

Neurosurgical implants —

Part 1: Specification for sterile, single-use hydrocephalus shunts and components

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- Association for Spina Bifida and Hydrocephalus
- British Association of Paediatric Surgeons
- British Surgical Trades Association Incorporated
- Department of Health and Social Security
- Electroencephalographic Society
- 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

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Contents

	Page
Committees responsible	Inside front cover
Foreword	ii
Section 1. General	
1 Scope	1
2 Definitions	1
Section 2. General requirements for complete shunts and for components	
3 Surface finish	2
4 Extractable materials	2
5 Type test for freedom from biological hazard	2
6 Packaging	2
7 Labelling	2
Section 3. Additional requirements for complete shunts	
8 Type and size designation	4
9 Connectors	4
10 Pressure and flow characteristics	4
11 Freedom from reflux	4
12 Labelling	4
13 Accompanying documentation	4
Section 4. Additional requirements for valves and catheters with integral valves supplied as separate components	
14 Type and size designation	5
15 Pressure and flow characteristics	5
16 Freedom from reflux	5
17 Labelling	5
18 Accompanying documentation	5
Section 5. Additional requirements for other components supplied separately	
19 Type and size designation	6
20 Labelling	6
Appendix A Guidance on materials	7
Appendix B Suggested method of test for durability	7
Appendix C Method of determination of acidity and alkalinity	9
Appendix D Method for determination of pressure and flow characteristics	9
Appendix E Method of test for reflux	11
Figure 1 — Example of apparatus for evaluation of pressure and flow characteristics and durability of shunts and components	8
Figure 2 — Configurations for testing valves for freedom from reflux	12
Publications referred to	Inside back cover

Foreword

This Part of BS 6788 has been prepared under the direction of the Health Care Standards Committee and takes cognizance of the work on hydrocephalus shunts in progress within Technical Committee 150 “Implants for Surgery” of the International Organization for Standardization (ISO).

The purpose of a hydrocephalus shunt is to relieve excessive pressure within the ventricular system, to prevent over-drainage of fluid and to resist reflux.

Imaging and investigative techniques such as Nuclear Magnetic Resonance (NMR) [Magnetic Resonance Imaging (MRI)] involve placing the patient in a strong magnetic field. This may result in severe stresses on magnetizable materials, even moving them through tissues. Magnetizable materials (i.e. materials that are, or could become, ferromagnetic) should be avoided if possible in hydrocephalus shunts, but if used a suitable warning is to be included in the product labelling. It may be necessary to exclude the use of magnetizable materials in future editions of this Part of BS 6788. It is suggested that the manufacturer encloses with each complete shunt a card or other document suitable for retention by the patient that gives details of the shunt and of the hazards that may arise from exposure to electromagnetic forces.

It is recommended that shunts and components be manufactured and sterilized in accordance with the recommendations in the “Guide to Good Manufacturing Practice for Sterile Medical Devices and Surgical Products”¹⁾.

Consideration is being given to the development of a method for assessing the radio-opacity of medical devices such as shunts. In the absence of a method of test, it is not possible to include radio-opacity as a requirement in this Part of BS 6788, but it is strongly recommended that either all parts of the shunt or component are radio-opaque or that they carry radio-opaque markers, so as to allow their visualization within the body, and the packaging of such items be marked to show that they are radio-opaque. Guidance on materials is given in Appendix A.

Because of the considerable length of time over which a shunt or component may be required to function after implantation, it is felt that it should be type-tested to ensure its durability. It has not yet been found feasible to specify a method of durability testing, but a method is proposed in Appendix B, and it is suggested that this method be used and evaluated with a view to its inclusion in a future revision of this Part of BS 6788.

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 12, 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.

¹⁾ Published by the Department of Health and Social Security and available from Her Majesty's Stationery Office. ISBN 0 11 320770 0.

Section 1. General

1 Scope

This Part of BS 6788 specifies requirements for sterile, single-use hydrocephalus shunts and components.

It applies to hydrocephalus shunts of the following types:

- a) complete sterile, single-use hydrocephalus shunts of the one-piece type;
- b) complete sterile, single-use hydrocephalus shunts of the multi-piece type, supplied either assembled by the manufacturer, or in kit form for assembly by the clinician.

This standard also applies to sterile, single-use shunt components, such as valves, catheters, catheters with integral valves, connectors, reservoirs/priming devices, anti-syphon devices and pressure transducers supplied separately and intended either:

- 1) to be assembled by the clinician to form a complete shunt; or
- 2) for purposes such as incorporation as an ancillary component to a complete shunt; or
- 3) as a replacement part of an implanted shunt.

NOTE 1 Guidance on materials is given in Appendix A.

NOTE 2 A suggested method of durability testing is given in Appendix B.

NOTE 3 The titles of the publications referred to in this standard are listed on the inside back cover.

2 Definitions

For the purposes of this Part of BS 6788, the definitions given in BS 6324 apply together with the following.

