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Surgical implants

Part 2. Specification for materials for metal surgical implants

Implants
Partie 2. Spécification des matériaux pour les implants en métal

Chirurgische Implantate
Teil 2. Spezifikation für Material für chirurgische Einpflanzungen aus Metall

British Standards Institution

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Foreword

BS 3531 was first published in 1962 at the request of the Department of Health and Social Security (then the Ministry of Health) as a result of representations made by the British Orthopaedic Association. In 1968 a part revision of BS 3531 : 1962 was issued as BS 3531 : Part 1 which dealt with all materials. Since then it has been felt preferable to alter the format of the revision of BS 3531 and it is now the intention to publish separate Parts that incorporate requirements relevant to the design and fabrication of metal surgical implants, including components made of wrought austenitic stainless steel, cast cobalt-chromium-molybdenum, wrought cobalt-chromium-tungsten-nickel alloy, wrought commercially pure titanium and wrought titanium alloy.

Parts 1 to 4 inclusive are now being published and together these four Parts supersede BS 3531 : 1962 and BS 3531 : Part 1 : 1968 which are therefore now withdrawn.

In preparing this Part cognizance has been taken of proposals under consideration by the international committee ISO/TC 150, Implants for surgery.

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

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

The Parts of BS 3531 currently published are as follows. a

Part 1	Specification for basic requirements: finish, marking and packaging
Part 2	Specification for materials for metal surgical implants
Part 3	Specification for forged components made of wrought stainless steel, wrought titanium and of wrought titanium alloy
Part 4	Specification for castings made of cobalt-chromium-molybdenum alloy
Part 5	Specification for surgical bone screws of 4 mm, 3.5 mm and 3 mm nominal sizes, countersunk surfaces on bone plates, twist drills, taps and screwdrivers a
Part 6	Specification for skeletal pins and wires
Part 7	Specification for acrylic bone cement
Part 8	Specification for ceramic materials based on alumina
Part 9	Specification for general requirements for orthopaedic joint replacements
Part 10	Specification for classification, designation of dimensions and general requirements for partial and total hip joint replacements a
Part 11	Specification for staples for use in orthopaedic surgery
Part 12	Classification and designation of dimensions for knee joint prostheses'

'Other British Standards on subjects related to orthopaedic surgical implants are BS 3507, BS 4106 and DD 87.'

A summary of typical properties of the materials covered by this standard is given for information in appendix A.' 1

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British Standard

Surgical implants

Part 2. Specification for materials for metal surgical implants

Section one. General

1. Scope

This Part 2 of BS 3531 specifies requirements for materials for metal surgical implants as follows.

(a) Wrought austenitic stainless steel.
(b) Cobalt-chromium-molybdenum casting alloy.
(c) Wrought cobalt-chromium-tungsten-nickel alloy.
(d) Wrought unalloyed titanium.
(e) Wrought titanium alloy.

2. References

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

3. Definitions

For the purposes of this Part of this British Standard the following definitions apply.

3.1 batch. Any quantity of pieces of similar form and condition, made from the same parent metal and, if heat treated, heat treated together.

3.2 master melt. Product of a single furnace charge, usually in the form of ingot or cast bar, intended for further processing.

3.3 unit cast. Product of a single furnace charge used to produce a single mould of castings.

3.4 investment castings. Precision castings produced by a process which involves the investment of an expendable pattern.

3.5 re-melting stock. Metal supplied in cast or wrought form, the chemical composition of which has been established by analysis.

3.6 vacuum melting. Melting in a crucible (usually by electric induction) contained in a sealed chamber in which the pressure is sufficiently below the normal atmospheric level to prevent oxidation of reactive elements.

3.7 vacuum casting. Casting into a mould contained within the chamber so that the reduced pressure is maintained throughout the time the metal is molten. For certain alloys partial repressurization with a suitable inert gas may be necessary.

3.8 vacuum re-melting. Re-melting of metal (the chemical composition of which has been established by analysis) under vacuum or reduced pressure conditions to preclude any possible chemical composition changes.

3.9 electro-slag refining (electro-flux refining). Method of melting or re-melting in which an electrode of predetermined composition is progressively melted whilst immersed in a protective, electrically conductive and often refining molten slag through which the droplets of melted metal fall to coalesce and solidify as a new metal ingot.

3.10 ingot. As-cast product of a single master melt or re-melt.

3.11 billet. Semi-finished wrought product intended for rolling or forging, usually square in cross section.

3.12 bar. Rolled product usually of rectangular, circular, hexagonal or other specified section.

NOTE. Bars may also be produced by forging and casting.

3.13 forging. Article produced by shaping metal under a hammer or press.

NOTE. Forging may be carried out at any predetermined temperature.

3.14 annealing. Process of heat treatment comprising heating a metal above its recrystallization temperature and cooling at a suitable rate to produce softening.

