

Designation: F565 - 04 (Reapproved 2013) F565 - 04 (Reapproved 2018)

Standard Practice for Care and Handling of Orthopedic Implants and Instruments¹

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

- 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-safety, health, and healthenvironmental 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."

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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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