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Neurosurgical implants — Sterile, single-use hydrocephalus shunts

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

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Foreword

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This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 285, *Non-active surgical implants,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This fourth edition cancels and replaces the third edition (ISO 7197:2006) which has been technically revised.

The main changes are as follows:

— subclause 4.1 has been completely revised;

— terminology has been clarified and references have been updated.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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 that 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 can 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, for example:

   — gravitation valves, which are 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.

Due to the important technical differences, specific testing procedures are necessary to investigate the performance of the different valves.

The benefit of this document 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 specify the important requirements for shunts as a basis for investigations during development as well as for quality control during manufacture.

Neurosurgical implants — Sterile, single-use hydrocephalus shunts

1 Scope

This document specifies the performance requirements for sterile, single-use non-active hydrocephalus shunts. This includes not only the valve, but also additional components such as tubes and reservoirs.

This document does not provide any recommendations on which type of valve is most suitable for any specific context of use.

This document specifies the mechanical and technical requirements to manufacture shunts and the technical information of the valve to be supplied by the manufacturer.

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

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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/TR 14283, *Implants for surgery — Essential principles of safety and performance*

ISO 14630:2024, *Non-active surgical implants — General requirements*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/TR 14283, ISO 14630 and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
information supplied by the manufacturer
label, instructions for use, implant card, and any other information that is related to the identification, technical description, intended purpose and proper use of the medical device, but excluding shipping documents

Note 1 to entry: The proper use includes the installation, use, maintenance and disposal of the shunt.

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
implantable single-use device intended to regulate the pressure of cerebro-spinal fluid

Note 1 to entry: Typically consisting of an inflow catheter, a pressure-controlling device, and an outflow catheter.

Note 2 to entry: In this document when not otherwise specified, the term “shunt” refers to the hydrocephalus shunt.

3.4
proximal catheter
part of a *hydrocephalus shunt* (3.3) assembly that is inserted into the cerebral ventricles or any other site in the craniospinal axis to provide access to a fluid compartment of the central nervous system (e.g. into a lateral ventricle) and therefore constitutes the inflow pathway for the diversion of fluid through a shunt system

3.5
valve
element of a *hydrocephalus shunt* (3.2) assembly that functions as a major resistance to the cerebro-spinal fluid flow thus controlling the relationship between pressure and flow of cerebrospinal fluid and resists reflux of blood or other fluids into the shunt assembly

Note 1 to entry: In contrast to a *valved catheter* (3.6), a valve does not provide a significant portion of tubing for the fluid pathway.

3.6
valved catheter
assembly or element of a shunt which provides a pathway for diversion of cerebro-spinal fluid to an internal delivery site and contains one or more *valves* (3.5), typically a tip valve, and a significant portion of tubing for the fluid pathway

4 General requirements for shunts

4.1 General

The sample size and representative device (or device configuration) shall be justified and stated for each applicable requirement. It shall be specifically ensured that test specimens shall be tested in the final finished form, after sterilization.

4.2 Radiopacity

The shunt shall be radiopaque or shall carry radiopaque markers.

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

NOTE Guidance on the determination of radiopacity for medical devices can be found in ASTM F640[3].

4.3 Biocompatibility

The biocompatibility of the shunt and the accompanying components required for implantation 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 (e.g. no air bubbles present when pressurized and submerged under water) 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 ml/h 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 implant 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 characteristics should not be changed by 1 m of H_2O (9,806 7 kPa) of 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 ± 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 magnetic resonance imaging conditions

In order to determine the conditions for which a shunt may be imaged using magnetic resonance, performance tests that measure the magnetic properties of the finished implant shall be done.

NOTE 1 Investigation of the magnetic properties of the base material from which the shunt is constructed is not sufficient to assess the magnetic resonance imaging (MRI) compatibility of the finished implant.

The worst-case shunt for each evaluation shall be identified, noting that the worst case can be different for each test.

Testing and analyses shall be performed on the identified worst-case shunt to determine magnetically induced forces, moments and heating, and to determine the image artefact produced by the shunt under worst-case MR scanning conditions.

NOTE 2 Testing for determining magnetic properties of implants are available in ASTM F2052[4] (induced displacement force), ASTM F2213[7] (induced torque), ASTM F2182[6] (radio frequency induced heating) and ASTM F2119[5] (artefact images).

The worst-case scanning conditions shall be indicated on the labelling.

The resulting analyses concerning the MRI safety condition (safe, conditional or unsafe) shall be properly identified in the implant label by using appropriate graphical symbols.

NOTE 3 Labelling for the identification of the MRI condition, including appropriated label icons, can be found in ASTM F2503[8] and IEC 62570[2].

For MRI conditional implants, the applicable information to ensure the scanning safe condition shall be established. Conditions for scanning shall include magnetic field strength(s), maximum spatial field gradient, acceptable specific absorption rate (SAR) and the extent of the expected image artefact for a specific scan sequence.

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 may drain back in a pressure range between 0 kPa and 4,903 3 kPa (0 mm 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 in accordance with the following test method:

— immerse the valve in distilled, degassed water;

— keep the water temperature at (37 ± 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), and the influence of the posture should be considered.

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 14630:2024, 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 at a flow rate of 20 ml/h shall be given in the accompanying documentation.

— Shunt and components through which the fluid flow is uni-directional shall be marked to indicate the intended direction of flow (e.g. by means of an arrow) using a method that is visible and obvious to the implanting surgeon.

7 Packaging

The requirements of ISO 14630:2024 Clause 10 shall apply. 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.

8 Information supplied by the manufacturer

8.1 General

The requirements of ISO 14630:2024, Clause 11 and 8.2 shall apply.

8.2 Instructions for use

The instructions for use shall include:

a) instructions for assembly of the shunt system;

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

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

d) dimensions of components;

e) an indication regarding how the flow direction of the device can be determined;

f) a method for puncture and indication on how often a puncture is possible and what either cannula or needle, or both, should be used (see 4.4);

g) the flow characteristic of the valve in a standard configuration (e.g. with proximal and distal catheters included) 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;

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

i) 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 kPa and 4,903 3 kPa (0 mm