



Test Method for Standard Test Method for Evaluating the Potential for Galvanic Corrosion for Medical Implants¹

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1. Scope

1.1 This test method covers conducting galvanic corrosion tests to characterize the behavior of two dissimilar metals in electrical contact that are to be used in the human body as medical implants or as component parts to medical implants. Examples of the types of devices that might be assessed include overlapping stents of different alloys, stent and stent marker combinations, orthopedic plates and screws where one or more of the screws are of a different alloy than the rest of the device, and multi-part constructs where two or more alloys are used for the various component parts. Devices which are to be partially implanted, but in long-term contact within the body (such as external fixation devices) may also be evaluated using this method.

1.2 This test method covers the selection of specimens, specimen preparation, test environment, method of exposure, and method for evaluating the results to characterize the behavior of galvanic couples in an electrolyte.

1.3 Devices and device components are intended to be tested in their finished condition, as would be implanted (that is, the metallurgical and surface condition of the sample should be in or as close as possible to the same condition as in the finished device).

1.4 This test method does not address other types of corrosion and degradation damage that may occur in a device such as fretting, crevices, or the effect of any galvanically induced potentials on stress corrosion and corrosion fatigue. Surface modifications, such as from scratches (possibly introduced during implantation) or effects of welding (during manufacture), are also not addressed. These mechanisms are outside of the scope of this test method.

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 and health practices and determine the applicability of regulatory limitations prior to use.*

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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NOTE 1—Additional information on galvanic corrosion testing and examples of the conduct and evaluation of galvanic corrosion tests in electrolytes are given in Ref. (1).²

2. Referenced Documents

2.1 ASTM Standards:³

D1193 Specification for Reagent Water

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

G1 Practice for Preparing, Cleaning, and Evaluating Corrosion Test Specimens

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

G16 Guide for Applying Statistics to Analysis of Corrosion Data

G31 Guide for Laboratory Immersion Corrosion Testing of Metals

G46 Guide for Examination and Evaluation of Pitting Corrosion

G59 Test Method for Conducting Potentiodynamic Polarization Resistance Measurements

G71 Guide for Conducting and Evaluating Galvanic Corrosion Tests in Electrolytes

G82 Guide for Development and Use of a Galvanic Series for Predicting Galvanic Corrosion Performance

G102 Practice for Calculation of Corrosion Rates and Related Information from Electrochemical Measurements

3. Significance and Use

3.1 Implantable medical devices can be made of dissimilar metals or come into electrical contact with dissimilar metals

² The boldface number in parentheses refers to the reference provided at the end of the document.

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.