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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.

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, etc. These particles should be removed in order 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 employed 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 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 should be considered to confirm that acidic cleaning will not affect the mechanical properties of alloys susceptible to hydrogen contamination effects.

5.2.2.3 Ultrasonically agitated cleaning agent.

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[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.

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5.2.3 An acidic cleaning process may be employed. For titanium, titanium alloys and tantalum some possible cleaning processes may be found in Practice B 600.

NOTE 3—Prior to an acidic cleaning, degreasing shall be considered where appropriate, in order 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. Product Marking

6.1 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.

6.1.1 Details on marking are found in Practice F 983.

6.2 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.

6.3 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.

6.4 The making nomenclature shall be documented.

6.5 Some methods of marking are as follows:

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

6.5.2 Chemical etching using an anodic electrolytic procedure,

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

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

6.5.5 Marking with vibrator-type contact,

6.5.6 Electro-pencil marking, and

6.5.7 Marking with laser beam.

6.6 Depending on the implant, its material, and the type of marking method and procedure, the marking may be applied prior to or after the final surface treatment. (See 7.4).

7. Final Surface Treatment

7.1 Implants shall be given a final surface treatment before they are packaged.

7.2 Final surface treatments for materials specified under section 2.1 are as follows:

7.2.1 Immerse in 20 to 45 volume % nitric acid (specific gravity 1.1197 to 1.285) at room temperature for a minimum of 30 min. For an accelerated process, a 20 to 25 % acid solution, heated at 120 to 140°F (40 to 60°C), may be used for a minimum of 20 min. (See Specification A 967 and Practice A 380).

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.

7.2.2 Employ a neutralizing procedure for product designs where acidic liquid could be trapped.

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

7.3 Alternatively, for stainless steel and cobalt alloys a final electropolishing procedure can provide passive surface conditions and cleansing from certain foreign material (see Specification A 967).

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

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

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

8. Inspection

8.1 The surfaces of the finished implants, at least representative samples of a production lot, shall be inspected using visual examination with the unaided eye (but corrected where necessary). Other surface inspection methods may be used in addition.

9. Keywords

9.1 alkaline cleaner; cleaning; electropolishing; final inspection; marking; metal implants; passivation; surface treatment

APPENDIX

(Nonmandatory Information)

X1. RATIONALE

X1.1 The surface treatment and marking of implants can influence the following important qualities: 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 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 which are representative of the manufacturing process by which the implant is produced.

SUMMARY OF CHANGES

(*1*) The discontinued standards (F 55, F 56, F 642, F 643, F 644, and F 666), were removed from the Referenced Documents section during the F 86-00 revision. The balance of the metallic implant material standards previously included in the Referenced Documents section have been deleted since they were not mentioned in the text and it is considered impractical to revise this document every time a new metallic implant material standard is published. Paragraph 3.1 documents that this standard is applicable for metallic surgical implants manufactured from iron, cobalt, titanium, and tantalum base materials.

(*2*) The different sections of the standard have been rearranged in a logical order, and the section on Final Surface Treatment has been slightly extended in consideration of the increased use of titanium materials.

(*3*) The passivation treatment in clause 7.2.1 has been adjusted to agree with the latest version of A 967.

(*4*) The information specified in 7.3 was previously changed in the F 86-00 revision to omit the nitric acid rinse required after electropolishing since it is recognized that electropolishing is a satisfactory passivation treatment.

(*5*) A Significance and Use section has been added to this standard in accordance with form and style guidelines for ASTM Practices and Guides.

(*6*) The statement “This standard has been approved for use by agencies of the Department of Defense” has been deleted.

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