

Orthopaedic implants —

Part 5: Specification for production of castings made of cobalt-chromium-molybdenum alloy

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Committees responsible for this British Standard

The preparation of this British Standard was entrusted by the Health Care Standards Policy Committee (HCC/-) to Technical Committee HCC/18, upon which the following bodies were represented:

- British Forging Industry Association
- British Industrial Ceramic Manufacturers' Association
- British Institute of Surgical Technologists
- British Investment Casting Trade Association
- British Orthopaedic Association
- British Steel Industry
- British Surgical Trades Association
- Department of Health
- Department of Trade and Industry (Laboratory of the Government Chemist)
- Department of Trade and Industry (National Engineering Laboratory)
- Department of Trade and Industry (National Physical Laboratory)
- Ministry of Defence
- Royal College of Surgeons of England
- Royal Veterinary College
- Scottish Office
- Sterilised Suture Manufacturers' Association
- Coopted members

The following bodies were also represented in the drafting of the standard, through subcommittees and panels:

- British Ceramic Research Ltd.
- British Dental Association
- British Medical Association
- Institute of Sterile Services Management

This British Standard, having been prepared under the direction of the Health Care Standards Policy Committee, was published under the authority of the Board of BSI and comes into effect on 31 August 1990

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Foreword

This Part of BS 7254 has been prepared under the direction of the Health Care Standards Policy Committee and supersedes BS 3531-4:1987 which is withdrawn.

Requirements for orthopaedic implants (then termed “surgical implants”) were first published in 1962 as BS 3531. In 1968 a part revision of BS 3531:1962 was issued as BS 3531-1, which dealt with surgical implants made of all materials. In 1980 the first four Parts of a multi-part version of BS 3531 were published. Part 4:1980 gave requirements for cast implants made of cobalt-chromium-molybdenum alloy.

Part 4:1980 was revised in 1987 in the form of a process specification applying to the production of castings as intermediate products for conversion into implants by means of machining or other finishing operations.

Such castings may either be purchased by an implant manufacturer or finisher from a subcontracted foundry, or be produced in the foundry department of an implant manufacturer. This change was considered necessary because of different production control methods adopted by different manufacturers and because different finishing operations are required for different types of implant.

It is strongly recommended that castings should be manufactured according to the recommendations given in the “Guide to Good Manufacturing Practice for Orthopaedic Implants”¹⁾.

In view of the increase in the number of Parts, and with a view to facilitating the implementation of published or forthcoming international implant standards, the British Standard relating to implants has been restructured. Accordingly, the number BS 3531 is reserved for standards on implants for osteosynthesis, BS 7251 covers joint prostheses, BS 7252 covers metallic materials for surgical implants, BS 7253 covers non-metallic materials for surgical implants and BS 7254 covers orthopaedic implants, i.e. aspects common to both osteosynthesis and joint replacement.

This edition of BS 7254-5 introduces editorial changes to reflect this restructuring and up-dates cross-references but otherwise makes no changes to the specification for production of castings previously published as BS 3531-4:1987. It does not reflect a full review or revision of the standard, which will be undertaken in due course.

Product certification. Users of this British Standard are advised to consider the desirability of third party certification of product conformity with this British Standard based on testing and continuing surveillance, which may be coupled with assessment of a supplier’s quality systems against the appropriate Part of BS 5750.

Enquiries as to the availability of third party certification schemes will be forwarded by BSI to the Association of Certification Bodies. If a third party certification scheme does not already exist, users should consider approaching an appropriate body from the list of Association members.

¹⁾ Complied by the Department of Health and Social Security; published and available from Her Majesty’s Stationery Office. ISBN 011 320846 4.