



Designation: F 1542 – 94 (Reapproved 2000)

Standard Specification for the Requirements and Disclosure of Self-Closing Aneurysm Clips¹

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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 Implants²

F 56 Specification for Stainless Steel Sheet and Strip for Surgical Implants²

F 67 Specification for Unalloyed Titanium for Surgical Implant Applications³

F 75 Specification for Cast Cobalt-Chromium-Molybdenum Alloy for Surgical Implant Applications³

F 90 Specification for Wrought Cobalt-Chromium-Tungsten-Nickel Alloy for Surgical Implant Applications³

F 136 Specification for Wrought Titanium 6Al-4V ELI Alloy for Surgical Implant Applications³

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 Tissues⁴

F 469 Practice for Assessment of Compatibility of Nonporous Polymeric Materials for Surgical Implants with Regard to Effect of Materials on Tissues⁴

F 560 Specification for Unalloyed Tantalum for Surgical Implant Applications³

F 562 Specification for Wrought Cobalt-Nickel-Chromium-Molybdenum Alloy for Surgical Implant Applications³

F 563 Specification for Wrought Cobalt-Nickel-Chromium-Molybdenum-Tungsten-Iron Alloy for Surgical Implant Applications³

F 688 Specification for Wrought Cobalt-Nickel-Chromium-Molybdenum Alloy Plate, Sheet, and Foil for Surgical Implants³

F 700 Practice for Care and Handling of Intracranial Aneurysm Clips and Instruments³

F 748 Practice for Selecting Generic Biological Test Methods for Materials and Devices³

F 981 Practice for Assessment of Compatibility of Biomaterials (Non-Porous) for Surgical Implants with Respect to Effect of Materials in Muscle and Bone³

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 $\pm 10\%$ 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

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.

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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.

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 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 applicator(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:*