Designation: F 565 – 04 (Reapproved 2009)ε1

Standard Practice for Care and Handling of Orthopedic Implants and Instruments[1]

This standard is issued under the fixed designation F 565; 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.

ε1 NOTE—Units information was editorially corrected in August 2009.

1. Scope

1.1 This practice covers recommended procedures for the handling of orthopedic implants and instruments.

1.2 Hospital receiving personnel, central supply personnel, operating room personnel, surgeons, and occasionally other individuals will handle orthopedic implants and instruments. All personnel should be informed of recommended care and handling procedures to prevent damage ~~of~~to orthopedic implants and instruments.

1.3 This practice does not cover producer level handling and packaging procedures.

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1.4 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.5 *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. Terminology

2.1 *Definitions of Terms Specific to This Standard:*

2.1.1 *orthopedic implant*—a device introduced by surgically penetrating the skin or mucosa of the body with the intention that it remain within or attached to the skeleton within the body following the surgery. This device is referred to in this practice as an "implant."

2.1.2 *orthopedic instrument*—any cooperative device used during surgical procedures involving the implantation of orthopedic 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 pre-sterilized packages, envelopes, or other containers. These wrappings should not be removed by the receiving personnel.

3.1.2 Carefully unwrap and handle non-sterilized 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*—Perform transport in a manner to preclude any damage or alteration to the received condition of the implant or instrument.

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, medical device reporting, 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.

[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 F04.21 on Osteosynthesis.

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