Technical Guide to Engraving and Laser Passivation for Medical Technology

Apply the Latest Laser Technology to Reduce Production and Inventory Costs
Laser passivation can be integrated into the laser engraving process, adding very little to per part cost.

A Technical Look at Engraving and Laser Passivation for MedTech

Apply the right laser system to effectively meet quality requirements and achieve high-volume.

Overview

Until recently, passivation of stainless steel medical devices has been accomplished either chemically or electrochemically. However, the process is quite expensive. Fortunately, there is a new laser passivation process that passes the ASTM F1089-10 standard test method for corrosion of surgical instruments. This breakthrough means that medical device manufacturers will reduce production and inventory costs.

Stainless steels are engraved for a number of reasons, such as for branding and functionality. Engravings are chosen over surface marks for their longevity and smoothness. The added depth of an engraving will often surpass the life of a medical device or instrument. A chromium oxide layer coats stainless steel, preventing it from corroding. The lifetime of the device or instrument is often determined by the robustness of the protective oxide layer. Once that oxide layer is breached and corrosion begins, the device or instrument must be discarded.

Rotary cutter and lasers can both engrave most metals including 304 stainless steel. The resulting machined surface from a rotary cutter has a bright, shiny appearance. By contrast, the surface after engraving with a laser will have a matte finish. For differing reasons, both the rotary and laser engraved part will need to go through a post-process to passivate the surface.

Stainless steel resists corrosion by building up a chromium oxide layer that grows on a surface free of oil, grease, and contaminates in the presence of oxygen. Since the protective layer occurs naturally it is considered passive. A continuous protective chromium oxide layer is important on any medical device or instrument because a single site that corrodes will propagate undercutting the passivation.

A rotary cutter is made from steel harder
than 304 stainless steel. As such, the cutter does not have the same chemical composition and will quickly corrode. During the engraving, small particles of the cutter become embedded into the surface of the stainless steel. If these particles are allowed to remain, they will corrode and inhibit the creation of the chromium oxide layer.

Laser engraving ablates the stainless steel. To minimize any thermal effect of the engraving, a short pulse duration laser is chosen. Chrome that was at the surface has been ablated away or pinned to the carbon in the grain boundaries, leaving free iron on the surface. As with the rotary process, the engraved surface will corrode. In order to fix this problem, two traditional and one novel methods were used to remove the nucleating spots for corrosion.

Nitric and citric acids are the most commonly used chemicals for passivating stainless steel. Hot nitric acid is a strong mineral acid that quickly dissolves iron compounds and most other trace metals on the surface. Additionally, nitric acid is a strong oxidizer that generates the passive chromium oxide layer at the same time. Citric acid is an organic acid and does an excellent job of removing iron from all surfaces. By contrast, citric acid is not an oxidizer. The passivating chromium oxide layer is grown by exposure to ambient oxygen.

Both chemical passivation methods result in a shiny engraved surface. A four to 10 percent citric acid passivation is capable of passing the ASTM F1089-10 but is often not used in aggressive chemical or physical environments. The advantages for citric acid is that it is safer to use, is biodegradable, and produces fewer effluent concerns.

Times of up to two hours at temperatures of 70°C with a concentration of 20% to 50% nitric acid result in a more robust passivation layer. Autoclaving is both chemically and thermally aggressive to an oxide layer. Every autoclaving cycle will thin an oxide layer. Being thicker and denser means that the passivation layer created by a nitric acid passivation process will last longer than one produced using citric acid. Thermal cycling during autoclaving expands the metal more than the passivation layer expands. The denser layer is less likely to be damaged by the heating and cooling during sterilization.

Passivation uses strictly chemical energy whereas electropolishing uses electrochemical energy to strip away metals that may lead to corrosion. Often referred to as reverse plating, electropolishing uses a rectified current passed through the part, which is immersed in an electrolyte bath.

Electropolishing dissolves high points faster than the low points on the surface of the part. This process reduces the surface area and allows for a more uniform oxide layer to form. Preferential dissolution also occurs. The higher the amount of chromium in the steel, the higher the corrosion resistance. High chromium content also reduces the strength and workability of the steel. At the surface, strength is not an issue. By preferentially dissolving the iron, a ratio of chromium to iron can be as high as 1.5:1. The smooth and chromium rich surface readily oxidizes, which creates a thick protective oxide layer.
An in situ laser process duplicates all but one of the results of both passivation and electropolishing. Native stainless steel was created by dissolving the free iron back into the matrix. Surface roughness and, thus, area was reduced by flowing the engraved surface. Enrichment of the surface chromium using electropolishing was undetermined.

Materials have a laser ablation threshold that is a combination of wavelength, pulse duration, and fluency. Above the threshold ablation occurs and the metal can be engraved. Below the threshold, the surface can melt. Just at the threshold, the iron can be pushed back into a solid solution and the surface smoothed. The new surface is now smooth, contains no free iron, and is of the correct composition to form the protective chromium oxide layer. To assist in the oxide formation, the laser heats up the metal.

Using the laser means that there is no added process step to lower yield or add costs. The move from engraving to passivating is done in the process recipe and the parts do not need to leave the laser engraver. Because passivation and electropolishing are wet processes, there is a limit to when they can be done in the manufacturing sequence.

A fully finished part can be laser engraved and laser passivated, which allows for the part to be engraved after sale and with the branding or regulatory markings for that specific market.

Post- engraving processing is needed on stainless steel medical instruments and devices.

Chemical passivation has the advantage of being the traditional low cost process. For single-use products, it is cost competitive with laser passivation. Electropolishing, though the most expensive per part, produces the most robust protective chromium oxide layer.

Laser passivation can be integrated into the laser engraving process, adding very little to the per part cost, while at the same time, increasing yield due to fewer processing steps. In addition, the engraving and passivating can be done on a finished part, reducing the amount of product in finished good inventory.

About ESI

ESI’s integrated solutions allow industrial designers and process engineers to control the power of laser light to transform materials in ways that differentiate their consumer electronics, wearable devices, semiconductor circuits and high-precision components for market advantage. ESI’s laser-based manufacturing solutions feature the micro-machining industry’s highest precision and speed, and target the lowest total cost of ownership. ESI is headquartered in Portland, Ore., with global operations from the Pacific Northwest to the Pacific Rim. More information is available at www.esi.com.