Designation: F647 – 22

Standard Practice for Evaluating and Specifying Implantable Shunt Assemblies for Neurosurgical Application[1]

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INTRODUCTION

A hydrocephalus shunt assembly is a one-way pressure-activated or flow-controlling device or combination of devices intended to be surgically implanted in the body of a patient with hydrocephalus and designed to divert cerebrospinal fluid (CSF) from fluid compartments in the central nervous system (CNS) (the cerebral ventricles or other site within the cerebrospinal fluid system) to an internal delivery site (internal shunt) in another part of the body or an external collection site (external shunt), for the purpose of relieving elevated intracranial pressure or CSF volume.

A hydrocephalus shunt system typically consists of three basic elements: (*1*) an inflow (proximal) catheter, which drains CSF from the ventricular system, lumbar subarachnoid space, or extraventricular structure and transmits it to (*2*) an arrangement of one or more valves which regulate(s) the differential pressure or controls flow through the system, and (*3*) an outflow (distal) catheter which drains CSF into the cardiovascular system via the peritoneal cavity, heart, or other suitable drainage site. In addition, specialized accessory devices such as reservoirs, antisiphon 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 specialized needs of the patient.

Because of the considerable length of time over which a shunt or component may be required to function after implantation, it is felt that it should be type-tested to ensure its durability. It has not yet been found feasible to specify a test method of durability testing, but a test method is proposed in Appendix X1.

1. Scope

1.1 This practice covers requirements for the evaluation and specification of implantable shunts as related to resistance to flow, direction of flow, materials, radiopacity, mechanical properties, finish, sterility, and labeling of shunt assemblies.

1.2 Devices to which this practice is applicable include, but are not limited to, those that are temporarily implanted to effect external drainage; or permanently implanted to effect shunting of fluid from a cerebral ventricle, a cyst, the subarachnoid space to the peritoneal cavity, the venous circulation, or some other suitable internal delivery site, and intracranial bypass.

1.3 *Limitations*—Although this practice includes a standard test method for the evaluation of pressure/flow characteristics of shunts or shunt components, it does not include specific pressure/flow requirements.

1.4 The following components that individually or in combination comprise shunt assemblies are considered to be within the scope of this practice: catheters (such as atrial, peritoneal, ventricular), connectors, implantable accessory devices (such as antisiphon devices and reservoirs), valved catheters, and valves.

NOTE 1—The standards in Section 2 contain provisions that, through reference in this text, constitute provisions of this practice. At the time of publication, the editions indicated are valid. All standards are subject to revision, and parties to agreements based on this practice are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Devices or components, or both, whose structures are comparable to that outlined in these standards are acceptable.

1.5 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.6 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the*

[1] This practice is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.31 on Neurosurgical Standards.

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Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.

2. Referenced Documents

2.1 *ASTM Standards:*[2]

F55 Specification for Stainless Steel Bar and Wire for Surgical Implants (Withdrawn 1989)[3]

F67 Specification for Unalloyed Titanium, for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700)

F75 Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075)

F90 Specification for Wrought Cobalt-20Chromium-15Tungsten-10Nickel Alloy for Surgical Implant Applications (UNS R30605)

F138 Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)

F469 Practice for Assessment of Compatibility of Nonporous Polymeric Materials for Surgical Implants with Regard to Effect of Materials on Tissue (Withdrawn 1986)[3]

F604 Specification for Silicone Elastomers Used in Medical Applications (Withdrawn 2001)[3]

F640 Test Methods for Determining Radiopacity for Medical Use

NOTE 2—A suggested method of durability testing is given in Appendix X2.

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *antisiphon device*—a device implanted to counteract the affects of the hydrostatic column of the outflow catheter. This is to minimize the gravity (also termed "siphoning") effect of a hydrostatic pressure that may be created by the elevation of the proximal (inflow) catheter in relation to the distal (outflow) catheter, thus preventing the excessive drainage of CSF caused by gravity.

3.1.1.1 *Discussion*—The Committee adopted the terms *siphon effect* and *antisiphon device* for this practice because they are used in the medical literature. However, such devices are designed to counteract the effects of gravity on the fluid in the distal catheter when the patient is standing.

3.1.2 *batch*—a quantity of material that consists of a homogeneous mixture of common ingredients or a quantity of devices processed and controlled as an integral production run.

3.1.3 *calibration*—the act of fixing, checking, or correcting on a schedule, the accuracy and precision of a measuring instrument and maintaining records of these activities.

3.1.4 *chambered valve*—an element of a hydrocephalus shunt containing one or more valve mechanisms that is to facilitate selective flushing in the proximal or distal direction.

3.1.5 *connector*—a device intended for the joining and fixation of implantable shunt components at operation.

3.1.6 *distal (outflow) catheter*—that part of a hydrocephalus shunt assembly that provides a passive outflow pathway for the diversion of fluid from a compartment of the central nervous system to the peritoneal cavity, venous circulation, or other internal delivery site. The outflow catheter may or may not contain a pressure/flow regulating device.

3.1.7 *flow-impedance device*—those components of a shunt assembly which, by virtue of their resistance properties, provide the principal means of controlling intracranial pressure or flow of cerebrospinal fluid, or both. Flow-impedance devices include valved catheters and valves and the relevant constituent parts thereof.

3.1.8 *fluid compartment*—the portion of the central nervous system (CNS) including the ventricles and subdural space, and extraventricular structures such as cysts and hygromas.

3.1.9 *functional range*—the representative pressure/flow characteristics of a shunt or shunt element usually expressed in graphical form.

3.1.10 *hydrocephalus*—the state of excessive accumulation of cerebrospinal fluid (CSF) within the ventricular system of the head due to a disturbance of secretion, flow, or absorption, usually resulting in a pathological increase in intracranial pressure (ICP).

