BRITISH STANDARD

BS 7254 :
Part 5 : 1990

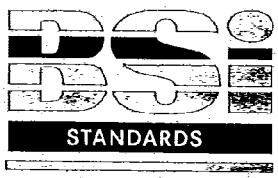
UDC 615.461 : 616.71-74 :
006.3/.8

Orthopaedic implants

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

Implants
Partie 5. Production de moulages à base d'alliages cobalt-chrome-molybdène - Spécifications

Implantate
Teil 5. Herstellung von Gussstücken aus Kobalt-Chrom-Molybdänlegierungen



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

First published, as BS 3531, July 1962
First part revision (Part 1 only) December 1968
Second part revision (Part 4 only) July 1980
Third revision February 1987
Fourth revision as BS 7254 : Part 5 August 1990

The following BSI references relate to the work on this standard:
Committee reference HCC/18
Draft announced *BSI News*, October 1989

ISBN 0 580 18323 8

Amendments issued since publication

Amd. No.	Date	Text affected

Contents

Foreword

This Part of BS 7254 has been prepared under the direction of the Health Care Standards Policy Committee and supersedes BS 3531 : Part 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 : Part 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 : Part 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 : Part 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.

Compliance with a British Standard does not of itself confer immunity from legal obligations.

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

Specification

1 Scope

This Part of BS 7254 specifies requirements for the production of castings made of cobalt-chromium-molybdenum alloy for use in the manufacture of surgical implants.

NOTE 1. This Part of BS 7254 applies to castings produced by a subcontractor and dispatched to an implant manufacturer and to castings produced by an implant manufacturer's foundry for conversion into finished implants by the same manufacturer. See appendix A for information to be supplied by the purchaser.

NOTE 2. The titles of the publications referred to in this standard are listed on the inside back cover.

2 Definitions

For the purposes of this Part of BS 7254, the definitions given in BS 6324 apply, together with the following.

2.1 implant manufacturer

The person or company that markets the finished implant.

2.2 tree

An integral group of castings, together with the material contained within the feed system, produced by casting into a multi-cavity mould.

2.3 purchaser

The company that commissions and buys castings from a subcontracted foundry, or the department of an implant manufacturing company that requisitions castings produced in that company's foundry.

3 Composition of re-melting stock

Castings shall be made of re-melting stock that is certificated to comply with the requirements for cast cobalt-chromium-molybdenum alloy specified in BS 7252 : Part 4, and to which no additions shall be made (see clause 9(g)).

NOTE. All re-melting stock should be stored and identified in order to prevent use of an incorrect alloy and/or contamination with other materials. If furnaces are used for melting alloys of different compositions, care should be taken to prevent contamination of the alloy.

4 Process control

At the initiation of the casting process for a new design of product (involving casting design, gating, tree assembly, coating, casting method or casting temperature parameters) or on subsequent modification of any design feature or process parameter, castings shall be metallographically examined to determine that no abrupt change in grain size or other detrimental metallographic features occur in regions expected to be most highly stressed in service.

The validated casting process shall be documented and all products produced by this process shall be certificated to this effect (see clause 9(h)).

5 Chemical analysis of castings

Analysis of test samples shall be carried out as follows.

(a) In foundries where only cobalt-chromium-molybdenum alloy complying with BS 7252 : Part 4 is in use, the first and last unit cast of each master melt shall be analysed quantitatively.

If the composition of the first unit cast does not comply with that given in table 1 of BS 7252 : Part 4 : 1990, that consignment of master melt shall be rejected.

If the last unit cast does not comply with the composition given in table 1 of BS 7252 : Part 4 : 1990 each tree of components cast from that master melt shall be checked quantitatively and any tree of which the composition is found not to comply with that given in table 1 of BS 7252 : Part 4 : 1990 shall be rejected.

(b) In foundries where other alloys are in use, the first and last unit cast of each master melt shall be tested as described in (a). All other unit casts shall be monitored and any unit casts of incorrect composition shall be rejected.

6 Mechanical testing

6.1 Tensile test pieces shall be obtained by one or both of the following methods (see item (a) of appendix A):

(a) tensile test pieces cast integrally with, or gated to, castings;

(b) tensile test pieces, cast under similar conditions to the castings they represent, but cast in a separate mould from the same melt.

6.2 Tensile test pieces shall be of the dimensions of one of the proportional round test pieces specified in BS 18 (see item (a) of appendix A).

6.3 If castings are to be supplied in the as-cast condition, a minimum of two as-cast tensile test pieces shall be tested from each master melt.

If castings are heat treated, tensile test pieces shall be heat treated together with the castings they represent and one tensile test piece shall be tested after heat treatment. If castings are to be supplied in any other special condition (see item (b) of appendix A), the relevant test pieces shall be in the same condition.

In the case of castings which are given repeated, or a series of, heat treatments, sufficient tensile test pieces shall be prepared to allow one test after each heat treatment and any retests. (See item (a) of appendix A.)

6.4 Tensile test pieces shall be tested in accordance with BS 18 and shall comply with the values given in table 2 of BS 7252 : Part 4 : 1990 (see item (a) of appendix A).

6.5 If any tensile test piece does not comply with **6.4**, one or both of the following procedures shall be adopted (see clause **9**(j) and item (a) of appendix A).

(a) Two further tensile test pieces from the same batch shall be tested.

