SLOVENSKI STANDARD
oSIST prEN ISO 7197:2023

01-september-2023

Nadomešča:
SIST EN ISO 7197:2009

Nevrokirurški vsadki (implantati) - Sterilni hidrocefalni stiki (kretnice) za enkratno uporabo (ISO/DIS 7197:2023)

Neurosurgical implants - Sterile, single-use hydrocephalus shunts (ISO/DIS 7197:2023)

Neurochirurgische Implantate - Sterile Hydrozephalus-Shunts zum Einmalgebrauch und deren Bestandteile (ISO/DIS 7197:2023)

Implants neurochirurgicaux - Systèmes de dérivation stériles, non réutilisables, pour hydrocéphalie (ISO/DIS 7197:2023)

Ta slovenski standard je istoveten z: **prEN ISO 7197**

ICS:

11.040.40	Implantanti za kirurgijo, protetiko in ortetiko	Implants for surgery, prosthetics and orthotics

oSIST prEN ISO 7197:2023 **en,fr,de**

DRAFT INTERNATIONAL STANDARD

ISO/DIS 7197

ISO/TC **150**

Secretariat: **DIN**

Voting begins on:
2023-06-12

Voting terminates on:
2023-09-04

Neurosurgical implants — Sterile, single-use hydrocephalus shunts

ICS: 11.040.40

This document is circulated as received from the committee secretariat.

ISO/CEN PARALLEL PROCESSING

Reference number
ISO/DIS 7197:2023(E)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

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 7197:2006) which has been technically revised.

The main changes compared to the previous edition are as follows:

— complete revision of 4.1 “MRI compatibility”;

— additional clarifying edits regarding terminology and updated standard references.

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.

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

1 Scope

This document specifies safety and 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 gives no recommendation concerning the superiority of a certain type of valve.

For manufacturing, it specifies the mechanical and technical requirements. This document specifies the technical information supplied by the manufacturer, including the technical information of the valve. In respect to the principles of the different valve types, this document specifies characteristics for each type.

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.

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 14630:2012, *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 and ISO 14630 and the following apply.

3.1
Information supplied by the manufacturer
label, instructions for use, implant card, and any other information that is related to 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 CSF

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
lumbo-peritoneal drainage
drainage of CSF from the lumbar sub-arachnoid spaces into the peritoneum

3.5
ventriculo-atrial drainage
drainage of CSF from the ventricles into the right atrium of the heart

3.6
ventriculo-peritoneal drainage
drainage of CSF from the ventricles into the peritoneum

3.7
antisiphon device
a device implanted to counteract the effects of the hydrostatic column of the outflow catheter. This is to minimize the gravity (also termed “siphoning”) effect of a hydrostatic pressure that may be created by the elevation of the proximal (inflow) catheter in relation to the distal (outflow) catheter thus preventing the excessive drainage of CSF caused by gravity.

3.8
fluid compartment
the portion of the central nervous system (CNS) including the ventricles and subdural space, and extraventricular structures such as cysts and hygromas.

3.9
modifiable connection
a portion of the shunt assembly in which components are intended to be modified by the surgeon during a surgical procedure (for example, the length of a tube can be adjusted to accommodate the height of the patient).

3.10
nonmodifiable connection
see preassembled connection.

3.11
preassembled connection
a portion of the shunt assembly the components of which are preassembled at the time of manufacture and are intended to be permanently fixed and not modified during a surgical procedure (for example, the site where the valve is chemically bonded or mechanically joined to tubing).

3.12
proximal (inflow) catheter
that part of a hydrocephalus shunt 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 (for example, into a lateral ventricle) and therefore constitutes the inflow pathway for the diversion of fluid through a shunt system.

3.13
shunt filter
a device intended to remove particulate matter from the CSF before it passes through the shunt.

3.14
valve
an element of a hydrocephalus shunt assembly that functions as a major resistance to the CSF flow thus controlling the relationship between pressure and flow of cerebrospinal fluid and resists reflux of blood or other fluids into the shunt assembly. In contrast to a valved catheter, it does not provide a significant portion of tubing for the fluid pathway.