# INTERNATIONAL STANDARD

Second edition
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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*



ISO 7197
ISO 7197:1997(E)

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International Organization for Standardization
Case postale 56 • CH-1211 Genève 20 • Switzerland
Internet central@iso.ch
X.400 c=ch; a=400net; p=iso; o=isocs; s=central
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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 voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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

This second edition cancels and replaces the first edition (ISO 7197:1989), which has been technically revised.

## Introduction

A hydrocephalus shunt system typically consists of three basic elements: (1) an inflow (proximal) catheter, which drains cerebrospinal fluid (CSF) from the ventricular system, lumbar subarachnoid space or extraventricular CSF space and transmits it to (2) a valve which regulates the differential pressure or controls flow through the system, and (3) an outflow (distal) catheter which drains CSF into the cardiovascular system, the peritoneal cavity or other suitable drainage site. In addition, specialized accessory devices, such as reservoirs, siphoning-preventing devices and on-off valves and filters, are added at the discretion of the physician to modify performance or adapt the basic system to the particular needs of the patient.

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

## 1 Scope

This International Standard specifies requirements for sterile, single-use hydrocephalus shunts and components.

This International Standard is applicable to but is not limited to:

a) complete sterile, single-use hydrocephalus shunts of the one-piece type; or

b) complete sterile, single-use hydrocephalus shunts of the multipiece type, supplied either assembled by the manufacturer or in kit form for assembly by the physician; or

c) sterile, single-use shunt components which (individually or in combination) comprise shunt assemblies, for example: valves, valved catheters (catheter with integral valves), inflow or outflow catheters (such as arterial, peritoneal, ventricular catheters), connectors, implantable accessory devices (such as siphoning-preventing devices, measuring devices and reservoirs/priming devices).



## 2 Normative references



The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 10993-1:1992, *Biological evaluation of medical devices — Part 1: Guidance on selection of tests.*

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

ISO 11137:1995, *Sterilization of health care products — Requirements for validation and routine control — Radiation sterilization.*

ISO 11138-3:1995, *Sterilization of health care products — Biological indicators — Part 3: Biological indicators for moist heat sterilization.*

IEC 601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety.*

ASTM F640:1979, *Standard Test Method for Radiopacity of Plastics for Medical Use.*

## 3 Definitions

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

**3.1 accessory device**
Component of a hydrocephalus shunt designed to perform a specific additional function (i.e. on-off valve, siphoning-preventing device, measuring device, reservoirs, connectors, retaining clips and filters).

**3.2 adjustable or programmable valve**
Valve with multiple functional ranges that can be set prior to or after implantation.

**3.3 chambered valve**
Component of a hydrocephalus shunt containing one or more valve mechanisms separated by a compartment that may be designed to allow pumping of the fluid through the shunt or accessing to the shunt.

**3.4 closing pressure**
Inlet pressure at which the valve closes to prevent further flow.

**3.5 connector**
Device intended for the joining and fixation of implantable shunt components.

**3.6 environmental pressure**
External pressure exerted on the valve or accessory components to mimic local tissue pressure *in vivo*.

**3.7 fluid compartment**
Portion of the central nervous system (CNS) including the ventricles and extraventricular structures such as subarachnoidal fluid collections, cysts, hygromas and syrinxes.



**3.8 functional range**
Representative pressure/flow characteristics of a shunt or shunt element.

NOTE This is usually expressed in graphical form.



**3.9 hydrocephalus**
State of excessive accumulation of cerebrospinal fluid (CSF) within the ventricular system of the head due to a disturbance of secretion, flow or absorption.

**3.10 hydrocephalus shunt**
One-piece device or multi-piece device or combination of devices intended to be surgically implanted in the body of a patient with hydrocephalus or other disturbance of the CSF circulation and designed to divert CSF from a fluid compartment in the CNS to a internal delivery site in another part of the body or an external collection site (external shunt), for the purpose of diminishing elevated intracranial pressure (ICP) or CSF volume.

**3.11 one-piece hydrocephalus shunt assembly**
One-piece complete single-use hydrocephalus shunt assembled by the manufacturer, typically consisting of an inflow catheter, pressure-activated flow-controlling device or combination of devices and an outflow catheter and/or accessory devices.

