

Implants for osteosynthesis —

**Part 15: Specification for devices for the
fixation of the ends of the femur in
adults**

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
- Department of Health
- Institute of Sterile Services Management
- Medical Sterile Products Association
- Ministry of Defence
- National Association of Theatre Nurses
- Royal College of Surgeons of England
- Royal Veterinary College
- Scottish Office

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National foreword

This Part of BS 3531 has been prepared under the direction of the Health Care Standards Policy Committee. It is identical with ISO 8615:1991 *Implants for surgery — Fixation devices for use in the ends of the femur in adults*, published by the International Organization for Standardization (ISO) and supersedes BS 3531-15:1990 which is withdrawn.

Requirements for orthopaedic implants (then termed “surgical implants”) were published in 1962 as BS 3531. In 1968 a part revision of BS 3531:1962 was issued as BS 3531-1, 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.

A further 19 Parts of BS 3531 were subsequently published, Part 15:1984 giving requirements for femoral fixation devices for use in adults. 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, the British Standards relating to implants has been restructured. Accordingly, the number BS 3531 now only covers implants for osteosynthesis, BS 7251 covers joint prostheses, BS 7252 covers metallic material for surgical implants, BS 7253 cover non-metallic materials for surgical implants and BS 7254 cover orthopaedic implants, i.e. aspects common to both osteosynthesis and joint replacement.

The revision in 1990 introduced editorial changes to reflect this restructuring and updated cross-references but otherwise made no changes to the *specification for devices for the fixation of the ends of the femur in adults* which was first published as BS 3531-15:1984.

This edition of BS 3531-15 specifies the materials, dimensions, surface finish, packaging and marking of metal surgical implants used for the fixation of fractures and osteotomies of the upper and lower ends of the femur in adults.

Users of femoral fixation devices should always take care that the correct type and size of instrument is used when fitting and adjusting the device, as failure to do so can result in damage to the device. When using nuts fitted with nylon locking bushes, care should be exercised to ensure that the nut is fully tightened, so that the thread of the nail or screw projects beyond the nylon bush. If, for any reason, such a nut is removed from the nail of screw during an operation it should be discarded and replaced with a new nut. Similar considerations exist if the components of a fixation device are fastened together by a bolt fitted with a nylon locking insert. Care should be also be taken to avoid the mixing of components from different devices during, for instance, preparation for sterilization.

Once implantation has been completed, an implant should never be reused after removal.

It is strongly recommended that the products specified in this section of BS 3531 should be manufactured according to the recommendations given in the “Quality Systems for Orthopaedic Implants 1990 Good Manufacturing Practice”¹⁾.

Cross-references

International Standard	Corresponding British Standard
ISO 261:1973	BS 3643 <i>ISO metric screw threads</i> Part 1:1981 <i>Principles and basic data</i> (Technically equivalent)
ISO 272:1982	BS 3692:1967 <i>Specification for ISO metric precision hexagon bolts, screws and nuts. Metric units</i> (Technically equivalent) BS 7252 <i>Metallic materials for surgical implants</i>
ISO 5832-1:1987	Part 1:1990 <i>Specification for wrought stainless steel</i> (Identical)

¹⁾ Compiled by the Department of Health; published and available from Her Majesty’s Stationery Office, 49 High Holborn, London WC1 6HB for personal callers, or by post from HMSO, P.O. BOX 276, London SW8 5DT

International Standard	Corresponding British Standard
ISO 5832-2:1978	Part 2:1990 <i>Specification for unalloyed titanium</i> (Identical)
ISO 5832-4:1978	Part 4:1990 <i>Specification for cobalt-chromium-molybdenum casting alloy</i> (Identical)
ISO 5832-5:1978	Part 5:1990 <i>Specification for wrought cobalt-chromium-tungsten-nickel alloy</i> (Identical)
ISO 5832-6:1980	Part 6:1990 <i>Specification for wrought cobalt-nickel-chromium-molybdenum alloy</i> (Identical)
ISO 5832-7:1984	Part 7:1990 <i>Specification for cobalt-chromium-nickel-molybdenum-iron alloy</i> (Identical)
ISO 5832-8:1987	Part 8:1990 <i>Specification for cobalt-nickel-chromium-molybdenum-tungsten-iron-alloy</i> (Identical)
ISO 5835:1991	BS 3531 <i>Implants for osteosynthesis</i> Section 5.3:1991 <i>Specification for the dimensions of screws having hexagonal drive connection, spherical under-surfaces and asymmetrical thread</i> (Identical)
ISO 5836:1988	Section 23.3:1991 <i>Specification for holes corresponding to screws with asymmetrical thread and spherical undersurfaces</i> (Identical)
ISO 6018:1987	BS 7254 <i>Orthopaedic implants</i> Part 1:1990 <i>Specification for marking, packaging and labelling</i> (Identical)

The Technical Committee has reviewed the provisions of ISO 965-2:1980, ISO 5832-3:1990, ISO 9268:1988 and ISO 9269:1988 to which normative reference is made in the text and has decided that they are acceptable for use in conjunction with this Part of BS 3531.

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 product 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 are 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.

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

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

Summary of pages

This document comprises a front cover, an inside front cover, pages i to iv, pages 1 to 12, an inside back cover and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.