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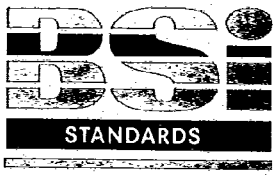
Orthopaedic implants

Part 4. Recommendations for retrieval and examination of implants and associated tissues

Implants orthopédiques
Partie 4. Recommandations pour le retrait et l'examen des implants et des tissus associés

Orthopädische Implantate
Teil 4. Empfehlungen für die Entnahme und Untersuchung von Implantaten und zugehörigem Gewebe



Committees responsible for this British Standard

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British Institute of Surgical Technologists
British Investment Casting Trade Association
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British Orthopaedic Association
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British Surgical Trades Association
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Contents

Foreword

This Part of BS 7254 has been prepared under the direction of the Health Care Standards Policy Committee and supersedes BS 3531 : Part 22 : 1988 which is withdrawn.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 : Part 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 : Part 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 : Part 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.

Compliance with a British Standard does not of itself confer immunity from legal obligations.

Recommendations

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.

2.2 Procedure

In order to allow the maximum information to be obtained, the implant should be removed in a way which causes it minimal damage but is consistent with the requirements of surgical procedures. It is particularly important to protect bearing surfaces of, for instance, a total joint prosthesis and the fracture surfaces of a broken implant. However, certain techniques of removal unavoidably cause damage, e.g. drilling into the articular surface of a plastics acetabular component

During removal, note should be taken of the orientation of the implant and all component parts. For example, screws should be removed in such a way that their positions in a bone plate may be identified subsequently, and they should be placed in separate, shatter-proof containers, numbered sequentially from proximal to distal, immediately upon removal. The orientation of bone plates may be identified by inserting a suture through the most proximal hole or slot. Pieces of bone cement that

have become detached from the implant or bone should be retrieved and handled in the same manner as the implant itself.

All observations regarding the condition of the implant and surrounding tissues before, during and after implant removal should be recorded. A photographic record of the implant in situ, of the surgical site and of the removed implant is recommended. It may also be desirable to make a preliminary examination of the implant immediately upon removal (see **6.2**). However, handling of the implant should be minimized and it should be placed in shatter-proof protective or storage containers when not being examined.

2.3 Microbiological sampling

The advice of a microbiologist should be sought when planning retrieval of an implant. Samples for microbiological examination should be taken in collaboration with the microbiologist, and should be taken as soon as the implant, tissue, tissue fluid etc. is exposed. All samples should be placed immediately in the appropriate culture medium. Incorrect handling of the samples can invalidate results.

2.4 Tissue sampling

Samples of tissue adjacent to the implant and from other relevant sites (for example lymph nodes or any tissue with abnormal appearance) should be taken wherever possible and subjected to histological examination, since the interfacial reactions are of importance in determining long-term human tissue acceptability.

A record of the location of the site of tissue excision and an indication of the tissue orientation relative to the implant should be made. If possible, the proximal end of the sample should be marked and the sample should be maintained at its original length, e.g. with plastics muscle biopsy clamps or other means.

Any collection of fluid within the tissues or in a joint should be aspirated and saved for examination.

3 Handling and sterilization of removed implant and associated samples

3.1 Handling

All operative, biopsy and autopsy procedures should be carried out using procedures, and under conditions, appropriate to the safety of the patient and the surgical staff. Where rubber gloves are worn, gloves complying with BS 1884 or BS 4005 are recommended.

Unless and until disinfection or sterilization procedures have been completed, all retrieved implants and associated samples should be treated as though they are infected. When there is contamination with blood there is always the risk of transmission of hepatitis or other virus mediated disease.

Guidance on handling procedures and precautions may be found in Health Notice HN(87)1 'Decontamination of equipment, linen or other surfaces contaminated with Hepatitis B or Human Immunodeficiency Virus'[1], Health Notice HN(87)22 'Decontamination of health care equipment prior to inspection, service or repair'[1], the DHSS 'Code of practice for the prevention of infection in clinical laboratories and post-mortem rooms'[2], and in the chapter dealing with precautions for invasive procedures including specimen taking, in 'LAV-HTLV3 Causative agent of AIDS and related conditions - revised guidelines, 1986'[1].

