

Non-metallic materials for surgical implants —

Part 4: Specification for ultra-high molecular mass polyethylene in powder form

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The preparation of this British Standard was entrusted by the Health Care Standards Policy Committee (HCC/-) to Technical Committee HCC/18, upon which the following bodies were represented:

- British Forging Industry Association
- British Industrial Ceramic Manufacturers' Association
- British Institute of Surgical Technologists
- British Investment Casting Trade Association
- British Orthopaedic Association
- British Steel Industry
- British Surgical Trades Association
- Department of Health
- Department of Trade and Industry (National Engineering Laboratory)
- Department of Trade and Industry (Laboratory of the Government Chemist)
- Department of Trade and Industry (National Physical Laboratory)
- Ministry of Defence
- Royal College of Surgeons of England
- Royal Veterinary College
- Scottish Office
- Sterilised Suture Manufacturers' Association
- Coopted members

The following body was also represented in the drafting of the standard, through subcommittees and panels:

British Ceramic Research Ltd.

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
1 Scope	1
2 Definition	1
3 Classification	1
4 Flow properties	1
5 Limits of contamination	1
6 Test certificate	1
7 Labelling	1
Appendix A Method for determining the flow value	2
Appendix B Method for determining the relative solution viscosity	7
Appendix C Method for determination of particulate matter	8
Figure 1 — Specimen holder for determining the flow value	4
Figure 2 — Test specimen for determining the flow value	5
Figure 3 — Schematic diagram of the apparatus for determining the flow value	6
Figure 4 — Typical temporal curve of the elongation of test specimen during determination of flow value (schematic diagram)	7
Table 1 — Maximum ash and trace elements	1
Publications referred to	Inside back cover

Foreword

This Part of BS 7253 has been prepared under the direction of the Health Care Standards Policy Committee. It is a revision of BS 3531-20:1986, 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. 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.

BS 3531-20:1986 was identical with ISO 5834-1:1985 “*Implants for surgery — Ultra-high molecular weight polyethylene — Part 1: Powder form*”, published by the International Organization for Standardization (ISO), but the material known as type B in BS 3531-20:1986 has ceased to be commercially available, having been replaced by a material of slightly different composition. It was therefore necessary to revise BS 3531-20:1986 and, because the change of composition has not yet been reflected by a revision of ISO 5834-1:1985, BS 7253-4 differs technically from ISO 5834-1.

Two types of powder are specified, grade A and grade B. These grades have different average molecular masses and molecular mass distribution, resulting in different processing characteristics. Grade A is normally considered suitable for compression moulding into block form, whereas grade B is suitable for compression moulding into block form and into individual finished components, and for extrusion into rod, bar and profiles.

Attention is drawn to BS 7253-5:1990, which specifies requirements for ultra-high molecular mass polyethylene in moulded form.

WARNING NOTE. Attention is drawn to the fact that this British Standard calls for the use of substances that may be injurious to health or may represent fire hazards. Attention is drawn especially to Appendix A, Appendix B and Appendix C. Such substances should be used only by trained personnel, using correct safety procedures and wearing safety clothing and protective devices.

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 8, 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.