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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.

3.1.41 *unit*—individual device(s) or object(s) defined in the relevant product standard or regulation.

3.1.42 *use-by date*—a date that may be established by the manufacturer after which the device is not to be implanted.

3.1.43 *valve*—an element of a hydrocephalus shunt assembly that functions as a major resistance to the CSF flow, thus controlling the relationship between pressure and flow of cerebrospinal fluid, and resists reflux of blood or other fluids into the shunt assembly. In contrast to a valved catheter, it does not provide a significant portion of tubing for the fluid pathway.

3.1.44 *valved catheter*—an assembly or element of a shunt which provides a pathway for diversion of CSF to an internal delivery site and contains one or more valves, typically, a tip valve, and a significant portion of tubing for the fluid pathway.

4. Significance and Use

4.1 This practice provides minimum requirements for the ensurance of safety and efficacy. It provides a common language whereby the function of these surgical implants is described.

5. Materials

5.1 Metals used in the fabrication of implantable shunt components shall conform to specifications as referenced in 2.1.

5.2 All polymeric materials shall have total levels of extractable antimony, arsenic, bismuth, copper, lead, cadmium, mercury, and tin not exceeding 10 ppm (each), when tested by conventional methods of extraction and microanalysis conforming to the *United States Pharmacopeia* (*USP*), spectrographic analysis, or other machine methods that are proven reliable. The shunt manufacturer shall use Specification F604 to provide guidance in the selection of silicone elastomeric materials appropriate for shunt application.

5.3 *Biocompatibility (Polymeric Materials):*

5.3.1 Each polymeric formulation shall be shown to produce an acceptable level of tissue reaction by cell culture,[4] hemolysis (*USP*), pyrogenicity (*USP*), extraction and intracutaneous injection in rabbits (*USP*), and by Practice F469 or any comparable procedures.

5.3.2 Each batch of polymeric material shall be biocompatible when tested by cell culture or seven-day rabbit implant (*USP*).

5.4 Interfacing surfaces of mated shunt components must be of the same material composition or recognized compatible materials (for example, connector-catheter interfacing materials).

5.5 Guidance for selection of materials is contained in Appendix X2.

6. General Requirements for Complete Shunts and Components

6.1 *Physical Requirements:*

6.1.1 *Surface Finish*—When examined with normal or corrected vision at a distance of 300 to 450 mm and at an illuminance of 2150 ± 215 lx, the surface of all implantable shunts and components of a shunt assembly that have passed through all stages of manufacture, including sterilization, shall be clean, smooth, and free from surface irregularities, flash, molding and extrusion defects, and extraneous particles that would be expected to compromise the function of the device.

6.1.2 *Radiopacity*—When tested by the method described in Annex A1, all integral components and connectors of the shunt or component shall be radiopaque or shall carry radiopaque markers, so as to allow their visualization by X-rays. Composite structures or assemblies may contain radiolucent portions if surrounding or overlay material clearly identifies the location of nonradiopaque elements and enables any discontinuities to be readily apparent.

6.1.3 *Magnetic Resonance Imaging (MRI) Compatibility*—Imaging and investigative techniques such as nuclear magnetic resonance (NMR) and magnetic resonance imaging (MRI) involve placing the patient in a strong magnetic field. This may result in severe stresses on magnetizable materials (that is, 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 degrade an MRI image to the point of making it diagnostically or therapeutically useless), even moving them through tissues. Magnetizable materials should be avoided if possible in hydrocephalus shunts but, if used, a suitable warning shall be included in the product labeling (see 6.4.2.6).

6.1.4 *Biological Properties*—In the absence of a test method for freedom from biological hazard, it is not possible to lay down requirements for toxicity or biocompatibility in this standard. It is essential that such tests are carried out on the initial formulation of materials and whenever there is a major change in the formulation or processing, or both.

6.1.5 Specific guidance on the biological properties of materials is given in Appendix X2.

6.2 *Mechanical Properties:*

6.2.1 Where applicable, shunt assemblies, valved catheters, valves, and catheters with integral valves shall be evaluated for security of assembly and absence of assembly leakage and for tensile strength. They shall be sufficiently strong and flexible as to permit manipulation and be resistant to stresses ordinarily associated with placement and use.

6.2.2 For any given shunt component and where appropriate, the manufacturer shall subject device(s) (test specimens) to testing of those mechanical properties that are pertinent to *in vivo* performance.

6.2.3 Testing shall be performed on a finished product(s) selected in accordance with the manufacturer's usual quality assurance program.

6.2.3.1 The manufacturer shall specifically ensure the security of assembly of nonmodifiable junction sites, by subjecting a test specimen of the assembly to an applied load. Nonmodifiable junctions shall be as strong as modifiable junctions (assembled according to the manufacturer's instructions for use) when tested in a similar manner.

