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British Standard

Orthopaedic implants

Part 1. Specification for marking, packaging and labelling

Implants orthopédiques
Partie 1. Marquage, emballage et étiquetage — Spécifications

Orthopädische Implantate
Teil 1. Kennzeichnung und Verpackung

National foreword

This Part of BS 7254 has been prepared under the direction of the Health Care Standards Policy Committee and is identical with ISO 6018 : 1987 'Orthopaedic implants — General requirements for marking, packaging and labelling', published by the International Organization for Standardization (ISO). This Part of BS 7254, together with BS 7254 : Part 2, supersedes BS 3531 : Part 1 : 1980, which is withdrawn.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, the British Standard relating to implants 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.

General requirements for materials and finish of orthopaedic implants are published as BS 7254 : Part 2 which, together with this Part of BS 7254 supersedes BS 3531 : Part 1 : 1980.

This Part of BS 7254 which includes, essentially, those clauses in BS 3531 : Part 1 : 1980 that specified the marking, packaging and labelling of implants, has been primarily drafted to enable it to be referenced in other standards specifying orthopaedic implants. It has been assumed that when a reference is made to this standard, the reference should state which of the provisions in this standard are relevant to the specific implant.

BS 7254 : Part 2 is derived from those clauses of BS 3531 : Part 1 : 1980 that specified materials which are the most suitable in the light of present knowledge to provide optimum mechanical properties in relation to requirements for corrosion resistance and biological compatibility with living tissues.

Other than the above, this Part of BS 7254 differs from BS 3531 : Part 1 : 1980 only in that in note 2 to clause **4.2** a more limited coding is suggested to indicate the metallic materials commonly used in orthopaedic implants. The earlier standard not only specified the use of a coding system but it was more comprehensive.

Cross-reference

International standard	Corresponding British Standard
ISO 2014 : 1976	BS 5249 Representation of elements of data in interchanges using data processing systems Part 1 : 1976 Representation of dates and times (Technically equivalent)

British Standards Institution

Additional information

This Part of BS 7254 refers in clause **7** (see also item (f) of clause **6**) to the need to give details of any resterilization procedure for orthopaedic implants. In those details it is important to state the method or methods of resterilization which are permitted for the particular implant and that the resterilization procedure should be validated before use.

Although not a requirement of this standard, the Technical Committee responsible for its preparation recommends that duplicates of the label specified in clause **6** should be supplied with each implant. These duplicate labels should be self-adhesive so that they may be affixed to the patient's case record and to the operating theatre record book at the time of implantation. If these labels cannot include all the information required by clause **6**, they should contain sufficient for the batch or lot of a specific implant to be traced.

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

1 Scope and field of application

This International Standard specifies general requirements for the marking, packaging and labelling of orthopaedic implants supplied either sterile or as manufactured, i.e. prior to sterilization.

NOTE — The requirements of an International Standard for a particular implant take precedence over the requirements of this International Standard.

2 Reference

ISO 2014, *Writing of calendar dates in all-numeric form.*

3 Definitions

For the purposes of this International Standard, the following definitions apply.

3.1 sterile: In microbiology, free from all living organisms; in practice, the condition of a product that has been subjected to a validated sterilization process and maintained in this state by suitable protection.

3.2 sterilized: Term used to denote an object that has been subjected to a validated sterilization process.

3.3 unit: Individual device(s) or object(s) defined in the relevant product standard or regulation.

3.4 kit: A number of components to be used for a single purpose on the same occasion.

3.5 unit pack: A pack containing a single unit or kit.

3.6 multiple pack: A pack containing a number of unit packs.

3.7 sterile pack: A pack intended to maintain the sterility of the contents and comprising an inner and outer container.

3.8 inner container: The packaging that is in direct contact with the implant.

3.9 outer container: The packaging that envelops the inner container such that sterility and the integrity of the contents are maintained.

4 Identification marking of orthopaedic implants

4.1 General

Each implant shall be identified by means of the information listed in 4.2 and in accordance with the requirements specified in 4.3.

4.2 Marking

The identification marking of the implant shall comprise the following information (see, however, 4.3.2):

a) the name or trade-mark of the manufacturer or supplier;

b) the designation of the material, comprising either the full reference of the relevant International Standard(s) (if available) for the material, or the relevant symbol;

NOTES

1 If a relevant International Standard is not available, an equivalent national standard may be used.

2 The following symbols have been agreed for use in conjunction with metallic materials:

S — stainless steel;

T — titanium and its alloys;

C — cobalt-based alloys.

c) the manufacturer's traceability code for the implant;

d) the designated size and type, if applicable.

4.3 Application of marking

4.3.1 If not excluded by the relevant International Standard(s) for a particular implant, implants shall be marked with the information listed in 4.2 in characters not less than 1 mm high (see, however, 4.3.2).

4.3.2 Implants having insufficient space to accommodate all the information listed in 4.2 a) to d) shall be marked with the information required by as many of items a) to d) as possible.

NOTE — The method and site of marking should not deleteriously affect the satisfactory functioning of the implant.

5 General requirements for packaging

5.1 Each implant should be supplied clean and, with the exception of small implants, shall be packaged in a unit pack that will protect the implant from mechanical damage. All points or sharp edges shall be suitably protected by packaging to prevent damage to the implant or to the pack.

NOTE — Packaged implants may be supplied either in the sterile condition, in which case they are labelled as such (see item e) in clause 6), or in the non-sterile condition.

5.2 If two or more implants are packaged as a kit in the same unit pack, each implant shall be separated from the others by suitable material.

5.3 In cases where a number of unit packs are contained in a multiple pack, the multiple pack shall protect the contents during transit and storage.

5.4 Each pack shall be capable of being opened easily by hand, and such that sterile products shall be capable of being presented sterile and ready for use. The outer container shall be designed so that once opened it should not be possible to reseal; however, if it is possible to reseal the outer container, it shall be clearly visible that the outer container has been opened and resealed.

6 Labelling

The following information, if applicable, shall appear legibly on or in each pack:

a) the name or registered trade-mark and address of the manufacturer;

b) the batch or lot number, related to records of raw materials, manufacture, packaging and sterilization;

c) a description of the contents, including name, size and material(s);

d) an indication as to whether the implant is for single use;

e) the words "STERILE UNLESS PACKAGE DAMAGED" or equivalent wording and an indication of the sterilization process used shall appear on the label of packaged parts which have been sterilized by a recognized process;

NOTE — Attention is drawn to the existence in some countries of national regulations regarding the identification of sterile implants.

f) if the implant is not to be re-sterilized, it shall be clearly indicated;

g) the recommended method of opening the sterile pack to ensure sterile presentation at the time of use;

h) if storage and transportation conditions are pertinent, these should be clearly indicated;

i) expiry date (year and month) or date of manufacture, expressed in accordance with ISO 2014.

NOTE — If sterilization is the last stage of manufacture, the date of sterilization should be recorded on the pack.

7 Product information

For non-sterile implants and for sterile implants if re-sterilization is permitted, accompanying literature describing sterilization/re-sterilization procedures shall be included in the pack.

Publications referred to

See national foreword.

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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/49, upon which the following bodies were represented:

British Orthopaedic Association
British Surgical Trades Association Incorporated
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