**3.12 inflow catheter; proximal catheter**
Part of a hydrocephalus shunt that is inserted into the cerebral ventricles or any other site in the craniospinal axis to provide access to a fluid compartment of the CNS (for example, into a lateral ventricle) and therefore constitutes the inflow pathway for the diversion of fluid through a shunt system.

**3.13 inlet pressure**
Hydrostatic pressure at the inlet of the valve or active component.

**3.14 magnetic compatibility**
Characteristic of a device which can be used in environmental magnetic and electromagnetic fields of daily life without affecting the patient and/or shunt function.

**3.15 magnetic resonance (MR) compatibility**
Characteristic of a device which can be used in diagnostic devices using magnetic resonance techniques without affecting the patient and/or shunt function.

NOTE Adverse effects of three main types may arise from lack of compatibility:

a) displacement of the device or device's components leading to device migration, dysfunction or change in function due to high magnetic fields;

b) local tissue damage because of induced currents and/or temperature rise;

c) appreciable degradation of diagnostic images.

**3.16 multipiece hydrocephalus shunt assembly**
Complete sterile, single-use hydrocephalus shunt, supplied either assembled by the manufacturer or in kit form for assembly by the physician, typically consisting of an inflow catheter, pressure-activated flow-controlling device or combination of devices and an outflow catheter with requisite connectors and/or accessory devices required for assembly.

**3.17 on-off device**
Accessory device that closes or opens the shunt system by external manipulation.

**3.18 opening pressure**
Inlet pressure required to initiate flow through the valve.

**3.19 outflow catheter; distal catheter**
Part of a hydrocephalus shunt assembly which provides an outflow pathway for the diversion of fluid from a compartment of the central nervous system to the peritoneal cavity, venous circulation or other internal or external delivery site.



**3.20 outlet pressure**
Hydrostatic pressure at the outlet of the valve or active components.



**3.21 preassembled junction (non-modifiable junction)**
Portion of a hydrocephalus shunt assembly which is assembled at the time of manufacture and is intended to be permanently fixed and not modified during a surgical procedure.

Example The site where the valve is chemically bonded to tubing is a preassembled junction.

**3.22 pressure**
Pressure relative to the actual ambient atmospheric pressure.

**3.23 reflux**
Flow of fluid within a hydrocephalus shunt towards the inflow catheter.

**3.24 shunt** (noun)
See hydrocephalus shunt

**3.25 shunt** (verb)
Act of draining CSF from the CNS.

**3.26 shunt filter**
Accessory device, intended to remove particulate matter from the CSF before it passes through the shunt, and designed to prevent the spread of neoplastic cells into the peritoneum or cardiovascular system following a shunting procedure.

**3.27 siphoning-preventing device**
Device or component of device designed to prevent reflux due to differential pressure across the shunt system occurring when the position of the patient changes from horizontal to vertical, or the reverse.

**3.28 test specimen**
Device, or sample of devices, representative of the population of devices.

**3.29 tip valve**
Outflow catheter that includes the functions of the valve.

**3.30 valve**
Element of a hydrocephalus shunt that (a) is intended to resist reflux and (b) functions to control the relationship between pressure and flow of cerebrospinal fluid.

NOTE Valve constructions may be based on different principles, e.g. diaphragm valve, ball-cone valve, slit valve, needle valve.

# 4 General requirements for hydrocephalus shunts and accessory devices

## 4.1 Physical requirements

### 4.1.1 Surface finish

When examined with normal or corrected vision at a distance of 300 mm to 450 mm and at an illuminance of 2150 lx ± 215 lx, the surface of shunts and accessory devices 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.

### 4.1.2 Radiopacity



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



Tests shall be carried out in accordance with ASTM F640.

## 4.2 Mechanical requirements



### 4.2.1 General

For any given accessory device and, where appropriate, the manufacturer shall subject device(s) (test specimens) to tests of those mechanical properties which are pertinent to its intended performance.

### 4.2.2 Resistance to breakage of preassembled junctions

Preassembled junctions shall not break by subjecting a test specimen to an axial force of 10 N for 1 min, unless otherwise indicated by the manufacturer.

### 4.2.3 Leaktightness

Non-modifiable junctions of a test specimen of the assembly shall be leaktight when subjected to water pressure of 12 kPa for 5 min. Modifiable junctions shall have the same leaktightness properties as non-modifiable junctions (assembled according to the manufacturer's instructions) when tested in a similar manner.

