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Designation: F 86 – 00~~0~~1

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:*

[1] This practice is under the jurisdiction of ASTM Committee ~~F-4~~ F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.12 on Metallurgical Materials.

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

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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 67 Specification~~ 983 Practice ~~for Unalloyed Titanium for Surgical Implant Applications[4]~~
~~F 75 Specification for Cast Cobalt-Chromium-Molybdenum Alloy for Surgical Implant Applications[4]~~
~~F 90 Specification for Wrought Cobalt-20 Chromium-15 Tungsten-10 Nickel Alloy for Surgical Implant Applications (UNS R30605)[4]~~
~~F 136 Specification for Wrought Titanium-6 Aluminium-4 Vanadium ELI (Extra Low Interstitials) Alloy (R56401) for Surgical Implant Applications[4]~~
~~F 138 Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants[4]~~
~~F 139 Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Sheet and Strip for Surgical Implants (UNS 531673)[4]~~
~~F 560 Specification for Unalloyed Tantalum for Surgical Implant Applications[4]~~
~~F 562 Specification for Wrought Cobalt-35 Nickel-20 Chromium-10 Molybdenum Alloy for Surgical Implant Applications[4]~~
~~F 563 Specification for Wrought Cobalt-Nickel-Chromium-Molybdenum-Tungsten-Iron Alloy for Surgical Implant Applications[4]~~
~~F 620 Specification for Titanium-6 Aluminium-4 Vanadium ELI Alloy Forgings for Surgical Implants (UNS R56401)[4]~~
~~F 621 Specification for Stainless Steel Forgings for Surgical Implants~~
~~F 688 Specification for Wrought Cobalt-35 Nickel-20 Chromium-10 Molybdenum Alloy Plate, Sheet, and Foil for Surgical Implants[4]~~
~~F 745 Specification for 18 Chromium-12.5 Nickel-2.5 Molybdenum Stainless Steel for Cast and Solution-Annealed Surgical Implant Applications[4]~~
~~F 799 Specification for Cobalt-28 Chromium-6 Molybdenum Alloy for Surgical Implants (UNS R31537)[4]~~
~~F 961 Specification for Cobalt-35 Nickel-20 Chromium-10 Molybdenum Alloy Forgings for Surgical Implants (UNS R30035)[4]~~
~~F 983 Practice for~~ Permanent Marking of Orthopaedic Implant Components
~~F 1058 Specification for Wrought Cobalt-Chromium-Nickel-Molybdenum-Iron Alloy for Surgical Implant Applications[4]~~
~~F 1091 Specification for Wrought Cobalt-20 Chromium-15 Tungsten-10 Nickel Alloy Surgical Fixation Wire (UNS R30605)~~
~~F 1108 Specification for Titanium-6 Aluminium-4 Vanadium Alloy Castings for Surgical Implants (UNS R56406)[4]~~
~~F 1295 Specification for Wrought Titanium-6 Aluminium-7 Niobium Alloy for Surgical Implant Applications (UNS R56700)[4]~~
~~F 1314 Specification for Wrought Nitrogen Strengthened-22 Chromium-12.5 Nickel-5 Manganese-2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants[4]~~
~~F 1341 Specification for Unalloyed Titanium Wire for Surgical Implant Applications[4]~~
~~F 1350 Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Surgical Fixation Wire (UNS S31673)[4]~~
~~F 1472 Specification for Wrought Titanium-6 Aluminium-4 Vanadium Alloy for Surgical Implant Applications (UNS R56400)[4]~~
~~F 1537 Specification for Wrought Cobalt-28 Chromium-6 Molybdenum Alloy for Surgical Implants[4]~~
~~F 1586 Specification for Wrought Nitrogen Strengthened-21 Chromium-10 Nickel-3 Manganese-2.5 Molybdenum Stainless Steel Bar for Surgical Implants[4]~~
~~F 1713 Standard Specification for Wrought Titanium-13 Niobium-13 Zirconium Alloy for Surgical Implant Applications[4]~~
~~F 1813 Specification for Wrought Titanium-12 Molybdenum-6 Zirconium-2 Iron Alloy for Surgical Implant Applications[4]~~

[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.

3. ~~Description of Acceptable Surface Characteristics~~

~~3.1 Metallic implants, when inspected~~Significance and Use

3.1 The surface treatments documented in ~~accordance with~~ this ~~practice, shall be free~~ specification are intended to improve the corrosion resistance of ~~surface imperfections such as toolmarks, nicks, scratches, cracks, cavities, burrs,~~ metallic surgical implants manufactured from iron, cobalt, titanium, and tantalum base materials.

3.2 Iron particles, ceramic media, and other ~~defects that would impair~~ foreign particles may become smeared over or imbedded into the ~~serviceability~~ surface of ~~the device. The surfaces shall~~ implants during processing operations such as forming, machining, tumbling, bead blasting, and so forth. These particles should be ~~cleaned~~ removed to minimize ~~the presence of foreign material.~~

~~3.2 Specific finish requirements such as texture,~~ localized rust formation and superficial blemishes.

3.3 The various chemical and electrochemical surface ~~roughness, or additional surface~~ treatments ~~shall be included~~ 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 ~~production specification.~~

~~3.3 The implants shall~~ surface treatment such as secondary passivation in nitric acid should be ~~g~~ evaluated for localized implant surfaces that have electrochemical or laser product markings created after the final surface ~~treatment according to Section 6.~~ 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

~~4~~5.1 The surface of the implants shall be cleaned to minimize foreign material.

