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NSAI Standards

Irish Standard
I.S. EN ISO 7197:2009

Neurosurgical implants - Sterile, single-use hydrocephalus shunts and components (ISO 7197:2006, including Cor 1:2007)

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EUROPEAN STANDARD

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EN ISO 7197

May 2009

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Supersedes EN ISO 7197:2006

English Version

Neurosurgical implants - Sterile, single-use hydrocephalus shunts and components (ISO 7197:2006, including Cor 1:2007)

Implants neurochirurgicaux - Systèmes de dérivation et composants stériles, non réutilisables, pour hydrocéphalie (ISO 7197:2006, Cor 1:2007 inclus)

Neurochirurgische Implantate - Sterile Hydrozephalus-Shunts zum Einmalgebrauch und deren Bestandteile (ISO 7197:2006, einschließlich Cor 1:2007)

This European Standard was approved by CEN on 19 April 2009.

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Foreword

The text of ISO 7197:2006, including Cor 1:2007 has been prepared by Technical Committee ISO/TC 150 “Implants for surgery” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 7197:2009 by Technical Committee CEN/TC 285 “Non-active surgical implants” the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by November 2009, and conflicting national standards shall be withdrawn at the latest by March 2010.

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

This document supersedes EN ISO 7197:2006.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EC Directive.

For relationship with EC Directive, see informative Annex ZA, which is an integral part of this document.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of ISO 7197:2006, including Cor 1:2007 has been approved by CEN as a EN ISO 7197:2009 without any modification.

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Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on medical devices.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in table ZA confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA — Correspondence between this European Standard and Directive 93/42/EEC

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
All	1, 2, 3, 4, 5	Part of ER 1 relating to the risk of use error is not covered by current Standard.
4.2	2	
4.3	7.1, 7.2	Part of ER 7.1 relating to biophysical and modelling research is not covered by this European Standard.
4.4	7.5	
4.5	3, 4, 13.6.d)	
4.6	3, 4, 9.1	
4.7	2, 13.6.d), 13.6.e)	
4.8	4, 9.2, 12.7.1	
4.9	12.7.1	
4.10	9.1, 9.2	
4.11	12.7.1	
5.1.1	2, 4	
5.1.2	4	
5.1.3	4, 9.2	
5.2	9.1, 12.7.1	
6	13.1	ER 13.1 is covered via EN ISO 14630.
7	5, 7.2	

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8.1	13	The part of ER 13.3.a) relating to the information on the authorized representative is not addressed by this European Standard.
8.2	13.6	The ER 13.3 f is only partly addressed in this European Standard: safety issue of single use. The part of ER 13.6.h) relating to single use is not addressed in this European Standard. ER 13.6 q is not addressed in this European Standard.
8.3	13.6.e)	
	6.a	ER 6.a) is not addressed by this European Standard.

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

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I.S. EN ISO 7197:2009

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
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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.

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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.

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