3.15 sheet. A cold-rolled flat product supplied in flat lengths.

3.16 strip. A cold-rolled flat product supplied in long lengths in the coiled condition.

3.17 plate. A hot- or cold-rolled flat product thicker than 3 mm, supplied in flat lengths.

4. Identification

4.1 All bars of diameter or major sectional diameter of over 18 mm shall be stamped on or near the end of each bar, or by roller marking along its length, with the specification number, the cast number and the batch number.

4.2 Bars of diameter or major sectional dimensions of 18 mm or less shall be marked in accordance with 4.1 or, at the option of the manufacturer, may be wired bundles each of which shall bear a securely attached metal label stamped with the markings in accordance with 4.1.

4.3 Sheet strip and plate shall be stamped or indelibly marked in accordance with 4.1.

5. Delivery

5.1 Bars, sheets, strips and plates shall be suitably packaged to avoid damage in transit.

5.2 Each delivery shall be accompanied by a release certificate stating as a minimum the customer's order number, the specification, test results, cast number, batch number, size and quantity of items and delivery date.

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Section two. Wrought austenitic stainless steel

6. Composition

Wrought austenitic stainless steel shall be of composition A, B, C or D as given in table 1.'

Table 1. Composition of wrought austenitic stainless steel

Constituent element	Composition A	Composition B	Composition C	Composition D
	%	%	%	%
Carbon	0.080 max.	0.030 max.	0.030 max.	0.10 max.
Silicon	1.00 max.	1.00 max.	1.00 max.	0.75 max.
Manganese	2.00 max.	2.00 max.	2.00 max.	2.00 to 4.25
Phosphorus	0.025 max.	0.025 max.	0.025 max.	0.025 max.
Sulphur	0.010 max.	0.010 max.	0.010 max.	0.010 max.
Chromium	17.0 to 20.0	17.0 to 20.0	17.0 to 20.0	19.0 to 22.0
Molybdenum	2.35 to 3.50	2.35 to 3.50	2.35 to 3.50	1.5 to 3.0
Nickel	13.0 to 16.0	13.0 to 16.0	13.0 to 16.0	8.0 to 11.0
Copper	0.25 max.	0.25 max.	0.25 max.	0.25 max.
Nitrogen	0.10 max.	0.10 max.	0.11 to 0.20	0.25 to 0.50
Niobium	–	–	–	0.25 to 0.80
Iron	Balance	Balance	Balance	Balance

Elements not quoted in the specification shall not be intentionally added to the steel without the agreement of the purchaser. Due precautions shall be taken to prevent their inclusion during manufacture. The purchaser, by agreement with the manufacturer, may set a limit to the amount of one or more such elements and may require the amount of such elements to be stated in the certificate of analysis.

An analysis of every ingot shall be made for the specified elements and a certificate of analysis, quoting the ingot number, shall be supplied to the purchaser.

Unless otherwise specified, steels of compositions B, C and D are suitable for general use in the fabrication of surgical implants. For those products requiring material of higher tensile strength, as specified in subsequent Parts of BS 3531, steel of composition A, C or D may be used.'

NOTE 1. Whilst austenitic stainless steels are normally considered to be non-magnetic, it is possible for components, which have been subject to cold work during manufacture, to exhibit a certain degree of magnetism up to a relative permeability (μ) of 1.01 (at magnetic field strength (H) of 8 kA/m) notwithstanding the fact that the composition is in accordance with the requirements of this standard.

NOTE 2. In view of the possibility of inducing intergranular corrosion, steel of composition A, or any component or part of a component made of steel of composition A, should not be held at a temperature between 450 °C and 850 °C. If heating to this range of temperature is an unavoidable part of the manufacturing process, it is essential that the material or component be annealed and rapidly cooled. Alternatively, the use of steel of composition B, C or D should be considered.

NOTE 3. The corrosion behaviour of all metals when immersed in an electrolyte may be varied by electro-chemical contact with a dissimilar metal. In the case of the stainless steels covered in this standard, it should be noted that corrosion of compositions A, B and C may be stimulated by contact with the more corrosion-resistant composition D under certain circumstances.

NOTE 4. Attention is drawn to the fact that it is claimed that some of the compositions of wrought austenitic stainless steel within the range of steels designated in this standard as 'composition D' are the subject of British patent no. 1 154 934, copies of which can be obtained from the Patent Office, 25 Southampton Buildings, London WC2A 1AY. BSI takes no position as to the validity of the patent or whether it is still in force. The patent is irrevocably endorsed 'licences of right' under Section 46 of the Patents Act 1977, which states:

'(3) Where such an entry is made in respect of a patent –

(a) any person shall, at any time after the entry is made, be entitled as of right to a licence under the patent on such terms as may be settled by agreement or, in default of agreement, by the Comptroller on the application of the proprietor of the patent or the person requiring the licence',

Licence details may be obtained from the registered proprietor of the patent.'