After all observations (see **6.2**) have been made on the implant in its immediate post-operative condition and any samples which are required have been taken, it should be decided whether further examination or tests are necessary in order to determine if disinfection or sterilization of the implant is indicated.

3.2 Cleansing and sterilization

The implant should initially be rinsed while immersed in water but not cleaned or scrubbed in any way. Unless contra-indicated by the prerequisites of subsequent methods of examination, implants should be sterilized. Experience has shown that immersion for 6 h in 2 % (*V/V*) aqueous glutaraldehyde solution[3] buffered to a pH value of between 7.5 and 8.5 is not harmful to metals and generally not harmful to plastics. This treatment, however, is inappropriate if absorption of tissue constituents by plastics materials is to be studied.

4 Packaging, labelling and transport of removed implant and associated samples

4.1 General principles

Subject to the requirements of the carrier as indicated in **4.2** and **4.3**, the following principles should be adopted.

Care should be taken to package the implant in a manner that will protect bearing surfaces, fracture surfaces, corners and edges from damage, and that will prevent sharp corners and edges from penetrating the package. Components of an implant should be packaged in separate inner containers, or

[1] Available from the Department of Health, 14 Russell Square, London WC1B 5EP.
[2] Prepared by the Department of Health and Social Security and available from Her Majesty's Stationery Office.
[3] The material known as 'Cidex', manufactured by Surgikos, Kirkton Campus, Livingston, Scotland EH54 7AT, is an example.

in a manner that will prevent contact between components. All packages should be labelled to identify the contents and to indicate the total number of packages in each consignment. They should be marked with the name and address of the sender.

The inner containers should be shatter-proof and sufficiently robust to resist the loads that may be exerted by the contents during handling and transit. Glass containers are unlikely to be suitable for other than non-metallic implants or small and light metallic implants.

Documentation (see clause 5) should be enclosed in, or securely affixed to, the outer package. It should not be placed in the inner container or in direct contact with the contents of the package.

Unsterilized implants and/or samples should not be sent by public carriers to non-medical addressees or to addressees that may not have the experience or facilities to handle infectious material safely.

4.2 Transport by public carrier

It should be noted that particular conditions of carriage may apply to the transportation by a public carrier of removed implants, components thereof, tissue samples and samples for microbiological or other medical examination. The conditions of carriage may vary, depending on whether the substance being transported contains body tissue or fluids, whether the substance has been disinfected or sterilized and whether it is in a condition that will prevent putrefaction during transit.

It is the responsibility of the sender to ensure compliance with the carrier's conditions. Details of the Post Office's requirements for the carriage of pathological specimens may be found in the 'Post Office Guide'[1] which is updated regularly, and guidance is available from the Customer Services Department of main post offices. For information purposes only, extracts from the 1986 Post Office Guide are given in appendix B. Enquiries for details of the requirements of other public carriers should be addressed to the appropriate carrier.

4.3 Transport within the hospital

The packaging, labelling and transport of the implant and associated samples should be in accordance with the requirements or recommendations for pathological specimens that are in effect at the hospital or centre at which the implant was removed.

5 Documentation

All retrieved material that is sent for testing should be accompanied by documentation including a copy of observations made and any information which will assist in the examination of the implant and in relating the findings to clinical factors.

As much relevant information as possible about the patient, case history and the implant should be collected and recorded. If applicable, the terms defined in BS 6324 should be used in compiling the documentation. Traceability should be established between the documentation and all radiographs, photographs and other pictorial records.

Examples of the information that should be compiled are given in appendix C. Documentation that contains personal information about the patient should be treated with the same confidentiality as that used for hospital notes, etc.

