

# Orthopaedic implants —

## Part 4: Recommendations for retrieval and examination of implants and associated tissues

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- British Orthopaedic Association
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# Contents

|                                                                                                                        | Page               |
|------------------------------------------------------------------------------------------------------------------------|--------------------|
| Committees responsible                                                                                                 | Inside front cover |
| Foreword                                                                                                               | ii                 |
| 0 Introduction                                                                                                         | 1                  |
| 1 Scope                                                                                                                | 1                  |
| 2 Retrieval and sampling                                                                                               | 1                  |
| 3 Handling and sterilization of removed implant and associated samples                                                 | 2                  |
| 4 Packaging, labelling and transport of removed implant and associated samples                                         | 3                  |
| 5 Documentation                                                                                                        | 3                  |
| 6 Examination of removed implant and associated samples                                                                | 4                  |
| Appendix A Checklist for retrieval of orthopaedic implants                                                             | 5                  |
| Appendix B Extract from 1986 issue of Post Office Guide                                                                | 6                  |
| Appendix C Examples of the information to be compiled and recorded when an implant is removed                          | 7                  |
| Appendix D Examples of the information to be compiled on metallurgical examination of removed implant and/or component | 9                  |
| Figure 1 — Checklist for retrieval of orthopaedic implants                                                             | 5                  |
| Publications referred to                                                                                               | Inside back cover  |

## Foreword

This Part of BS 7254 has been prepared under the direction of the Health Care Standards Policy Committee and supersedes BS 3531-22:1988 which is withdrawn. It takes cognizance of the work in progress within Technical Committee 150 Implants for surgery, of 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 22:1988 giving recommendations for retrieval and examination of orthopaedic implants. In view of the increase in the number of Parts, and with a view to facilitating the implementation of published or forthcoming ISO 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.

This edition of BS 7254-4 introduces editorial changes to reflect this restructuring, and up-dates cross-references but otherwise makes no changes to the recommendations for retrieval and examination of implants first published as BS 3531-22:1988. It does not reflect a full review or revision of the standard, which will be undertaken in due course.

Once implantation has been completed, an implant should never be reused after removal.

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 and ii, 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.

## 0 Introduction

Orthopaedic implants may be removed and retrieved from the body for a variety of reasons, including routine removal, upon completion of the treatment, removal at the time of a revision operation and removal because of failure, either of the treatment or of the implant itself. Implants may also be removed post-mortem.

Care should be taken to ascertain the legal ownership of an implant before any destructive tests are carried out. No destructive test should be performed until permission has been obtained from all parties who have, or may have, an interest in the outcome. It is important that this is borne in mind where there is any likelihood of regulation or litigation.

This Part of BS 7254 gives general guidance on procedures for the retrieval, handling and examination of implants and is intended to facilitate accurate comparison of results from different centres. Procedures and methods are not described in detail since they are many and varied, and will differ depending on the circumstances pertaining to each case and depending on the nature of the information required.

A summary of the stages involved in the handling and examination of retrieved implants and associated tissue is given for information in Appendix A.

The examination of retrieved orthopaedic implants permits analysis of the performance of implants and/or the materials from which they are made, including the reactions of the body tissues to the implant. The performance of any individual implant depends on various interacting factors and consideration needs to be given to design, materials, surgical technique and patient factors. Patient factors have often been ignored, even though it is known that the patient's level of activity, mass and physiological reactions may affect the acceptance and functional life of an implant. For performance analyses to be effective, the maximum possible data are required. A detailed analysis based on only one parameter may lead to inaccurate conclusions and such analyses should be avoided.

In drawing conclusions, a distinction should be made between the mechanism of failure and the cause of failure. This distinction is essential when determining whether the failure is related to clinical factors or to implant factors. Although the mechanism of failure of an implant is often very easy to determine, e.g. fatigue breakage, the actual cause of failure is multi-factorial and may be related to the quality of materials, the techniques of implantation, inappropriate patient activity, bone pathology, etc. Failure, e.g. breakage, of the implant does not necessarily mean that the problem is related to the device. A programme of examining retrieved implants may readily lead to identification of the mechanism of failure but the causes of failure may be much more difficult to determine without all available data, including clinical information, being available.

It should be noted that a much more detailed testing and reporting protocol than that given in this Part of BS 7254 will be required for clinical trials.

## 1 Scope

This part of BS 7254 recommends procedures for the retrieval, handling and examination of orthopaedic surgical implants and associated tissue samples which have been removed from the body, either living or post-mortem.

**NOTE** The titles of the publications referred to in this standard are listed on the inside back cover.

## 2 Retrieval and sampling

### 2.1 Planning

Before starting to remove the implant, the availability of up-to-date radiographs should be checked, and if necessary, new radiographs taken. Radiographic records should be made, even if the implant is to be removed post-mortem. It should be noted that little or no useful information can be obtained, or should be expected, from an implant removed from a cadaver that has undergone cremation.

It is important to decide what samples are required for laboratory testing and when they should be taken, because subsequent procedures such as washing and disinfection can invalidate results. An obvious example is samples for microbiological testing, which should be taken as soon as the implant is exposed, but histological properties of body tissue can also be affected.