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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.

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 and health practices and determine the applicability of regulatory limitations prior to use.*

NOTE 1—The following standards 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

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standards indicated below. Devices or components, or both, whose structures are comparable to that outlined in these standards are acceptable.

2. Referenced Documents

2.1 *ASTM Standards:*

F 55 Specification for Stainless Steel Bar and Wire for Surgical Implants[2]

F 56 Specification for Stainless Steel Sheet and Strip for Surgical Implants[2]

F 67 Specification for Unalloyed Titanium for Surgical Implant Applications[3]

F 75 Specification for Cast Cobalt-ChromiumMolybdenum Alloy for Surgical Implant Applications[3]

F 90 Specification for Wrought Cobalt-Chromium-Tungsten-Nickel Alloy for Surgical Implant Applications[3]

F 138 Specification for Stainless Steel Bar and Wire for Surgical Implants (Special Quality)[3]

F 469 Practice for Assessment of Compatibility of Nonporous Polymeric Materials for Surgical Implants with Regard to Effect of Materials on Tissue[4]

F 604 Classification for Silicone Elastomers Used in Medical Use[5]

F 640 Test Methods for Radiopacity of Plastics for Medical Use[3]

F 897 Practice for Measuring Fretting Corrosion of Osteosynthesis Plates and Screws[3]

2.2 *ISO Standard:*[6]

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) or; 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 degrade the MRI image to the point of making it diagnostically

[2] Discontinued; see *1991 Annual Book of ASTM Standards*, Vol 13.01.

[3] *Annual Book of ASTM Standards*, Vol 13.01.

[4] Discontinued; see *1987 Annual Book of ASTM Standards*, Vol 13.01.

[5] Discontinued; see 2000 *Annual Book of ASTM Standards*, Vol 13.01.

[6] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036.

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 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 Classification F 604 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,[7] hemolysis (*USP*), pyrogenicity (*USP*), extraction and intracutaneous injection in rabbits (*USP*) and by Practice F 469 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 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) (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 labelling (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.

6.2.3.2 The manufacturer shall specifically ensure absence of assembly leakage (defined as the formation of two drops or 0.1 mL) at nonmodifiable junction sites, by subjecting a test sample of the assembly to an applied pressure of 300 mm H_2O for 1 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.

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

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 uni-directional 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 labelled or marked with the following information:

6.4.3.1 A description of the contents, as specified in clauses 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, 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 both test pressures (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 one drop 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 Labelling and Accompanying Documentation*:

6.7.1 Labelling 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 labelled 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 labelled 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 anti-sipon device; bio-compatibility; 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,[7] 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 assure 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 F 640.

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.

A2. REFERENCE METHOD FOR DETERMINING PRESSURE AND FLOW CHARACTERISTICS

A2.1 Scope

A2.1.1 This test method defines a means whereby shunts or shunt elements of differing design or manufacture can be related in terms of pressure/flow characteristics by pumping of liquid at a number of constant rates through the shunt or component and measuring the pressure required to maintain each flow rate to the reference standard defined herein.

A2.2 Summary of Test Method

A2.2.1 The resultant flow/pressure in a shunt or shunt element is a function of the restriction of the device to the rate of flow and the sum of the resistances of the device, if all other factors are held constant.

A2.2.2 The test is intended:

A2.2.2.1 As a type test to prepare a curve showing mean values and the functional range for a particular design of shunt or component (see 6.5.3); and

A2.2.2.2 To establish that the performance of an individual shunt or component falls within the predetermined functional range (see 6.5.3.1). Other methods of equal or better precision may be used, but, in cases of dispute, the method given in this annex shall be the reference method. All equipment utilized is to be subject to a documented calibration program.

A2.3 Significance and Use

A2.3.1 Results of this test method can be used to define a curve representing the pressure/flow characteristics of a shunt or shunt element over a physiologic range of flow rates.

A2.3.2 From the individual pressure/flow curves obtained, a composite graph can be plotted that describes these characteristics for a given functional range of flow rates.

A2.4 Test Medium

A2.4.1 *Test Fluid*—The fluid medium used for testing the shunt or shunt elements shall be deaerated and deionized or distilled water at 37 ± 2°C.

