INTERNATIONAL STANDARD

ISO 7197

Third edition
2006-06-01

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

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

Reference number
ISO 7197:2006(E)

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 7197 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 3, *Neurosurgical implants*.

This third edition cancels and replaces the second edition (ISO 7197:1997) which has been technically revised.

Introduction

A shunt is defined as an artificial connection of two compartments inside the body. For the treatment of hydrocephalus, the ventriculo-atrial shunt has been introduced initially to control the intraventricular pressure in the brain of the patients. Today ventriculo-peritoneal shunts are preferably implanted. In special cases, a lumbo-peritoneal shunt is implanted. Normally a hydrocephalus shunt includes a valve which determines the resulting intraventricular pressure in the brain of the patients and influences the flow rate through the shunt.

The following types of valve are currently commercially available.

a) Conventional differential-pressure valves (DP-valves) are designed as ball-in-cone valves, membrane valves or silicone slit valves. They have one characteristic opening pressure. If the difference pressure between inlet and outlet exceeds this opening pressure the device opens. After opening, the different types of DP-valve show a wide range of different flow characteristics. Differences due to a changed posture of the patient have no intended impact on the function of the devices.

b) Adjustable DP-valves act like conventional DP-valves. In contrast to non-adjustable devices they introduce the possibility of a non-invasive readjustment of the opening characteristic after implantation. They do not take into account changes due to a changed posture of the patient.

c) Gravitation valves or hydrostatic devices take into account the changed physics in a shunt due to a changed posture of the patient. These devices aim to avoid an unphysiological negative intraventricular pressure in the upright position of the patient, which might be the consequence of the hydrostatic pressure in shunts with adjustable or not adjustable DP-valves. There are three different hydrostatic devices commercially available: flow-reducing devices, valves with a so-called “anti-siphon-device” or “siphon-control-device” and gravity-assisted devices.

d) Other adjustable valves, e.g.:

   — gravitation valves: adjustable hydrostatic devices present in addition to the characteristics of hydrostatic devices (group 4) with the possibility of a non-invasive readjustment of the opening performance of the device;

   — adjustable anti-siphon-device valves;

   — adjustable flow-reducing valves.

Although the technical and phenomenological performance of the devices is significantly different, no design has scientifically been proven to be superior. Due to the important technical differences, specific testing procedures are necessary to investigate the performance of the different valves.

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

1 Scope

This International Standard specifies safety and performance requirements for sterile, single-use non-active hydrocephalus shunts and components. This includes the components used in shunts, like valves, tubes and reservoirs.

This International Standard gives no recommendation concerning the superiority of a certain type of valve.

For manufacturing, it defines the mechanical and technical requirements. This International Standard defines the technical information of the valve, to be given by the manufacturer. In respect to the different principles of the valve types, specific characteristics are defined for each group as declared by the manufacturer.

The benefit of this International Standard for the surgeon and the patient is to understand the information given by the manufacturer and to obtain standardized information about the performance of a well working product with new design characteristics. The benefit for the manufacturer is to define the important requirements for shunts as a basis for investigations during development as well as for quality control during manufacture.

This International Standard does not apply to active implants for the treatment of hydrocephalus.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing*

ISO 14630:2005, *Non-active surgical implants — General requirement*

ASTM F2503-05, *Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
accompanying documents
document accompanying a medical device, or an accessory, and containing important information for the user, operator, installer or assembler of the medical device, particularly regarding safety supplied by the manufacturer

NOTE Adapted from ISO 14971:2000.

3.2
hydrocephalus
state of excessive accumulation of cerebro-spinal fluid CSF with the ventricular system of the head due to a disturbance of secretion, flow or absorption

3.3
hydrocephalus shunt
single-use device(s) typically consisting of an inflow catheter, a pressure-controlling device, and an outflow catheter intended to regulate the pressure of cerebro-spinal fluid CSF

3.4
instructions for use
parts of accompanying documents provided by the manufacturer, giving the necessary information for safe and proper use

3.5
lumbo-peritoneal drainage
drainage of cerebro-spinal fluid CSF from the lumbar sub-arachnoid spaces into the peritoneum

3.6
patient identification card
card identifying its holder and issuer, which carries data on the hydrocephalus shunt implanted

3.7
ventriculo-atrial drainage
drainage of cerebro-spinal fluid CSF from the ventricles into the right atrium of the heart

3.8
ventriculo-peritoneal drainage
drainage of cerebro-spinal fluid CSF from the ventricles into the peritoneum

4 General requirements for shunts

4.1 General

The sample size shall be justified and stated.