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7. Processing of steel

7.1 The steel shall be made by a double melting process.

For steels of compositions A and B that contain no added nitrogen, the primary process shall be electric arc, or induction melting, which may be carried out in a vacuum, and the secondary process shall be consumable electrode vacuum arc re-melting or by electro-slag refining.

For steels of compositions A and B that contain added nitrogen and steels of compositions C and D, the primary process shall be electric arc, or induction melting, and the secondary process shall be consumable electrode electro-slag refining.

7.2 The steel shall be free from pipe and segregation as revealed by macro-examination of billet or bar discs representing the full cross section of the ingot, and taken from ingot top, middle and bottom positions.

7.3 Re-heating for hot working shall be controlled to avoid deleterious effects.

8. Identification

Ingot products shall be identifiable with the particular ingots from which they were made.

9. Surface dressing

The ingots and intermediate stage billets shall be suitably surface dressed to ensure freedom from surface defects.

10. Cleanness

10.1 Billet slices of not less than 6 mm thickness and representative of the upper, middle and lower portions of each ingot shall be sectioned through the centre and specimens extending from surface to centre of the billet shall be polished on the longitudinal axial face. The whole of the polished area shall be examined microscopically for the presence of non-metallic inclusions in accordance with ISO 4967, Method A, Plate II.

10.2 The non-metallic inclusion content of specimens of the steel shall not exceed the limits given in table 2.

Table 2. Inclusion content limits

Type of inclusion	Inclusion content			
	Compositions A, B and C		Composition D	
	Thin	Thick	Thin	Thick
A. Sulphides	1.5	1.0	1.5	1.5
B. Aluminates	1.5	1.0	2.5	1.5
C. Silicates	1.5	1.0	2.5	1.5
D. Oxides, globular	1.5	1.0	2.5	1.5

10.3 Only material from each region corresponding to a representative billet slice which meets the cleanness requirements of 10.2 shall be acceptable for further processing. When a billet slice fails to meet the cleanness requirements of 10.2, further billet slices may be taken from the region concerned at the manufacturer's discretion.

11. Annealing

All material required in the fully annealed condition shall be heated for an appropriate length of time in a suitable atmosphere that shall not cause deleterious effects and at the following temperature:

(a) steels of compositions A, B and C at a temperature between 950 °C and 1150 °C;

(b) steel of composition D at a temperature between 1050 °C and 1150 °C.

The material shall be cooled freely in air or quenched in water or oil.

NOTE. For steel of composition A, reference should be made to note 2 of clause 6.

12. Freedom from defects

12.1 All material shall be free from harmful defects.

12.2 Notwithstanding the previous acceptance of material as complying with the requirements of this British Standard, any material that is found at a later stage to contain harmful defects shall be deemed not to comply with the requirements of this British Standard.

Section three. Stainless steel bars for machining, bars and billets for forging and sheet, strip and plate

13. Condition

Rolled or forged bars shall be made from material which complies with the requirements of section two and shall be supplied in the fully annealed condition unless otherwise specified by the purchaser.

Rolled bars shall be ground to ensure freedom from surface defects.

Sheet, strip and plate shall be descaled and shall be supplied in the fully annealed condition unless otherwise specified by the purchaser.

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14. Batch size

A batch (see 3.1) of bars, sheet, strip or plate shall consist of items of the same nominal cross section, made from the same ingot and, if applicable, heat treated together or consecutively in the same furnace under similar conditions.

15. Up-ending test

One specimen from each batch of bars or billets for forging shall be tested in accordance with British Standard 4S 100.

16. Micro-examination

16.1 Sampling. Samples shall be taken as follows.

(a) *Bars.* At least one sample consisting of a slice of not less than 6 mm thickness shall be taken for every 50 bars of a batch.

(b) *Sheet and plate.* At least one sample shall be taken for every 10 sheets or plates of a batch.

(c) *Strip.* At least one sample shall be taken from each coil of strip.

All samples shall be sectioned longitudinally through the centre and prepared and etched to reveal the microstructure.

16.2 Test specimens. The test specimens shall be in the annealed condition and shall be prepared in longitudinal and transverse sections by accepted metallographic polishing techniques.

16.3 Grain size. The grain size shall be not larger than standard grain size 4 measured in accordance with BS 4490.

If there is any failure of a sample to meet this requirement the batch shall be deemed not to comply with the requirements of this British Standard.

16.4 Carbide network. The microstructure, as revealed by etching in a suitable reagent, shall show no evidence of a continuous carbide network at grain boundaries.

Any failure of the specimen to meet this requirement for carbide network shall result in the whole of the batch being heat treated in accordance with clause 11. Subsequently, further retests either on five bars, five sheets or five plates selected at random from the batch, or on each coil of strip, shall all satisfy this requirement. If there is any failure the batch shall be deemed not to comply with the requirements of this British Standard.

