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.

Designation: F746 – 04 (Reapproved 2021)

Standard Test Method for Pitting or Crevice Corrosion of Metallic Surgical Implant Materials[1]

This standard is issued under the fixed designation F746; 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 test method covers the determination of resistance to either pitting or crevice corrosion of metals and alloys from which surgical implants will be produced. It is a modified version of an established test[2] and is used as a screening test to rank surgical implant alloys in order of their resistance to localized corrosion.

1.2 This test method applies only to passive metals and alloys. Nonpassive alloys (other than noble alloys) are susceptible to general corrosion and are not normally suitable for implant use.

1.3 This test method is intended for use as a laboratory screening test for metals and alloys which undergo pitting or crevice corrosion, or both.

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:*[3]

D1193 Specification for Reagent Water

F86 Practice for Surface Preparation and Marking of Metallic Surgical Implants

F2129 Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices

G3 Practice for Conventions Applicable to Electrochemical Measurements in Corrosion Testing

G5 Reference Test Method for Making Potentiodynamic Anodic Polarization Measurements

G15 Terminology Relating to Corrosion and Corrosion Testing (Withdrawn 2010)[4]

3. Summary of Test Method

3.1 A cylindrical specimen fitted with an inert tapered collar is immersed in a phosphate buffered saline electrolyte at 37 °C for 1 h to establish a corrosion potential. Pitting (or crevice corrosion) is then stimulated by potentiostatically polarizing the specimen to a potential much more noble than the corrosion potential. Stimulation of pitting (or crevice corrosion) will be marked by a large and generally increasing polarizing current.

3.2 Immediately after the stimulation step, the potential is decreased as rapidly as possible to one of several preselected potentials at, or more noble than, the corrosion potential. If the alloy is susceptible to pitting (or crevice corrosion) at the preselected potential, the polarizing current will remain at relatively high values and will fluctuate or increase with time. A post-test examination of the metal specimen establishes whether localized corrosion has occurred by pitting of the exposed surface or by preferential attack at the crevice formed by the tapered collar, or both.

3.3 If the pit (or crevice) surface repassivates at the preselected potential and localized corrosion is halted, the polarizing

[1] This test method is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.15 on Material Test Methods.

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[2] Syrett, B. C., *Corrosion*, Vol 33, 1977, p. 221.

[3] 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.

[4] The last approved version of this historical standard is referenced on www.astm.org.

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current will drop to values typical for passive surfaces and the current will decrease continuously. The parameter of interest, the critical potential for pitting (or crevice corrosion), is defined as the highest (most noble) preselected potential at which pit (or crevice) surfaces repassivate after the stimulation step.

4. Significance and Use

4.1 This test method is designed solely for determining comparative laboratory indices of performance. The results may be used for ranking alloys in order of increasing resistance to pitting and crevice corrosion under the specific conditions of this method. It should be noted that the method is intentionally designed to reach conditions that are sufficiently severe to cause breakdown of at least one alloy (Type 316 L stainless steel) currently considered acceptable for surgical implant use, and that those alloys which suffer pitting or crevice corrosion during the more severe portions of the test do not necessarily suffer localized corrosion when placed within the human body as a surgical implant.

5. Apparatus

5.1 The following required equipment is described in Reference Test Method G5:

5.1.1 *Standard Polarization Cell,* of 1000 cm^3.

5.1.2 *Electrode Holders,* for auxiliary and working electrodes.

5.1.3 *Potentiostat,* calibrated in accordance with Reference Test Method G5.

5.1.4 *Potential-Measuring Instrument.*

5.1.5 *Current-Measuring Instrument.*

5.1.6 *Anodic Polarization Circuit.*

5.1.7 *Platinum Auxiliary Electrodes.*

5.1.8 *Saturated Calomel Electrode* (SCE).

5.1.9 *Salt Bridge Probe.*

5.2 A cylindrical working electrode is fabricated from the test material by machining, grinding, and suggested final polishing with 600-grit metallographic paper. It is suggested that the part of the cylindrical specimen that is exposed to the test solution have a length of 20.00 ± 1.00 mm [0.787 ± 0.039 in.] and a diameter of 6.35 ± 0.03 mm [0.250 ± 0.001 in.] (see Fig. 1).

5.3 A crevice is created by fitting the cylindrical specimen with a tapered collar, machined from commercial purity polytetrafluoroethylene (PTFE). The collar should have an outer diameter of 12.70 ± 0.05 mm [0.500 ± 0.002 in.] and a thickness of 3.18 ± 0.20 mm [0.125 ± 0.008 in.]. The inside diameter of the tapered collar should range from 0.38 mm [0.015 in.] smaller than the diameter of the specimen to 0.38 mm [0.015 in.] larger. To be consistent with the dimensions suggested in 5.2, the inside diameter should taper from 5.97 ± 0.05 mm [0.235 ± 0.002 in.] to 6.73 ± 0.05 mm [0.265 ± 0.002 in.]. See Fig. 1 for drawing of the tapered collar. The relatively fine tolerances are needed to ensure a reproducible fit and crevice.

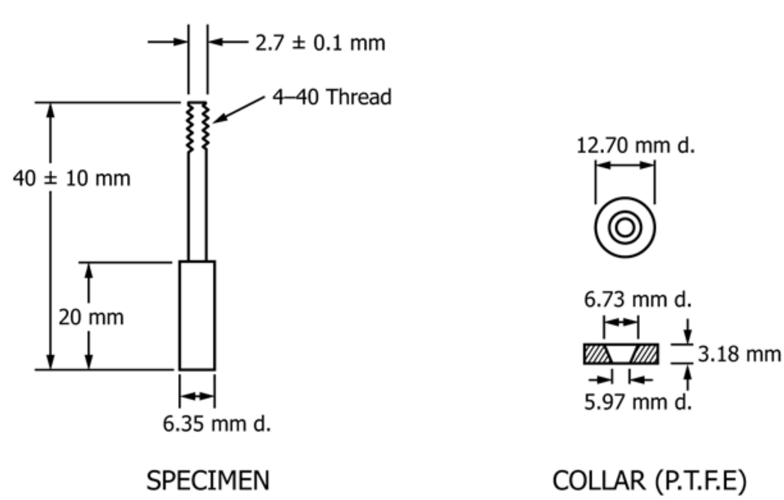
5.4 In Reference Test Method G5, the method of specimen attachment is to drill and tap the specimen to receive a threaded stainless steel connection rod. A 4-40 thread is used, typically. However, because many surgical implant alloys are not easily drilled, external threads may also be machined, ground, or cast, as illustrated in Fig. 1. A small stainless steel adapter is fitted onto these threads and the adapter then accepts the connection rod.

5.5 Determine the total exposed surface area of the specimen before placement of the PTFE collar, A_T; determine the area on the internal surface of the collar (the creviced area), A_C; and determine the exposed surface area of the specimen after placement of the collar, A_S (where: $A_S = A_T - A_C$). Dimensions should be measured to the nearest 0.1 mm.

5.5.1 *Example*—Using the dimensions suggested previously for the specimen diameter (d = 6.35 mm), the specimen length (l = 20.00 mm), and the collar thickness (t = 3.18 mm),

$$A_T = \pi dl + \frac{\pi d^2}{4} = 431 \text{ mm}^2 \quad (1)$$

$$A_C = \pi dt = 63 \text{ mm}^2 \quad (2)$$



NOTE 1—Unless shown, dimensional tolerances are given in text.

FIG. 1 Dimensions of Specimen and Collar