Attention is particularly drawn to the provisions of the Data Protection Act 1984 and to 'Responsibility in the use of personal medical information for research. Principles and guide to practice'.[2]

6 Examination of removed implant and associated samples

6.1 General

Care should be taken to ascertain the legal ownership of implants before any destructive tests are carried out, since implants may be used as evidence in subsequent litigation or may be required for examination by the implant manufacturer. No destructive test should be carried out until permission has been obtained from all parties who have, or may have, an interest in the outcome. Non-destructive methods of testing are of particular value and should be considered wherever possible. All implants and samples, unless subjected to a sterilization process, should be handled with gloved hands and taking suitable precautions against biological hazard.

6.2 Immediate post-operative examination

A preliminary examination should be undertaken immediately after removal and should include the recording of all manufacturer's identification marks, serial numbering and any other marking on the implant. Note should be made of the type of implant, serial/batch numbers, material identification, date codes and size. The presence of strongly adherent tissue should be recorded, since

[1] The Post Office Guide, published by The Post Office and available from most post offices.
[2] Available from the Publication Department, Medical Research Council, 20 Park Crescent, London W1N 4AL.

it may relate to interaction or corrosion processes. All evidence of fracture or deformation of the implant should be noted. A photographic record of features of interest is recommended. Still using gloved hands, the implant should then be carefully cleansed if necessary for detailed examination.

6.3 Initial examination

6.3.1 *Visual examination*

The implant should be examined by means of a low power (x 20 magnification) light microscope to identify corrosion, fatigue cracks and gross wear changes.

Radiographs of the implant in situ are valuable in relating implant characteristics to the clinical situation as a whole. If radiographs are available observations of resorption, loosening, cement breakage and inappropriate sites of application of the implant should be recorded.

In the case of broken implants a study of the clinical position from radiographs may indicate the reason for failure.

Observations should be recorded and related to orientation of the implant. Findings on individual components should be related to the implant as a whole and subsequently to the clinical situation.

6.3.2 *Microbiological examination*

Routine microbiological staining and culture methods alone are not appropriate in view of the variety of organisms that may be present. Special techniques are necessary to culture and identify some species. The microbiologist should be given full details of all antibiotic therapy that the patient has been receiving.

6.3.3 *Tissue examination*

Tissue samples should be examined by routine histopathological methods. Particular attention should be given to any interfacial reactions or to the presence of degradation or corrosion products of implant materials.

6.4 Detailed examination

Further detailed examination by advanced techniques may not be justified in the majority of cases. However, if further study is necessary, the following considerations should be taken into account.

Analyses of structure and mechanical properties and of wear behaviour should be carried out. In certain cases a more detailed examination of wear traces should be carried out, e.g. by replication techniques involving microscopy or laser holography. Examples of the information that should be compiled from metallurgical analyses are given in appendix D.

Composite materials may require special techniques, such as scanning electron microscopy in conjunction with mechanical testing, in order to determine changes in fibre matrix bonding and possible delamination.

Special methods of examination should be used in cases where the extraction of leachable components or the absorption of tissue constituents are to be studied, and for these purposes unsterilized and unwashed samples may need to be used.

Apparently inert materials may affect the immune system, producing reactions which simulate an inflammatory disorder without evidence of infection. In such cases special immunological and tissue culture techniques may be necessary.

Appendices

Appendix A. Checklist for retrieval of orthopaedic implants

A summary of the stages involved in the handling and examination of retrieved implants and associated tissue is shown in figure 1.

