

Neurosurgical implants —

Part 3: Specification for self-closing intracranial aneurysm clips

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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/24, upon which the following bodies were represented:

- Association for Spina Bifida and Hydrocephalus
- British Association of Paediatric Surgeons
- British Surgical Trades Association
- Department of Health
- Electroencephalographic Society
- Medical Research Council
- Medical Sterile Products Association
- Royal College of Surgeons of England
- Scottish Office
- Society for Research into Hydrocephalus and Spina Bifida
- Society of British Neurological Surgeons
- Coopted Members

This British Standard, having been prepared under the direction of the the Health Care Standards Policy Committee, was published under the authority of the Board of BSI and comes into effect on 31 May 1990

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Foreword

This Part of BS 6788 has been prepared under the direction of the Health Care Standards Policy Committee. It is technically related to ISO 9713 “*Neurosurgical implants — Self-closing intracranial aneurysm clips*” in preparation by Technical Committee ISO/TC 150, Implants for surgery, of the International Organization for Standardization (ISO), but differs chiefly in that it includes an additional alloy (see Appendix A) for the manufacture of clips.

Magnetic fields of considerable strength, e.g. 0.5 T to 2.5 T, are used in neurology with increasing frequency as part of diagnostic techniques such as magnetic resonance imaging (MRI) [also known as nuclear magnetic resonance (NMR)]. Exposure to electromagnetic radiation may pose a hazard to patients who have intracranial aneurysm clips because of the tendency of metallic clips to move when subjected to a strong magnetic field. This movement may result in the clip being removed from the aneurysm that it was intended to occlude and even to be moved through the tissues. Because of the very high field strengths, which are likely to become even higher as MRI techniques progress, even materials normally regarded as non-magnetic may exhibit some ferromagnetic properties. It is therefore essential that aneurysm clips should not have ferromagnetic properties.

A secondary effect is that the presence of a metallic clip may interfere with the MRI process, resulting in deterioration of the quality of the scanning image.

At present it has not been found possible to devise a test method to quantify the behaviour of a clip in a magnetic field and therefore to set criteria for the magnetic properties of the clip. However, such work is in progress, and it is expected that requirements will be included in a future revision of this standard.

The main intention of this British Standard is to help ensure that appropriate and comparable information is supplied in order to facilitate the choice of the correct clip by the surgeon. The closing force of the clip is an important factor in the selection process, and this standard requires that the manufacturer determine the closing force and state this value on the labelling. The actuation of some types of clip can result in a change in the closing force, and therefore a tolerance for the closing force is specified. This tolerance only applies to the first actuation of the clip as supplied, and repeated actuation by the surgeon before or during implantation can result in further change in the closing force. When the clip is known to exhibit this type of behaviour, the manufacturer is required to warn against repeated actuation.

Aneurysm clips supplied in the sterile condition 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 manufacturers registration scheme administered by the Department of Health.

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⁾ Compiled by the Department of Health and Social Security; published by and available from HMSO (ISBN 011 320770 0).

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.

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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.