Designation: F 1542 – 94 (Reapproved 2000)

Standard Specification for the Requirements and Disclosure of Self-Closing Aneurysm Clips[1]

This standard is issued under the fixed designation F 1542; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This specification covers requirements for the specific characteristics of self-closing aneurysm clips that are intended for permanent implantation. Appropriate test requirements are also included.

1.2 Since all of the properties that contribute to aneurysm clip performance may not be known, this specification is intended to reflect the state of our knowledge to date.

1.3 Miniatures of "microclips" that are not intended for the obliteration of aneurysms are excluded from this specification.

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-Chromium-Molybdenum Alloy for Surgical Implant Applications[3]

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

F 136 Specification for Wrought Titanium 6A1-4V ELI Alloy for Surgical Implant Applications[3]

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

F 139 Specification for Stainless Steel Sheet and Strip for Surgical Implants (Special Quality)[3]

F 361 Practice for Assessment of Compatibility of Metallic Materials for Surgical Implants with Respect to Effect of Materials on Tissues[4]

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

F 560 Specification for Unalloyed Tantalum for Surgical Implant Applications[3]

F 562 Specification for Wrought Cobalt-Nickel-Chromium-Molybdenum Alloy for Surgical Implant Applications[3]

F 563 Specification for Wrought Cobalt-Nickel-Chromium-Molybdenum-Tungsten-Iron Alloy for Surgical Implant Applications[3]

F 688 Specification for Wrought Cobalt-Nickel-Chromium-Molybdenum Alloy Plate, Sheet, and Foil for Surgical Implants[3]

F 700 Practice for Care and Handling of Intracranial Aneurysm Clips and Instruments[3]

F 748 Practice for Selecting Generic Biological Test Methods for Materials and Devices[3]

F 981 Practice for Assessment of Compatibility of Biomaterials (Non-Porous) for Surgical Implants with Respect to Effect of Materials in Muscle and Bone[3]

2.2 *ISO Standard:*[5]

ISO TC 150

3. Requirements

3.1 *General*—This section contains requirements for the disclosure of information on aneurysm clip force measurements and requirements for labeling the materials and biocompatibility of the device.

3.2 *Performance Disclosure*:

3.2.1 *Force (See X1.2)*—The manufacturer shall disclose the closing force (measured in g) exerted by the blades when tested in accordance with 4.2.

3.2.2 *Force Range*—The manufacturer shall measure each clip as defined in 3.2.1 and report either the closing force of the individual clip, a minimum closing force for that specific clip, or a range within which the specific clip lies. If a range is reported, defined ranges shall be no greater than ±10 % of the median force.

3.2.3 *Materials*:

3.2.3.1 The manufacturer shall disclose the generic names of the materials used in the manufacture of the clip. ASTM material specification nomenclature shall be used whenever available. If the clips are made of multiple components, the name of the material for each component shall be disclosed.

3.2.3.2 Clips will be manufactured so as to be nonferromagnetic. The aneurysm clip must possess the following material

[1] This specification 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.

Current edition approved Aug. 15, 1994. Published October 1994.

[2] Discontinued 1991—See *Annual Book of ASTM Standards*, Vol 13.01.

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

[4] Discontinued—See *Annual Book of ASTM Standards*, Vol 13.01.

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

property in order to be judged as nonferromagnetic. The force exerted on a finished aneurysm clip by a 1.5 tesla whole body MRI magnet must not exceed the gravitational force on the clip (that is, its own weight).

3.2.3.3 *(See X1.4)*—The materials and alloys used in aneurysm clips conforming to this specification should be fabricated in accordance with one of the following ASTM specifications: F 55, F 56, F 67, F 75, F 90, F 136, F 138, F 139, F 560, F 562, F 563, F 688, ISO TC 150, or subsequently approved ASTM Committee F04 standards. Clips manufactured with nonapproved materials must be labeled with a statement that they are made of a material for which there is no ISO or ASTM Committee F04 standard.