4.2 Radiopacity

All external parts of the shunt or accessory device shall be radiopaque or shall carry radiopaque markers.

All parts of the shunt shall be identifiable via X-ray examination.

NOTE Guidance can be found in ASTM F640.

4.3 Biocompatibility

The biocompatibility of hydrocephalus shunts and components shall be assessed. Guidance is given in the principles and methods recommended in ISO 10993-1.

4.4 Resistance to leakage

Resistance to leakage shall be measured using air. All parts of the shunt shall show no signs of leakage with a differential pressure from inside to outside of 9,806 7 kPa (1 m water column) within 5 min.

4.5 Control of the implanted shunt

The functionality of the shunt and the method of control of the implanted shunt shall be stated in the accompanying documents.

If no test is possible, the manufacturer shall state this fact in the instructions for use and the accompanying documents.

4.6 Pressure-flow characteristics of the valve, the components and the pre-assembled shunt

The pressure-flow characteristics of the valve shall be tested and monitored in the relevant flow range of (5 to 50) ml/h. A graph showing the pressure/flow characteristics shall be included in the accompanying documents.

The manufacturer shall state if the complete system (catheter, reservoir and other devices) causes fundamental changes in the pressure/flow characteristics. In this case, graphs showing the pressure/flow characteristics of the complete shunt and the components shall be included.

NOTE Fundamental change would be additional resistance due to an inner diameter of the catheter smaller than 1 mm (see 5.2).

If the device shows a posture-dependant function, the basic characteristic for the most important positions should be shown (see 5.1.3).

If the characteristic of the device depends on the subcutaneous pressure, the effects on the valve performance should be shown in the relevant ranges [see 8.2 g)].

4.7 Identification of shunts *in vivo*

The type of the valve as well as the direction of flow shall be detectable non-invasively. A method for the identification of the valve shall be given in the instructions for use and in the patient identification card. For adjustable devices, an X-ray image related to the basic understanding of the pressure settings shall be included in this information.

4.8 Ability to withstand overpressure

The functionality and integrity of the shunt shall not be affected by 9,806 7 kPa (1 m water column) positive pressure applied to the open shunt.

4.9 Dynamic breaking strength

The dynamic breaking strength of every component of the shunt shall be tested using a frequency of (1 $\pm$ 0,2) Hz. The tension shall be applied in flow direction and lead to an elongation of the shunt of 10 % or a maximum force of 5 N whichever comes first. Testing shall be carried out for 100 000 cycles.

During this test, no component shall rupture or break.

4.10 Behaviour under MR imaging conditions

For each of the components used for the shunt, the manufacturer shall state if it is MR unsafe, MR safe or MR compatible in accordance with ASTM F2503-05.

4.11 Bursting pressure

Each component of the shunt shall be capable of withstanding a positive pressure of 19,613 3 kPa (2 m of water column) inside the component without a significant change of its characteristics within a tolerance of

± 10 % of each specification. The characteristics shall be in the described range at the latest, two hours after the pressure has been applied.

5 Specific requirements for components

5.1 Valves

5.1.1 Reflux performance of shunts connecting the ventricle to the blood system

A maximum flow of 0,04 ml/min is allowed to be drained back in a pressure range between 0 and 4,903 3 kPa (0 and 500 mm of water column) against the flow direction.

5.1.2 Long term stability

The long term stability of a valve shall be demonstrated according to the following test method:

— immerse the valve in distilled, degassed water;

— keep the water temperature at blood temperature ± 5 °C;

— pump distilled, degassed water at an average flow rate of 20 ml/h through the valve for 28 d.

During testing time, the characteristics of the valve (e.g. flow rate or opening pressure) shall remain in the range which is stated in the instructions for use.

5.1.3 Influence of the changed posture of the patient on the valve performance

The manufacturer shall state in the instructions for use if the characteristics of the valve depend on the posture of the patient.

If the characteristics depend on the posture, the compliance of these characteristics with the values stated by the manufacturer shall be stated for horizontal and vertical position of the patient (see 4.6).

