

Orthopaedic joint prostheses —

Part 1: Specification for general requirements

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Committees responsible for this British Standard

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- British Institute of Surgical Technologists
- British Medical Association
- British Orthopaedic Association
- British Steel Industry
- British Surgical Trades Association Incorporated
- Department of Health
- Department of Trade and Industry (National Engineering Laboratory)
- Royal College of Surgeons of England
- Scottish Office
- Coopted members

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Foreword

This Part of BS 7251 has been prepared under the direction of the Health Care Standards Policy Committee and supersedes BS 3531-9:1982, which is withdrawn.

General requirements for joint prostheses were first published as BS 3531-9:1982. BS 3531, published in twenty-three Parts, gave requirements and guidance on joint prostheses, implants for osteosynthesis and materials for the manufacture of surgical implants. BS 3531 now applies only to implants for osteosynthesis; requirements and guidance specific to joint prostheses will form a separate standard (BS 7251); requirements for orthopaedic implants, i.e. aspects common to osteosynthesis and joint replacement, will form another separate standard (BS 7254); and requirements and guidance for materials will form two further separate standards (BS 7252 covering metals and BS 7253 covering non-metals). Attention is drawn to the recommendations for care and handling of implants and for the retrieval and examination of implants given in BS 7254-3 and BS 7254-4.

This Part of BS 7251 is related to ISO 5839:1985 “*Implants for surgery — Orthopaedic joint prostheses — Basic requirements*”, published by the International Organization for Standardization (ISO). It differs from ISO 5839 in a number of details, chiefly related to the metals of construction, the surface finish requirements, the means of sterilization and the marking of ceramic components.

This Part of BS 7251 differs from the superseded BS 3531-9:1982 chiefly in that whereas it requires components of joint prostheses to be marked with a traceability reference, it no longer requires that this reference shall take the form of a unique identifying mark. However, it should be noted that traceability of a component to some parts of its manufacturing history, in particular to radiographs taken during non-destructive testing to assess the soundness of metal castings, cannot be ensured in the absence of a unique identifying mark. It differs also in permitting metal components to be made from an enlarged range of materials and in specifying the material to be used for polyethylene components.

Orthopaedic joint prostheses are required to transmit load and translate motion, frequently under highly stressed conditions. The components of joint prostheses should ideally function from the time of implantation for the remainder of a patient's life span. This introduces difficulties in testing suitable materials, because accelerated laboratory studies present major problems and there are difficulties in evaluating the stresses on joint prostheses during use.

The objective of BS 7251 is to provide a framework within which surveillance of manufacture can be established, and specifications for components can be developed.

Requirements for acrylic bone cement, commonly used in the implantation of joint prostheses, may be found in BS 7253-1. Requirements for knee joint prostheses may be found in BS 7251-2 and requirements for hip joint prostheses may be found in BS 7251-3 and BS 7251-4. Methods for the determination of endurance properties of stemmed femoral components of hip joint prostheses may be found in BS 7251-5 and BS 7251-6. Consideration is to be given to the preparation of further Parts of BS 7251 to cover methods of test of other mechanical properties of joint prostheses.

It is strongly recommended that the products specified in this Part of BS 7251 should be manufactured according to the recommendations given in the “Guide to Good Manufacturing Practice for Orthopaedic Implants”¹⁾.

¹⁾ Compiled by the Department of Health and Social Security; published and available from Her Majesty's Stationery Office. ISBN 0 11 320846 4.