Designation: F983 – 86 (Reapproved 2013)

Standard Practice for Permanent Marking of Orthopaedic Implant Components[1]

This standard is issued under the fixed designation F983; 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 It is common practice for orthopaedic implant manufacturers to apply permanent identification to implant components. In this regard, Practice F86 describes recommended locations and methods of marking for metallic implants.

1.2 The purpose of this practice is to (*1*) recommend that orthopaedic implants be permanently marked, and (*2*) recommend practical amounts of information that should be included in the marking. It is recognized, however, that marking is not practical in some cases (see 4.1).

1.3 *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. Referenced Documents

2.1 *ASTM Standards:*[2]

F86 Practice for Surface Preparation and Marking of Metallic Surgical Implants

3. Methods of Marking

3.1 For metallic implants, the procedures described in Practice F86 should be followed.

3.2 For nonmetallic implants, other methods should be devised and utilized.

3.3 In any case, however, the marking method should (*a*) not compromise implant performance significantly, and (*b*) provide legibility over the anticipated service life of the implant.

4. Information Included in Permanent Marking

4.1 Orthopaedic implants vary widely in size (for example, from wire to total joint prostheses), and the amount of information that practically can be included in marking varies accordingly. Some implants, such as threaded pins and cerclage wire and very small bone screws, do not provide any surfaces which can be marked practically.

4.2 *Standard Information*—Where implant size and shape allow, it is recommended that the following information be included in permanent marking:

4.2.1 *Manufacturer:*

4.2.2 *Material*—The use of generic names or ASTM standards, or both, in addition to or in place of trade names is recommended, where applicable.

4.2.3 Implant component catalog number or model number.

4.2.4 Implant component serial number or lot number.

4.3 *Minimum Information*—Where implant size and shape allow, it is recommended that the manufacturer mark smaller implants with symbols or letters selected by the manufacturer which identify (*a*) the manufacturer and (*b*) the material from which the component is made. The system of symbols or letters should be described in the manufacturer's product literature.

4.4 *Optional Information*—Manufacturers may wish to include additional information in the permanent marking, indicating, for example, implant size and whether an implant is intended for right limb or left limb reconstruction.

---

[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.

Current edition approved Oct. 1, 2013. Published October 2013. Originally approved in 1986. Last previous edition approved in 2009 as F983 – 86(2009). DOI: 10.1520/F0983-86R13.

[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

APPENDIX

(Nonmandatory Information)

X1. RATIONALE

X1.1 The intent of this practice is to provide needed information to users of orthopaedic implants under two different circumstances. First, many implants are removed from their packages outside the operating room long before surgery takes place, so that they may be sterilized or otherwise prepared for use. Permanent, readily understood marking will provide for positive identification of the implants under such circumstances. Second, when an implant is surgically removed, positive identification is desirable information for deciding the course of subsequent patient care and for purposes of research in implant utilization and performance.