Designation: F86 – 21

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

This standard is issued under the fixed designation F86; 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 provides descriptions of surface characteristics, surface preparation, and marking for metallic surgical implants, with the purpose of improving the corrosion resistance of the implant surfaces and markings.

1.2 Marking nomenclature and neutralization of endotoxin are not specified in this practice (see X1.4).

1.3 Surface requirements and marking methods included in the implant specification shall take precedence over requirements listed in this practice, where appropriate.

1.4 The values stated in either SI units or inch-pound units are to be regarded separately as standard. The values stated in each system may not be exact equivalents; therefore, each system shall be used independently of the other. Combining values from the two systems may result in nonconformance with the 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. Referenced Documents

2.1 *ASTM Standards:*[2]

A380/A380M Practice for Cleaning, Descaling, and Passivation of Stainless Steel Parts, Equipment, and Systems

A967/A967M Specification for Chemical Passivation Treatments for Stainless Steel Parts

B600 Guide for Descaling and Cleaning Titanium and Titanium Alloy Surfaces

B912 Specification for Passivation of Stainless Steels Using Electropolishing

E2148 Guide for Using Documents Related to Metalworking or Metal Removal Fluid Health and Safety

E2275 Practice for Evaluating Water-Miscible Metalworking Fluid Bioresistance and Antimicrobial Pesticide Performance

E2657 Practice for Determination of Endotoxin Concentrations in Water-Miscible Metalworking Fluids

F748 Practice for Selecting Generic Biological Test Methods for Materials and Devices

F983 Practice for Permanent Marking of Orthopaedic Implant Components

2.2 *ISO Standard:*[3]

ISO 10993-11:2017 Biological Evaluation of Medical Devices—Part 11: Tests for Systemic Toxicity, Annex G

2.3 *USP Standard:*[4]

USP General Chapter <161> Medical Devices—Bacterial Endotoxin and Pyrogen Tests (2019)

2.4 *FDA Document:*[5]

FDA Guidance for Industry: Pyrogens and Endotoxins Testing: Questions and Answers, 2012 (updated in 2019)

2.5 *AAMI Standard:*[6]

AAMI ST72:2019 Bacterial endotoxins—Test methods, routine monitoring, and alternatives to batch testing

3. Significance and Use

3.1 The objective of surface treatments as documented in this practice is to improve the corrosion resistance of metallic

[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] 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.

[3] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

[4] Available from U.S. Pharmacopeial Convention (USP), 12601 Twinbrook Pkwy., Rockville, MD 20852-1790, http://www.usp.org.

[5] Available from U.S. Food and Drug Administration (FDA), 10903 New Hampshire Ave., Silver Spring, MD 20993, http://www.fda.gov.

[6] Available from Association for the Advancement of Medical Instrumentation (AAMI), 4301 N. Fairfax Dr., Suite 301, Arlington, VA 22203-1633, http://www.aami.org.

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

surgical implants including, but not limited to, those manufactured from iron, cobalt, nickel, titanium, and tantalum base materials.

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

3.3 The various chemical and electrochemical surface treatments specified by this practice are used to remove objectionable surface contaminants and to restore maximum corrosion resistance to, or promote the creation of, an inert or passive surface, such as a metal oxide film, as is applicable to the specific material. Some of these treatments are referred to as passivation treatments. The preferred surface treatment for a given application varies depending on the implant material and the nature of the surface contaminants.

3.4 Depending on the implant, its material, and the type of marking method and procedure, the marking may be applied before or after a chemical or electrochemical surface treatment. When marking is performed after the surface treatment, the localized implant surface shall be evaluated to determine if there is a need for additional surface treatment.

NOTE 1—The need for additional surface treatment is likely for stainless steel with all marking methods, and for nonferrous alloys when the marking method involves direct or second-hand contact with iron-based or other material that would be considered an objectionable surface contaminant.

3.5 The selection of procedures to be applied to the implants, and additional requirements which are not covered by this practice, may be included in the implant production specification.

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 tool marks, 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 an appropriate surface treatment according to Section 6.

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.

NOTE 2—Anhydrous methanol and other solvents known to cause environmentally assisted cracking of titanium and its alloys should be avoided.

5.2.2 A method such as one of the following for the removal of adherent foreign material, if necessary:

5.2.2.1 Hot alkaline cleaner, used as recommended.

5.2.2.2 Alkaline cleaner applied electrochemically as recommended.

NOTE 3—Avoid cathodic cleaning of metals known to be susceptible to hydrogen contamination and anodic cleaning of metals known to be susceptible to pitting.

5.2.2.3 Ultrasonically agitated cleaning agent.

5.2.3 An acidic cleaning process may be used. For titanium, titanium alloys, and tantalum, some possible cleaning processes may be found in Guide B600.

NOTE 4—Before an acidic cleaning, degreasing shall be considered where appropriate to make the acidic cleaning effective in a uniform manner. In addition, testing to confirm that acidic cleaning will not affect the mechanical properties of materials susceptible to hydrogen contamination effects, either with or without a relief bake, should be considered.