A2.5 Apparatus

A2.5.1 *Test Rig*:

A2.5.1.1 The test apparatus shall consist of a source reservoir, constant-temperature water bath, a variable-speed pump having a flow rate, in millilitres per hour, accurate to ±5 %, a water manometer or equivalent calibrated in millimetres H_2O, tee or y-connector, connecting tubing, an apparatus to maintain constant water level in the bath, the appropriate adaptor for the shunt or shunt element to be tested.

A2.5.1.2 The tee or y-connector shall be joined directly to the shunt or shunt element to be tested.

NOTE A2.1—For testing of valves with or without integral catheters, the outlet of the shunt system shall be submerged in the water bath.

A2.5.1.3 The test fluid temperature must be equal to the water-bath temperature prior to flow through the tee connector so as to be at 37 ± 2°C at the site of shunt or shunt element test.

A2.5.2 The test apparatus comprises the following elements:

A2.5.2.1 *Variable-Speed Pump*, capable of maintaining, within ±5 %, any pumping rate up to 65 mL/h in the test rig, and any necessary silicone elastomer pump tubing;

A2.5.2.2 *Water Bath*, capable of being controlled at 37 ± 2°C with means to maintain the water level constant within ±2 mm;

A2.5.2.3 *Means of Connecting the Shunt*, or component to the test rig without occluding inflow aperture(s);

A2.5.2.4 *Connecting Tubing*,

NOTE A2.2—This should contain a coiled portion of sufficient length that, when immersed in the water bath, allows the test fluid (see A2.4.1) to come to a temperature of 37 ± 2°C during its passage through it.

A2.5.2.5 *Manometer*, graduated in conventional millimetres of water (mm H_2O)[8,9] or suitably calibrated transducer.

A2.5.2.6 *Borosilicate Laboratory Glassware*.

A2.6 Test Specimens

A2.6.1 The test shall be carried out on shunts or components that have passed through all stages of manufacture, including sterilization but not previously implanted and within the manufacturer's use before date, and, in the case of multipiece complete shunts, have been assembled in accordance with the manufacturer's instructions.

A2.7 Procedure

A2.7.1 Prepare the test specimen by performing all pre-use steps included in the documentation.

A2.7.2 Prefill and soak the test specimen in deaerated water that is deionized or distilled at 37 ± 2°C for a sufficient period of time to reach an equilibrium state, maintaining the temperature by means of the water bath (see A2.5.2.2) to ensure a stable pressure/flow characteristic.

A2.7.3 Top up the water bath with the test fluid (see A2.4.1) and bring the contents to 37 ± 2°C. Connect the test specimen to the adaptor (as shown in Fig. A2.1) in such a manner as not to introduce air into the liquid pathway of the test system.

A2.7.4 Purge all air from the liquid pathway of the test element and the testing apparatus by irrigating at a gage pressure not to exceed 500 mm H_2O (0.71 psi; 4.9 kPa).

A2.7.5 Zero the pressure level of measuring device (manometer or equivalent) by having the zero level of the manometer by adjusting its position so that the zero graduation mark is level with the surface of the test fluid in the water bath (see Fig. A2.1). The level of the water bath shall remain constant within ±2 mm.

A2.7.6 Adjust the pump speed (see A2.5.2.1) to provide a flow rate of between 55 and 65 mL/h. Allow the flow rate to stabilize.

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[8] The Hewlett-Packard Faxitron, or equivalent, has been found suitable for this purpose.

[9] 1 mm H_2O = 1 kgf/m^2 = 9807 Pa; the use of the unit "mm H_2O" is deprecated in ISO 31-3 (the unit "kPa" is preferred for fluid pressure), however, values are given in conventional millimetres of water since this unit is widely used in practice.

A2.7.7 Readjust the pump speed and read the manometer or pressure transducer pressure level after stabilization, in order of diminishing flow rates and including one determination at 50 and 5 mL/h for a minimum of three flow rates at 30, 20, and 10 mL/h with a tolerance of ±5 mL/hr at each point or with a tolerance as stated in A2.5.2.1. An alternate method is to readjust the pump speed in increasing flow rates from 5 to 50 mL/h.

A2.7.8 Repeat A2.7 for each test specimen using the same flow rates.

