BRITISH STANDARD

BS 7254 : Section 6.1 : 1990

Orthopaedic implants

Part 6. Forgings

Section 6.1 Specification for production of forgings

Implants orthopédiques
Partie 6. Pièces forgées
Section 6.1 Production des pièces forgées — Spécifications

Orthopädische Implantate
Teil 6. Schmiedestücke
Abschnitt 6.1 Herstellung von Schmiedestücken

BSI STANDARDS

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 Incorporated
Department of Health
Department of Trade and Industry (National Engineering Laboratory)
Department of Trade and Industry (Laboratory of the Government Chemist)
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 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 December 1990

The following BSI references relate to the work on this standard:
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Foreword

This Section of BS 7254 has been prepared under the direction of the Health Care Standards Policy Committee and, together with BS 7254 : Section 6.2, supersedes BS 3531 : Part 3 : 1980 which is withdrawn.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 3 : 1980 comprising requirements for forged components made of stainless steel, titanium and titanium alloy. Between 1980 and 1988 a further nineteen Parts of BS 3531 were published specifying materials, design and performance, and giving guidance for different types of surgical implant.

In view of the increase in the number of Parts, and with a view to facilitating the implementation of published and forthcoming international implant standards, BS 3531 has been restructured. Accordingly, the number BS 3531 is reserved for standards for 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.

The greatest difference between BS 7254 : Part 6 and BS 3531 : Part 3 : 1980 is that BS 7254 : Part 6 comprises two Sections, Section 6.1 giving requirements for the production of forgings and Section 6.2 giving a method for specifying forgings. Sections 6.1 and 6.2 apply only to forgings which have not been machined or subjected to other finishing operations and which are, therefore, intermediate products for further processing and not, in themselves, finished implants. Such forgings may either be purchased by an implant manufacturer or finisher from a subcontracted forger, or be produced in the forging department of an implant manufacturer. This change was considered necessary because of the different production control methods adopted by different manufacturers and because different metallurgical properties and finishing operations are required for different types of implant.

BS 7254 : Part 6 also differs from BS 3531 : Part 3 : 1980 in that it applies to forgings made from any of the wrought metals and alloys specified in BS 7252, i.e. stainless steel, unalloyed titanium, titanium alloy and cobalt-based alloys.

It is strongly recommended that forgings should be manufactured according to the recommendations given in the 'Guide to Good Manufacturing Practice for Orthopaedic Implants'[1].

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.

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[1] Compiled 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 Section of BS 7254 specifies requirements for the production of closed-die forgings of stainless steel, unalloyed titanium, titanium alloy or cobalt-based alloys for use in the manufacture of surgical implants.

NOTE 1. Attention is drawn to the method for specifying forgings given in BS 7254 : Section 6.2.

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 British Standard the definitions contained in BS 6324 apply, together with the following.

2.1 closed-die forging

An article formed by pressing or hammering a metal into a closed die.

2.2 batch (lot)

Forgings to the same pattern produced from material from the same cast during one production run and, if heat treatment is required, heat-treated together.

3 Composition of forging stock

Forgings shall be made from wrought forging stock of stainless steel, unalloyed titanium, titanium alloy or cobalt-based alloys that complies with BS 7252 : Part 1, 2, 3, 5, 6, 7, 8 or 9.

NOTE 1. It is strongly recommended that the forging stock is certificated to comply with the relevant Part of BS 7252.

NOTE 2. All forging stock should be stored and identified in such a way as to prevent use of an incorrect alloy.

4 Process control

4.1 Temperature

The temperature during forging shall be controlled to avoid underheating and overheating. For unalloyed titanium and titanium alloys, heating for forging shall be carried out in an oxidizing atmosphere.

NOTE The oxidizing atmosphere is intended to minimize pick-up of hydrogen.

4.2 Shear banding

The forging process shall be carried out in such a way as to prevent the formation of shear bands in the material.

4.3 Surface

4.3.1 *General*

All forgings shall be descaled and pickled.