5.2.3.1 If acidic cleaning methods are used, this shall be stated in the implant production specification.

5.3 A neutralizing treatment shall be carried out where appropriate.

5.4 An adequate rinsing operation shall be carried out.

5.5 An adequate drying cycle shall follow.

6. Surface Treatment

6.1 Implants shall be given a surface treatment before they are packaged in order to create, restore, promote, or otherwise ensure a passive surface. The surface treatment used should be specified in the production procedure documentation. A number of different surface treatments may be acceptable including, but not limited to, acid treatment, electropolishing, anodizing, and oxidation. The following surface treatments are provided as examples, and this list should not be considered restrictive:

NOTE 5—While this standard does not specify endotoxin neutralization, the manufacturer is responsible for appropriate monitoring and control of endotoxin in cleaning and treatment baths, post-treatment testing for the presence of endotoxin and other residual contaminants that may present biological hazards, and the elimination of such as appropriate. See X1.4.

6.2 Certain acid treatments for the removal of surface free iron can provide passive surface conditions for stainless steel, and also for nonferrous metals and alloys that possess or may possess iron contamination on the implant surface. Such treatments provide passivation by surface oxidation and are able to dissolve certain foreign material that might be present from previous operations; they are, therefore, particularly recommended when no other treatments that would remove such foreign material take place. (See X1.3, Specification A967/A967M, and Practice A380/A380M.)

6.2.1 Example acid surface treatments are as follows:

6.2.2 Immerse in a 20 to 45 volume % nitric acid solution, at a temperature range from 20 to 30 °C [70 to 90 °F], for a minimum of 30 min. This passivation treatment is equivalent to the Nitric 2 treatment in Specification A967/A967M.

6.2.3 For an accelerated process, a 20 to 25 volume % nitric acid solution, heated at a temperature range from 50 to 60 °C [120 to 140 °F], may be used for a minimum of 20 min. This passivation treatment is equivalent to the Nitric 3 treatment in Specification A967/A967M.

6.2.4 Other combinations of temperature and time using nitric acid, with or without other chemical additives, may be viable as well.

6.2.5 Use a neutralizing procedure for product designs in which acidic liquid could be trapped.

6.2.6 A thorough water rinsing process and a drying process are essential.

6.3 An electropolishing procedure can provide passive surface conditions and cleansing from certain foreign material for iron, cobalt, nickel, titanium, and tantalum base materials (see Specification A967/A967M or Specification B912).

6.4 Electrochemical anodizing processes for titanium and tantalum base materials can provide passivating and cleaning effects similar to those produced by electrochemical polishing procedures. Alternative oxidation treatments can render passive surfaces as well. Some possible surface treatment processes may be found in Guide B600.

7. Product Marking

7.1 Markings are applied to the implant surfaces to provide traceability, if the size and configuration of the implant are sufficient for such markings. To minimize potential adverse effects, it is necessary to use an appropriate marking procedure and technique, to select a suitable location for the marking of the implant, and to perform a surface treatment prior to marking, after marking, or both, as appropriate.

7.1.1 Recommendations on the informational content of markings are found in Practice F983.

7.2 Identify or label metallic implants in a manner that will minimize potential impairment of the mechanical properties and corrosion resistance, and will not elicit an adverse tissue response.

7.3 Locate the marking or labeling on the implant at a point of low stress in such a manner as not to intersect the edges of drilled holes, countersinks, or the edges of the implant. Indicate the location of the marking on the manufacturing drawing of the implant.

7.4 The marking nomenclature shall be documented.

7.5 Some methods of marking are as follows (this list should not be considered restrictive):

7.5.1 Mechanical imprinting of round-bottom and round-edge characters,

7.5.2 Chemical etching using an anodic electrolytic procedure,

7.5.3 Marking with a round rotating burr under low-contact pressure,

7.5.4 Casting of markings into the surface using round-edge and round-bottom characters,

7.5.5 Marking with vibrator-type contact,

7.5.6 Electro-pencil marking, and

7.5.7 Marking with a laser beam.

8. Inspection

8.1 The surfaces of the finished implants, at least of representative samples from a production lot, shall be inspected using visual examination with the unaided eye (with vision corrected if necessary). Other surface inspection methods at least as selective as unaided visual examination may be used, and also may be included in the implant production specification, in addition to or instead of unaided visual examination.

NOTE 6—Some methods to evaluate corrosion resistance and check for the presence of surface iron can be found in Specification A967/A967M.

9. Keywords

9.1 alkaline cleaners; cleaning; electropolishing; final inspections; markings; metal implants; passivation; surface treatments

APPENDIX

(Nonmandatory Information)

X1. RATIONALE AND ADDITIONAL INFORMATION

X1.1 The surface treatment and marking of implants can influence the following: local tissue response, bonding or lack of bonding to tissues as indicated by the application, and fatigue strength of implants.

X1.2 Local tissue response of metallic implants is affected by corrosion that, in turn, may be affected by embedded foreign particles and other factors. Foreign material on the surfaces as a result of manufacturing operations may jeopardize the compatibility even in the absence of corrosion, or may affect contacting implant components. Specifications and control of surface characteristics to inhibit local undesirable tissue response are therefore required.

X1.3 *Acid Passivation of Nonferrous Alloys*—Nonferrous metals and alloys do not inherently require an acid passivation treatment, such as that described by Specification A967/A967M for stainless steel, in order to possess or form an acceptable surface according to the requirements of this standard. However, exogenous surface contamination in the form of free iron (for example, due to contact with steel tooling) may develop into surface rust if not removed. Nonferrous parts with known or potential free iron contamination may be treated and tested according to Specification A967/