Designation: F982 – 86 (Reapproved 2008)

Standard Specification for Disclosure of Characteristics of Surgically Implanted Clamps for Carotid Occlusion[1]

This standard is issued under the fixed designation F982; 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 disclosure of specific characteristics of screw-type adjustable clamps that are designed for the gradual permanent occlusion of carotid arteries. These devices consist of an implantable portion and an externally projecting removable screwdriver (see Fig. 1).

1.2 The following precautionary caveat pertains only to the test method portion, Section 5, of this specification: *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.*

2. Referenced Documents

2.1 The designations and titles of the applicable documents for this specification are listed in Annex A1 in the following groups:

2.1.1 Materials,
2.1.2 Finishing,
2.1.3 Biocompatibility,
2.1.4 Handling, and
2.1.5 Analysis.

3. Terminology

3.1 *Descriptions of Terms Specific to This Standard (see):*

3.1.1 *access plate*—portion of the device that closes the frame.

3.1.2 *cap*—covering device to seal the lumen of the stem when the screwdriver is not in place.

3.1.3 *collar*—threaded portion of the frame that acts as a guide and counter torque surface for the pressure plate screw.

3.1.4 *frame*—encircling portion of the device, usually U-shaped.

3.1.5 *guide*—cylinder within the stem to provide counter torque and guidance for the screwdriver.

3.1.6 *hinge*—means of attaching the access plate to the frame.

3.1.7 *pressure plate*—movable compressing plate.

3.1.8 *pressure plate screw*—threaded shaft that advances the pressure plate.

3.1.9 *screwdriver*—device used to provide torque to the pressure plate screw. The screwdriver should have permanently marked scale indicating advance ratio by millimetres.

3.1.10 *set screw*—screw that secures the access plate to the frame.

3.1.11 *stem*—cylinder that is used to hold the frame and to provide counter torque for the screwdriver.

4. General Requirements

4.1 This section contains requirements for disclosure of information on screw-type adjustable clamps.

4.2 *Performance Disclosure:*

4.2.1 *Materials:*

4.2.1.1 The manufacturer shall disclose the generic names of the materials used in the manufacture of the clamp. Whenever available, ASTM material specification nomenclature shall be used (Annex A1). If multiple components are used, the names of each component shall be disclosed.

4.2.1.2 The metals and alloys or other materials used in clamps that conform to this specification should be fabricated of approved materials in accordance with the ASTM specifications listed in A1.2.1.

4.2.2 *Finishing*—Surface cleanliness and characteristics should meet the requirements of the ASTM specifications listed in A1.2.2. There should be no debris visible at 20× and no imperfections visible to the naked eye.

4.2.3 *Biocompatibility*—Clamps should be biocompatible with the tissue in which they are intended to be implanted. Metal components shall meet ASTM biologic compatibility requirements or equivalents listed in A1.2.3. Nonporous polymeric materials should conform to the ASTM requirements or equivalents listed in the Annex.

4.2.4 *Handling*—Handling procedures should be similar to those suggested by several ASTM standards listed in A1.2.4.

[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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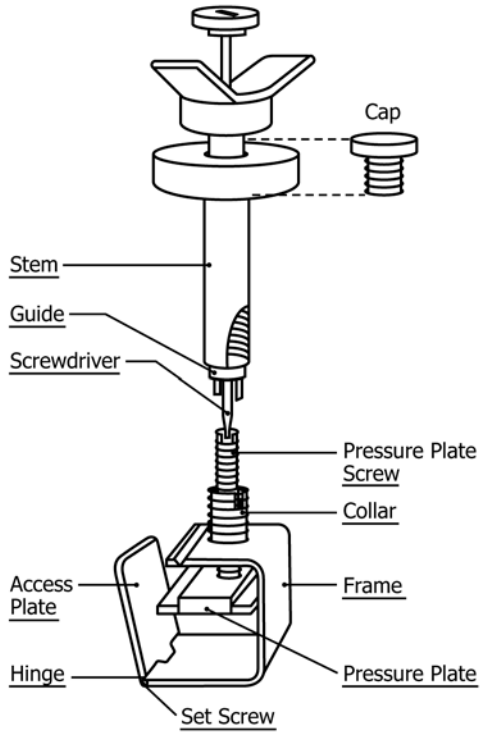

FIG. 1 Screw-Type Adjustable Clamp Components

4.2.5 *Analysis*—Analysis of clips removed for any reason should resemble that specified for removal of orthopedic implants (see A1.2.5).