4.3.2 *Forgings made of unalloyed titanium or of titanium alloy*

All oxide scale and oxygen-enriched material, including α case, shall be removed from the surface of titanium and titanium alloy forgings.

5 Hydrogen content of forgings made of unalloyed titanium or of titanium alloy

When determined upon a cross section taken from the region of the highest practicable surface area to volume ratio, i.e. at the smallest cross-sectional area of the forging, the hydrogen content shall not exceed 0.015 % (m/m).

6 Mechanical testing of annealed forgings

Tensile test pieces shall be prepared and tested in accordance with BS 18, and the tensile properties shall comply with the tensile properties of the relevant metal as specified in the relevant Part of BS 7252.

7 Microstructure

7.1 General

When sectioned and the microstructure examined, the forging shall be free from evidence of underheating, overheating, harmful segregation, surface contamination and shear banding.

7.2 Grain structure

7.2.1 *Forgings made of stainless steel*

When determined in accordance with BS 4990, the grain size shall be not larger than standard grain size 4. The carbide network shall comply with BS 7252 : Part 1 or 9 as appropriate to the type of steel.

7.2.2 *Forgings made of unalloyed titanium*

When determined in accordance with ASTM E112, the grain size shall be uniform and not coarser than micro-grain size number 5.

7.2.3 *Forgings made of titanium alloy*

When assessed in accordance with Publication ETTC 2, the grain structure shall comply with the microstructural acceptance limits for standard quality alloy.

8 Identification and delivery

8.1 The forgings shall be parcelled in batches and packaged so as to protect them from damage in transit.

8.2 To each parcel there shall be attached a durable label on which at least the following information shall be given:

(a) the name or identification symbol of the manufacturer of the forgings;

(b) the quantity of forgings and the design reference;

(c) the batch number.

8.3 Each delivery shall be accompanied by a release certificate giving at least the following information:

(a) the name and address of the supplier;

(b) the purchase or requisition number;

(c) the test report for the batch;

(d) the identity of the forging schedule;

(e) the batch number;

(f) the cast number of the forging stock;

(g) the quantity of forgings and the design reference;

(h) the delivery date;

(i) the number of this British Standard, i.e. BS 7254 : Section 6.1[1)]

[1)] Marking BS 7254 : Section 6.1 on 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 reponsibility of the person making the claim. Such a declaration is not to be confused with third party certification of conformity which may also be desirable.

Publication(s) referred to

BS 18	Method for tensile testing of metals (including aerospace materials)
BS 3531[1)]	Implants for osteosynthesis
BS 4490	Methods for micrographic determination of the grain size of steel
BS 5750[1)]	Quality systems
BS 6324	Terms relating to surgical implants
BS 7251[1)]	Orthopaedic joint prostheses
BS 7252	Metallic materials for surgical implants Part 1 Specification for wrought stainless steel Part 2 Specification for unalloyed titanium Part 3 Specification for wrought titanium 6-aluminium 4-vanadium alloy Part 5 Specification for wrought cobalt-chromium-tungsten-nickel alloy Part 6 Specification for wrought cobalt-nickel-chromium-molybdenum alloy Part 7 Specification for cobalt-chromium-nickel-molybdenum-iron alloy Part 8 Specification for wrought cobalt-nickel-chromium-molybdenum-tungsten-iron alloy Part 9 Specification for high-nitrogen stainless steel
BS 7253[1)]	Non-metallic materials for surgical implants
BS 7254	Orthopaedic implants Part 6 Forgings Section 6.2 Method for specifying forgings
ASTM E112	Standard methods for estimating the average grain size of metals[2)]
Publication ETTC 2	'Microstructural standards for alpha + beta titanium alloy bars[3)]

[1)] Referred to in foreword only.

[2)] ASTM publications are available from American Technical Publishers Ltd., 68a Wilbury Way, Hitchin, Hertfordshire SG4 0TP.

[3)] Published in 1979 by the Technical Committee of European Titanium Producers (ETTC) and available from IMI Titanium Ltd, Technical Services Department, P.O. Box 704, Witton, Birmingham B6 7UR.

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Information on standards

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