Standard Practice for Care and Handling of Neurosurgical Implants and Instruments¹

This standard is issued under the fixed designation F701; 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 neurosurgical implants and instruments.
- 1.2 This practice is intended to inform hospital receiving personnel, central supply personnel, operating room personnel, and other individuals who will handle neurosurgical implants and instruments of recommended care and handling procedures to prevent damage of neurosurgical implants and instruments.

2. Terminology

- 2.1 Definitions:
- 2.1.1 *neurosurgical implant*—for the purpose of this practice, a device introduced by surgically penetrating the skin or mucosa of the body with the intention that it remain indefinitely within the body following surgery. This device is referred to in this practice as an "implant."
- 2.1.2 neurosurgical instrument—any cooperative device used during surgical procedures involving the implantation of neurosurgical implants. This device is referred to in this practice as an "instrument."

3. Receiving Implants and Instruments

- 3.1 Receipt:
- 3.1.1 Many implants are wrapped in special sterilizable or presterilized packages, envelopes, or other containers. These wrappings should not be removed by the personnel who receive the packages.
- 3.1.2 Carefully unwrap and handle nonsterilized implants and instruments upon receipt in such a manner to avoid scratching, marking, or abrasion by other implants, instruments, unpackaging tools, or by such mishaps as 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 when received.
- 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.

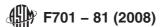
Current edition approved Feb. 1, 2008. Published March 2008. Originally approved in 1981. Last previous edition approved in 2002 as F701-81 (2002). DOI: 10.1520/F0701-81R08.

3.3 Storage:

- 3.3.1 Store implants or instruments prior to use in such a manner as to maintain the device's surface finish or configuration, or both.
- 3.3.2 Many implants are identified by a serial or lot number, or both, on the package label, package insert, or surface of the device. Record these control numbers and retain for transfer to patient records to facilitate inventory, stock rotation, and possible traceability to the manufacturer.
- 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.
- 3.3.5 Store the implants and instruments in the operating room in such a manner as to isolate the instruments from the implants.
- 3.3.6 *Mixing Metals*—Maintain neurosurgical implants and instruments of different metals separately to avoid the possibility of mixing during surgery.

4. Cleaning and Sterilization

- 4.1 Prior to initial sterilization and promptly following each surgical procedure, thoroughly and carefully clean all instruments and implants. Ultrasonic cleaners, mechanized washers, 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 surface or configuration.
- 4.2 Closely follow the manufacturer's recommendations on cleaning. In hand scrubbing, use soft brushes and avoid harsh chemicals or harsh cleaning solutions.
- 4.3 After cleaning, rinse the neurosurgical implants and instruments completely free of all residuals, soap, detergent, or cleaning solutions. Dry thoroughly after rinsing. Devote special attention to hinges, pivots, chemicals, and water.
- 4.4 Lubricate instruments that require lubrication immediately after drying. Follow the recommendations of the manufacturers of such instruments explicitly as to method, type, and amount of lubricant. Insufficient or excessive lubrication can be nearly as disastrous as no lubrication.



- 4.5 Carry out sterilization by steam autoclaving or other methods in a manner that protects the integrity of the implants and instruments.
- 4.6 Sterilize implants and instruments of polymeric materials in accordance with methods recommended by the manufacturer.
- 4.7 Do not sterilize implants in contact with instruments or implants of other materials. Metallic oxide could transfer to the implant initiating an unacceptable condition.
- 4.8 Do not expose instrument cutting edges and teeth to the hazard of dulling.

5. Contouring and Modifying Implants and Instruments

5.1 Attempts to contour an implant may alter its performance characteristics.

- 5.2 Neurosurgical instruments, in general, have a long service life, but mishandling or inadequate protection can quickly diminish the instrument's life expectancy.
- 5.3 Dispose of instruments whose performance capabilities have been jeopardized by mishandling or improper care. Dispose of neurosurgical implants that exhibit surface or configuration damage.

6. Reuse

6.1 Do not use neurosurgical implants that previously have been implanted and subsequently removed at surgery or autopsy.

7. Keywords

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

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