BSI

BS 7254 : Part 2 : 1990

British Standard

Orthopaedic implants

Part 2. Specification for general requirements for materials and finish

Implants orthopédiques
Partie 2. Caractéristiques générales des matériaux et finitions — Spécifications

Orthopädische Implantate
Teil 2. Allgemeine Anforderungen an Werkstoffe und Oberflächenbeschaffenheit

Foreword

This Part of BS 7254 has been prepared under the direction of the Health Care Standards Policy Committee and, together with BS 7254 : Part 1, supersedes BS 3531 : Part 1 : 1980 which is withdrawn.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 revision of BS 3531 were published, Part 1 : 1980 comprising requirements for general aspects and for marking and packaging of surgical implants. Between 1980 and 1988 a further 19 Parts of BS 3531 were published specifying materials, design and performance, and giving guidance on different types of surgical implants.

In view of the growth of the number of Parts, and with a view to facilitating the implementation of published and forthcoming ISO implant standards, BS 3531 is being restructured. Accordingly, the number BS 3531 will be reserved for standards for implants for osteosynthesis, BS 7251 will cover joint prostheses, BS 7252 will cover metallic materials for surgical implants, BS 7253 will cover non-metallic materials for surgical implants and BS 7254 will cover orthopaedic implants, i.e. aspects common to both osteosynthesis and joint replacement.

Requirements for marking and packaging of orthopaedic implants are published as BS 7254 : Part 1.

The materials specified are those which are the most suitable in the light of present knowledge to provide optimum mechanical properties in relation to requirements for corrosion resistance and physiological compatibility with living tissues. All metals will corrode or erode in the body to a greater or lesser extent depending on the local conditions.

In determining the choice of material to be used in any particular case, due regard should be paid to its mechanical properties, e.g. wrought titanium is unsuitable for load bearing surfaces that involve movement of metal on metal.

Orthopaedic implants should not be used again after removal from the patient.

It is strongly recommended that the products specified in this Part of BS 7254 should be manufactured according to the recommendations given in the 'Guide to Good Manufacturing Practice for Orthopaedic Implants'*.

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 continued 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 Scope

This Part of BS 7254 specifies general requirements for materials and finish of orthopaedic implants used for bone surgery including osteosynthesis and joint replacement, and made of wrought austenitic stainless steel, cast cobalt-based alloys, wrought cobalt-based alloys, wrought titanium, wrought titanium alloy and non-metallic materials.

NOTE 1. This Part of BS 7254 gives requirements for implants for osteosynthesis and for partial and total joint prostheses. These requirements may be referred to in, or superseded by, Parts of BS 3531 and BS 7251 as regards particular types of orthopaedic implant. However, it is unlikely that every type of orthopaedic implant will be covered by a Part of BS 3531 or BS 7251 and, if no individual product specification exists, this Part of BS 7254 is intended to give requirements applicable to orthopaedic implants in general.

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

2 Orthopaedic implants made of wrought stainless steel

2.1 Material and fabrication

Orthopaedic implants or components of implants shall be machined or forged from wrought austenitic stainless steel complying with BS 7252 : Part 1 or Part 9. The implant shall not be made from castings and welding methods shall not be employed.

2.2 Finish

The surfaces of implants made of stainless steel shall be free from draw marks, pits, burrs and surface contamination. Unless contra-indicated by requirements for the surface finish and geometry of the product, all surfaces of the implant shall be mechanically polished and/or electro-polished followed by degreasing, cleaning and a final passivation process.

Mechanical polishing shall be undertaken with an iron-free abrasive, following which the surfaces shall be degreased and cleaned.

Implants shall be degreased and cleaned before any electro-polishing process takes place.

Passivation shall be undertaken. After passivation, implants shall be washed and dried.

NOTE. Treatment with aqueous nitric acid solution of about 1.18 relative density (about 30 % (*m/m*)) at a temperature of between 40 °C and 60 °C for at least 15 min is a recommended passivation process. Other passivation processes which also ensure the removal of iron particles which may have become embedded in the surface during machining operations may be used.

In order to ensure that mechanically polished implants are clean, it is recommended that they should be cleaned by an ultrasonic process using trichloroethylene or other suitable solvent with continuous filtration.

3 Orthopaedic implants made of cast cobalt-based alloy

3.1 Material

Orthopaedic implants or components of implants shall be made from cast cobalt-chromium-molybdenum alloy complying with BS 7252 : Part 4.

3.2 Finish

The surfaces of implants made of cast cobalt-based alloy shall be free from contamination, pits and marks resulting from the manufacturing process, e.g. grinding, milling and polishing. All sharp edges and burrs shall be removed.

The surface finish shall be a matt finish unless a mechanically polished surface is specially required.

