



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 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.

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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.