3.3 *Biocompatibility*—Aneurysm clips should be biocompatible with the tissue in which they are intended to be implanted. Components shall meet the biologic compatibility requirements of Practices F 361, F 469, F 748, and F 981, or other equivalent practices wherever applicable.

3.4 *Clip Nomenclature Disclosure*:

3.4.1 *General*—This section contains requirements for a standard nomenclature for self-closing aneurysm clips.

3.4.2 The manufacturer shall use the following type nomenclature to describe its clips and disclose this information where applicable:

3.4.2.1 *Blade Geometry*:

(1) Straight,
(2) Angled,
(3) Curved,
(4) Angled tip,
(5) Vessel encircling,
(6) Fenestrated,
(7) Bayonet, and
(8) Other (describe).

3.4.2.2 *Blade and Clip Dimensions*:

(1) Length of the blade (the blade being defined as the contact surfaces of the clip, when the clip is in the closed position; in straight blade clips, this being the measured contact surface and in curved blades, the measured arc cord length of the contact surface);

(2) Blade width (indicate mean width for tapered blade);

(3) Blade cross section (flat, rolled, round, or other (describe in detail));

(4) Clip length;

(5) Maximum opening at the tip; and

(6) Inside diameter of encircling clip.

3.4.2.3 *Spring Type*:

(1) Integral single bend,
(2) Integral coil,
(3) Inserted coil,
(4) Noncontinuous ring,
(5) Torsion bar, and
(6) Other (describe).

3.4.2.4 *Surface Finish*:

(*1*) *Blade Gripping Surfaces:*

(a) Smooth,
(b) Serrated, and
(c) Other (describe).

(*2*) *Clip Body:*

(a) Polished,
(b) Matte,
(c) Satin, and
(d) Other (describe).

(*3*) *Material Treatment:*

(a) Passivated,
(b) Electropolish, and
(c) Other (describe).

3.5 *Labeling Requirements (See X1.5)*—The labeling for aneurysm clips within the scope of this specification must comply with the following requirements as a minimum:

3.5.1 *Unit Labeling*—Each clip will have imprinted on it a unique code to allow traceability in accordance with FDA guidelines.

3.5.2 The following information shall be available with the unit package:

3.5.2.1 Manufacturer's identification or lot number;
3.5.2.2 Blade geometry (3.4.2.1);
3.5.2.3 Blade length (3.4.2.2);
3.5.2.4 Blade width (3.4.2.2);
3.5.2.5 Gripping surface (3.4.2.4);
3.5.2.6 Force (4.2);
3.5.2.7 Manufacturer's name;
3.5.2.8 Identification of catalog number;
3.5.2.9 Composition of material(s), including ASTM material specifications, if applicable, from which the clip is made; and
3.5.2.10 Specification of the ferromagnetic property(s) of the aneurysm clip or its component (see 4.3).

3.5.3 *Product Information*—As a minimum, the following data should be available in the manufacturer's and distributor's ordering information.

3.5.3.1 Blade geometry (3.4.2.1);
3.5.3.2 Blade length (3.4.2.2);
3.5.3.3 Blade width (3.4.2.2);
3.5.3.4 Spring type (3.4.2.3);
3.5.3.5 Surface finish (3.4.2.4);
3.5.3.6 Force (4.2);
3.5.3.7 Composition of materials, including ASTM material specifications, if applicable, from which the clip is made;
3.5.3.8 A statement suggesting that only applier(s) designed specifically for the particular clip(s) be used (specify catalog number);
3.5.3.9 A statement referencing Practice F 700;
3.5.3.10 Specification of the ferromagnetic property(s) of the aneurysm clip or its component (see 4.3); and
3.5.3.11 Identification or catalog number.

4. Tests

4.1 *Significance*—This force measurement test provides information on the closing force of the clip under circumstances approximating its neurosurgical application.

