

Implants for osteosynthesis —

Part 14: Intramedullary nailing systems —

Section 14.2 Specification for medullary pins (Rush type) and introducer/extractors

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 Incorporated
- 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
- Coopted members

This British Standard, having been prepared under the direction of the Health Care Standards Policy Committee, was published under the authority of the Board of BSI and comes into effect on 31 August 1990

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The following BSI references relate to the work on this standard:
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Contents

	Page
Committees responsible	Inside front cover
Foreword	ii
Section 1. General	
1 Scope	1
Section 2. Medullary pins (Rush type)	
2 Materials	1
3 Method of manufacture	1
4 Finish	1
5 Dimensions and design	1
6 Mechanical properties	2
7 Marking and packaging	2
Section 3. Introducer/extractors for use with medullary pins	
8 Materials	3
9 Dimensions	3
Figure 1 — Medullary pin	2
Figure 2 — Introducer/extractor for use with medullary pins	3
Table 1 — Dimensions and range of sizes of medullary pins	1
Table 2 — Minimum tensile strength and minimum elongation of pins made of austenitic stainless steel	2
Table 3 — Dimensions of introducer/extractors for use with medullary pins	3
Publications referred to	Inside back cover

Foreword

This Section of BS 3531 has been prepared under the direction of the Health Care Standards Policy Committee and supersedes BS 3531-14:1984, which is withdrawn.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, Part 14:1984 giving requirements for Rush type medullary pins and introducer/extractors. 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 BS 3531 is reserved for standards for 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.

In the restructure, the opportunity has been taken to group together specifications for medullary nailing systems as BS 3531-14, which will be published in a number of Sections.

This Section of BS 3531 introduces editorial changes to reflect this restructuring and up-dates cross-references but otherwise makes no changes to the specification for medullary pins and introducer/extractors first published as BS 3531-14:1984. It does not reflect a full review or revision of the standard which will be undertaken in due course.

The technical requirements of this Section of BS 3531 are based extensively on those of ISO 5837-2:1980 “*Implants for surgery — Intramedullary nailing systems — Part 2: Medullary pins*” prepared by Technical Committee 150, Implants for surgery, of the International Organization for Standardization (ISO) but with the following additional requirements:

- a) a maximum value for the width of the crook end;
- b) mechanical properties for the pins;
- c) materials of construction in accordance with BS 7252;
- d) marking and packaging in accordance with BS 7254-1;
- e) restrictions on shape of point;
- f) dimensions for relevant introducer/extractors.

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 “Guide to Good Manufacturing Practice for Orthopaedic Implants”.¹⁾

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.

¹⁾ Compiled by the Department of Health and Social Security; published and available from Her Majesty’s Stationary Office ISBN 0 11 320846 4.