4.2.6 *Reporting of Failures*—All failures should be reported both to the manufacturer and to the Food and Drug Administration (FDA).

4.2.7 *Advance Ratio*—The manufacturer shall disclose the distance (millimetres) advanced by the pressure plate for each full revolution of the screwdriver (see also 5.1).

4.2.8 *Pressure Plate Induced Laceration of Vessel*—The manufacturer shall disclose the torque at which the pressure plate will cause vessel laceration (see also 5.2).

4.2.9 *Slip Resistance of the Clamp*—The manufacturer shall disclose whether the set screw will unwind and the pressure plate will retreat in the face of pulsatile pressure of 150/80 at 80 cpm applied to the pressure plate when it is 2 mm from closure and when it is at the closed position (see also 5.3).

5. Test Methods

5.1 *Advance Ratio*—This measurement must be accurate to ±0.35 mm.

5.2 *Vessel Damage*—Implant the clamp aseptically around a dog carotid artery and close using a torque wrench. Implant several animals, each having their clamp tightened to a different torque. Sacrifice the animals two weeks later and examine microscopically as well as histologically to determine if there is laceration. Clamps can be tightened to a torque just below that which will cause laceration.

5.3 *Slip Resistance*— Perform the study *in vitro* using dog carotid arteries (average diameter 5 mm) or tubes of similar distensibility and a pulse duplicator system. Set the pulse duplicator to create a pulsatile cycle of pressure similar to the physiologic systolic-diastolic pattern (150/80 at 80 cpm). During the experiment, keep the artery in a normal saline bath and connect it to the pulse duplicator system. Close the clamp to a gap of 2 mm. Turn on the pulse duplicator and measure the position of the pressure plate relative to the basis of the frame every 24 h for 72 h to determine if there has been any retreat of the pressure plate. Perform a second test keeping the pulse duplicator functioning at the same setting but with the clamp closed down to occlude the artery using the torque determined safe as detailed in 5.2. Again, measure the position of the pressure plate every 24 h for 72 h. A backoff of 0.2 mm (90° turn) will be the maximum permitted. Measurement must be accurate to ±0.35 mm.

6. Labeling Requirements

6.1 All labeling must be consistent with applicable Federal Regulations. In addition, the labeling for carotid occlusive clamps within the scope of this specification should comply with the following requirements:

6.1.1 *Package Label*—The following information shall be available with the unit package:

6.1.1.1 Manufacturer's name,
6.1.1.2 Trade name,
6.1.1.3 Catalog number,
6.1.1.4 Manufacturer's identification or lot number,
6.1.1.5 Material(s),
6.1.1.6 Magnetic properties,
6.1.1.7 Advance ratio,
6.1.1.8 Torque which causes vessel laceration, and
6.1.1.9 Slip resistance.

6.1.2 *Product Insert*—The product insert should include the following information:

6.1.2.1 Manufacturer's name,
6.1.2.2 Trade name,
6.1.2.3 Catalog number,
6.1.2.4 Manufacturer's identification or lot number,
6.1.2.5 Size,
6.1.2.6 Length of compression plate,
6.1.2.7 Width of compression plate,
6.1.2.8 Compression surface,
6.1.2.9 Advance ratio,
6.1.2.10 Internal dimensions of clamp when fully opened,
6.1.2.11 Material(s),
6.1.2.12 Magnetic properties,
6.1.2.13 Torque which causes vessel laceration, and
6.1.2.14 Slip resistance.

6.1.3 *Catalog Information*—Recommendation that only the screwdriver specifically designed for the particular clamp be used (specify catalog number).

7. Keywords

7.1 cardiovascular surgical devices; carotid occlusion; clamps; disclosure; occlusions; resistance-slip; screw-type clamps

ANNEX

(Mandatory Information)

A1. APPLICABLE DOCUMENTS AND RATIONALE

A1.1 Background

A1.1.1 It is believed that the major sources for device-specific complications will result from suboptimal control of the following:

A1.1.1.1 Functional failure,

A1.1.1.2 Vessel trauma, and

A1.1.1.3 Biocompatibility.

A1.1.2 The ASTM standards listed in A1.2 were designed to prevent such possibilities.