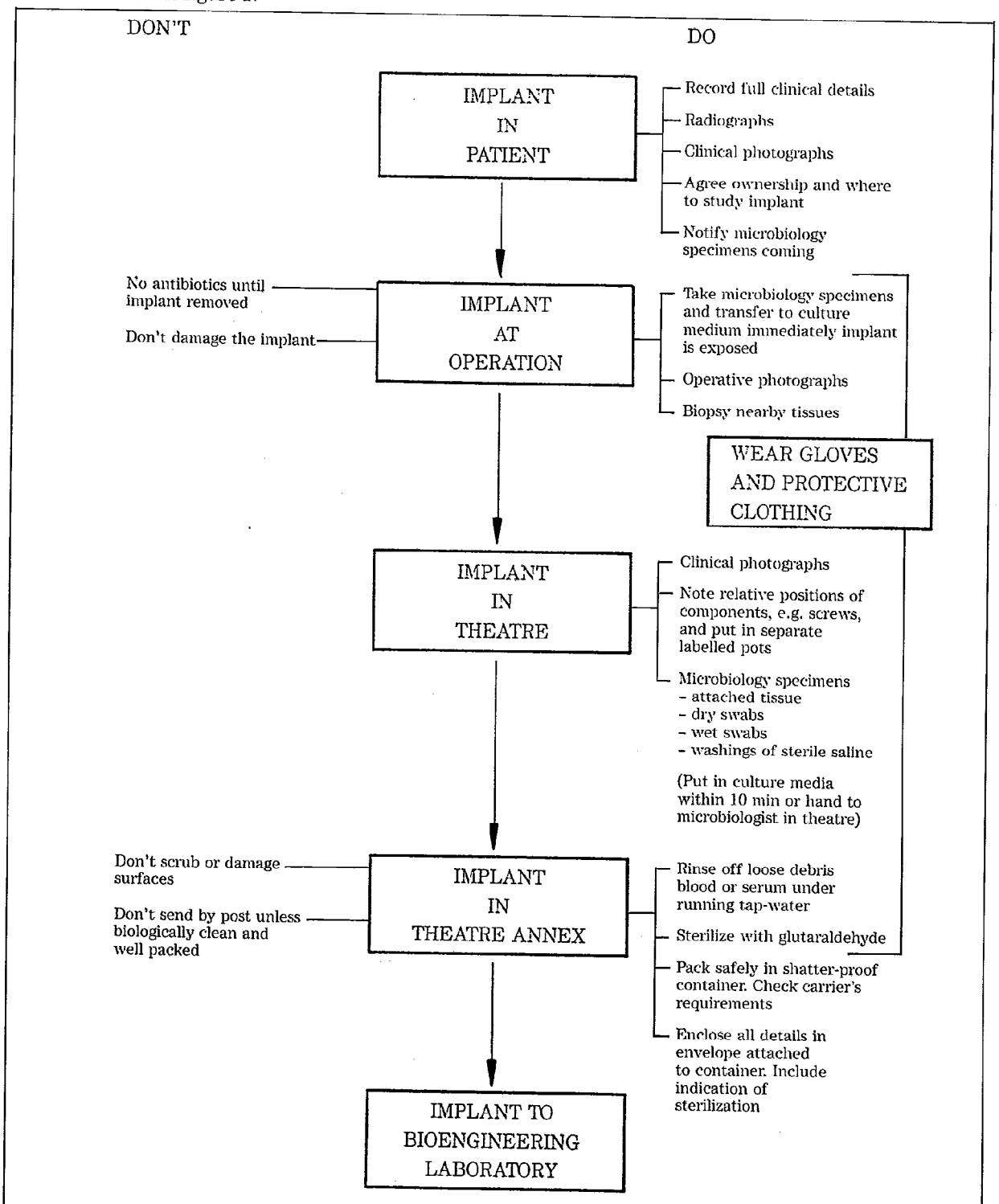

Figure 1. Checklist for retrieval of orthopaedic implants

Appendix B. Extract from 1986 issue of Post Office Guide

NOTE. This extract is given for information only. The Post Office Guide is updated regularly and it is the responsibility of the sender of the specimen to ensure that the packaging complies with the requirements in force at the time.

Pathological specimens

Pathological specimens – articles sent for medical examination or analysis

1 Deleterious substances are normally prohibited from transmission by post. An exception is made for pathological specimens excluding those known or suspected to contain Hazard Group 4 pathogens. Pathological specimens may be sent for medical examination or analysis to a recognized medical laboratory or institution; or to a qualified medical practitioner; or to a registered dental practitioner; or to a veterinary surgeon.

2 Only the FIRST CLASS LETTER POST or DATAPOST services may be used. The parcel post service may not be used.

3 There is a range of packaging types which is acceptable to the Post Office for the sending of pathological specimens.

Packaging requirements

In all cases, the following must be strictly observed.

