

Implants for osteosynthesis —

Part 23: Bone plates —

Section 23.3: Specification for holes corresponding to screws with asymmetrical thread and spherical undersurfaces

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
- National Association of Theatre Nurses
- Royal College of Surgeons of England
- Royal Veterinary College
- Scottish Office

This British Standard, having been prepared under the direction of the Health Care Standards Policy Committee, was published under the authority of the Standards Board and comes into effect on 29 November 1991

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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 5836:1988 “*Implants for surgery — Metal bone plates — Holes corresponding to screws with asymmetrical thread and spherical under-surface*”, published by the International Organization for Standardization (ISO).

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 3531-1, 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.

The revision of BS 3531-5 offered the opportunity to facilitate the implementation of published and forthcoming standards, and to separate, in different Parts of BS 3531, requirements for bone plates from those for bone screws and auxiliary equipment. Accordingly, therefore, bone plates are covered by BS 3531-23, published in a number of Sections, whilst screws and auxiliary equipment are retained in BS 3531-5, also published in Sections. BS 3531 now only covers implants for osteosynthesis, BS 7251 covers joint prostheses, BS 7252 covers metallic materials for surgical implants, BS 7253 covers non-metallic materials for surgical implants and BS 7254 covers orthopaedic implants, i.e. aspects common to both osteosynthesis and joint replacement.

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-reference

International Standard	Corresponding British Standard
ISO 5835:1991 ^a	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)

^a Now published.

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.

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Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, pages 1 to 8, 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.

¹⁾ Compiled by the Department of Health; published and available from HMSO, 49 High Holborn, London WC1 6HB for personal callers, or by post from HMSO, P O Box 276, London SW8 5DT

1 Scope and field of application

This International Standard specifies the dimensions and tolerances of holes in bone plates used as surgical implants so as to facilitate correct fixing using screws complying with ISO 5835.

NOTE 1 This International Standard does not deal with the shape and dimensions of the plates or with the spacing (centre-to-centre distance) of the holes.

NOTE 2 The interrelationship of International Standards dealing with bone screws, bone plates and relevant tools is shown for information in Annex A.

2 Reference

ISO 5835, *Implants for surgery — Metal bone screws with hexagonal drive connection — Spherical under-surface of head — Dimensions*²⁾.

3 Dimensions and tolerances

3.1 Type A (with cylindrical hole)

Type A holes shall be as given in Figure 1 and Table 1.

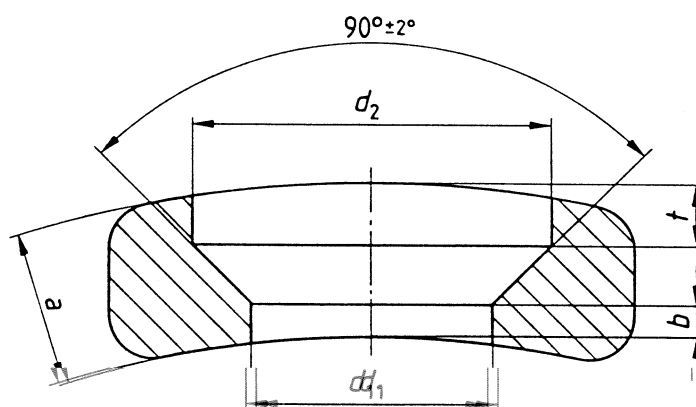


Figure 1 — Type A hole

²⁾ At present at the stage of draft.