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Third edition  
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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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## Foreword

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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.