4 Every pathological specimen must be enclosed in a primary container hermetically sealed or otherwise securely closed. Except where otherwise specifically permitted, the capacity of the primary container must not exceed 50 ml (although multi-specimen packs may be approved). The primary container must be wrapped in sufficient absorbent material (e.g. cellulose wadding or cotton wool) to absorb all possible leakage in the event of damage, and sealed in a leakproof plastic bag.

5 The receptacle and its immediate packaging must then be placed in one of the following:

(a) a polypropylene clip-down container;

(b) a cylindrical light-metal container;

(c) a strong cardboard box with full-depth lid;

(d) the appropriate groove in a two-piece polystyrene box. Any empty spaces must be filled with absorbent material. The two parts of the box must then be firmly held together by self-adhesive plastic tape.

6 Whichever of the above methods is used, we recommend the use of a padded bag as an additional outer cover. Royal Mail lightweight packs, on sale at main post office counters, are suitable padded bags.

7 Multiple-specimen packs are acceptable provided that each primary container is separated from the next by soft absorbent packaging material to prevent contact.

Post Office agreement to be obtained for non-standard packaging

8 If none of the approved range of packs is suitable then any person or organization intending to send pathological specimens through the post using other types of packaging must first apply to the Post Office for permission, and submit samples of the packaging types to be used, together with a written assurance that this proposed packaging conforms to the requirements in 4 and 5 above. Applications must be made to Postal Regional Headquarters (Customer Services) – addresses on pages 5/6 – enclosing sample packs (minus specimen) and giving details of amounts and types of specimens to be sent.

9 The Post Office's agreement will refer to the particular packaging types submitted; if a user wishes at any time to use different non-standard packaging, it must be submitted to the Post Office for approval.

Labelling	10 The outer cover or wrapping must be conspicuously labelled 'PATHOLOGICAL SPECIMEN – FRAGILE WITH CARE'. It must show the name and address of the sender to be contacted in case of damage or leakage.
Vaccines, etc	11 Therapeutic and diagnostic substances such as blood products, serum or vaccines which may contain living organisms, and semen for artificial insemination purposes are accepted under the same conditions as for pathological specimens.
Warning	12 Any packet of this kind found in the parcel post, or not packaged and marked as directed, will be stopped and may be destroyed with all its wrapping and enclosures. Any person who sends by post a deleterious substance for medical examination or analysis without conforming to the above regulations, may be liable to prosecution.

Appendix C. Examples of the information to be compiled and recorded when an implant is removed

C.1 Details of patient

Examples of patient details to be recorded are as follows:

(a) name;
(b) reference (hospital) number;
(c) age (date of birth);
(d) gender;
(e) mass;
(f) occupation;
(g) type of implant;
(h) location of implant.

NOTE. Attention is drawn to the need to preserve the confidentiality of details relating to the patient (see clause 5).

C.2 Case history

C.2.1 Examples of case history information to be recorded are as follows:

(a) date of implantation;
(b) date and causes of death;
(c) diagnosis at implantation, including contributory factors, e.g. trauma, senility, alcoholism, pre-existing pathology;
(d) details of implantation operation, including if and why antibiotic cover given, surgeon, hospital/theatre, details of implant;
(e) details of other operative interventions;
(f) skin sensitivity data;
(g) activity patterns and levels, especially any considered to be unusual for the type of treatment;
(h) radiograph review (see **C.2.2**), and dates;
(i) reasons for removal of implant (see **C.2.3**);
(j) date of removal;
(k) details of removal operation, including surgeon and hospital/theatre;
(l) findings at surgery (see **C.2.4**);
(m) record of samples taken and examinations requested.

C.2.2 Examples of findings at review of radiographs are as follows:

(a) bony change in relation to implant;
(b) absorption or rarefaction of bone;
(c) increased density of bone (sclerosis or compaction);
(d) non-union of bone;
(e) bone fragments held apart;
(f) migration of implant;
(g) malalignment of implant;
(h) fracture of bone;
(i) penetration of implant across joint space;
(j) penetration of implant through bone;
(k) fracture of implant;
(l) .permanent deformation of implant.

