Designation: ~~F565 – 04 (Reapproved 2018)~~ F565 – 21

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

This standard is issued under the fixed designation F565; 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~~ 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 to orthopedic implants and instruments.

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

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, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.6 *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 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.

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[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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***A Summary of Changes section appears at the end of this standard**

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 such a manner as 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 and instruments are identified by a serial ~~or~~number, lot number, ~~or both,~~ Unique Device Identification (UDI), or a data matrix on the package label, package insert, or surface of the device. Record these control numbers from implants and retain for transfer to patient ~~records,~~records to facilitate inventory, stock rotation, medical device reporting, and possible traceability to the manufacturer. If it is a reusable device, verify that the device identification number (serial number, lot number, UDI, or data matrix) on the surface of the device is legible after cleaning/sterilization cycles prior to storing.

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.

4. Handling

4.1 ~~*Mixing*~~*Separating Metals*—Maintain orthopedic implants and instruments of different metals separately to avoid the possibility of mixing during surgery.

4.2 *Cleaning and Sterilization:*

4.2.1 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.

4.2.2 Closely follow the manufacturer's recommendations on cleaning. When hand scrubbing, use soft brushes and avoid harsh chemicals or harsh cleaning solutions.

4.2.3 After cleaning, rinse the orthopedic implants and instruments completely free of all residuals, soap, detergent, or cleaning ~~solutions.~~solution. Following rinsing, dry them thoroughly. Devote special attention to hinges, pivots, box locks, and other recesses since these are points that entrap both chemicals and rinse water.

4.2.4 Lubricate instruments 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. Insufficient or excessive lubrication can be nearly as ~~disastrous~~harmful as no lubrication.

4.2.5 Carry out sterilization by steam autoclaving or other methods in a manner that protects the integrity of the implants and instruments.

4.2.6 Sterilize implants and instruments of polymeric materials in accordance with methods recommended by the manufacturer.

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

4.2.8 Do not expose instrumental cutting edges and teeth to the hazard of dulling.

4.3 *Appearance*—Dispose of orthopedic implants that exhibit surface or configuration damage.

4.4 *Contouring and Modifying Implants and Instruments:*

4.4.1 Contouring or clamping of orthopedic implants, when necessary, shall be performed by the surgeon in a manner that will cause the least damage to the implant.

4.4.2 It is recommended that metallic orthopedic implants should not be sharply bent, re-bent, angulated at a screw hole, notched, or scratched.

4.4.3 Reshaping or contouring may cause complete loss of performance for instruments. It is recommended that orthopedic instruments be handled with care to prevent costly reworking or destruction. If modifications are necessary, the instrument should not be sharply bent, re-bent, or angulated.

4.4.4 Orthopedic instruments in general have a long service life, but mishandling or inadequate protection can quickly diminish the instrument's life expectancy.

4.4.5 Dispose of instruments whose performance capabilities have been jeopardized by mishandling or improper care.

5. Reuse

5.1 Avoid the reimplantation of previously implanted orthopedic implants.

5.2 Trial fitting of an orthopedic implant in a patient, followed by proper cleaning and sterilization if not immediately implanted in the same patient, may not in all instances be considered as reimplantation. The user is cautioned that any mechanical alteration of the components (for example, plate bending), coating damage, or surface damage (for example, nicks, dents, ~~and~~or scratches) ~~should prevent~~ make the device ~~from being reimplanted.~~unsuitable for reimplantation. In addition, certain coatings (porous coating,