

## Ni Ion Leaching Testing for your Nitinol Medical Device

### The Challenge:

Nitinol's (NiTi's) highly elastic and shape memory mechanical properties have made it a material of choice for medical devices that are used in high deployment/cyclic strain indications such as stents, embolism devices, heart valves and more. With an increasing awareness of the effects of nickel toxicity in medical devices, recent publications have focused on the effect of surface treatment for NiTi devices and how it affects the corrosion resistance of the device. While surface treatments can improve corrosion resistance, cyclic loading may lead to surface micro-fractures creating localized corrosion and pitting.



An FDA guidance document issued on August 18, 2015 "Select Updates for Non-Clinical Engineering Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems" recommends considering the potential for nickel ion release from devices containing nickel-rich alloys. A journal paper by Sullivan et al (Shap. Mem. Superelasticity, 2015, 1:319-327) tested nickel release from five groups of Nitinol stents manufactured by various processing methods and showed strong correlations between oxide layer thickness and cumulative Ni release. The paper also found that testing of multiple stents such as those in an overlapped condition or larger-sized stents such as those implanted into the superficial femoral artery may generate nickel release rates higher than USP's permissible daily exposure for nickel of 0.5 µg/Kg/day. Furthermore, Sullivan et al showed that radial compression levels affected some stents but not all.

### The Solution:

Since the FDA guidance document recommends that testing should be performed on as-manufactured devices after subjecting the device to simulated use testing, MDT has come up with a novel test setup that allows for **in vitro nickel ion release measurements during fatigue testing**. This type of testing closely mimics physiologic conditions and captures both the initial bolus release of nickel as well as the longer term nickel ion release profile in vitro. Nickel ions are captured in a suitable, low volume reservoir as the device is being radially fatigued. Fluid samples are regularly tested using inductively coupled plasma optical emission spectrometry (ICP-OES). This test setup can be readily modified for different types of medical devices, for which nickel ion release characterization combined with mechanical loading is desired.

Nickel Ion leaching is an important consideration with medical devices that are deployed within the human vasculature. The nickel ion release measurement evaluation method developed by MDT enables the researcher to evaluate the effect fatigue has on nickel ion leaching. Contact MDT today to discuss testing your NiTi or other nickel-rich material derived medical device design under physiologically-relevant conditions.