shear banding

If shear bands are present in the material, they shall not impair the application of the product.

5.3 Surface

5.3.1 General

All products produced by hot forgings shall be descaled by suitable techniques and pickled if necessary.

5.3.2 Forgings made of unalloyed titanium or of titanium alloy

All oxide scale and oxygen-enriched material, including α case, shall be removed from the surface of unalloyed titanium and titanium alloy forgings.

5.4 Hydrogen content of forgings made of unalloyed titanium or of titanium alloy

When determined upon a cross-section taken from the smallest cross-sectional area of the forging, the hydrogen content shall not exceed 0,015 % (mass fraction).

5.5 Heat treatment

Any heat treatment after the forging operation shall be agreed between the supplier of the forgings and the customer.

NOTE To achieve specific properties in the finished product, alternative conditions may be specified such as hot-forging, warm-working or cold-forging,

6 Mechanical testing of forgings

Tensile test pieces shall be prepared and tested in accordance with ISO 6892. For annealed forgings, the tensile properties shall comply with the relevant part of ISO 5832.

7 Microstructure

7.1 General

When sectioned and the microstructure examined, the forging shall be free from evidence of underheating, overheating and harmful segregation. The surface shall be free of defects detrimental to the application of the finished product.

7.2 Grain size

7.2.1 Forgings made of stainless steel

After forging, the structure of the material shall comply with the requirements of the relevant part of ISO 5832.

7.2.2 Forgings made of unalloyed titanium

When determined in accordance with ASTM E112, the grain size shall be uniform and not larger than standard grain size 5.

7.2.3 Forgings made of titanium alloy

When determined in accordance with ETTC Publication 2, the microstructure shall comply with the acceptance limits given in that part of ISO 5832 corresponding to the type of titanium alloy.

8 Traceability

Batch traceability (see 3.2) shall be maintained throughout manufacture and delivery.

9 Identification and delivery

9.1 The forgings shall be parcelled in batches and packaged so as to protect them from damage in transit.

9.2 To each parcel a durable label shall be attached on which at least the following information shall be given:

- a) the name or identification symbol of the manufacturer of the forgings;
- b) the quantity of forgings and the design reference;
- c) the batch number.

9.3 Each delivery shall be accompanied by a release certificate (or a manufacturer's declaration of conformity, in accordance with EN 10204) giving at least the following information:

- a) the name and address of the supplier;
- b) the purchase or requisition number;
- c) the identity of the forgings schedule;
- d) the numbers of the applicable International Standards;
- e) the heat number of the forging stock;
- f) the batch number;
- g) the quantity of the forgings and the design reference;
- h) the test report for the batch;
- i) the delivery date.

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Descriptors: medical equipment, surgical implants, metallurgical products, forgings, specifications, manufacturing requirements, microstructure, traceability, tests, mechanical tests, identification methods, labels.

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