

ASTM F2129

Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices¹

1.1. This test method assesses the corrosion susceptibility of small, metallic, implant medical devices, or components thereof, using cyclic (forward and reverse) potentiodynamic polarization. Examples of device types that may be evaluated by this test method include, but are not limited to, vascular stents, ureteral stents, filters, support segments of endovascular grafts, cardia occluders, aneurysm or ligation clips, staples, and so forth.

1.2 This test method is used to assess a device in its final form and finish, as it would be implanted. These small devices should be tested in their entirety...

1.3 Because of the variety of configurations and sizes of implants, this test method provides a variety of specimen holder configurations.

1.4 This test method is intended for use on implantable devices made from metals with a relatively high resistance to corrosion.

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.*

at a glance ...

According to the U.S. Food and Drug Administration (FDA), members of the medical device industry should “develop and apply non-clinical test protocols, test methods and test reports that support the safety and effectiveness of intravascular stents and their associated delivery systems.”² The method above has been recommended by the FDA for manufacturers of metallic, medical implant devices to test such devices for corrosion resistance thereby ensuring their safe and effective use in the human body.

in other words...

The FDA demands that all metallic medical implant devices undergo testing and be proven to be corrosion resistant, however, no established corrosion resistance guidelines have been provided. The FDA suggests using ASTM F2129 but the test does not provide a pass/fail criteria. Therefore, it is up to each medical device company to provide data that justifies the corrosion resistant properties of their products.

¹ASTM F2129-06

²Guidance for Industry and FDA Staff: Non-Clinical Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems