

STANDARD TEST FOR CONDUCTING CYCLIC POTENTIODYNAMIC POLARIZATION MEASUREMENTS TO DETERMINE THE CORROSION SUSCEPTIBILITY OF SMALL IMPLANT DEVICES.

BACKGROUND AND SCOPE

The FDA requires a variety of test data to demonstrate the efficacy and safety of a medical device before it can be implanted in patients. Corrosion test data is required as corrosion can weaken a device as well as cause adverse biological responses in patients. Metallic medical devices that are designed for permanent implantation must be assessed for corrosion resistance according to the ASTM F-2129 *Standard Test for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices*.

The case study evaluates 3 different processing conditions used to produce a specific medical device. These three samples were evaluated in order to assess which condition results in the best corrosion resistance.

PROCEDURE

Each device was connected to the potentiostat and immersed in de-aerated Hanks Balanced Salt Solution (HBSS), which was kept at body temperature. The potential was monitored for an hour to reach and determine the rest potential. Each device was then anodically scanned until the breakdown potential was reached, and cathodically scanned back to the rest potential.

RESULTS

The potential is plotted against the log of the exchange current density as shown in figure 1. The following parameters are obtained from the plot: E_r , E_b , E_p (for materials that exhibit a protection potential), and E_{zc} .

PARAMETER	DESCRIPTION
Breakdown Potential (Eb)	Potential at which pitting begins
Rest Potential (Er)	Open circuit potential
Protection Potential (Ep)	Potential at which material re-passivates
Ezc	Potential at zero current

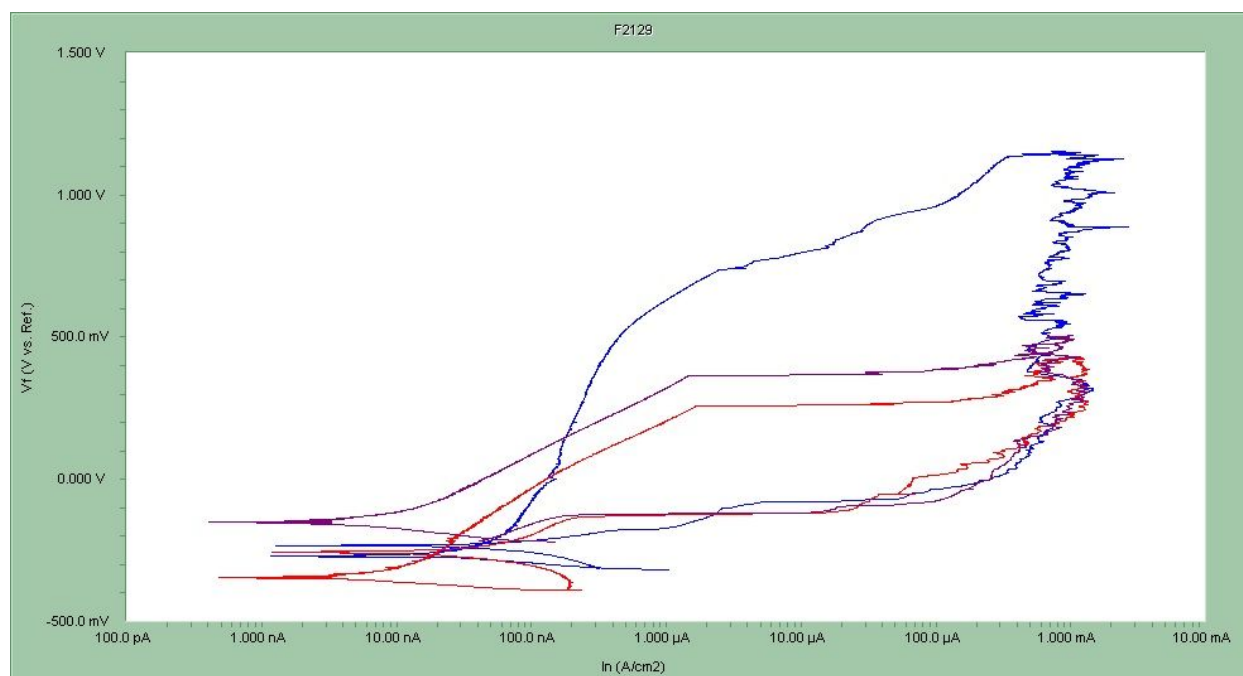


Figure 1: Plot of Exchange Current Density vs. Potential

DISCUSSION

Device #3 (blue curve) had a breakdown potential of over a volt, which was double the breakdown potential of the other two samples. The processing conditions for this device were ideal, and created a surface finish that was not as susceptible to corrosion as the other two samples.