INTERNATIONAL STANDARD

ISO 7197

Second edition
1997-11-01

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

Implants pour neurochirurgie — Systèmes de dérivation et composants stériles, non réutilisables, pour hydrocéphalie

Reference number
ISO 7197:1997(E)

Contents

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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.*