

Implants for osteosynthesis —

Part 11: Specification for staples with parallel legs

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

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

© BSI 08-1999

First published April 1982
Second edition October 1990
Third edition November 1991

The following BSI references relate to the work on this standard:
Committee reference HCC/22
Draft for comment 87/50453 DC

ISBN 0 580 20265 8

Amendments issued since publication

Amd. No.	Date	Comments

Contents

	Page
Committees responsible	Inside front cover
National foreword	ii
1 Scope and field of application	1
2 References	1
3 Design	1
4 Size designation	3
5 Tolerances	3
6 Materials	3
7 Finish	5
8 Packaging	5
9 Marking of packages	5
Annex A Guidance on use and selection of staples	6
Figure 1 — Examples of typical forms of staples for use in orthopaedic surgery	2
Figure 2 — Parallelism of legs	4
Table — Tensile properties of wire made from austenitic stainless steel	4
Publication(s) referred to	Inside back cover

National foreword

This Part of BS 3531 has been prepared under the direction of the Health Care Standards Policy Committee and supersedes BS 3531-11:1990, which is withdrawn. It is identical with ISO 8827:1988 *“Implants for surgery — Staples with parallel legs for orthopaedic use — General requirements”*, 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, Part 11:1982 giving requirements for orthopaedic staples. In view of the increase in the number of Parts, and with a view to facilitating the implementation of published or forthcoming international implant standards, the British Standard relating to implants has been restructured. Accordingly, the number of 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.

The revision of BS 3531-11 in 1990 introduced editorial changes to reflect this restructuring and to update cross-references but otherwise made no changes to the specification for staples which was first published as BS 3531-11:1982 and amended in October 1983.

This revision of BS 3531-11 now covers general requirements and the designation of dimensions and tolerances of staples with parallel legs intended for use in orthopaedic surgery.

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 System for Orthopaedic Implants 1990 Good Manufacturing Practice”*¹⁾.

Cross-references

International Standard	Corresponding British Standard
	BS 7252 <i>Metallic materials for surgical implants</i>
ISO 5832-1:1987	Part 1:1990 <i>Specification for wrought stainless steel</i> (Identical)
ISO 5832-4:1978	Part 4:1990 <i>Specification for cobalt-chromium-molybdenum casting alloy</i> (Identical)
IEC 5832-5:1978	Part 5:1990 <i>Specification for wrought cobalt-chromium-tungsten-nickel alloy</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 5832-3 and ISO 6892 to which reference is made in the text and has decided that they are acceptable for use in conjunction with this Part of BS 3531. A related British Standard to ISO 5832-3 is BS 7252-3.

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

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.

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 6, 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.