A2.8 Interpretation of Results

A2.8.1 *Type Testing of Shunts or Components*—Calculate the mean pressure for all replicate test shunts or components at a flow rate of 50 mL/h. Note the lowest and the highest individual pressures. Repeat this calculation for each of the four remaining flow rates.

A2.8.1.1 Construct a graph of flow rate (expressed in millilitres per hour and plotted as the abscissa) against pressure (expressed in conventional millimetres of water and plotted as the ordinate) showing the average, lowest and highest pressures at each of the chosen flow rates.

A2.8.1.2 A composite graph shall be derived that is representative of the device population tested. The composite graph is used for labeling requirements (see 6.4.2, and 6.4.3) of this practice.

A2.8.1.3 Representation of this composite graph shall show the typical minimum and maximum data points for each flow rate. Flow rates shall be plotted on the horizontal axis and pressure on the vertical axis.

A2.8.1.4 A population of valves needs to be tested a sufficient number of times to establish the statistical confidence level for reproducibility of the pressure/flow characteristics. This information should be used in the labeling to report the statistical confidence that the device will perform between labeled minimum and maximum.

A2.8.2 *Shunts or Components with Intended Linear Pressure/Flow Response Curves*:

A2.8.2.1 For each design (nominal classification) of shunt or shunt component, note the lowest individual pressure, P_{min}, in millimetres of water, recorded at a flow rate of 5 mL/h and the highest individual pressure, P_{max}, in millimeters of water, recorded at a flow rate of 50 mL/h; express the final results in the following form:

$$\frac{P_{min}}{5\ \text{mL/h}} \quad to \quad \frac{P_{max}}{50\ \text{mL/h}} \tag{A2.1}$$

Example:

$$\frac{10\ \text{mm}\ H_2O}{5\ \text{mL/h}} \quad \text{to} \quad \frac{80\ \text{mm}\ H_2O}{50\ \text{mL/h}} \tag{A2.2}$$

A2.8.2.2 For each nominal classification of shunts or valved shunt components, the manufacturer shall make available a graph representative of the pressure/flow characteristics used to define the above nominal resistance range for that device population. The statistical confidence level for reproducibility of the pressure/flow characteristics shall be used in the labeling to report the statistical confidence that the device will perform between labeled minimum and maximum.

A2.8.2.3 This arrangement shall be referred to as the" functional range" of the shunt or component.

A2.9 Report

A2.9.1 Report the following information:

A2.9.1.1 Type testing of shunts or components;

A2.9.1.2 The identity of the type of shunt or component;

A2.9.1.3 The functional range of the type of shunt or component (see A2.8.2.2); and,

A2.9.1.4 A graph of pressure plotted against flow rate of the type of shunt or component (see A2.8).

A2.9.2 *Other Testing of Shunts or Components*:

A2.9.2.1 The identity of the test shunt or component;

A2.9.2.2 The pressures, as given in A2.8.2;

A2.9.2.3 A statement as to whether the performance of the individual shunt or component lies within the functional range for the design (that is, whether the values of [P_{min} (5 mL/h)] and [P_{max} (50 mL/h)] are higher and lower, respectively, than the corresponding values determined by type testing and stated by the manufacturer).

A3. REFERENCE TEST METHOD FOR REFLUX

A3.1 Principle

A3.1.1 Filling of the valve with liquid and application of hydrostatic pressure in an attempt to induce reflux.

A3.1.2 Other methods of equal or better precision may be used, but, in cases of dispute, the method given in this annex shall be the reference method.

A3.2 Reagent

A3.2.1 *Deaerated Water*, that is distilled or deionized.

A3.3 Apparatus

A3.3.1 *Connecting Tubing and Connectors*.

A3.3.2 *Borosilicate Laboratory Glassware*.

A3.3.3 *Tubing Clamps*.

A3.3.4 *Clock or Stop Watch*.

A3.4 Test Specimens

A3.4.1 Carry out the test on shunts or components that have passed through all stages of manufacture, including sterilization.

