

Specification for

Sterile epidural catheters and introducer needles for single use

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The preparation of this British Standard was entrusted by the Health Care Standards Policy Committee (HCC/-) to Technical Committee HCC/27, upon which the following bodies were represented:

- Association for Medical Physics Technology
- Association of Anaesthetists of Great Britain and Ireland
- Association of Clinical Pathologists
- British Dietetic Association (PENG)
- British Health-Care Trade and Industry Council
- British Institute of Radiology
- British Paediatric Association
- British Plastics Federation
- British Rubber Manufacturers' Association
- British Surgical Trades Association Incorporated
- College of Radiographers
- Department of Health and Social Security
- Disposable Hypodermic and Allied Equipment Manufacturers' Association (UK)
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- Malaysian Rubber Producers' Research Association
- Medical Sterile Products Association
- National Association of Theatre Nurses
- Pharmaceutical Society of Great Britain
- Royal College of Radiologists
- Royal College of Surgeons of England
- 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 July 1989

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Foreword

This first revision of BS 6196 was prepared under the direction of the Health Care Standards Policy Committee.

BS 6196 was first published in 1982 and was prepared at the request of the Department of Health and Social Security.

The main differences from the 1982 edition, which is now withdrawn, are as follows.

- a) Requirements for freedom from biological hazard are introduced.
- b) The minimum length of the epidural catheter is not specified, so as to allow shorter catheters for specialized applications such as paediatric use. However, it is still recognized that epidural catheters for adult use should be at least 900 mm in length.
- c) Additional distance marks on the epidural catheter are introduced at the request of clinicians, who find them useful in fine adjustment of the extent of catheter insertion. A separate system of distance marking is introduced for catheters for paediatric use.
- d) A fixed length for the epidural introducer needle is not specified, so as to permit, at the request of clinicians, a range of lengths (in multiples of 10 mm) for particular applications such as paediatric use or use in obese patients.

The committee responsible for this standard has not found it practicable to specify criteria for rigidity or resistance to kinking, coiling or knotting, nor to specify particular materials with these characteristics. However, design guidance is given in Appendix A.

It has not yet been found possible to specify a satisfactory method of measuring radio-opacity. However, the packaging of epidural catheters that are made of material which is inherently radio-opaque, or to which a radio-opacifying agent has been admixed, is to be marked "RADIO-OPAQUE".

Single-use epidural equipment should be manufactured and sterilized in accordance with the recommendations in the "Guide to Good Manufacturing Practice for Sterile Medical Devices and Surgical Products"¹⁾. Attention is also drawn to the Manufacturer's Registration Scheme administered by the Department of Health and Social Security.

Single-use epidural equipment should never be reused, nor subjected to any further sterilization process before use.

WARNING NOTE. Attention is particularly drawn to the danger of pulling back the catheter through the epidural introducer needle (see clause 6) because on occasions a piece of the catheter has been severed and left in the epidural space. Due cognizance should be taken of this possibility when assessing compatibility of materials of construction with human tissue.

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 continuing 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⁾ Published by the Department of Health and Social Security and available from HMSO, 49 High Holborn, London, WC1. (ISBN 0 11 320770 0).

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Summary of pages

This document comprises a front cover, an inside front cover, pages i to iv, 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.

