BRITISH STANDARD

BS 7254 : Section 6.2 : 1990

Orthopaedic implants

Part 6. Forgings

Section 6.2 Method for specifying forgings

Implants orthopédiques
Partie 6. Pièces forgées
Section 6.2 Méthode de spécification des pièces forgées

Orthopädische Implantate
Teil 6. Schmiedestücke
Abschnitt 6.2 Verfahren zur Festlegung von Anforderungen an Schmiedestücke

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:
Committee reference HCC/18
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Contents

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Care Standards Policy Committee and, together with BS 7254 : Section 6.1, supersedes BS 3531 : Part 3 : 1980 which is withdrawn.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 6.2 giving a method for specifying forgings and Section 6.1 giving requirements for the production of 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.

As this Section of BS 7254 : Part 6 is based on requirements to be agreed between the purchaser and the forger, it is not appropriate for any claim to be made that a forging complies with BS 7254 : Section 6.2.

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)]

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.

Method

1 Scope

This Section of BS 7254 describes a method for specifying requirements for 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 requirements for the production of forgings specified in BS 7254 : Section 6.1.

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.

closed-die forging

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

3 Information to be supplied by the purchaser to the forger

The information listed in items (a) to (i) shall be supplied by the purchaser to the forger, if necessary in consultation with the forging stock supplier and/or the forger:

(a) forging schedule, giving details of the forgings and the forging process;

NOTE 1. At the initiation of the forging process for a new design of product or on subsequent modification of any design feature or process parameter, the forger should compile a forging schedule containing all details of the metal, production, processing, inspection and testing of the forgings as agreed by the purchaser. All forgings produced by this process should be certificated to this effect.

(b) forging drawing, showing any particular grain flow required and the frequency at which the grain flow should be checked;

NOTE 2. If a particular grain flow is required by the purchaser, one forging taken at the beginning of production of each new pattern of forging should be sectioned and etched to reveal the grain flow. The grain flow should comply with the requirements of the forging drawing. If no particular grain flow is required by the purchaser, the grain flow is at the forger's discretion. Subsequently, unless otherwise agreed with the purchaser, one forging should be checked when there is a significant change in the forging process.

(c) condition (i.e. annealed, as forged, cold-worked or warm-worked) in which the forgings are to be supplied;

NOTE 3. The strength of forgings, with the exception of titanium alloy forgings, may be increased by cold-working or warm-working.

(d) tensile properties of as forged, cold-worked or warm-worked forgings.

NOTE 4. See BS 7254 : Section 6.1 regarding the tensile properties of annealed forgings.

(e) condition of supply drawing, showing dimensions and tolerances;

(f) sampling plans;

NOTE 5. The sampling plans and acceptance/rejection numbers should be based on BS 6001 : Part 1.

(g) details of tensile test pieces;

NOTE 6. The size and type of test piece, and the region of the forging from which it is taken, should be given.

(h) list of defects which are to be categorized as harmful;

(i) details of non-destructive testing.

NOTE 7. Every descaled and pickled forging should be examined either by a dye penetrant test in accordance with BS 6443 or by visual examination using × 2 magnification, and should be free from harmful defects. The appropriate number (see item (f)) of descaled and pickled forgings should be ground along the flashline and similarly examined.

Publications referred to

BS 3531[1)]	Implants for osteosynthesis
BS 6001	Sampling procedures for inspection by attributes Part 1 Specification for sampling plans indexed by acceptable quality level (AQL) for lot-by-lot inspection
BS 6324	Terms relating to surgical implants
BS 6443	Method for penetrant flaw detection
BS 7251[1)]	Orthopaedic joint prostheses
BS 7252[1)]	Metallic materials for surgical implants
BS 7253[1)]	Non-metallic materials for surgical implants
BS 7254	Orthopaedic implants Part 6 Forgings Section 6.1 Specification for production of forgings

[1)] Referred to in the foreword only.

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