[4] *Journal of Pharmacological Science*, Vol 54, No. 156, 1965.

6.2.3.2 The manufacturer shall specifically ensure absence of assembly leakage at nonmodifiable junction sites, by subjecting a test sample of the assembly to an applied pressure of 1000 mm H_2O for 5 min. Nonmodifiable junctions shall have the same properties to resist leakage as modifiable junctions (assembled according to the manufacturer's instructions for use) when tested in a similar manner.

6.2.3.3 The manufacturer shall specifically ensure that test specimens shall be tested by the method used or recommended after sterilization if the shunt is packaged and sold after sterilization.

6.2.3.4 Particulars of the test methodology used by each manufacturer, including test apparatus, etc., shall be documented and retained for a minimum of 25 years for permanently implanted products and in no case less than two years from the date of release for commercial distribution by the manufacturer.

6.3 *Packaging:*

6.3.1 *Unit Container:*

6.3.1.1 Each shunt or component shall be individually packaged and sealed in a unit container, the materials of which shall be non-fibrous and lint-free.

6.3.1.2 The construction of the unit container shall be such that once it has been opened, this fact shall be evident.

NOTE 3—The packaging material should have no deleterious effects on the contents of the unit container. The unit container should provide adequate physical protection to the contents under normal conditions of handling, transit, and storage, and be constructed so that, once opened, it cannot be easily resealed.

6.3.1.3 The unit container should maintain the sterility of the contents and be constructed so as to facilitate the aseptic presentation of the device for use.

6.3.1.4 If shunts or catheters are not packaged in the straight configuration, they should be packaged in such a manner that no permanent deformation is produced.

6.3.2 *Shelf Containers*—One or a number of unit containers, each containing the same model of shunt or component, shall be packaged in a shelf container.

NOTE 4—The shelf container should provide protection of the contents under normal conditions of handling, transit, and storage. One or a number of shelf containers may additionally be packaged in an outer or transit container.

6.4 *Labeling, Packaging, and Sterility:*

6.4.1 *Shunts and Components:*

NOTE 5—It is recommended that shunts and components through which the fluid flow is unidirectional shall be marked to indicate the intended direction of flow (for example, by means of an arrow) using a method that is visible and obvious to the implanting surgeon.

6.4.2 *Unit Container*—The following information shall be marked on the unit container or given in a leaflet or insert:

6.4.2.1 The particular information specified in 6.1.2 and 6.1.3, as appropriate;

6.4.2.2 The words "STERILE" and "NONPYROGENIC";

6.4.2.3 The name or registered trademark, or both, of the manufacturer or supplier;

6.4.2.4 The batch number and date of manufacture (year and month) or a batch number from which the date of manufacture can be determined;

6.4.2.5 If appropriate, the word "RADIOPAQUE" or equivalent;

6.4.2.6 If appropriate, a warning that the contents contain magnetizable materials (including notation on patient ID card);

6.4.2.7 If the contents may be resterilized, full instructions for resterilization, indicating the recommended maximum number of sterilization cycles;

6.4.2.8 A warning against use of the contents if the unit container is open or damaged;

6.4.2.9 Directions for opening the container and aseptic presentation of the contents;

6.4.2.10 In the case of contents having a determined shelf life, the "use before" date (year) beyond which the contents should not be implanted;

6.4.2.11 The words "SINGLE USE" or equivalent phrase;

6.4.2.12 Any special instructions for storage of the unit container.

6.4.3 *Shelf Container*—The shelf container shall be either wholly or partially transparent so that the unit container markings are visible; or labeled or marked with the following information:

6.4.3.1 A description of the contents, as specified in 6.1.2 or 6.1.3 (as appropriate), and number of contents;

6.4.3.2 The words "STERILE" and "NONPYROGENIC";

6.4.3.3 The name and address of the manufacturer or supplier;

6.4.3.4 The batch number and date of manufacture (year and month) or a batch number from which the date of manufacture can be determined;

6.4.3.5 Any special instructions for storage; and

6.4.3.6 In the case of contents having a determined shelf life, the expiry date (year) beyond which the contents should not be implanted.

6.5 *Additional Requirements for Complete Shunts, Valves, and Catheters with Integral Valves and Components:*

6.5.1 *Type and Size Designation*—The type and size of the shunt shall be designated by means of the following information:

6.5.1.1 The function of the valve/catheter (for example, inflow, outflow, etc.);

6.5.1.2 The nominal operating characteristics of valve (for example, high, medium, low);

6.5.1.3 The overall nominal length of component expressed in millimetres or centimetres, stating the unit used;

6.5.1.4 The nominal inside and outside diameters of the tubular portions of the component at connection point, expressed in millimetres.