The matt finish shall be achieved by an iron-free medium, and subsequently the medium shall be removed from the implant by a cleaning operation.

Mechanical polishing shall be achieved by an iron-free polishing medium and traces of polishing medium shall be removed by a cleaning operation.

4 Orthopaedic implants made of wrought cobalt-based alloy

4.1 Material

Orthopaedic implants or components of implants shall be machined or forged from wrought cobalt-based alloy complying with BS 7252 : Parts 5, 6, 7 or 8. They shall not be made from castings.

4.2 Finish

The surfaces of implants made of wrought cobalt-based alloys shall be finished in accordance with **3.2**.

5 Orthopaedic implants made of wrought titanium

5.1 Material

Orthopaedic implants or components of implants shall be manufactured by forging, machining or welding of wrought titanium grades 4A or 4B complying with BS 7252 : Part 2, except when the design or method of fabrication requires a greater ductility of the material for which grades 1, 2 or 3 may be used, the type with the highest practicable tensile strength being selected. Forged components shall be descaled and annealed.

NOTE 1. The five specified grades of wrought commercially pure titanium vary from the weakest grade 1 to the strongest grade 4B. From the clinical standpoint, the stress imposed on the majority of surgical implants is such that grade 4A material is to be preferred. If the method of fabrication requires a more ductile form of the material than grade 4A, grade 3 material will usually be found to give sufficient strength, for example, for the fabrication of bracket plates requiring shaping and hip-caps which are spun or pressed.

Because of the greater flexibility of wrought titanium as compared with some other materials, orthopaedic implants made of wrought titanium should be designed to give the required degree of rigidity.

NOTE 2. Within the present state of knowledge, wrought titanium as specified in **5.1** may not prove to be suitable for some types of metal-to-metal load-bearing moving surfaces, e.g. jointed components.

NOTE 3. Commercially pure titanium (all grades), and Ti 6-Al 4-V may be welded using electron beam, argon arc, plasma arc, resistance welding or other techniques. In all cases, the weld area, including hot metal remote from the weld, should be protected from atmospheric contamination by carrying out the welding in vacuum or an inert gas environment.

NOTE 4. The relationship between the current nomenclature of commercially pure titanium grades and titanium alloy and the obsolete nomenclature is as given in table 1.

Table 1. Nomenclature of titanium and titanium alloy						
Source	Titanium					Titanium alloy
Current nomenclature	1	2	3	4A	4B	Ti 6-Al 4-V
BS 3531 : Part 2 : 1980	T1	T2	T3	T4, T5	–	TA1
BS 3531 : Part 1 : 1968	T115	T120	T130	T155, T160	–	B1

5.2 Finish

The surfaces of implants made of titanium shall be free from contamination, pits and marks resulting from the manufacturing process, e.g. grinding, milling, pressing and polishing.

The final finish shall be either a mirror polish achieved by mechanical means or a matt finish achieved by vapour blasting, peening or mechanical polishing. Iron-free abrasives shall be used for polishing and the finished implant shall be cleaned, degreased and treated to free the surface of metallic and other contaminants which may have become embedded during manufacture.

NOTE. Titanium implants may be anodized.

6 Orthopaedic implants made of wrought titanium alloy

6.1 Material

Orthopaedic implants or components of implants shall be manufactured by forging, machining or welding of wrought titanium alloy complying with BS 7252 : Part 3. Forged components shall be descaled and annealed (see also note 3 to **5.1**).

6.2 Finish

The surfaces of implants made of wrought titanium alloy shall be finished in accordance with **5.2**.

7 Orthopaedic implants made of non-metallic materials

Orthopaedic implants or components of implants made of ultra-high-molecular mass polyethylene shall be made of material complying with BS 7253 : Parts 4 or 5.

Orthopaedic implants or components of implants made of ceramic material shall be made of material complying with BS 7253 : Part 2.

Orthopaedic implants or components of implants made of silicone elastomer shall be made of material complying with BS 7253 : Part 3.

Publications referred to

BS 3531 Implants for osteosynthesis

BS 5750* Quality Systems

BS 7251 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 4 Specification for cobalt-chromium-molybdenum casting 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 Non-metallic materials for surgical implants
Part 2 Specification for ceramic materials based on alumina
Part 3 Specification for surgical implants made of heat-vulcanized silicone elastomer
Part 4 Specification for ultra-high molecular mass polyethylene in powder form
Part 5 Specification for ultra-high molecular mass polyethylene in moulded form

BS 7254 Orthopaedic implants
Part 1 Specification for marking, packaging and labelling

*Referred to in the foreword only.

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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/22, upon which the following bodies were represented:

British Institute of Surgical Technologists
British Investment Casting Trade Association
British Medical Association
British Orthopaedic Association
British Steel Industry
British Surgical Trades Association Incorporated
Department of Health
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