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Neurosurgical implants — Sterile, single-use hydrocephalus shunts and components

Implants pour neurochirurgie — Systèmes de dérivation et composants stériles, non réutilisables, pour hydrocéphalie

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International Organization for Standardization
Case postale 56 • CH-1211 Genève 20 • Switzerland
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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

Draft International Standards adopted by the technical committees are circulated to the member bodies for approval before their acceptance as International Standards by the ISO Council. They are approved in accordance with ISO procedures requiring at least 75 % approval by the member bodies voting.

International Standard ISO 7197 was prepared by Technical Committee ISO/TC 150, *Implants for surgery.*

Annexes A, B and C form an integral part of the standard. Annexes D and E are for information only.

Introduction

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 from future editions of this International Standard. 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 hazards that may arise from exposure to electromagnetic forces.

In the absence of a test method for freedom from biological hazard, it is not possible to lay down requirements for toxicity or bicompatibility in this International Standard. It is essential that such tests are carried out and, in this International Standard, the shunt manufacturer is required to make available upon request details of the test methods used and the results obtained. Tests should be carried out on the initial formulation of materials and whenever there is a major change in the formulation and/or processing.

In the absence of a test method, it is not possible to include radio-opacity as a requirement in this International Standard, but it is strongly recommended either that 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 annex D.

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 annex E, and it is suggested that this method be used and evaluated with a view to its being included in a future edition of this International Standard.

Neurosurgical implants — Sterile, single-use hydrocephalus shunts and components

Section 1 : General

1.1 Scope

This International Standard 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 International 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

a) to be assembled by the clinician to form a complete shunt; or

b) for purposes such as incorporation as an ancillary component to a complete shunt; or

c) as a replacement part of an implanted shunt.

NOTE — Guidance on materials is given in annex D; a suggested method of durability testing is given in annex E.

1.2 Definitions

For the purposes of this International Standard, the following definitions apply.

1.2.1 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.

1.2.2 hydrocephalus shunt: 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.

1.2.3 valve: 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.

1.2.4 reflux: Flow of fluid within a hydrocephalus shunt towards the cerebral ventricles or cerebrospinal fluid system.

1.2.5 inflow catheter [1]**:** That part of a hydrocephalus shunt that is inserted into the cerebral ventricles or other site in the cerebrospinal fluid system.

1.2.6 outflow catheter [1]**:** That part of a hydrocephalus shunt that drains excess cerebrospinal fluid to another part of the body.

1.2.7 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.

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

Section 2: General requirements for complete shunts and for components

2.1 Surface finish

When examined with normal or corrected vision at a distance of 300 mm to 450 mm and at an illuminance of 2 150 lx ± 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.

2.2 Extractable materials

2.2.1 Limits for acidity and alkalinity

When tested in accordance with annex A, the extract shall have a pH-value within one unit of that of the blank solution.

2.2.2 Limits for extractable metals

An extract prepared in accordance with annex A shall not contain more than 0,1mg/kg of cadmium or more than 1mg/kg each of lead, tin, zinc or iron in excess of that contained in the blank solution.

2.3 Packaging

2.3.1 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.

2.3.2 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.

2.4 Marking and labelling

2.4.1 Shunts and components

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

2.4.2 Unit container

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

a) the particular information specified in clauses 3.5, 4.4 or 5.2, 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) the word "RADIO-OPAQUE" or equivalent, if appropriate;

f) a warning that the contents contain magnetizable materials, if appropriate;

g) full instructions for re-sterilization, indicating the recommended maximum number of sterilization cycles, if the contents may be re-sterilized;

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) the expiry date (year) beyond which the contents should not be implanted, in the case of contents having a determined shelf-life;

k) the words "SINGLE USE" or equivalent phrase;

l) instructions for storage if the shelf container is as specified in 2.4.3a).

2.4.3 *Shelf container*

The shelf container shall be either

a) wholly or partially transparent so that the unit container markings are visible; or

b) labelled or marked with the following information :

1) a description of the contents, as specified in item a) in clauses 3.5, 4.4 or 5.2 (as appropriate), and number of contents,

2) the word "STERILE",

3) the name and address of the manufacturer or supplier,

4) the batch number and date of manufacture (year and month) or a batch number from which the date of manufacture can be determined,

5) instructions for storage,

6) the expiry date (year) beyond which the contents should not be implanted, in the case of contents having a determined shelf-life.

2.4.4 Outer or transit containers

The outer or transit container shall be labelled or marked with the following information :

a) a description of the contents, as specified in item a) in clauses 3.5, 4.4 or 5.2 (as appropriate), and number of contents;

b) the name and address of the manufacturer or supplier;

c) the batch number and date of manufacture (year and month) or a batch number from which the date of manufacture can be determined;

d) the date of sterilization (year and month), if different from the date specified in 2.4.4c);

e) instructions for storage;

f) the expiry date (year) beyond which the contents should not be implanted, in the case of contents having a determined shelf-life.