16.5 Delta ferrite. Suitably etched specimens shall not show the presence of delta ferrite by microscopic examination at a magnification of 100 x diameters. If there is any failure the batch shall be deemed not to comply with the requirements of this British Standard.

17. Tensile test

17.1 Samples for tensile testing shall be taken as follows.

(a) *Bars.* At least one sample shall be taken for every 50 bars of a batch.

(b) *Sheets and plates.* At least one sample shall be taken for every 10 sheets or plates of a batch.

(c) *Strip.* At least one sample shall be taken from each coil of strip.'

17.2 For bars up to and including 28.6 mm diameter or minor sectional dimension the test pieces shall be machined co-axially with the bars.

17.3 For bars over 28.6 mm diameter up to and including 63.5 mm diameter, or minor sectional dimensions, the longitudinal axis of the test pieces shall be not less than 14.3 mm from the surface of the bars.

17.4 The tensile test piece shall be prepared and tested as follows.

(a) *Bars.* In accordance with BS 18.

(b) *Sheet, strip and plate.* In accordance with British Standard 4A 4 : Part 1.

17.5 The proof stress shall be obtained from an accurately determined load-extension or stress-extension diagram. The test piece shall be broken in tension and the tensile strength and elongation shall be reported.

17.6 The mechanical properties obtained from test pieces in the annealed condition, selected and prepared in accordance with **17.1** to **17.5**, shall be in accordance with table 3.

17.7 If there is any failure to comply with the specified tensile properties, the sample bar, sheet, plate or coil of strip shall be deemed not to comply with the requirements of this British Standard. Tests either on samples taken from each of a further five bars, five sheets or five plates selected at random from the batch, or on samples from each coil of strip, shall all meet the specified tensile requirement. If this is not the case, the whole batch shall be deemed not to comply with the requirements of this British Standard.' Re-heat treatment may be undertaken at the discretion of the manufacturer or supplier. After re-heat treatment, the material shall comply with the requirements of **16.4**.

18. Hardness test

18.1 Unless otherwise agreed between the purchaser and the manufacturer, 10 % of the bars, sheets or plates and each coil of strip in each batch shall be hardness tested.

Unless otherwise agreed between the purchaser and the manufacturer, the items so tested shall have a hardness as given in table 3.'

18.2 The hardness test shall be conducted in accordance with BS 240 : Part 1. The ratio of F/D^2 to be used shall be 30.

18.3 In any batch, if any item fails to comply with the specified hardness requirement, it shall be deemed not to comply with the requirements of this British Standard and the remaining items shall be hardness tested.'

18.4 Any item or batch not complying with the requirements of **18.1**, **18.2** and **18.3** may be re-annealed in accordance with clause **11** and retested for hardness. Such heat treated items shall be retested and shall comply with the requirements of **16.3** (grain size), **16.4** (carbide network) and **17.6** (tensile test).

19. Intergranular corrosion test

19.1 Samples shall be taken as follows.

(a) *Bars.* At least one sample shall be taken for every 50 bars of a batch.

(b) *Sheets and plates.* At least one sample shall be taken for every 50 sheets or plates of a batch.

(c) *Strip.* At least one sample shall be taken from each coil of strip.

Table 3. Wrought stainless steel : mechanical properties in the fully annealed condition

Property	Compositions A and B	Composition C	Composition D
Tensile strength, N/mm² *	465 min.	550 min.	740 min.
0.2 % proof stress, N/mm²	170 min.	270 min.	430 min.
Elongation, % (on gauge length of $5.65\sqrt{S_o}$ †)	40 min.	35 min.	35 min.
Hardness HB	183 max.	225 max.	269 max.

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All samples shall be tested in accordance with BS 5903 : 1980 and shall be found satisfactory according to the criteria given in clause 10 of that standard. Steel of composition A shall be tested in the as-supplied condition. Steels of compositions B, C and D shall be heated at 650 °C for 30 min and allowed to cool to ambient temperature prior to testing.

19.2 If there is any failure to meet the requirements of **19.1** the batch shall be deemed not to comply with the requirements of this British Standard.

19.3 Items which do not comply with the requirements of **19.1** may be re-annealed in accordance with clause **11.**

19.4 At least two samples shall be taken from a re-annealed batch and all tests shall be in accordance with **19.1** for the batch to be accepted.

19.5 Re-annealed items shall be retested and shall comply with the requirements of **16.3** (grain size), **16.4** (carbide network), **17.6** (tensile test) and **18.1** (hardness).

20. Dimensional tolerances

This standard does not specify dimensional tolerances.

NOTE. It is recommended that dimensional tolerances should be agreed between the purchaser and the manufacturer.

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