

## Electrochemical Evaluations is a leader in corrosion testing of small medical devices

### Alloys Tested:

- Nitinol
- Type 316L Stainless Steel
- 316LVM Stainless Steel
- Titanium
- MP35N
- Elgiloy
- Platinum
- Platinum/Iridium
- Gold Joints

### Medical Devices Tested:

- Biliary Stents
- Coronary Stents
- Cardiovascular Stents
- Drug-Eluting Stents (also called coated or medicated stents)
- Stent Grafts
- Co-Deployed Stents
- Embolization Coils
- Nitinol Filters
- Dental Implants

Corrosion resistance is tested by placing the metallic medical implant in an environment that simulates the inside of the human body using a buffered saline (or simulated bile) solution at 37°C (98.6°F) using what we call a three electrode system. Applying Ohm's law ( $E=IR$ ) where E is voltage, I is current, and R is resistance in the circuit, the voltage is steadily increased while the current produced is recorded by a computer. The resistance in the system is due, in part, to the passive (oxide) film at the surface of the metal. The ultimate goal of the F2129 procedure is to break down the passive film which is indicated by a notable increase in current observed during the test. The data is plotted and interpreted for several key data points. Each metal sample has different results; however, the similarity of the results within a given set of samples is essential in determining if the medical device is fit for use in the human body.



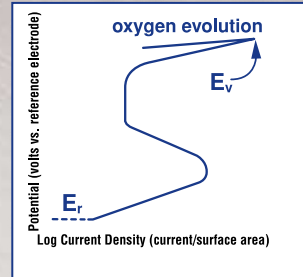
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# We've Got Corrosion Testing Down to a Science



## Electrochemical Evaluations, LLC

## In our industry, there is no room for error...



Electrochemical Evaluations specializes in testing medical devices for corrosion resistance so that they can be implanted safely and effectively in the human body as well as meet all federal codes and regulations.

We use the most current electrochemical testing equipment and procedures available. Utilizing our highly accurate data interpretation system, we can satisfy any and all electrochemical testing needs.

With over a decade of experience in the rapidly progressing

field of medical device corrosion testing, Electrochemical Evaluations has quickly become a leader in the development and implementation of electrochemical procedures both to continue advances in our industry and to benefit our clients.

Not only can we meet all of your corrosion testing needs, but we can also help develop a proactive program to avoid potential corrosion problems. By working as a team, we can evaluate your processing parameters including surface finish and heat treatment of the devices.

We're sure you won't find another testing laboratory that is as thorough, resourceful and reliable. We guarantee that we'll do the job right - each time, every time.

## ...so we go above and beyond.



The Food and Drug Administration (FDA) recommends 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 exhibits the corrosion resistant properties of their products.

The interpretation of corrosion testing has been widely fragmented over the years and various techniques have been employed, often resulting in data that could not be compared

between testing laboratories. The ASTM F04 Committee on Medical and Surgical Materials and Devices, formed in 1962, accepted the task of unifying the community at large with a standard test method.

Our staff has worked with the F04 committee, other laboratories and the FDA on revising and clarifying government standards, and were instrumental in molding the 2001 version of ASTM F2129, the first version of this corrosion testing standard. Since then, our director has continued working to revise the standard and to remove ambiguity. With his help, it was modified once again in 2006.

With our experience and as advocates for progress in our industry, we continue to exceed our clients' expectations.



# We know the success of your business relies on our expertise.