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ELECTROPOLISHING:

Art Form or Reproducible Science?

Onyx's state-of-the-art electropolishing line.

During the manufacture of orthopedic implants, many processes affect the outcome of the final product. However, it can be argued that none is more important than the chemical finishing process performed on the implant. There are many techniques for removing oils and manufacturing residues, other techniques for removing burrs or improving surface finish, and still other techniques for providing a passive, corrosion-resistant surface; however, a well designed, validated and rigorously maintained electropolishing system has the benefit of combining all of the above outcomes with other favorable results as well.

What is Electropolishing?

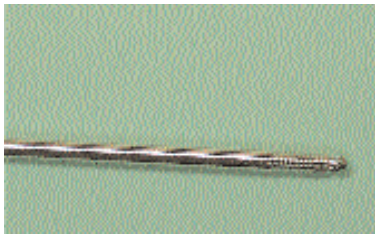
Electropolishing, simply put, is a metal removal process. It combines the use of a specifically designed chemical, the solution, with appropriate amounts of DC current to remove metal from the part. What makes electropolishing truly unique is that while the process removes the metal, it improves the surface finish, removes burrs without necessarily dulling the sharp edges, and leaves a very passive surface that exhibits enhanced corrosion resistance. Electropolishing can be performed on all types of stainless steels that would typically be used in the manufacture of implants and instruments, including 300 and 400 series stainless steels, 17-4 stainless steel, cobalt chrome, and other less popular grades of stainless as well.

How Does An Electropolishing System Work?

Electropolishing systems for stainless steel vary in complexity and layout, but they all share common traits. The systems usually begin with some sort of cleaning process, move on to a rinse/pre-treat process, enter the electropolish tank, move through a rinse/post-treat process, and finish with a final rinse/drying process. It is important to note that parts exhibiting large quantities of manufacturing oils or other compounds will require a pre-cleaning, degreasing step before they ever enter the electropolishing system.

A typical electropolishing process starts with the cleaning of the part utilizing an alkaline electrocleaning bath. By applying positive, direct current to the part, a reaction takes place at the surface of the part that releases gaseous oxygen. This oxygen actually helps to mechanically scrub the surface of the part, aiding in removal of any remaining manufacturing residue. By using a positive charge on the part, metals already dissolved in the bath are prevented from depositing on the surface of the part. Any oils or other residues that are present on the part are emulsified in the electrocleaner. After cleaning, the alkaline cleaner must be removed from all features of the part including holes, threads, etc. There are many ways to do this, but most systems typically include a water rinse, a dip in a combination of sulfuric and phosphoric acid, and then another water rinse. This stage is crucial to the final outcome of the part, as any cleaner not properly rinsed off or neutralized will show up on the final part as "frosting" or other visual defects.

The next step is the electropolishing bath itself. There is no one electropolishing solution that works for every type of stainless steel. However, most contain a combination of sulfuric and phosphoric acids with a small amount of additional chemicals that are proprietary to each manufacturer's solution. A positively charged DC current is applied to the parts once they are submerged in the solution. Burrs and surface peaks tend to have higher charge densities and thus show high material removal rates as the metal dissolves into the bath. Areas with lower current densities show a much slower material removal rate. This variation in current



Electropolished finish of CoCr.

densities allows electropolishing to remove burrs and smooth surfaces without removing excessive material or dulling sharp edges. For this reason, electropolished stainless steel parts, especially 300 series stainless steel parts, have a shiny, chrome-like appearance.

At the same time, certain elements of the material's structure are easily removed from the surface of the part while other elements are left behind. In stainless steel, iron is much more easily removed form the surface layer than chromium and nickel. This surface layer is rich in nickel and chromium oxides and is very passive.

After electropolishing, the parts are rinsed in water to remove as much of the electropolishing solution as possible. Next, they are dipped in a solution of nitric acid to help remove any byproducts from the electropolishing process. This is a critical step for ensuring there are no chemical or biological residues left on the part and that the part looks its best when completed.

The final rinse stage varies from system to system but typically includes a cold water rinse followed by a hot water rinse to remove any of the nitric on the parts. Most systems set up to run medical parts include de-ionized water in the hot and cold rinse sections as well as some sort of drying station for the parts.

Why Electropolish?

The main benefits of electropolishing stainless steel in a well designed, rigorously maintained and validated system include:

- Very passive surface rich with chromium and nickel oxides
- Improved surface finish
- Burr removal
- Improved corrosion resistance
- No chemical residuals as measured by a cytotoxicity test
- No biological residuals as measured by a bioburden test

Electropolishing is not a panacea — it cannot correct other flaws in a manufacturing line. Large burrs with thick roots will not come off in a standard run. A part with poor surface finish will not come out looking like a chrome bumper from a 1957 Chevy. But, when done correctly, electropolishing can enhance a part aesthetically and provide many performance enhancements to the part as well.

Validation and Maintenance

An electropolishing system is extraordinarily complex. Many variables must be understood and controlled to ensure a good result. Some of these variables include time of the parts in the bath, current applied to the parts, bath temperature, solution concentration and specific gravity, ppm and ph of the rinse water, metal content (in solution) of the baths as well as many others. Because the chemicals are extremely caustic, the entire system must be designed and maintained to prevent the corrosion of system components.

With all of the variables that affect the outcome of the parts, the only way to ensure that, even under extreme conditions, the system will produce good results is to validate the system. A thorough validation includes moving all critical variables to the extreme acceptable limits and testing the resulting parts to confirm acceptability in terms of passive surface, chemical residual, bioburden, surface finish, luster, etc. Only when the performance envelope of the system is fully defined and verified can the system be considered validated. This is especially critical when considering that many of the required outcomes of an electropolished implant, such as passive surface and the elimination of chemical or biological residuals, cannot easily be verified or inspected.

Once an electropolishing system has been validated, it is necessary to develop a detailed maintenance plan that encompasses all of the important variables tested in the validation. The maintenance plan must also account for the changes to physical components due to corrosive effects of the various chemicals. Constant monitoring and adjusting of critical parameters must be performed, and results recorded, in order to produce results consistent with the validation.

Without a good validation and maintenance plan, no electropolishing system can hope to meet ISO or FDA requirements. More importantly, device performance can be compromised if proper validation and good, consistent maintenance is not performed. Validation is not a standalone process. Any change to the process, however subtle, must yield an appropriate revalidation of the system.

Conclusion

Electropolishing can provide a combination of benefits not found in other finishing processes. Yet, without proper control and maintenance, it is very easy to do more harm than good to the parts. To the implant manufacturer, electropolishing is essential. Although complicated and ever changing, the final results far outweigh the cost, energy, time and surveillance required to keep a thoroughly planned and designed system up and running.

Editor: Onyx Medical Corporation is an innovative, woman-owned small business that provides full-service contract manufacturing services exclusively for the orthopedic industry. It specializes in the manufacture of comprehensive lines of wires, guide pins, half pins, drills and screws for the trauma and reconstruction markets.

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