Designation: ~~F897 – 02 (Reapproved 2013)~~ F897 – 19

Standard Test Method for Measuring Fretting Corrosion of Osteosynthesis Plates and Screws[1]

This standard is issued under the fixed designation F897; 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 provides a screening test for determining the amount of metal loss from plates and screws used for osteosynthesis (internal fixation of broken bones) due to fretting corrosion in the contact area between the screw head and the plate hole countersink area. The implants are used in the form they would be used clinically. The machine described generates a relative motion between plates and screws which simulates one type of motion pattern that can occur when these devices are used clinically.

1.2 Since the environmental and stress conditions used in this test method may not be identical to those experienced by bone plates in the human body, this test method may produce fretting corrosion rates that are lower or higher than those experienced in practice. The recommended axial load of 400 N was selected as being in a range where the amount of fretting corrosion is not sensitive to small changes in axial load (**1**).[2] The combination of the recommended load and angular displacement are such that a measurable amount of fretting corrosion of surgical alloys occurs in a comparatively short period of time (7 to 14 days). **(Refs 1-3)**

1.3 The device is designed so as to facilitate sterilization of the test specimens and test chambers to permit testing with proteinaceous solutions that would become contaminated with microbial growth in nonsterile conditions.

1.4 The specimens used can be standard osteosynthesis implants or can be materials fabricated into the appropriate shapes.

1.5 This test method may be used for testing the fretting corrosion of metal plates and screws of similar or different alloy compositions, or it may be used for testing the fretting corrosion of metal-nonmetal combinations. This test method may also be used for wear or degradation studies of nonmetallic materials. This test method may be used as a screening test to rank the corrosivities of saline or proteinaceous solutions, or to rank metal-to-metal couples for resistance to fretting corrosion, or to study other material combinations.

1.6 The values stated in either SI units or inch-pound units are to be regarded separately as standard. The values stated in each system are not necessarily exact equivalents; therefore, to ensure conformance with the standard, each system shall be used independently of the other, and values from the two systems shall not be combined.

1.7 *This standard ~~may involve hazardous materials, operations, and equipment. This standard~~ does not purport to address all of the safety ~~concerns~~ concerns, if any, associated with its use. It is the responsibility of ~~whoever uses~~ the user of this standard to ~~consult and~~ establish appropriate ~~safety~~ safety, health, and ~~health~~environmental practices and determine the applicability of regulatory limitations prior to use.*

1.8 *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]

D1886 Test Methods for Nickel in Water

F86 Practice for Surface Preparation and Marking of Metallic Surgical Implants

---

[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.

Current edition approved ~~March 1, 2013~~Nov. 1, 2019. Published ~~March 2013~~December 2019. Originally approved in 1984. Last previous edition approved in ~~2007~~2013 as F897 – 02~~(2007).~~(2013). DOI: ~~10.1520/F0897-02R13.~~10.1520/F0897-19.

[2] The boldface numbers in parentheses refer to the list of references at the end of this standard.

[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.

F382 Specification and Test Method for Metallic Bone Plates
F543 Specification and Test Methods for Metallic Medical Bone Screws
G1 Practice for Preparing, Cleaning, and Evaluating Corrosion Test Specimens

3. Summary of Test Method

3.1 A two-hole plate is attached to two plastic rods with bone screws, with flexible spacers between the plate and the rods, placed in a glass beaker, and the beaker sealed with a flexible rubber cover. This assembly is steam sterilized, and then a sterile solution is injected through the rubber cover into the beaker. This assembly is then mounted in the fretting apparatus which, when set in motion, produces a rocking motion and, therefore, a small cyclic displacement between the mating surfaces of the plate and screws. The amount of fretting corrosion is determined at the end of the test by measurement of the weight loss of the plates and screws and by chemical analysis of the solutions.

4. Significance and Use

4.1 It is well known from examination of implants after use that plates and screws used for osteosynthesis are subjected to metal loss due to corrosion at the plate-screw interfaces. One of the mechanisms of this corrosive attack is fretting corrosion due to relative motion (micromotion) between the screw heads and plate-hole countersinks.

4.2 It is also known that release of corrosion products into the tissues surrounding an implant may have adverse effects on local tissue or have systemic effects. Thus, it is important to minimize the amount of tissue exposure to corrosion products.

4.3 Screws and plates are available in different configurations in accordance with Specifications F543 and F382. This test method may be used to evaluate the effects of different combinations of screw and plate designs. As new materials and device designs are developed for use in the treatment of fractured bones, it is important to determine the effects these developments have on the amount of metal loss due to fretting corrosion.

4.4 This test method provides a standardized screening test for ranking metal plates and screws in terms of resistance to fretting corrosion and for determining the influence of different solutions on fretting corrosion rates.

4.5 This test method may also be used to generate corrosion products either for chemical analysis of the products or for testing for biological reactions to corrosion products using animal or cell culture methods.

4.6 It is well known that fretting corrosion rates depend on normal load or pressure, frequency, sliding amplitude, materials, surface treatments, and environmental factors. (**4**) Therefore, when determining the effect of changing one of these parameters (for example, material or environment), all others must be kept constant to facilitate interpretation of the results.

5. Apparatus

5.1 *Steam Autoclave,* capable of maintaining 121 ± 2°C [250 ± 4°F], and equipped with a thermometer, pressure gauge, vent cock, and a rack to hold the test assemblies above the water level.

5.2 *Microbalance,* with a 0.01-mg scale.

5.3 *Fretting Apparatus,* as described in 5.3.1 – 5.3.4 and illustrated in Fig. 1 and Fig. 2.

5.3.1 The fretting apparatus is driven by a slow speed gear motor connected to a horizontal rotating shaft. Round disks with machined flats (cams) are mounted on the shaft as shown in Fig. 1. For multiple specimen testing, there may be more than one cam on the drive shaft.