C.2.3 Examples of reasons for removal of implant are as follows:

(a) routine (completion of treatment);
(b) early infection (< 6 months);
(c) late infection (> 6 months);
(d) breakage or deformation of implant;
(e) pain in the vicinity of implant;
(f) stiffness of joint in vicinity of implant;
(g) prominent bursae;
(h) instability of union;
(i) unsatisfactory position of implant;
(j) non-union of bone;
(k) allergic or hypersensitive reaction;
(l) removed post mortem.

C.2.4 Examples of findings at surgery are as follows:

(a) pus;
(b) scar tissue;
(c) granulation tissue;
(d) foreign body reaction (debris or stained tissue);
(e) bursal fluid;
(f) implant easily removed;
(g) fractured grouting agent;
(h) caseation;
(i) bony reaction;
(j) large amounts of adherent tissue.

C.3 Details of removed implant

Examples of details of removed implant to be recorded are as follows:

(a) type and size;
(b) manufacturer;
(c) catalogue number;
(d) serial/unique/date codes/other identifying numbers or marks;
(e) materials of construction;
(f) treatment post-operatively, i.e. whether and how sterilized, cleansed.

Appendix D. Examples of the information to be compiled on metallurgical examination of removed implant and/or component

D.1 Macroscopic examination

The presence, location and estimated degree of the following should be given:

(a) wear or burnishing;

(b) galling;

(c) scratching;

(d) change of shape;

(e) mechanical damage;

(f) macroporosity.

D.2 Microscopical examination

The location of the phenomenon and the orientation of the sample should be given for the following:

(a) inclusion content;

(b) grain size;

(c) grain boundary constituents;

(d) microporosity;

(e) other distinguishing features, e.g. cast stainless steel delta ferrite.

D.3 Type of material

The following information should be given:

(a) chemical composition, giving method of analysis used.

D.4 Corrosion

The location and estimated extent of the following should be given:

(a) no corrosion detected;

(b) general corrosion;

(c) pitting corrosion;

(d) crevice corrosion;

(e) galvanic corrosion;

(f) unable to identify.

D.5 Mode of mechanical failure

The mode of mechanical failure should be identified, as follows, giving the location of the failure and the method of identification:

(a) fatigue;

(b) torsion;

(c) impact;

(d) stress corrosion;

(e) static overstress, causing plastic deformation;

(f) corrosion fatigue;

(g) combination (identify);

(h) other (specify);

(i) unable to specify.

D.6 Mechanical properties

The mechanical properties should be determined as follows, giving the method used:

(a) sample size and orientation;

(b) hardness (giving hardness scale);

(c) 0.2 % offset yield stress;

(d) ultimate tensile strength;

(e) percentage elongation;

(f) percentage reduction in area.

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Publications referred to

BS 1884	Specification for rubber post-mortem gloves
BS 4005	Specification for single use, sterilized surgical rubber gloves
BS 6324	Terms relating to surgical implants Part 1 Glossary of general medical terms Part 2 Glossary of terms relating to mechanics Part 3 Glossary of terms relating to materials Part 4 Glossary of orthopaedic surgical terms
BS 7251[1]	Orthopaedic joint prostheses
BS 7252[1]	Metallic materials for surgical implants
BS 7253[1]	Non-metallic materials for surgical implants
HN(87)1[2]	Decontamination of equipment, linen or other surfaces contaminated with Hepatitis B or Human Immunodeficiency Virus
HN(87)22[2]	Decontamination of health care equipment prior to inspection, service or repair
Medical Research Council,	Responsibility in the use of personal medical information for research. Principles and guide to practice[3]
Post Office Guide[4]	
DHSS	Code of practice for the prevention of infection in clinical laboratories and post-mortem rooms[5].
DHSS	LAV-HTLV3 Causative agent of AIDS and related conditions – revised guidelines, 1986[2]

[1] Referred to in the foreword only.
[2] Available from the Department of Health, 14 Russell Square, London WC1B 5EP.
[3] Available from the Publication Department, Medical Research Council, 20 Park Crescent, London W1N 4AL.
[4] Available from post offices.
[5] Available from Her Majesty's Stationery Office.

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