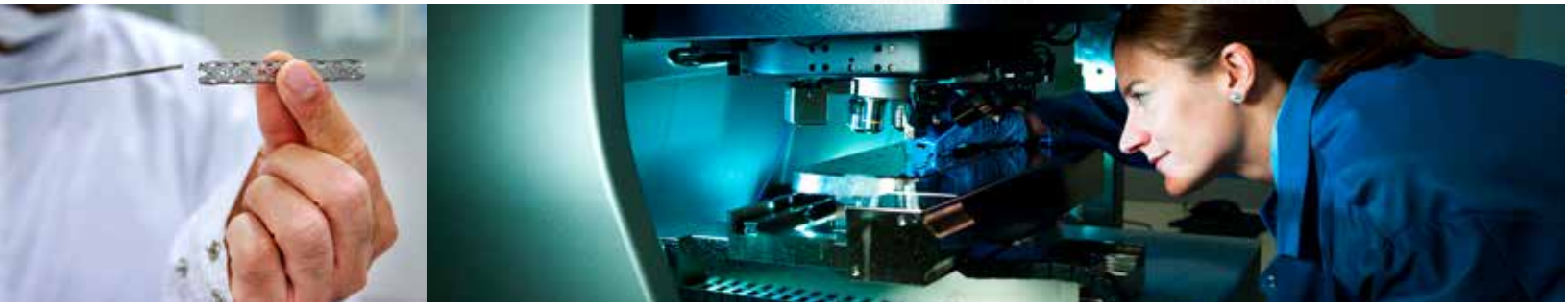
eurofins | EAG Laboratories



Assessing nickel leaching on cardiovascular stents

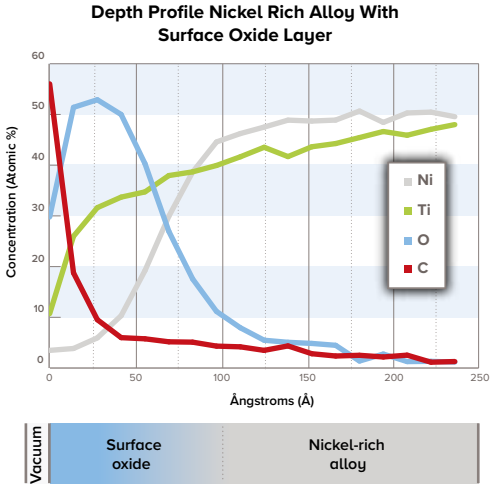
Eurofins | EAG Laboratories scientists have the scientific expertise and regulatory know-how to perform the assessments needed to evaluate potential corrosion and leaching of nickel-rich implanted medical devices (including nitinol, stainless steel and MP35N) that are used in cardiovascular therapies. The scientists at EAG Laboratories can help you navigate the FDA guidance document on intravascular stents and associated delivery systems for a successful submission.

How we can help

Performing all the required testing for evaluating nickel-rich devices, EAG Laboratories also offers insight to potential failure modes and provides a complete, concise report. From evaluating pitting corrosion to characterizing surfaces, these tests provide answers to questions of nickel ion leaching.

Corrosion testing

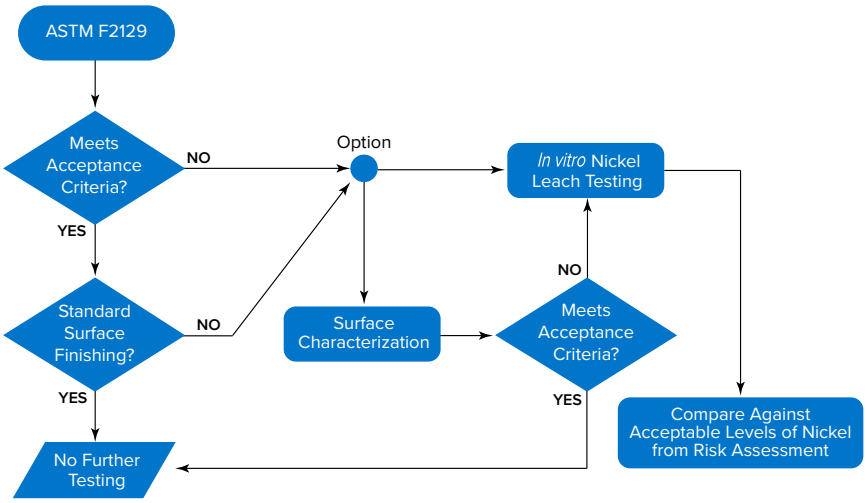
It is important to evaluate implanted



devices for corrosion as this can be an indication of performance and safety. EAG Laboratories can characterize for pitting corrosion potential using ASTM Method F2129. As stated in the method, we can assess small metallic implant devices for corrosion susceptibility using pontentiodynamic polarization.

Surface Characterization

Due to the small lateral dimensions found on implantable devices, like



intravascular stents, only a limited number of analytical techniques are able to meet the requirements of measuring surface composition or oxide thickness. For devices with micron scale features and typical oxide thickness in the range of 2-200nm, Auger Electron Spectroscopy simultaneously meets the spatial resolution and vertical sampling requirements of nitinol and similar materials.

Nickel release testing

When stent materials fail to meet corrosion resistance and surface passivation criteria, nickel ion release testing is recommended to help evaluate the safety of the material. FDA Guidance issued in 2015 provides a standard protocol for in vitro nickel ion release testing. EAG scientists have the technical expertise to conduct a protocol-driven study to measure concentrations of nickel ion leached from a stent device under simulated conditions in a controlled environment, over a recommended testing period of at least 60 days. Normalized nickel ion release rates are an effective tool when comparing different nickel-rich alloy based devices.

Failure investigations

EAG scientists have years of experience investigating material failures in medical devices. Electron microscopy, spectrochemical analysis and metallographic examination of stents or other medical devices are powerful tools for understanding the failure mode. Resolving the signatures for fatigue, corrosion, hydrogen embrittlement, manufacturing defects, material inclusions, surface treatments or improper handling leads to practical process improvements.