5.3.2 The flats on the cams are machined so as to produce 2° of relative motion between the posts of the test assemblies.

NOTE 1—A suggested combination of short post length and plunger displacement is a 5-cm post with a 1.9-mm displacement.

5.3.3 The shaft rotation rate and the number of machined flats shall be such that the flats produce one oscillation of the plunger per second.

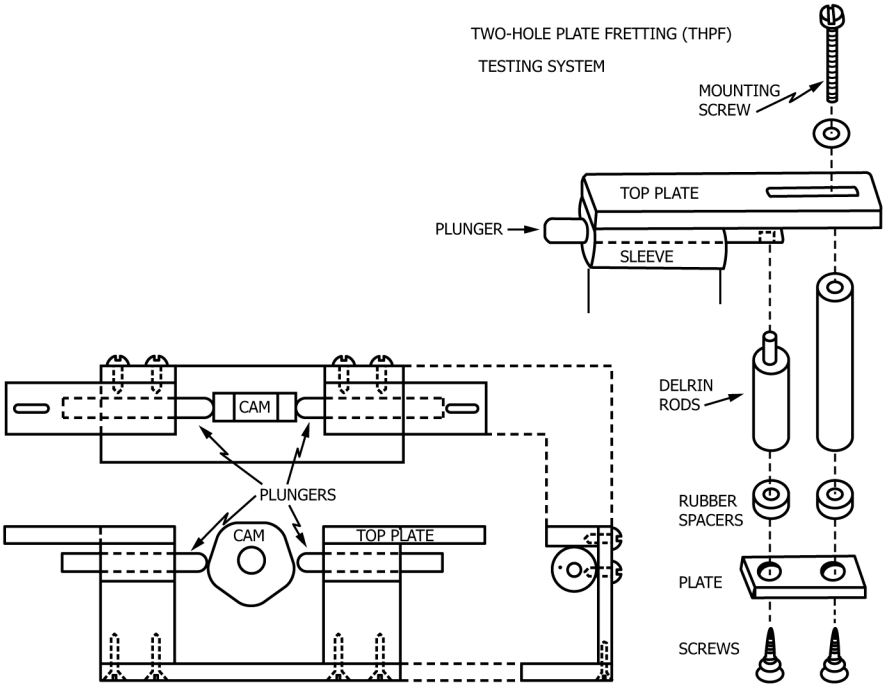
5.3.4 Test assembly holding and driving frames are mounted symmetrically on each side of the rotating cams. The oscillating plunger is springloaded and held in the guide sleeve. The hole in the top plate is slotted to permit adjustment of the position of the test assemblies.

5.4 *Test Assemblies,* consisting of two plastic rods, and two flexible spacers, the two-hole plate, two bone screws, one beaker, and the rubber cover.

5.4.1 The longer rod is threaded at one end to mate with a mounting screw, while the other end is threaded to mate with the bone screw.

5.4.2 The shorter rod has a reduced diameter at one end to mate with the oscillating horizontal plunger, while the other end is threaded to mate with a bone screw.

5.4.3 The flexible spacers made of, for example, polydimethylsiloxane or buna-n, are used to maintain axial loads on the screws and to permit the necessary axial displacements associated with the rocking motion of the screws, while at the same time preventing fatigue failure of the screws. The screws are tightened such that there is a 400 ± 50 N load on the screws; a different



NOTE 1—Figure shows assembly drawings of one pair of test positions on each side of a cam, and of the relationships between the screws, plate, spacers, and polyacetal rods.

FIG. 1 Two-Hole Plate Fretting (THPF) Testing System

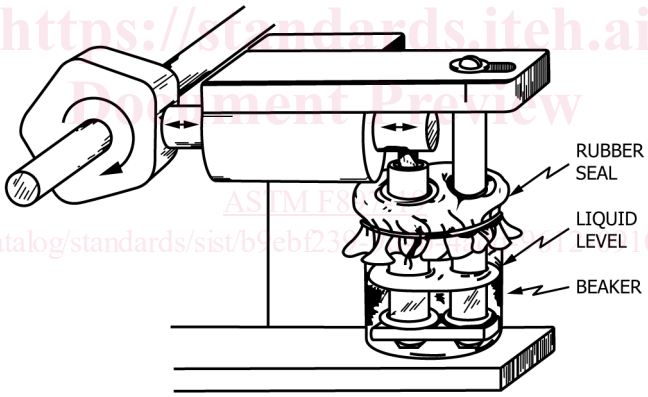


FIG. 2 Assembled Test Chamber with Rubber Seal

load may be used, but in such cases the load must be reported (see 10.1). In actual operation, it may be easier to measure the screw torque rather than the axial load; a method for determining the relationships between torque and load is given in Appendix X2.

5.4.4 *Test Specimen Plates and Screws,* as described in Section 7.

5.4.5 *Beakers,* autoclavable borosilicate glass.

5.4.6 *Rubber Cover,* made from a thin piece of flexible rubber with two holes punched out to make a tight fit around the plastic rods. Heavy gauge (0.3 mm thick) latex dental dam has been used effectively for this purpose. The cover is secured to the beaker with wire, rubber bands, or by some other appropriate device.

6. Reagents and Materials

6.1 The basic test solution shall be 0.9 % NaCl in distilled water. Measure the pH of the solutions before conducting the test. If necessary, buffer them to ensure they are in the range of 6.5 to 7.5.

6.2 Other solutions may include other "physiologic" saline and electrolyte solutions for injection (USP) or saline and protein solutions. If proteins are used, the solutions shall be sterile in accordance with 8.1.5. Protein solutions may either be purchased sterile, or sterilized by filtration. These shall be reported in accordance with 10.1.