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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.

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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] 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.**

4.3 The implants shall be given an appropriate final surface treatment according to Section ~~7~~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 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.Product Marking**~~

~~6.1Markings 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.~~

~~6.1.1Details on marking are found in Practice F983.~~

~~6.2Identify 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.~~

~~6.3Locate 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.~~

~~6.4The marking nomenclature shall be documented.~~

~~6.5Some methods of marking are as follows:~~

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

~~6.5.2Chemical etching using an anodic electrolytic procedure,~~

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

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

~~6.5.5Marking with vibrator-type contact,~~

~~6.5.6Electro-pencil marking, and~~

~~6.5.7Marking with laser beam.~~

~~6.6Depending 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 7.6).~~

~~**7.**~~

6. Final Surface Treatment

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

~~7.2Final surface treatments are as follows:~~

~~7.2.1Immerse 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 to 120 to 140°F (49 to 60°C), may be used for a minimum of 20 min. (See Specification~~

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 (specific gravity 1.1197 to 1.285) at room temperature for a minimum of 30 min. The room temperature passivation treatment is equivalent to the Nitric 2 treatment at 70 to 90°F (21 to 32°C) in Specification