A3.5 Procedure

A3.5.1 *Testing of Chambered Valves*—If necessary, detach the chambered valve(s) from the shunt or component. Connect lengths of tubing to both ends of the valve under test. Fill the assembly with test fluid (deaerated water that is distilled or deionized), removing all air. Position the valve so that the outlet end is uppermost and press the valve chamber repeatedly

until a meniscus forms in the tubing at a distance of 10 and 50 mm above the valve or fill the valve using a syringe. The inlet tubing shall be at the level of the valve unit. Stop pressing and observe the meniscus for 1 min to determine if it remains static. No more than two drops (0.1 cc) will form in 1 min.

A3.5.2 *Testing of Tip Valves*—If necessary, detach the tip valve from the shunt or component. Hold the valve and associated tubing vertically and fill it with test fluid, keeping the outlet and under the liquid surface. Dry the outer surface of the tubing. Lower the inlet end of the tubing to a distance of 10 mm and below the level of the liquid in the vessel. Observe the inlet end of the tubing for 1 min for signs of leakage and record the findings. Repeat the test with the inlet end of the tubing at distances of 50 and 140 mm (±2 mm at each point) below the level of the liquid.

APPENDIXES

(Nonmandatory Information)

X1. SUGGESTED TEST METHOD FOR DURABILITY

X1.1 General

X1.1.1 It is felt that shunts and at least certain components should be subjected to some form of accelerated durability test in order to demonstrate that they are able to meet the demands imposed upon them during the period (possibly several years) for which they may remain implanted. The main properties of interest are that:

X1.1.1.1 The pressure and flow characteristics remain within design limits;

X1.1.1.2 The valves continue to function correctly (particularly with regard to their resistance to reflux); and

X1.1.1.3 Connections and unions between components remain sound.

X1.1.1.4 Given that these properties relate chiefly to the design and materials of the shunt or component, a durability test is envisaged as being applied as a type test to preproduction devices, but not to routine production (although the test could be used in this way). Consequently it is suggested that the test be applied whenever, in view of the manufacturer, the design materials are significantly modified.

X1.1.1.5 Although it is feasible for all components to be tested for durability, practical considerations of time and cost may constrain the amount of testing that can be carried out. In this case, priority should be given to testing complete shunts (both one-piece and multipiece), valves, catheters with integral valves and other components having moving parts or containing permanent unions within their structure.

X1.1.1.6 It is recommended that the test method described in X1.2 to X1.7 be applied as outlined below in order to provide experience and data on which to base test conditions and pass/fail criteria for inclusion in a future edition of this practice.

X1.2 Principle

X1.2.1 Immersion of the shunt or component in water at elevated temperature; pumping of water in a pulsed fashion through the shunt or component so as to open and close the valve(s) repeatedly. Examination of the shunt or component for signs of mechanical damage; then test in accordance with Annex A2 and Annex A3 to establish if the functional range or the reflux properties have been impaired.

X1.3 Reagent—Test Fluid

X1.3.1 Deaerated water that is distilled or deionized.

X1.4 Apparatus

X1.4.1 *Test Rig*—The test rig shall comprise the following elements:

X1.4.1.1 *Variable Speed Pump*, capable of maintaining, within ±5 %, the selected pumping rate;

X1.4.1.2 *Water Bath*, capable of being controlled at 37 ± 2°C;

X1.4.1.3 *Means of Connecting the Shunt or Component to the Test Rig*, without occluding inflow aperture(s);

X1.4.1.4 *Silicone Elastomer Pump Tubing*, of dimensions to produce selected flow rate;

X1.4.1.5 *Silicone Elastomer Connecting Tubing;*

NOTE X1.1—This should contain a coiled portion of sufficient length that, when immersed in the water bath (see X1.4.1.3), allows the test fluid (see X1.3) to come to a temperature of 37 ± 2°C during its passage through it.

X1.4.1.6 *Manometer*, graduated in conventional millimetres of water (mm H_2O), or a suitable calibrated transducer.

NOTE X1.2—An example of the test rig is shown in Fig. A2.1 .

X1.5 Test Specimens

X1.5.1 Carry out the test shunts or components that have passed through all stages of manufacture, including sterilization, and, in the case of multipiece shunts, have been assembled in accordance with the manufacturer's instructions.

X1.6 Procedure

X1.6.1 Soak the test specimen in the test fluid (see X1.3) at 37 ± 2°C for at least 24 h, maintaining the temperature by means of the water bath (see Appendix X2.4.1.2).

