



Designation: F983 – 86 (Reapproved 2018)

# Standard Practice for Permanent Marking of Orthopaedic Implant Components<sup>1</sup>

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 ( $\epsilon$ ) 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, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.4 *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. Referenced Documents

2.1 *ASTM Standards:*<sup>2</sup>

F86 Practice for Surface Preparation and Marking of Metallic Surgical Implants

<sup>1</sup> 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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<sup>2</sup> For referenced ASTM standards, visit the ASTM website, [www.astm.org](http://www.astm.org), or contact ASTM Customer Service at [service@astm.org](mailto:service@astm.org). For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

## 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.