Designation: F700 – 93 (Reapproved 2022)

Standard Practice for Care and Handling of Intracranial Aneurysm Clips and Instruments[1]

This standard is issued under the fixed designation F700; 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 practice covers recommended procedures for handling of neurosurgical intracranial aneurysm clips and the clip appliers (instruments).

1.2 This practice is intended to inform hospital receiving personnel, central supply personnel, operating room personnel, and other individuals who will handle intracranial aneurysm clips and the instruments related thereto of recommended care and handling procedures to prevent damage of intracranial aneurysm clips and instruments.

1.3 Handling and packaging procedures for the product are not a part of this practice and are covered in other practices.

1.4 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Terminology

2.1 *Definitions:*

2.1.1 *clip applier*—any clip holder designed specifically for a particular type clip used during surgical procedures involving the implantation of intracranial aneurysm clips. This device is referred to in this practice as a clip applier.

2.1.2 *intracranial aneurysm clip*—a device introduced surgically to occlude the blood inlet into an intracranial aneurysm with the intention that it remain within the body following the surgery. This device is referred to in this practice as an "implant," specifically as an intracranial aneurysm clip.

3. Receiving Implants and Instruments

3.1 *Receipt:*

3.1.1 Many implants are wrapped in special packages, envelopes, or other containers. These wrappings should not be removed by the receiving personnel.

3.1.2 Carefully handle nonsterilized implants and instruments upon receipt to avoid scratching, marking, or abrasion by other implants, instruments, unpacking tools, or by dropping or otherwise endangering the surface finish or configuration.

3.2 *Transport*—Transport in a manner to preclude any damage or alteration to the received condition of the implant or instrument (clip applier).

3.3 *Storage:*

3.3.1 Store the aneurysm clips and appliers prior to use in such a manner to maintain the device's surface finish or configuration, or both.

3.3.2 Implants will be identified by a unique code on the surface of the device. When implanted, it is necessary that the type of aneurysm clip and its code be noted in the operative report.

3.3.3 *Stock Rotation*—The principle of first in, first out, is recommended.

3.3.4 Store implants in the operating room in such a manner as to isolate and protect the implant's surface, sterility, and configuration. Keep implants made of different metals separated.

4. Cleaning and Sterilization

4.1 Prior to resterilization and promptly following each surgical procedure, thoroughly and carefully clean all instruments and implants with approved cleaning techniques. Ultrasonic cleaners or hand scrubbing are suitable methods if carefully done. The method employed should be utilized to prevent impact, scratching, bending, or surface contact with any materials that might affect the implant or instrument configuration. Aneurysm clips must not be opened except by their specific applier.

4.2 Any clip that has been implanted or in direct contact with blood or body fluids and is not used in the procedure should not be reused in any subsequent procedure. The clips should be discarded; in accordance with tracing requirements, the manufacturer must be informed of each clip that is discarded.

[1] This practice 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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4.3 After cleaning, rinse the neurosurgical intracranial aneurysm clips and instruments completely free of all residuals including soap, detergent, or cleaning solutions and dry thoroughly. Devote special attention to hinges on the instruments and recesses on the clips since these are points that entrap both chemicals and rinse water. In so doing, the clip must not be opened except by its designated applier.

4.4 Lubricate clip appliers that require lubrication immediately after drying. Follow the recommendations of the manufacturers of such instruments explicitly as to the method, type, and amount of lubricant. Do not lubricate the clips.

4.5 Carry out sterilization by steam autoclaving or other methods in a manner that protects the integrity of the aneurysm clips and appliers.

4.6 Do not sterilize implants in contact with instruments or implants of other materials. Metallic oxide could transfer to the implant, initiating an unacceptable condition.

5. Use of Neurosurgical Intracranial Aneurysm Clips and Appliers

5.1 Open and close an aneurysm clip with the clip applier specifically manufactured to handle that particular aneurysm clip. At no time should an aneurysm clip be opened with the fingertips.

5.1.1 Any aneurysm clip that has been opened with the fingertips should be discarded and never used in a patient.

5.2 No attempt should be made to alter the configuration of preformed aneurysm clip legs or springs.

5.2.1 Dispose of intracranial aneurysm clips that exhibit surface or configuration damage.

5.2.2 Dispose of intracranial aneurysm clips whose performance capabilities have been jeopardized by mishandling or improper care.

6. Keywords

6.1 handling of implants; instruments; material handling; neurosurgical medical/devices applications