NOTE Leakage is defined as greater than 0,025 ml of test fluid escaping from the test specimen during the test period.

### 4.2.4 Opening and closing pressure

If opening and/or closing pressure is specified by the manufacturer as part of the functional range of the hydrocephalus valve, testing shall be carried out according to 5.1.

### 4.2.5 Reflux

If reflux prevention is declared by the manufacturer as part of the functional range of the hydrocephalus valve, testing shall be carried out according to 5.4.

#### 4.2.6 Pressure/flow characteristics

The manufacturer shall provide the functional range for each design of valve,as determined by tests in accordance with 5.3.

Sufficient valve samples shall be tested to establish the statistical confidence level for reproducibility of the pressure/flow characteristics.

##### 4.2.6.1 Connectors and mounting clamps

If additional connectors or mounting clamps are supplied for use in conjunction with valves and catheters with integral valves, the properties of the connectors shall be such that the flow through the shunt with the connections in place shall not, when tested according to 5.3, differ by more than 5 % or more than 5 $mmH_2O$ from the values determined for the shunt without the additional connectors in place.

If the difference is greater, the manufacturer shall state the pressure/flow characteristics when the connector is in place.

##### 4.2.6.2 Other components

Specialized components of shunt systems include but are not limited to reservoirs, siphoning preventing devices, filters and CSF access ports. In addition to the general requirements of 4.1 and 4.2, such specialized accessory devices of shunts shall not increase the resistance of the shunt by more than 10 %, otherwise such changes shall be stated.

#### 4.2.7 Long-term functional stability



Valves and accessory devices shall maintain their functional range when tested according to 5.5.



### 4.3 Biocompatibility



Hydrocephalus shunts and components shall be demonstrated to be biocompatible when assessed according to the principles and methods recommended in 10993-1.

### 4.4 Sterilization

Shunt systems shall be sterilized according to ISO 11135, ISO 11137 and/or ISO 11138-3.

### 4.5 Type and size designation

For each designed type and size of shunt, the manufacturer shall provide the following information:

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

b) type of valve;

c) nominal overall length of component expressed in millimetres;

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

## 5 Test methods

### 5.1 General

The test shall be carried out on shunts or accessory devices that have passed through all stages of manufacture, including sterilization but not previously implanted and within the manufacturer's indicated "Use before" date, and, in the case of multipiece complete shunts, that have been assembled in accordance with the manufacturer's instructions.

## 5.2 Reference test method for opening and closing pressures

### 5.2.1 Scope

This test defines a method whereby the opening and closing pressures of any valve can be evaluated.

### 5.2.2 Principle

This test is intended:

a) to provide a manufacturer with a means to collect data to determine the opening and closing pressures of a particular design of valve.

b) as a type-test to verify that the opening and/or closing pressure of an individual valve is within the manufacturer's specification.

Alternative methods for determining the opening and closing pressures of the hydrocephalus valve may be used and may include pressure-drop detection (proximal or distal), an electronic balance or a proximal pressure transducer/manometer.

For distal slit valves, the valve shall be submerged and a proximal method of detection of the opening and closing pressures shall be used.

### 5.2.3 Reagents

**5.2.3.1 Test fluid**, consisting of deaerated and deionized or distilled water at (37 ± 2) °C.



### 5.2.4 Apparatus

**5.2.4.1 Test rig,** as shown in figure 1, or a similar circuit comprising the following elements:



a) pump, capable of maintaining a flowrate of 20 ml/h;

b) water bath, at (37 ± 2) °C with a means of maintaining the water level constant within ± 2 mm;

c) means of connecting the shunt or shunt component to the test rig without occluding inflow aperture(s);

d) connecting tubing with an internal diameter consistent with tubings specified for use with the test specimen (see note 1);

e) manometer, consisting of a water column open to air, graduated in millimetres, having a diameter of 2,5 mm and capable of being read to an accuracy of 0,5 mm (see note 2).

NOTE 1 This should include a coiled portion of sufficient length that, when immersed in the water bath, the test fluid (5.2.3.1) will reach a temperature of (37 ± 2) °C during its passage through the tubing.

NOTE 2 The reading of the manometer, $h$ , expressed in millimetres, is converted to the pressure, $p$, expressed in pascals, using the following equation: $p = 9{,}81h$.

