
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.