

Implants for osteosynthesis —

Part 5: Bone screws and auxiliary equipment —

Section 5.4 Specification for screws having symmetrical and asymmetrical thread and conical under-surfaces

UDC 621.882.2:616-089

NO COPYING WITHOUT BSI PERMISSION EXCEPT AS PERMITTED BY COPYRIGHT LAW



Document Sharing Hub

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:

- Association of British Health-care Industries
- 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 15 May 1993

© BSI 08-1999
First published May 1990
Second edition May 1993

The following BSI references relate to the work on this standard:
Committee reference HCC/22
Draft for comment 87/50451 DC

ISBN 0 580 22153 9

Amendments issued since publication

Amd. No.	Date	Comments

Contents

	Page
Committees responsible	Inside front cover
National foreword	ii
0 Introduction	1
1 Scope and field of application	1
2 Reference	1
3 Code for screw thread	1
4 Dimensions and tolerances	1
5 Marking and packaging	7
Annex A Interrelationship of International Standard dealing with bone screws, bone plates and relevant tools	8
Annex B Bibliography: International Standards referred to in table of Annex A	9
Figure 1 — Screw with single-slot recess	2
Figure 2 — Screw with cruciate recess	3
Figure 3 — Screwhead with combined cruciate-slot and cross-recessed drive connection	4
Figure 4 — Illustration of HC thread form	4
Figure 5 — Screw with cross-recessed head	5
Figure 6 — Asymmetrical thread HD	6
Figure 7 — Cross-recessed drive connection	7
Table 1 — Dimensions of screw with single-slot recess	2
Table 2 — Dimensions of screw with cruciate recess	3
Table 3 — Dimensions of symmetrical thread HC	5
Table 4 — Dimensions of screw with cross-recessed head	5
Table 5 — Dimensions of asymmetrical thread HD	6
Table 6 — Dimensions of cross-recessed drive connection	7
List of references	Inside back cover

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 9268:1988 *Implants for surgery — Metal bone screws with conical under-surface of head — Dimensions*, published by the International Organization for Standardization (ISO) and supersedes BS 3531-5.4:1990 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 3531-1, 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.

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 3531-23, also published in Sections. BS 3531-5:1982 has been withdrawn.

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 impants, i.e. aspects common to osteosynthesis and joint replacement.

BS 3531-5.4 was first published in 1990 and specified dimensions, tolerances, materials and mechanical properties for bone screws of nominal sizes 4 mm, 3.5 mm and 3 mm.

This revision of BS 3531-5.4 now specifies only the dimensions and tolerances for bone screws of nominal sizes 4.5 mm, 4.2 mm, 3.9 mm and 2.9 mm. Mechanical properties are specified in BS 3531-5.6.

The screws specified in this Section of BS 3531 are suitable for use with the screwdrivers specified in BS 3531-5.2 and for use with the taps and drills specified in BS 3531-5.5, and will fit with the holes and slots in bone plates specified in BS 3531-23.2.

It is strongly recommended that the products specified in this Section of BS 3531 should be manufactured according to the recommendations given in *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)

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.

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, PO Box 276, London SW8 5DT.

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 10, 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.

