
International Standard



5839

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● Implants for surgery — Orthopaedic joint prostheses — Basic requirements

Implants chirurgicaux — Prothèses articulaires orthopédiques — Spécifications de base

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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.

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. They are approved in accordance with ISO procedures requiring at least 75 % approval by the member bodies voting.

International Standard ISO 5839 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*.

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Implants for surgery — Orthopaedic joint prostheses — Basic requirements

0 Introduction

Orthopaedic joint prostheses are designed to transmit load and translate movement under high stress conditions. The task of preparing International Standards to cover all eventualities is complicated by the limited range of biologically suitable materials.

The purpose of this International Standard, and of other International Standards relating to joint prostheses, is to provide direction in the control of manufacture and standard specifications for the different components of prostheses.

The insertion and removal of a prosthesis for the purposes of trial fitting at the time of the operation can damage the prosthesis. For this reason, reduction tests should be carried out using a test prosthesis, except in those cases where the prostheses are designed with protection for the bearing areas of the components. It is important, once implantation has been completed, that no components are used again after removal.

It is also necessary to take into account requirements for components of prostheses for partial and total replacement of particular joints. ISO 7206/1 and ISO 7207/1 deal, respectively, with partial and total hip joint prostheses and partial and total knee joint prostheses. Requirements for acrylic bone cement, commonly used in the implantation of joint prostheses, may be found in ISO 5833/1.

1 Scope and field of application

This International Standard specifies basic requirements for partial and total joint prostheses used in orthopaedic surgery, including those such as:

- a) hip joint prostheses;
- b) knee joint prostheses;
- c) ankle joint prostheses;
- d) shoulder joint prostheses;
- e) elbow joint prostheses;

- f) wrist joint prostheses;
- g) finger joint prostheses;
- h) toe joint prostheses.

Guidance on the use of joint prostheses is given in the annex.

2 References

ISO 5832, *Implants for surgery — Metallic materials —*

Part 1: Wrought stainless steel.

Part 2: Unalloyed titanium.

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

Part 4: Cobalt-chromium-molybdenum casting alloy.

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

Part 6: Wrought cobalt-nickel-chromium-molybdenum alloy.

Part 7: Forgeable and cold-formed cobalt-chromium-nickel-molybdenum-iron alloy.

ISO 5833/1, *Implants for surgery — Acrylic resin cements — Part 1: Orthopaedic applications.*

ISO 5834, *Implants for surgery — Ultra-high molecular weight polyethylene —*

Part 1: Powder form.

Part 2: Moulded forms.

ISO 6018, *Implants for surgery — General requirements for marking, packaging and labelling.*¹⁾

ISO 6474, *Implants for surgery — Ceramic materials based on alumina.*

ISO 7206/1, *Implants for surgery — Partial and total hip joint prostheses — Part 1: Classification, designation of dimensions and requirements.*

ISO 7207/1, *Implants for surgery — Partial and total knee joint prostheses — Part 1: Classification, definitions and designation of dimensions.*

1) At present at the stage of draft.

3 Materials

NOTE — All components should be manufactured using recognized methods of quality control, for example those used in the production of aerospace components.

3.1 Metals

Metal components for joint prostheses shall be made of one or more of the following materials:

- wrought stainless steel of composition B, in accordance with ISO 5832/1 (see clause 5);
- unalloyed titanium, in accordance with ISO 5832/2;
- wrought titanium 6-aluminium 4-vanadium alloy, in accordance with ISO 5832/3;
- cobalt-chromium-molybdenum casting alloy, in accordance with ISO 5832/4;
- wrought cobalt-chromium-tungsten-nickel alloy, in accordance with ISO 5832/5;
- wrought cobalt-nickel-chromium-molybdenum alloy, in accordance with ISO 5832/6;
- forgeable and cold-formed cobalt-chromium-nickel-molybdenum-iron alloy, in accordance with ISO 5832/7.

3.2 Plastics

Components made of ultra-high molecular weight polyethylene shall be made of material complying with the requirements of ISO 5834.

NOTES

- 1 Reference may be made to ISO 5833/1 for requirements for acrylic resin cements.
- 2 Components made of ultra-high molecular weight polyethylene should be stabilized, and the methods of processing and storing should maintain the dimensional stability of the component. Local heating should be avoided. Stress-relief annealing of semi-finished products may be required to ensure dimensional stability and freedom from distortion in the finished product. Details of suitable conditions should be obtained from the manufacturer of the polymer. The manufacturer of the component should keep records of the stabilization processes used.

3.3 Ceramics

Components made of alumina ceramic materials shall be of material complying with the requirements of ISO 6474.

4 Sterility

Prostheses and components shall, according to the requirements of the purchaser, be supplied either sterile or unsterile.

5 Design

Stainless steel shall not be used in combination with any other metal or alloy.

Stainless steel, unalloyed titanium and titanium alloys shall not form the contiguous bearing surfaces of joint prostheses.

NOTE — The following combinations have been found to be satisfactory:

- a) Stainless steel/polyethylene;
- b) Cobalt-based alloys/polyethylene;
- c) Unalloyed titanium/polyethylene;
- d) Titanium alloy/polyethylene;
- e) Alumina/polyethylene;
- f) Alumina/alumina.

6 Finish

6.1 Metals

6.1.1 General

The surfaces of metallic components, when examined with the naked eye (corrected if necessary), shall be free of imperfections such as scale, toolmarks, nicks, scratches, cracks, cavities, burrs and other defects that would impair the serviceability of the implant.

The surfaces, when examined with the naked eye (corrected if necessary), shall be free of embedded or deposited finishing materials or other contaminants. Components shall be cleaned, degreased, rinsed and dried. All polishing operations shall be performed using an iron-free medium.

6.1.2 Bearing surfaces

Bearing surfaces shall be polished to a mirror finish.

6.1.3 Non-bearing surfaces

Non-bearing surfaces intended to be in contact with soft tissues shall have either a polished or a satin finish.

6.1.4 Surface treatment

All surfaces shall be rendered passive by a process suitable for the metal concerned.

6.2 Plastics materials

The bearing surfaces of components made of plastics materials shall, in the as-delivered condition, be free from particulate contamination when examined with the naked eye (corrected if necessary). At no stage shall the bearing surfaces be prepared by a method employing an abrasive or polishing compound.