If either tensile test piece does not comply with **6.4**, the batch shall be rejected.

(b) The batch shall be re-heat treated and two tensile test pieces shall be tested. If either tensile test piece does not comply with **6.4**, the batch shall be rejected.

7 Non-destructive testing

7.1 Radiographic examination

If castings are to be radiographically examined (see item (c) of appendix A), the examination shall be made by a technique shown to be sensitive to better than 2 %, in order to achieve an acceptable quality of radiographic image.

If the casting being tested is subsequently to be converted into a finished implant that will bear a unique reference number (see item (d) of appendix A), the radiograph(s) of that casting shall be marked so as to allow traceability of the radiograph and casting (see clause **9**(d) and (k)).

NOTE. Guidance may be obtained from BS 2737, BS 3683, BS 3971, BS 4080 and British Standard M 34.

7.2 Penetrant flaw detection

If castings are to be examined by a liquid penetrant flaw detection technique (see item (e) of appendix A), the examination shall be made in accordance with BS 6443 (see clause **9**(k)).

NOTE. The results of penetrant flaw detection testing during manufacture may not be an indication of the integrity of the finished component.

8 Rectification of defects in castings

8.1 Any rectification of defects by welding shall exclude repairs in the regions stated to be subjected to high stress in service (see item (f) of appendix A).

8.2 Following any repair by welding of castings to be supplied in the heat-treated condition, the castings shall be heat treated (see clause **9**(i) and item (b) of appendix A).

9 Identification and delivery

Each batch of castings shall be accompanied by a release certificate giving at least the following information and statements:

(a) the purchase or requisition number;

(b) the master melt identity;

(c) the batch number;

(d) if appropriate, the traceability numbers unique to each casting in the batch (see **7.1**);

(e) the results of all testing performed on the batch, including the chemical composition (see clause **5**);

(f) a statement that the castings have been produced in accordance with this Part of BS 7254, for example, by recording the number and date of this British Standard, i.e. BS 7254 : Part 5 : 1990[1)]

(g) a statement that the re-melting stock complied with BS 7252 : Part 4 (see clause **3**);

(h) a statement that the castings were produced by the documented process (see clause **4**);

(i) a statement as to whether the castings and associated tensile test pieces are in the as-cast or heat-treated condition, or any other special condition;

(j) a statement that the batch has passed the tensile tests detailed in clause **6**, including whether retests and/or re-heat treatment was necessary;

(k) if appropriate, a statement that the batch has passed the non-destructive tests detailed in **7.1** and/or **7.2**;

(l) if appropriate, a statement that defects have been repaired and the requirements of clause **8** have been satisfied.

NOTE. If a batch of castings is shipped from a subcontractor or foundry, it should be packaged so as to prevent transit damage. A batch may be subdivided for shipment, in which case each package should be identifiable with regard to the other packages and to the accompanying documentation listed in (a) to (l).

If a batch of castings is transferred within the same manufacturing premises (e.g. from the foundry to the machining department) it should be accompanied by the release certificate, but packaging may not be required.

[1)] Marking BS 7254 : Part 5 : 1990 or in relation to a product represents a manufacturer's declaration of conformity, i.e. a claim by or on behalf of the manufacturer that the product meets the requirements of the standard. The accuracy of the claim is therefore solely the responsibility of the person making the claim. Such a declaration is not be confused with third party certification of conformity, which may also be desirable.

Appendix

Appendix A. Information to be supplied by the purchaser

The following information should be supplied to the foundry by the purchaser of the castings when placing an order or requisition.

(a) The method of obtaining tensile test pieces (see **6.1**), the dimensions of the test pieces (see **6.2**), the number of test pieces (see **6.3**), the method of tensile test (see **6.4**) and the procedure to be used in the case of retests (see **6.5**).

(b) Whether the castings and associated tensile test pieces are to be supplied in the as-cast condition or in the heat-treated condition or in any other special condition (see **6.3** and **8.2**).

(c) Whether radiographic examination of the castings is required and, if so, the details of the examination procedure and the pass/fail criteria (see **7.1**).

(d) Whether each casting is to be uniquely traceable to all production and testing records.

(e) Whether penetrant flaw detection of the castings is required and, if so, the details of the examination procedure and the pass/fail criteria (see **7.2**).

(f) Whether defects in castings may be repaired and, if so, a statement identifying the regions of the casting that are subjected to high stress in service and in which repairs are prohibited (see **8.1**).

Publications referred to

BS 18	Methods for tensile testing of metals (including aerospace materials)
BS 2737	Terminology of internal defects in castings as revealed by radiography
BS 3531[1)]	Implants for osteosynthesis
BS 3683	Glossary of terms used in non-destructive testing
BS 3971	Specification for image quality indicators for industrial radiography (including guidance on their use)
BS 4080	Methods for non-destructive testing of steel castings
BS 5750[1)]	Quality systems
BS 6324	Terms relating to surgical implants
BS 6443	Method for penetrant flaw detection
BS 7251[1)]	Orthopaedic joint prostheses
BS 7252	Metallic materials for surgical implants Part 4 Specification for cobalt-chromium-molybdenum casting alloy
BS 7253[1)]	Non-metallic materials for surgical implants
British Standard M 34	Method of preparation and use of radiographic techniques

[1)] Referred to in the foreword only.

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