

Implants for osteosynthesis —

Part 5: Bone screws and auxiliary equipment —

Section 5.3 Specification for the dimensions of screws having hexagonal drive connection, spherical under-surfaces and asymmetrical thread

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 Section of BS 3531 has been prepared under the direction of the Health Care Standards Policy Committee. It is identical with ISO 5835:1991 *“Implants for surgery — Metal bone screws with hexagonal drive connection, spherical under-surface of head, asymmetrical thread — Dimensions”*, published by the International Organization for Standardization (ISO) and supersedes BS 3531-5.3:1990, which is withdrawn.

BS 3531-5 was first published in 1982 and gave requirements for particular types of bone screw, for taps, drills and screwdrivers, and for holes and slots in bone plates. The revision of BS 3531-5 offered the opportunity to facilitate the implementation of published and forthcoming International Standards, and to separate, in different Parts of BS 3531, requirements for screws and auxiliary equipment from those for bone plates. Requirements for bone screws and their auxiliary equipment are retained in BS 3531-5, which is now published in a number of Sections, whilst requirements for bone plates are specified in BS 3531-23, also published in Sections. BS 3531-5:1982 is withdrawn.

This revision of Section 5.3 introduces the requirements for screws with hexagonal drive connections.

The screws specified in this Section of BS 3531 are suitable for use with the keys specified in BS 3531-5.1.

The mechanical requirements and test methods are given in BS 3531-5.6.

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 6018:1987	BS 7254 <i>Orthopaedic implants</i> Part 1:1990 <i>Specification for marking, packaging and labelling</i> (Identical)
ISO 6475:1989	BS 3531 <i>Implants for osteosynthesis</i> Section 5.6:1991 <i>Specification for the mechanical requirements and test methods for screws having asymmetrical thread and spherical undersurface</i> (Identical)

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 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.

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, PO Box 276, London SW8 5DT.

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.

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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.