5.2 Resistance of tubing and components

In addition to the pressure flow graph of the valve, the manufacturer shall describe the influence of tubing or other additional components in the accompanying documents.

NOTE This can be done by an additional pressure-flow diagram.

6 Marking and labelling of shunts

The requirements of ISO 14630:2005 11.2, 11.5 and the following shall apply.

— Information on how the opening pressure was measured shall be stated in the accompanying documentation.

— The characteristic pressure depending performance shall be given at a flow rate of 20 ml/h.

7 Packaging

The requirements of ISO 14630:2005 Clause 10 shall apply.

8 Information supplied by the manufacturer

8.1 General

The requirements of ISO 14630:2005 Clause 11 and the following shall apply.

8.2 Instructions for use

The instructions for use shall include:

a) instructions for the pre- and postoperative testing of the functionality of the shunt;

b) warning notices concerning the maximum positive and negative pressure that can be applied to the system without impairing its performance;

c) dimensions of components;

d) method for puncture and indication on how often a puncture is possible;

e) the flow characteristic of the valve shall be given in a pressure versus flow diagram in the range 5 ml/h to 50 ml/h; the measuring method shall be specified;

f) if the region in which the shunt is implanted has an influence on the valve characteristics, this shall be indicated and quantified;

g) if the flow characteristics depend on the subcutaneous pressure, this shall be indicated; if applicable, include a graph of valve pressure over ambient pressure (between 0 and 0,490 3 kPa (0 and 500 mm water column) measured under constant flow between 10 ml/h and 20 ml/h (medium production rate of an adult);

h) advice on if and how the flow characteristics of the shunt are affected by MR examination;

i) advice on if and how the flow characteristics of the adjustable shunt are affected by MR examination including indication of how the performance of the valve is affected by which magnetic field intensity;

j) instruction if and how the shunt shall be tested and/or readjusted after MR examination.

8.3 Patient identification card

A card, suitable for retention by the patient, shall be provided by the manufacturer.

This card shall contain the following:

a) information on the shunt (name, manufacturer, type, serial number);

b) X-ray image of the shunt;

c) X-ray images related to each pressure setting if applicable;

d) place for indication of date and location of implantation by the user;

e) a warning against the hazards of exposure to magnetic fields;

f) instruction if and how the shunt shall be tested and/or readjusted after MR examination.

Bibliography

[1] ISO 11134, *Sterilization of health care products — Requirements for validation and routine control — Industrial moist heat sterilization*

[2] ISO 11135:1994, *Medical devices — Validation and routine control of ethylene oxide sterilization*

[3] ISO 11137:1995 [1)], *Sterilization of health care products — Requirements for validation and routine control — Radiation sterilization*

[4] ISO 11137:1995/Cor. 1:1997, *Sterilization of health care products — Requirements for validation and routine control — Radiation sterilization — Technical Corrigendum 1*

[5] ISO 11137:1995/Amd. 1:2001, *Sterilization of health care products — Requirements for validation and routine control — Radiation sterilization — Amendment 1: Selection of items for dose setting*

[6] ISO 14155-1, *Clinical investigation of medical devices for human subjects — Part 1: General requirements*

[7] ISO 14155-2, *Clinical investigation of medical devices for human subjects — Part 2: Clinical investigation plans*

[8] ISO 14971:2000, *Medical devices — Application of risk management to medical devices*

[9] ASTM F640-79, *Standard Test Methods for Radiopacity of Plastics for Medical Use*

[10] ASTM F647-94, *Standard Practice for Evaluating and Specifying Implantable Shunt Assemblies for Neurosurgical Application*

[11] ASTM F2038-00e1, *Standard Guide for Silicone Elastomers, Gels and Foams Used in Medical Applications Part I — Formulations and Uncured Materials*

[12] ASTM F2042-00e1, *Standard Guide for Silicone Elastomers, Gels, and Foams Used in Medical Applications Part II — Crosslinking and Fabrication*

1) Shortly to be cancelled and replaced by:

ISO 11137-1, *Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 11137-2, *Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose*

ISO 11137-3, *Sterilization of health care products — Radiation — Part 3: Guidance on dosimetric aspects*.

ICS 11.040.40

Price based on 6 pages