Designation: F 86 – 01

Standard Practice for Surface Preparation and Marking of Metallic Surgical Implants[1]

This standard is issued under the fixed designation F 86; 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.

This standard has been approved for use by agencies of the Department of Defense.

1. Scope*

1.1 This practice provides a description of surface characteristics, methods of surface preparation, and methods of marking for metallic surgical implants. Marking nomenclature is not specified in this practice. Surface requirements and marking methods included in the implant specification shall take precedence over requirements listed in this practice, where appropriate.

1.2 *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:*

A 380 Practice for Cleaning and Descaling Stainless Steel Parts, Equipment, and Systems[2]

A 967 Specification for Chemical Passivation Treatments for Stainless Steel Parts[2]

B 600 Guide for Descaling and Cleaning Titanium and Titanium Alloy Surfaces[3]

F 983 Practice for Permanent Marking of Orthopaedic Implant Components[4]

3. Significance and Use

3.1 The surface treatments documented in this specification are intended to improve the corrosion resistance of metallic surgical implants manufactured from iron, cobalt, titanium, and tantalum base materials.

3.2 Iron particles, ceramic media, and other foreign particles may become smeared over or imbedded into the surface of implants during processing operations such as forming, machining, tumbling, bead blasting, and so forth. These particles should be removed to minimize localized rust formation and superficial blemishes.

3.3 The various chemical and electrochemical surface treatments specified in this standard are intended to remove objectionable surface contaminants and to restore maximum corrosion resistance to the passive oxide film.

3.4 The need for an additional implant surface treatment such as secondary passivation in nitric acid should be evaluated for localized implant surfaces that have electrochemical or laser product markings created after the final surface treatment.

4. Description of Acceptable Surface Characteristics

4.1 Metallic implants, when inspected in accordance with this practice, shall be free of surface imperfections such as toolmarks, nicks, scratches, cracks, cavities, burrs, and other defects that would impair the serviceability of the device. The surfaces shall be cleaned to minimize the presence of foreign material.

4.2 Specific finish requirements such as texture, surface roughness, or additional surface treatments shall be included in the implant production specification.

4.3 The implants shall be given a final surface treatment according to Section 7.

5. Cleaning

5.1 The surface of the implants shall be cleaned to minimize foreign material.

5.2 The cleaning operations used shall relate to the following as appropriate:

5.2.1 A method such as organic solvent degreasing for the removal of oils, greases, and other loose surface contaminants.

[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 F04.12 on Metallurgical Materials.

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[2] *Annual Book of ASTM Standards*, Vol. 01.03.

[3] *Annual Book of ASTM Standards*, Vol. 02.04.

[4] *Annual Book of ASTM Standards*, Vol. 13.01.

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