

Standard Specification for Disclosure of Characteristics of Surgically Implanted Clamps for Carotid Occlusion¹

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

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 March 27, 1986. Published May 1986.

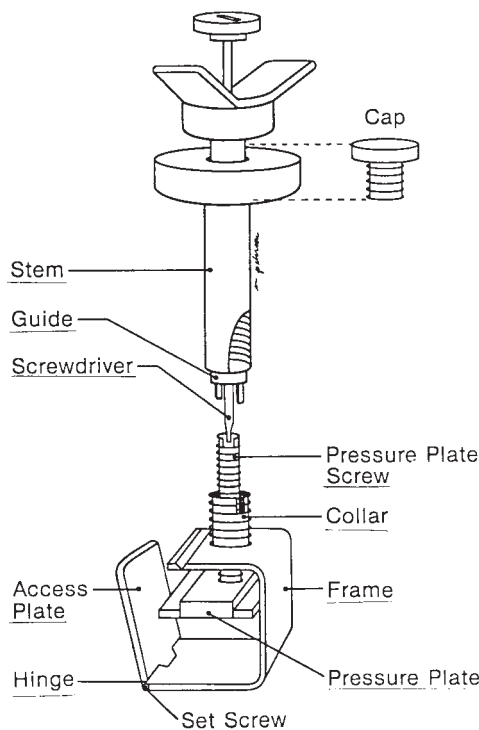


FIG. 1 Screw-Type Adjustable Clamp Components

- 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.