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

This standard is issued under the fixed designation F 982; 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 Fig. 1):*

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.

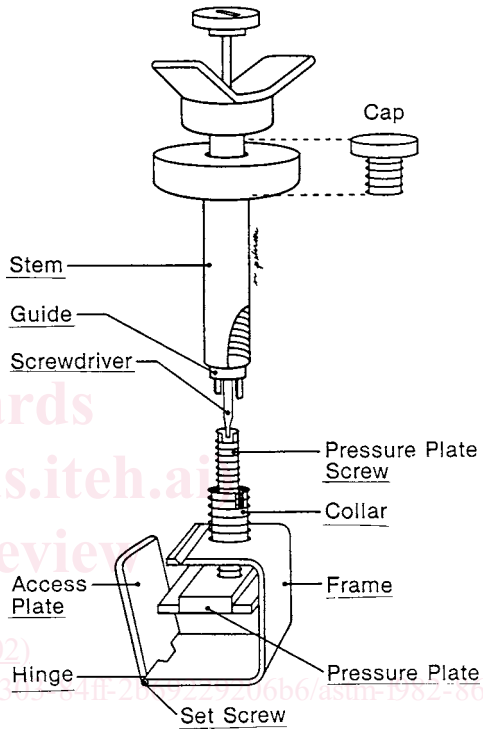

FIG. 1 Screw-Type Adjustable Clamp Components

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.

[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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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.

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