4.2 *Force Measurement*:

4.2.1 The closing force shall be measured at a point one-third the length of the blade measured from its tip at a blade separation distance of 1.0 mm. In the case of clips that are not designed for blade contact along the blade's entire working length, the closing force will be measured at the midpoint of the region of the blade contact.

4.2.2 The manufacturer will perform a test on each finished clip and report its performance as specified in 3.2.2.

4.3 *Non-Ferromagnetic Property*—The operational definition of a non-ferromagnetic aneurysm clip, stated in 3.2.3.2, is met if, and only if, the clip passes the following test:

4.3.1 The magnetic force on the clip is proportional to the product $\vec{B} \cdot \vec{\nabla B}$, where $\vec{B}$ = the magnetic field intensity and $\vec{\nabla B}$ = the gradient of magnetic field intensity.

4.3.1.1 In general, the $\vec{B} \cdot \vec{\nabla B}$ product is maximum in the vicinity (usually just inside) of the portal of the magnet. Note that the magnitudes of $\vec{B}$ and $\vec{\nabla B}$ are those at the local site at which the force measurement is made.

4.3.1.2 The clip is suspended at the end of a string and held stationary in the vertical direction (that is, perpendicular to the ground) while it is placed in position at the portal of the imaging magnet. Following release of the clip, the deflection of the string from the vertical is then observed. The magnetic force is less than the gravitational force (that is, the clip's weight) if the deflection of the string with respect to the vertical is less than 45°. The clip is then judged to be non-ferromagnetic and suitable for implantation.

4.3.2 There are four caveats. First, for a given magnet, it will be necessary to find the position at which the $\vec{B} \cdot \vec{\nabla B}$ product is maximum. Second, this position is likely to be different in magnets from different manufacturers. It may be necessary to collect data from these magnets using the test described in 4.3.1. Third, the specification described above deals only with the magnetic force on a finished, unimplanted clip. The possibility exists that nominally non-ferromagnetic clips may product image artifacts due to local distortion of the radiofrequency field or due to mild ferromagnetism induced by bending of the clips during placement. Fourth, a deflection of less than 45° at the portal of a 1.5 tesla magnet does not preclude a deflection exceeding 45° at a higher magnetic field strength.

APPENDIX

(Nonmandatory Information)

X1. RATIONALE FOR DEVELOPMENT OF THE SPECIFICATION

X1.1 *General Rationale*—This specification is intended to provide a common language for communication between producers, users, engineers, government agencies, and designers of self-closing aneurysm clips; to provide uniformity in reporting performance characteristics, test methodology, and nomenclature; and to be versatile enough to cover new products and test methods as they are introduced.

X1.2 The surgeon must have available quantitative data on the clip closing force to select an optimal clip for a particular aneurysm. Clips are marketed with a variety of closing forces and may be indistinguishable otherwise.

X1.3 Because of the increasing importance of magnetic resonance as an imaging modality at 1.5 tesla, the expectation that even higher strength magnets will be introduced in the future, and the fact that implanted aneurysm clips made of ferromagnetic alloys may move or even become dislodged in these magnetic fields, it is important that aneurysm clips be non-ferromagnetic. Inasmuch as non-ferromagnetic alloys may be converted to a ferromagnetic state by the working processes, it is essential that testing be conducted on the finished clip and that all clips be identified clearly as to the ferromagnetic (or non-ferromagnetic state).

X1.4 The materials designated are those shown to be reasonably corrosion resistant at the physiologic conditions of the biologic environment and are not susceptible to intergranular corrosion attack, are non-toxic, and are biocompatible. Other materials have been used successfully for aneurysm clips. Some clip designs made with these materials are considered by surgeons to be essential and potentially lifesaving but have not been able to be made of other materials. The use of these materials is therefore not proscribed, but appropriate labeling is required.

X1.5 Labeling requirements are to ensure that the medical community has available sufficient information to facilitate the proper selection of self-closing aneurysm clips for safe and effective use. Specific coding imprinted on each clip is necessary to allow traceability in accordance with FDA requirements.