INTERNATIONAL STANDARD

ISO 7197

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

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

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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

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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.

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.