~~4~~5.2 The cleaning operations ~~employed~~ used shall relate to the following as appropriate:

~~4~~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.

~~4~~5.2.2 A method such as one of the following for the removal of adherent foreign material, if necessary.

~~4~~5.2.2.1 Hot alkaline cleaner used as recommended.

~~4~~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.

~~4~~5.2.2.3 Ultrasonically agitated cleaning agent.

~~4~~5.2.3 An acidic cleaning process may be ~~employed.~~ used. For titanium, titanium alloys, and tantalum, some possible cleaning processes may be found in Practice B 600.

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

~~4~~5.2.3.1 If acidic cleaning methods are used, this shall be stated in the implant production specification.

~~4~~5.3 A neutralizing treatment shall be carried out where appropriate.

~~4~~5.4 An adequate rinsing operation shall be carried out.

~~4~~5.5 An adequate drying cycle shall follow.

~~5. Product Marking~~

~~5.1 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.~~

~~5.1.1 Details on marking are found in Practice F 983.~~

~~5.2 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.~~

~~5.3 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.~~

~~5.4 The making nomenclature shall be documented.~~

~~5.5 Some methods of marking are as follows:~~

5.5.1 Mechanical imprinting of round-bottom and round-edge characters,
5.5.2 Chemical etching using an anodic electrolytic procedure,
5.5.3 Marking with a round rotating burr under low-contact pressure,
5.5.4 Casting of markings into the surface using round-edge and round-bottom characters,
5.5.5 Marking with vibrator-type contact,
5.5.6 Electro-pencil marking, and
5.5.7 Marking with laser beam.
5.6 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 6.4).

6. Final Surface Treatment

6.1 Implants shall be given a final surface treatment before theyProduct Marking
6.1 Markings are packaged.
6.2 Final surface treatments for materials specified under section 2.1 are as follows:
6.2.1 Immerse in 20 applied to 45 volume % nitric acid (specific gravity 1.1197 the implant surfaces to 1.285) at room temperature for a minimum provide traceability if the size and configuration of 30 min. For the implant are sufficient for such markings. To minimize potential adverse effects, it is necessary to use an accelerated process, a 20 appropriate marking procedure and technique and to 25 % acid solution, heated at 120 to 140°F (40 to 60°C), may be used for select a minimum suitable location for the marking of 20 min. (See Specification A 967 and the implant.
6.1.1 Details on marking are found in Practice A 380).
This treatment provides passivation by surface oxidation, and is able to dissolve certain foreign material F 983.
6.2 Identify or label metallic implants in a manner that might be present from previous operations; it is therefore particularly recommended when no other treatments take place that would remove 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 foreign material.
6.2.2 Employ a neutralizing procedure for product designs where acidic liquid could 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 marking nomenclature shall be trapped.
6.2.3 A thorough water rinsing process and a drying process documented.
6.5 Some methods of marking are essential.
6.3 Alternatively, for stainless steel as follows:
6.5.1 Mechanical imprinting of round-bottom and cobalt alloys round-edge characters,
6.5.2 Chemical etching using an anodic electrolytic procedure,
6.5.3 Marking with a final electropolishing procedure can provide passive round rotating burr under low-contact pressure,
6.5.4 Casting of markings into the surface conditions using round-edge and cleansing from certain foreign material (see Specification A 967).
6.4 For titanium base materials electrochemical anodizing processes can provide similar passivating and cleaning effects as 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 electrochemical polishing procedures have. Alternative oxidation treatments can render passive surfaces as well.
6.5 If alternative surface treatments for implants are used, these treatments should be specified in implant, its material, and the production procedure documentation.
6.6 If marking type of implants is performed marking method and procedure, the marking may be applied before or after the final surface treatment, it must be evaluated whether a secondary passivation treatment is necessary or not. treatment. (See 7.6).

7. Final Surface Treatment

7.1 Implantsp shall be given a final surface ttreatment before they are packaged.
7.2 Final surface treatments are as follows:
7.2.1 ThImmerse in 20 to 45 volume % nitrfic aceid (specific gravity 1.1197 to 1.285) at room temperature for a minimum of the finished implants, 30 min. For an accelerated process, a 20 to 25 % acid solution, heated at least representative samples 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 Use a production lot, shall neutralizing procedure for product designs in which 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 ~~u~~ cobalt alloys, a final electropolishing procedure can provide passive surface conditions and cle~~x~~ansing from certain foreign material (see Specification ~~w~~ A 967).

7.4 For titanium base materials, electrochemical anodizing processes can provide similar passivating and cleaning effects as the ~~unaided eye (but corrected where necessary). Other~~ electrochemical polishing procedures have. Alternative oxidation treatments can render passive surfaces as well.

7.5 If alternative surface ~~inspection methods may~~ treatments for implants are used, these treatments should be ~~u~~ 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

8~~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~~ that are representative of the manufacturing process by which the implant is produced.

SUMMARY OF CHANGES

(*1*) ~~At the occasion of the revision of this standard the titles of~~) The discontinued standards ~~have been removed~~ (F 55, F 56, F 642, F 643, F 644, ~~F 666), while on~~ and F 666) were removed from the ~~other hand~~ Referenced Documents section during the ~~list~~ F 86-00 revision. The balance of the metallic implant material standards previously included in the Referenced Documents ~~has~~ section have been ~~updated with~~ 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 ~~revised titles.~~ 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 6.2.1~~ 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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