6.5.2 *Connectors*—If additional connectors are supplied for use in conjunction with valves and catheters with integral valves, the dimensions of the connectors shall be such that the pressure and flow characteristics of the shunt with the connections in place shall not, when tested in accordance with Annex A2, differ by more than 10 % from the values determined for the shunt without the additional connectors in place.

6.5.3 *Resistance Properties*—The results for a preassembled shunt or a shunt sold as a kit, a valve, or a catheter with valves, when tested in accordance with Annex A2, shall lie within a specified confidence interval of the functional range of the type

of component stated by the manufacturer in accordance with published instructions for use.

6.5.3.1 The manufacturer shall be given the choice between providing pressure/flow characteristics of the assembled shunt and providing pressure/flow characteristics of each component in the kit, provided the manufacturer has obtained adequate data demonstrating the additive resistive effects of various shunt components, and the manufacturer properly explains these additive properties in the accompanying documentation.

6.5.3.2 Complete shunts, valved shunt assembly, or integral valves shall be tested in accordance with Annex A2.

6.5.3.3 The pressure/flow properties of a complete shunt, valve, or catheter with integral valve shall be such to provide resistance to flow of cerebrospinal fluid through the shunt, and to provide unidirectional flow in accordance with Annex A2.

6.5.3.4 Pressure/flow curves shall be plotted with flow rate on the horizontal axis and pressure on the vertical axis.

6.5.3.5 Evaluation of resistance properties shall be performed on a test specimen(s) prior to marketing and on a production-line basis thereafter.

6.5.4 *Freedom from Reflux*—When tested in accordance with Annex A3, the complete shunt, valve, catheter with integral valve, or component shall comply with the following requirements:

6.5.4.1 *Chambered Valves*—The meniscus shall remain static for at least 1 min at the test pressure (see A3.5.1). The meniscus shall remain static for at least 1 min (see A3.5.2). In the case of compressible valves, reflux shall not occur in the event that the chamber is compressed.

6.5.4.2 *Tip Valves*—Tip valves shall not show the continued formation of drops (less than 0.04 cc per minute) of liquid at the inlet end of the tubing at either test pressure (see A3.5.2).

6.6 *Security of Assembly/Assembly Leakage*—When assembled according to the manufacturer's instructions, all components supplied as a kit shall fit together securely without leakage.

6.6.1 Complete shunts, valves, and catheters with integral valves shall be evaluated for security of assembly and assembly leakage.

6.6.2 These components shall be evaluated to determine tensile force required to cause fracture, the test methodology and results being documented and retained by the manufacturer for a minimum of 25 years for permanently implanted products and, in no case, less than two years from the date of release for commercial distribution by the manufacturer.

6.6.3 Materials used in complete shunts, valves, and catheters with integral valves shall be tested in accordance with Appendix X2.

6.7 *Marking and Labeling and Accompanying Documentation:*

6.7.1 Labeling and product identification of shunts sold as a kit, valves, catheters with integral valves, and components shall include the following information:

6.7.1.1 A labeled and dimensioned diagram of the complete shunt, valve, catheter with integral valve, or component showing the direction of fluid flow; where the design is such that the intended direction of flow is ambiguous, the device shall be marked accordingly;

6.7.1.2 A statement whether the shunt has been tested by the manufacturer and the suitable tests, if any, the manufacturer recommends to the surgeon to determine whether or not the shunt falls in a specific band range;

6.7.1.3 A statement of or a code for the nominal flow resistance of the valve in accordance with Annex A2 or other manufacturer's criteria.

6.7.2 *Accompanying Documentation*—Each complete shunt, valve, catheter with integral valve, and components supplied as separate items shall be accompanied by documentation that includes the following information:

6.7.2.1 A description of the contents, including the type and size in accordance with 6.4;

6.7.2.2 Instructions for assembly of the shunt or use of the valve, catheter with integral valve, and component(s) in the assembly of a shunt system;

6.7.2.3 A statement as to whether the preassembled shunt or shunt sold as a kit, a valve, or a catheter with integral valve should be tested prior to implantation using tests deemed by the manufacturer to be appropriate for use in the operating room and intended to assess the following: patency; freedom from reflux; and, whenever possible and practical, a simple test designed to assess operating (pressure or flow) characteristics and to verify that these are within the nominal range specified by the manufacturer.

6.7.2.4 The instructions shall emphasize the need for the use of sterile, lint-free apparatus and reagents and aseptic technique in carrying out the test.

6.7.2.5 A statement that non-proprietary details of the methods used to test materials and the results obtained are available on request, giving the address to which such requests should be sent;

6.7.2.6 A labeled diagram showing the dimensions of those connection points the user will use for assembly of the component into the system and its method of incorporation into the final shunt system, showing the direction of fluid flow through the component;

6.7.2.7 Details of the pressure and flow characteristics of the type of shunt, valve, or catheter with integral valve in accordance with A2.9.1.3 and A2.9.1.4 and the interval level that the product will perform within the specified ranges.