X1.6.2 Top up the water bath with the test fluid and bring the contents to 37 ± 2°C.

X1.6.3 Purge all air from the liquid pathway of the test system by irrigating with test fluid at a pressure not exceeding 500 mm H_2O.

X1.6.4 Connect the test specimen as shown in Fig. A2.1 , taking care not to introduce air into the liquid pathway of the test system.

X1.6.5 Zero the manometer (see X1.4.1.6) by adjusting its position so that the zero graduation mark is level with the surface of the test fluid in the water bath.

X1.6.6 Start the pump (see X1.4.1.1) and adjust to a flow rate of between 5 and 15 mL/h greater than the flow rate selected for the test (see X1.6.7). Allow the flow rate to stabilize:

$$\frac{\text{Pulse frequency should be 0.5 Hz} \pm \text{0.25 Hz.}}{\text{Pulse frequency should be 0.5 Hz} \pm \text{0.25 Hz.}} \quad \text{(X1.1)}$$

X1.6.7 Adjust the pump to give a flow rate, either of a valve selected from the upper quartile of the range of flow rates for the shunt or component stated by the manufacturer, or (if no data are available) of 50 mL/h. When the flow rate has stabilized, record the manometer reading (see X1.4.1.6).

X1.6.8 Operate the pump at the rate described in X2.6.7 continuously for 28 days. Check the flow regularly and adjust if necessary. Check the manometer reading regularly. A change in pressure indicates the pressure of air bubbles, which should be purged from the system. If necessary, top up the water bath regularly.

X1.6.9 Remove the test specimen and rinse it twice with deaerated water. Examine the test specimen for breaks, loosening of unions and other evidence of mechanical damage.

X1.6.10 Determine the pressure and flow characteristics of the test specimen in accordance with Annex A2.

X1.6.11 Determine the reflux characteristics of the valves, if any, in accordance with Annex A3.

X1.7 Report

X1.7.1 Report the following information:

X1.7.1.1 The identity of the test specimen;

X1.7.1.2 The functional range of the test specimen (see Appendix X2.6.10) and a statement as to whether this falls within the range in any, stated by the manufacturer.

X1.7.1.3 The reflux properties (see Appendix X2.6.11) of the valves, if any, and a statement as to whether these comply with 6.5.4 and Annex A3; and

X1.7.1.4 A description of all defects and failures occurring during the 28-day test period, and during subsequent testing (see X1.6.9, X1.6.10, and X1.6.11).

X2. GUIDANCE ON MATERIALS

X2.1 The types of materials from which the shunt or component is made should be tested by appropriate published test methods to determine the following:

X2.1.1 The physical and chemical effects on the materials of body fluids and tissues with which the finished shunt or component is intended to come into contact; and

X2.1.2 The physical, chemical and biological effects of the materials on the body fluids and tissues with which the finished shunt or component is intended to come into contact.

X2.2 These records should be updated whenever the types or sources of materials are changed.

X2.3 Each polymeric formulation shall be shown to produce an acceptable level of tissue reaction by cell culture (or equivalent), hemolysis (*USP*), pyrogenicity (*USP* or equivalent), extraction and intracutaneous injection in rabbits (*USP* or equivalent), extraction and intracutaneous injection in rabbits (*USP*), and by Practice F 469 or equivalent.

X2.4 Each batch of polymeric material shall be biocompatible when tested by cell culture or seven-day rabbit implant (*USP*).

X2.4.1 Metals used in the fabrication of implantable shunt components shall conform with Specifications F 55, F 67, F 75, F 90, and F 138. The use of magnetizable materials should be avoided because of the possibility of movement of shunts or components through the body tissues when the patient is exposed to diagnostic investigations using high-strength magnetic fields, for example, nuclear magnetic resonance scanning (magnetic resonance imaging).

X2.5 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 Classification F 604 to provide guidance in the selection of silicone elastomeric materials appropriate for shunt application.

X2.6 The materials should be sufficiently flexible for the shunt or component to be manipulated without fracture, but should maintain resistance to kinking and applied pressure.

X2.7 Interfacing surfaces of mated shunt components must be of the same material composition or recognized compatible materials (for example, connector-catheter interfacing materials).