International Standard

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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.