Designation: F86 – 13

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.

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 and neutralization of endotoxin are not specified in this practice (see X1.3). Surface requirements and marking methods included in the implant specification shall take precedence over requirements listed in this practice, where appropriate.

1.2 The values stated in inch-pound units are to be regarded as standard. The values given in parentheses are mathematical conversions to SI units that are provided for information only and are not considered standard.

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]

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

A967 Specification for Chemical Passivation Treatments for Stainless Steel Parts

B600 Guide for Descaling and Cleaning Titanium and Titanium Alloy Surfaces

F983 Practice for Permanent Marking of Orthopaedic Implant Components

3. Significance and Use

3.1 The surface treatments documented in this practice 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 practice 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 an appropriate final 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 1—Anhydrous methanol and other solvents known to cause

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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.

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

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 2—Avoid cathodic cleaning of metals known to be susceptible to hydrogen contamination and anodic cleaning of metals known to be susceptible to pitting. In addition, testing to confirm that acidic cleaning will not affect the mechanical properties of alloys susceptible to hydrogen contamination effects should be considered .

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 3—Before an acidic cleaning, degreasing shall be considered where appropriate to make the acidic cleaning effective in a uniform manner.

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. Final Surface Treatment

6.1 Implants shall be given a final surface treatment before they are packaged. A number of different surface treatments are acceptable, including acid treatment, electropolishing, anodizing, and oxidation. The following surface treatments should not be considered restrictive:

6.2 Final nitric acid surface treatments are as follows:

6.2.1 Immerse in 20 to 45 volume % nitric acid at room temperature for a minimum of 30 min. The room temperature passivation treatment is equivalent to the Nitric 2 treatment at a temperature range from 70 to 90°F (21 to 32°C) in Specification A967. For an accelerated process, a 20 to 25 volume % acid solution, heated at a temperature in the range from 120 to 140°F (49 to 60°C), may be used for a minimum of 20 min. (See Specification A967 and Practice A380).

6.2.1.1 This treatment provides passivation by surface oxidation and is able to dissolve certain foreign material that might be present from previous operations; it is therefore particularly recommended when no other treatments take place that would remove such foreign material.

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

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

6.3 A final electropolishing procedure can provide passive surface conditions and cleansing from certain foreign material for stainless steel, cobalt, titanium, and tantalum alloys (see Specification A967).

6.4 Electrochemical anodizing processes for titanium and tantalum base materials can provide similar passivating and cleaning effects as the electrochemical polishing procedures have. Alternative oxidation treatments can render passive surfaces as well.

6.5 If acceptable alternative surface treatments for implants are used, these treatments should be specified in the production procedure documentation.

6.6 If marking of implants is performed after the final surface treatment, it must be evaluated whether a secondary passivation treatment is necessary or not.

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 and to select a suitable location for the marking of the implant.

7.1.1 Details on marking are found in Practice F983.

7.2 Identify or label metallic implants in a manner that will minimize potential impairment of the mechanical properties or corrosion resistance and will not elicit 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 edges of implants. 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:

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 laser beam.

7.6 Depending on the implant, its material, and the type of marking method and procedure, the marking may be applied before or after the final surface treatment. (See 6.6).

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 in addition to or instead of unaided visual examination.

9. Keywords

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

APPENDIX

(Nonmandatory Information)

X1. RATIONALE

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 Limited studies have indicated the nitric acid passivation treatments specified in this practice can neutralize endotoxin[3,4] left on an implant surface, while other passivation treatments (such as those referenced in Specification A967) cannot or have not been evaluated for this. In light of this information, it is imperative that the implant manufacturer observe the intended purposes of processes specified in this practice, such as described in Section 3, and note that neutralization of endotoxin is not among them. There are many different processes that can neutralize endotoxin, and fulfill other purposes, some of which have been published.[3,4] This practice does not currently include biological contaminants in its scope.

X1.4 The fatigue strength of implants is affected by the topography of the surfaces, residual stresses, and structure. The fatigue strength of a component may be determined experimentally. Therefore, to evaluate or test the fatigue strength of finished implants, they should have surface structures, residual stresses, surface treatments, and other characteristics that are representative of the manufacturing process by which the implant is produced.

[3] Merritt, K., Brown, S. A., Hitchins, V. M., "Ability of Nitric Acid or Acetone to Inactivate Bacterial Lipopolysaccharide (LPS)," *Tra Society for Biomaterials* , Vol 25, 2002, p. 339.

[4] Hitchins, V. M. and Merritt, K., "Decontaminating Particles Exposed to Bacterial Endotoxin (LPS)," *J Biomed Mater Res*, Vol 46, 1999, pp. 434–437.

SUMMARY OF CHANGES

Committee F04 has identified the location of selected changes to this standard since the last issue (F86 – 12a) that may impact the use of this standard. (Approved June 1, 2013.)

(1) Removed incorrect nitric acid specific gravity wording.