7. Additional Requirements for Implantable Accessory Devices Supplied Separately

7.1 *Other Components:*

7.1.1 *Implantable Accessory Devices*—Implantable accessory components of shunts such as reservoirs, antisiphon devices, and filters should not compromise the overall function of the shunt. Their contribution to the pressure/flow characteristics of the shunt should be tested and documented.

7.2 *External Drainage Catheters:*

7.2.1 *Mechanical Properties*—External drainage catheters shall be sufficiently strong and flexible as to permit manipulation and at the same time be resistant to stresses ordinarily associated with placement and use.

7.2.2 External drainage catheters shall be evaluated to determine tensile force required to cause failure, with test methodology and results documented and maintained.

7.3 *Antisiphon System*—The contribution to pressure/flow characteristics of an antisiphon device shall be specified at zero hydrostatic pressure (no siphon effect) and at a negative hydrostatic pressure (siphon effect) specified by the manufacturer.

8. Keywords

8.1 antisiphon device; biocompatibility; compatibility; hydrocephalus; magnetic resonance imaging (MRI); shunt; shunt assembly

ANNEXES

(Mandatory Information)

A1. TEST METHOD FOR DETERMINING RADIOPACITY OF SHUNT COMPONENTS

A1.1 Scope

A1.1.1 This test method provides the procedure and acceptance criteria upon which a judgment of acceptable radiopacity can be based and labeling claims substantiated.

A1.2 Significance and Use

A1.2.1 Radiopacity of shunt components is often desirable, in order to facilitate placement of the shunt at the time of surgery and to evaluate the continuity of the assembly and the position of individual shunt components after implantation.

A1.3 Apparatus and Materials

A1.3.1 *X-Ray Machine and Film,* of a type conventionally used (such as par-speed or hi-plus films) for clinical radiology. An industrial X-ray system may be used,[4] provided that clinical X-ray parameters are obtainable.

A1.3.2 *Sheet of Aluminum Alloy No. 1100,* having a thickness as specified by the manufacturer of a minimum 2.2 mm, interposed between the test samples and X-ray generator to identify discontinuities in the system.

A1.3.3 A standard number of specimens shall be tested to ensure that the observed radiographic properties are typical of the population.

A1.4 Test Specimens

A1.4.1 Test specimens shall consist of a finished product.

A1.4.2 A sufficient number of test specimens shall be tested as to ensure that the observed radiographic properties are typical of the population.

A1.5 Control Specimens

A1.5.1 The control for each exposure shall consist of a strip of aluminum alloy No. 1100, having a width that is equivalent (to the nearest 0.1 mm) to the outer diameter of the test specimen. If the maximum thickness of the intended radiopaque region of the product is less than 1.3 mm, then the control specimen must have the same thickness. Otherwise, the control shall be at least 0.7 mm thick.

A1.6 Apparatus/Procedure

A1.6.1 Place the test and control specimen on a cassette containing the X-ray film and intensifying screens. Then cover all specimens with aluminum sheet described in A1.3.2. Position the lead blocker around the aluminum sheet to prevent undercutting.

A1.6.2 Expose the film using the following parameters: a peak kilovoltage (kVp) in the range from 65 to 80, a focal spot to film distance of at least 24 in. (610 mm), and a milliampere-second (mA-s) exposure time selected so as to achieve a background density of 0.8 to 1.2 optical density units.

A1.6.3 Develop the exposed film in accordance with the film manufacturer's instructions.

A1.6.4 Determine the radiographic opacity of test and control specimens by carefully centering the aperture of the densitometer over each image and recording the density. (The aperture size of the densitometer should be chosen so as to be slightly smaller than the size of the image in order to avoid confounding the density measurement with the background density of the film. In this application, an aperture size of 2 mm will typically be required.) The density of the background should be recorded and observed to be in the range of A1.6.2.

A1.7 Acceptance Criterion

A1.7.1 If the optical density of the test specimen image where the test sample thickness is 1.3 mm or greater (counting both walls) is observed to be as low as or lower than that of the control specimen (within the limits of precision of the densitometer), the test specimen may be termed radiopaque. If the thickness of the device is less than 1.3 mm (counting both walls), its linear attenuation shall be at least 56 % of the aluminum standard, when measured in Method C of Test Methods F640.

A1.8 Report of Results

A1.8.1 Test results shall be documented and retained by the manufacturer in substantiation of radiopacity claims. The report shall include a description of the product tested (including physical dimensions, geometry, opacifier concentration, etc.) and of the procedure employed (with exposure parameters), and identification of test apparatus and materials.

A1.9 Precision and Bias

A1.9.1 The precision and bias of this test method have not yet been determined.