### 5.2.5 Procedure

**5.2.5.1** Prepare the test specimen by performing all pre-use steps included in the manufacturer's instructions for use.

**5.2.5.2** Prefill and soak the test specimen in the test fluid for a sufficient period of time to reach a state of equilibrium.

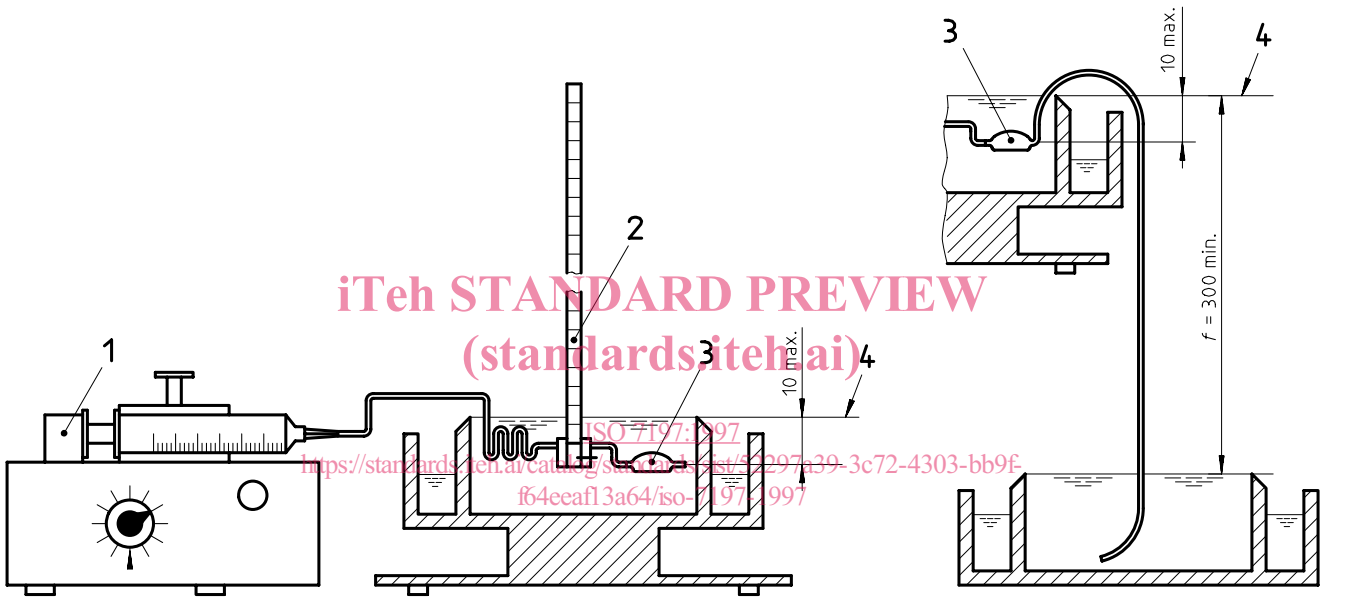
**5.2.5.3** Connect the test specimen to the measuring system in such a manner as to minimize the introduction of air into the liquid pathway of the test system.

**5.2.5.4** Purge all air from the liquid pathway of the test specimen and the test rig according to the manufacturer's recommendations.

**5.2.5.5** Zero the pressure level of the manometer by adjusting its position so that the level of meniscus in the manometer is level with the zero graduation mark (see figure 1). The outlet of the distal catheter shall be level with the surface of the water bath.

**5.2.5.6** Switch the pump on at a flowrate of 20 ml/h.

Dimensions in millimetres




a) Standard test rig

b) Test rig for siphoning-preventing devices



1 Pump
2 Manometer
3 Test specimen
4 Zero level

**Figure 1 — Example of a test rig for determining opening and closing pressures and influence of outlet pressure**

**5.2.5.7** Observe the water column rise in the manometer. Record as the opening pressure the level at which the water column starts to fall.

**5.2.5.8** Wait for the pressure in the manometer to stabilize and switch off the pump.

**5.2.5.9** Record the pressure to which the meniscus in the manometer falls and stabilizes as closing pressure.

**5.2.5.10** Repeat 5.2.5.6 to 5.2.5.9 at least six times.