2.1

hydrocephalus

state of excessive accumulation of cerebrospinal fluid within the ventricular system due to a disturbance of its secretion, its flow or its absorption, usually resulting in a pathological increase in intracranial pressure

2.2

hydrocephalus shunt

a device intended to be surgically implanted in the body of a patient with hydrocephalus and designed to divert cerebrospinal fluid from the cerebral ventricles or other site within the cerebrospinal fluid system to another part of the body

2.3

valve

an element of a hydrocephalus shunt that controls the relationship between pressure and flow of cerebrospinal fluid and that resists reflux of blood or other fluids into the shunt

NOTE A hydrocephalus shunt may contain more than one valve.

2.4

reflux

a flow of fluid within a hydrocephalus shunt towards the cerebral ventricles or cerebrospinal fluid system

2.5

inflow catheter²⁾

the part of a hydrocephalus shunt that is inserted into the cerebral ventricles or other site in the cerebrospinal fluid system

2.6

outflow catheter²⁾

the part of a hydrocephalus shunt that drains excess cerebrospinal fluid to another part of the body

2.7

sterile

free from all living organisms. In practice, the condition of a product that has been subjected to a sterilization process and maintained in this state by suitable protection

²⁾ Some hydrocephalus shunts comprise a single catheter which has an inflow end and an outflow end.

Section 2. General requirements for complete shunts and for components

3 Surface finish

When examined with normal or corrected vision at a distance of 300 mm to 450 mm and an illuminance of $2\,150 \pm 215$ lx, the surface of shunts and components that have passed through all stages of manufacture, including sterilization, shall be smooth and free from irregularities, flash, moulding and extrusion defects and extraneous particles.

4 Extractable materials

4.1 Limits for acidity and alkalinity

When tested in accordance with Appendix C, the extract shall have a pH value within one unit of that of the control fluid.

4.2 Limits for extractable metals

An extract prepared in accordance with Appendix C shall not contain more than 0.1 mg/kg cadmium or more than 1 mg/kg each of lead, tin, zinc or iron in excess of that contained in the control fluid.

5 Type test for freedom from biological hazard

Shunts and components shall, in their final form after sterilization, be tested according to the principles and methods recommended in BS 5736 for category A devices, and shall be assessed as being free from biological hazard.

NOTE 1 It is intended that this test be applied to the initial materials formulation and whenever there is a major change in the formulation and/or processing.

NOTE 2 The tests prescribed for category A devices in BS 5736-1 are: cell culture; local and systemic toxicity (acute toxicity, intracutaneous reactivity and pyrogenicity of extracts, BS 5736-3, BS 5736-4 and BS 5736-5 respectively); tissue implant (BS 5736-2); haemolysis; sensitization (BS 5736-6).

6 Packaging

6.1 Unit container

Each shunt or component shall be individually packaged and sealed in a unit container, the materials of which shall be non-fibrous and lint-free. The construction of the unit container shall be such that, once it has been opened, this fact shall be evident.

NOTE The packaging material should have no deleterious effects on the contents of the unit container. The unit container should provide adequate physical protection to the contents under normal conditions of handling, transit and storage, and be constructed so that, once opened, it cannot easily be resealed. The unit container should maintain the sterility of the contents and be constructed so as to facilitate the aseptic presentation of the device for use.

If shunts or catheters are packaged in the straight configuration, the unit container should afford protection against deformation. If packaged in the coiled configuration, they should be packaged in such a manner that no permanent deformation is produced.

6.2 Shelf containers

One or a number of unit containers each containing the same model of shunt or component shall be packaged in a shelf container.

NOTE The shelf container should provide protection to the contents under normal conditions of handling, transit and storage. One or a number of shelf containers may additionally be packaged in an outer or transit container.

7 Labelling

7.1 Unit container

The following information shall be given on the unit container or on a leaflet or insert:

- a) the particular information specified in clauses 12, 17 or 20 as appropriate;
- b) the word "STERILE";
- c) the name and/or registered trade mark of the manufacturer or supplier;
- d) the batch number and date of manufacture (year and month), or a batch number from which the date of manufacture can be determined;
- e) if appropriate, the word "RADIO-OPAQUE" or equivalent;
- f) if appropriate, a warning that the contents contain magnetizable materials;
- g) if the contents may be re-sterilized, full instructions for re-sterilization, indicating the recommended maximum number of sterilization cycles;
- h) a warning against use of the contents if the unit container is open or damaged;
- i) directions for opening the container and aseptic presentation of the contents;
- j) for contents having a determined shelf-life, the expiry date (year), beyond which the contents should not be implanted;
- k) the words "single-use" or equivalent phrase;
- l) the number and date of this British Standard, i.e. BS 6788-1:1986³⁾;
- m) instructions for storage if the unit container is as specified in 7.2 a).

NOTE *Marking of shunts and components.* It is recommended that shunts and components through which the fluid flow is unidirectional should be marked on their external surfaces to indicate the intended direction of flow, e.g. by means of an arrow.

³⁾ Marking BS 6788-1:1986 on or in relation to a product is a claim by the manufacturer that the product has been manufactured to the requirements of the standard. The accuracy of such a claim is therefore solely the manufacturer's responsibility. Enquiries as to the availability of third party certification should be addressed to the appropriate certification authority.