Section 3: Additional requirements for complete shunts

3.1 Type and size designation

The type and size of each catheter element and connector of the complete shunt shall be designated by means of the following information:

a) the nominal inside and outside diameters of the catheter element or connector, expressed in millimetres, and the overall length, expressed in millimetres or centimetres:

EXAMPLES

1,2 mm i.d. × 2,2 mm o.d./600 mm

or

1,2 mm i.d. × 2,2 mm o.d./60 cm

b) the type of catheter element.

3.2 Connectors

If additional connectors are supplied for use in conjunction with a complete shunt, the dimensions of the connectors shall be such that the pressure and flow characteristics of the shunt with the connectors in place shall not, when tested in accordance with annex B, differ by more than 10 % from the values determined for the shunt without the additional connectors in place.

3.3 Pressure and flow characteristics

The results for an individual shunt, when tested in accordance with annex B, shall lie within the functional range of the type of shunt stated by the manufacturer in accordance with items d) and e) in clause 3.6.

3.4 Freedom from reflux

When tested in accordance with annex C, shunts shall comply with the following requirements:

a) Chambered valves

1) The meniscus shall remain static for at least 1 min at both test pressures during the test described in C.5.1.1.

2) The meniscus shall remain static for at least 1 min during the test described in C.5.1.2.

3) It shall not be possible to compress the valve chamber manually and there shall be no continued formation of drops of liquid at the inlet end of the tubing during the test described in C.5.1.3.

b) Tip valves

Tip valves shall not show the continued formation of drops of liquid at the inlet end of the tubing at either test pressure during the test described in C.5.2.

3.5 Marking and labelling

The following particular information shall be given as specified in clause 2.4:

a) a description of the contents, including the type and size in accordance with clause 3.1;

b) a labelled and dimensioned diagram of the shunt showing the direction of fluid flow through the catheter and valve elements;

c) details of the pressure and flow characteristics of the type of shunt in accordance with items d) and e) in clause 3.6.

3.6 Accompanying documentation

Each shunt shall be accompanied by documentation that includes the following information:

a) instructions for assembly of the shunt;

b) a statement that the shunt should be tested prior to implantation, and instructions on how to carry out the test, including how to establish the patency of the shunt and how to assess the reflux and pressure and flow characteristics; the instructions shall emphasize the need for the use of sterile, lint-free apparatus and reagents and the use of aseptic techniques in carrying out the test;

c) a statement that details of the methods used to test materials and the results obtained (see annex D) are available on request, giving the address to which such requests should be sent;

d) the curve representing the pressure and flow characteristics of the type of shunt, determined in accordance with annex B;

e) the functional range of the type of shunt, determined in accordance with annex B.

NOTE — Accompanying documentation should not be enclosed in the unit container, but should preferably be enclosed in the shelf container.

Section 4: Additional requirements for valves and catheters with integral valves supplied as separate components

4.1 Type and size designation

The type and size of the component shall be designated by means of the following information :

a) the function of the valve/catheter (e.g. inflow, outflow);

b) the type of valve;

c) the overall length of component expressed in millimetres or centimetres, stating the unit used;

d) the nominal inside and outside diameters of the tubular portions of the component, expressed in millimetres.

4.2 Pressure and flow characteristics

The results for an individual component, when tested in accordance with annex B, shall lie within the functional range of the type of component stated by the manufacturer in accordance with items d) and e) in clause 4.5.

4.3 Freedom from reflux

When tested in accordance with annex C, the component shall comply with the requirements laid down in clause 3.4.

4.4 Marking and labelling

The following particular information shall be given as specified in clause 2.4:

a) a description of the contents, including the type and size in accordance with clause 4.1;

b) a labelled and dimensioned diagram of the component and its method of incorporation into the final shunt, showing the direction of fluid flow through the component;

c) details of the pressure and flow characteristics of the type of component in accordance with items d) and e) in clause 4.5.

4.5 Accompanying documentation

Each component shall be accompanied by documentation that includes the following information :

a) instructions for incorporation of the component into the final shunt;

b) instructions on how to test the component prior to implantation as specified in item b) in clause 3.6;

c) a statement that details of the methods used to test materials and the results obtained (see annex D) are available on request, giving the address to which such requests should be sent;

d) the curve representing the pressure and flow characteristics of the type of component, determined in accordance with annex B;

e) the functional range of the type of component, determined in accordance with annex B.

NOTE — Accompanying documentation should not be enclosed in the unit container, but should preferably be enclosed in the shelf container.

Section 5: Additional requirements for other components supplied separately

5.1 Type and size designation

The type and size of the component shall be designated by means of the following information:

a) the function of the component;

b) the overall length of the component, expressed in millimetres or centimetres, stating the unit used;

c) the nominal inside and outside diameters of the tubular portions of the component, expressed in millimetres.

5.2 Marking and labelling

The following particular information shall be given as specified in clause 2.4:

a) a description of the contents, including the type and size in accordance with clause 5.1;

b) the information detailed in item c) in clause 3.6 shall be given either in documentation accompanying each component or as part of the marking or labelling of the unit or shelf container;

c) for components having uni-directional fluid flow, a labelled and dimensioned diagram of the component and its method of incorporation into the final shunt, showing the direction of fluid flow through the component.

NOTE — Accompanying documentation should not be enclosed in the unit container, but should preferably be enclosed in the shelf container.