A1.2 Referenced Documents

A1.2.1 *ASTM Standards for Materials:*[2]

F55-82 Specification for Stainless Steel Bar and Wire for Surgical Implants

F56-82 Specification for Stainless Steel Sheet and Strip for Surgical Implants

F67-83 Specification for Unalloyed Titanium for Surgical Implant Applications

F75-82 Specification for Cast Cobalt-Chromium-Molybdenum Alloy for Surgical Implant Applications

F90-82 Specification for Wrought Cobalt-ChromiumTungsten-Nickel Alloy for Surgical Implant Applications

F136-79 Specification for Wrought Titanium 6A1-4V ELI Alloy for Surgical Implant Applications

F138-82 Specification for Stainless Steel Bars and Wire for Surgical Implants (Special Quality)

F139-82 Specification for Stainless Steel Sheet and Strip for Surgical Implants (Special Quality)

F560-78 Specification for Unalloyed Tantalum for Surgical Implant Applications

F562-84 Specification for Wrought Cobalt-Nickel-Chromium-Molybdenum Alloy for Surgical Implant Applications

F563-83 Specification for Wrought Cobalt-Nickel-Chromium-Molybdenum-Tungsten-Iron Alloy for Surgical Implant Applications

F602-78 Criteria for Implantable Thermoset Epoxy Plastics

F603-83 Specification for High-Purity Dense Aluminum Oxide for Surgical Implant Application

F604-78 Classification for Silicone Elastomers Used in Medical Applications

F620-79 Specification for Titanium 6A1-4V Alloy Forgings for Surgical Implants

F621-79 Specification for Stainless Steel Forgings for Surgical Implants

F624-81 Guide for Evaluation of Thermoplastic Polyurethane Solids and Solutions for Biomedical Applications

F639-79 Specification for Polyethylene Plastics for Medical Applications

F648-83 Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants

F665-80 Classification for Vinyl Chloride Plastics Used in Biomedical Application

F688-80 Specification for Wrought Cobalt-Nickel-Chromium-Molybdenum Alloy Plate, Sheet, and Foil for Surgical Implants

F702-81 Specification for Polysulfone Resin for Medical Applications

F745-81 Specification for Stainless Steel for Cast and Solution Annealed Surgical Implant Applications

F754-83 Specification for Implantable Polytetrafluoroethylene (PTFE) Polymer Fabricated in Sheet, Tube, and Rod Shapes

F755-82 Specification for Selection of Porous Polyethylene for Use in Surgical Implants

F799-82 Specification for Thermomechanically Processed Cobalt-Chromium-Molybdenum Alloy for Surgical Implants

A1.2.2 *ASTM Standards for Finishing:*[2]

F86-76 Practice for Surface Preparation and Marking of Metallic Surgical Implants

F601-78 Practice for Fluorescent Penetrant Inspection of Metallic Surgical Implants

F746-81 Test Method for Pitting or Crevice Corrosion of Metallic Surgical Implant Materials

A1.2.3 *ASTM Standards for Biocompatibility:*[2]

F361-80 Practice for Assessment of Compatibility of Metallic Materials for Surgical Implants with Respect to Effect of Materials on Tissue[3]

F469-78 Practice for Assessment of Compatibility of Nonporous Polymeric Materials for Surgical Implants with Regard to Effect of Materials on Tissue[3]

F619-79 Practice for Extraction of Medical Plastics

F719-81 Practice for Testing Biomaterials in Rabbits for Primary Skin Irritation

F720-81 Practice for Testing Guinea Pigs for Contact Allergens: Guinea Pig Maximization Test

F748-82 Practice for Selecting Generic Biological Test Methods for Materials and Devices

[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] Withdrawn.

F749-82 Practice for Evaluating Material Extracts by Intracutaneous Injection in the Rabbit

F750-82 Practice for Evaluating Material Extracts by Systemic Injection in the Mouse

F763-82 Practice for Short-Term Screening of Implant Materials

F813-83 Practice for Direct Contact Cell Culture Evaluation of Materials for Medical Devices

A1.2.4 *ASTM Standards for Handling:*[2]

F565-78 Practice for Care and Handling of Orthopedic Implants and Instruments

F700-81 Practice for Care and Handling of Intracranial Aneurysm Clips and Instruments

F701-81 Practice for Care and Handling of Neurosurgical Implants and Instruments

A1.2.5 *ASTM Standards for Analysis:*[2]

F561-78 Practice for Retrieval and Analysis of Metallic Orthopedic Implants