

Implants for osteosynthesis —

Part 23: Bone plates —

Section 23.1 Method for determination of bending strength and stiffness

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 28 June 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prepared under the direction of the Health Care Standards Policy Committee and supersedes BS 3531-23.1:1988, which is withdrawn. It is identical with ISO 9585:1990 *“Implants for surgery — Determination of bending strength and stiffness of bone plates”* 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.

BS 3531-23.1 was first published in 1988 at the request of the Department of Health and Social Security, to meet a need within the medical equipment industry for a method of assessing certain mechanical properties of plates used in osteosynthesis.

This edition of BS 3531-23.1 gives the equations to be used in determining the equivalent bending stiffness and bending strength.

Information on the strength and stiffness of bone plates will enable the bending characteristics of different plates relevant to surgical practice to be compared, and should assist the surgeon in deciding which plate should be used in particular clinical situations.

The value obtained for the bending strength relates to the load which will cause the plate to bend in clinical service and also to the force necessary to pre-form the plate in the operating theatre to match the bones to which it is to be attached. Currently there is controversy regarding the optimum stiffness of a plate which allows effective callus formation and healing of a fracture, and this method of testing will allow the stiffness of different plates to be compared quantitatively.

It is strongly recommended that products tested in accordance with this Section of BS 3531 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 test and continuing 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 and Social Security; published and available from Her Majesty’s Stationery Office, 49 High Holborn, London WC1 for personal callers, or by post from HMSO, P.O. Box 276, London SW8 5DT.