3.1.11 *hydrocephalus shunt*—a one-way pressure-activated or flow-controlling device or combination of devices intended to be surgically implanted in the body of a patient with hydrocephalus and designed to divert cerebrospinal fluid from a fluid compartment in the central nervous system or CNS (the cerebral ventricles or other site within the cerebrospinal fluid system) to an internal delivery site in another part of the body (internal shunt) or an external collection site (external shunt), for the purpose of relieving elevated intracranial pressure (ICP) or CSF volume.

3.1.12 *hydrocephalus shunt assembly*—a complete hydrocephalus shunt comprising all the components necessary for clinical use.

3.1.13 *implantable accessory device*—component intended to facilitate the treatment of hydrocephalus by: providing access to the shunt (such as reservoirs, antechambers, flushing devices); modifying the performance characteristics of the shunt (such as on/off and antisiphon devices); or reducing hazards attendant to the presence of the shunt assembly (such as in-line filters).

3.1.14 *implantable external drainage catheter*—that element of an external drainage device which provides access to a fluid compartment of the central nervous system.

3.1.15 *kit*—a number of components in a common package to be used for a single purpose on the same occasion.

3.1.16 *magnetizable*—a metal that has the capacity to acquire magnetic properties of sufficient force to become dangerous due to movement or thermal effects, or both, or to

[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[3] The last approved version of this historical standard is referenced on www.astm.org.

degrade the MRI image to the point of making it diagnostically or therapeutically useless. A shunt system that is magnetizable is not MRI-compatible.

3.1.17 *modifiable connection*—a portion of the shunt assembly in which components are intended to be modified by the surgeon during a surgical procedure (for example, the length of a tube can be adjusted to accommodate the height of the patient).

3.1.18 *multipiece hydrocephalus shunt assembly*—a 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 or flow-controlling device or combination of devices, and an outflow catheter with requisite connectors required for assembly.

3.1.19 *nominal category*—the generic performance category of the pressure/flow characteristics of the shunt assembly typically defined as "low," "medium," "high," etc., the limits of which are defined by the manufacturer.

3.1.20 *nonmodifiable connection*—see *preassembled connection*.

3.1.21 *one-piece hydrocephalus shunt assembly*—complete sterile, single-use hydrocephalus shunt consisting of an inflow catheter integral with a pressure-activated or flow-controlling device or combination of devices and an integral outflow catheter.

3.1.22 *on-off device*—an accessory component specifically designed to permit alternate opening and closing of the shunt system upon external activation.

3.1.23 *packaging*—the protective wrapping of shunt systems or components:

3.1.23.1 *inner container*—the packaging that is in direct contact with the implant.

3.1.23.2 *multiple pack*—a pack containing a number of unit packs.

3.1.23.3 *outer container or shelf container*—a package, carton, or other container that may contain one or more unit containers. The packaging that envelopes the inner container such that sterility and the integrity of that container is maintained.

3.1.23.4 *sterile pack*—a pack intended to maintain the sterility of the contents and comprising an inner and outer container.

3.1.23.5 *transit container*—a package, carton, or other container that may contain one or more unit containers used to protect the contents during shipping of the product from the manufacturer to the end user.

3.1.23.6 *unit container*—a package containing a single item or a combination of procedure-related components or products.

3.1.23.7 *unit pack*—a pack containing a single unit or kit.

3.1.24 *preassembled connection*—a portion of the shunt assembly, the components of which are preassembled at the time of manufacture and are intended to be permanently fixed and not modified during a surgical procedure (for example, the site where the valve is chemically bonded or mechanically joined to tubing).

3.1.25 *preimplantation test*—a test that is performed on the shunt assembly in the operating room prior to implantation.

3.1.26 *pressure/flow graph*—a graphic representation of the composite performance characteristics of a population of flow impedance devices.

3.1.27 *production line bench flow test*—a test method used by the manufacturer to verify that the pressure/flow characteristics of each individual flow impedance device conforms to its functional range.

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

3.1.29 *radiopacity*—the X-ray absorption properties that allow a shunt component to have clear and permanent visualization fluoroscopically or on X-ray film after implantation. (See Annex A1.)

3.1.30 *referee test method*—the methods in the published standard for the device. The method and the corresponding requirements will be invoked when the performance of the medical device will be questioned. The manufacturer need not use this referee test method in the usual inspection and quality control.

3.1.31 *reflux*—a flow of fluid within a hydrocephalus shunt towards the cerebral ventricles or cerebrospinal fluid system.

3.1.32 *shunt, v*—to drain CSF from the CNS.

3.1.33 *shunt assembly*—any device or combination of devices that functions to divert CSF from a fluid compartment of the central nervous system to an internal delivery site (internal shunt) or an external collection site (external shunt).

3.1.34 *shunt element*—any component of a hydrocephalus shunt.

3.1.35 *shunt filter*—a device intended to remove particulate matter from the CSF before it passes through the shunt.

3.1.36 *sterile*—in microbiology, free from all living organisms; in practice, the condition of a product that has been subjected to a validated sterilization process and maintained in this state by suitable protection.

3.1.37 *sterilized*—term used to denote an object that has been subjected to a validated sterilization process.

3.1.38 *test specimen*—a device or sample of devices representative of the population of devices.

3.1.39 *tip valve*—an element of a hydrocephalus shunt located at the distal catheter tip that controls pressure or establishes flow of cerebrospinal fluid and resists reflux of blood or other fluids into the shunt.

3.1.40 *traceability reference*—the number or other means of identification by which components can be traced to a specific manufacturing lot or batch.