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Hard Coating—Physical Vapor Deposition Processes Extend Life of Medical Devices

Background

The medical device industry has undergone change during the last decade. Up to the early 1990's, the requirement was for performance-driven products that could solve the many issues related to surgical procedures. Among those issues were longer instrument life and cutting edge retention so that instruments would cut tissue and bone more efficiently, last longer, and reduce temperatures, thereby minimizing necrosis.

Orthopedic implants that would perform better and survive longer in the body (requiring less revision) became important as more younger people became more active earlier in life. The need arose for implants that could perform for up to twenty-five years, as compared to previously accepted ten-year goals. In the ensuing years, with the rising cost of healthcare, there has been a shift toward reducing the corresponding cost of instruments and implant devices, and many instruments are now being categorized as disposable. Hence, we have renewed interest in the performance aspect of instruments and their life extension.

To meet these requirements, materials that were considered biomaterials (such as the 300 series stainless steels) needed to evolve to the next generation. This material provides excellent corrosion resistance but does not provide the properties necessary for obtaining and maintaining a good cutting edge. The material is soft and abrasive, and applications such as the cutting of bone material caused high wear of the edges. Precipitation-hardened stainless steels were sought for instruments because this material was harder and provided a better cutting edge and better corrosion resistance. In addition, 400 series stainless steels became popular because they could be hardened and tempered at lower temperatures, and they provided some level of corrosion resistance when passivated.

Surface Enhancement

Hard coating techniques, such as those deposited by Physical Vapor Deposition (PVD) processes, offer viable, cost effective solutions to improvement in material hardness, edge retention and corrosion resistance, and they can be applied to all of the above materials. Coatings can take

materials with less than optimum properties and improve them substantially. In addition, with the advent of battery or air-powered handheld instruments, and with requirements for the elimination of additional contaminants such as oils that are used to reduce friction and provide mechanical advantage for consistent performance of the instruments they drive, coatings providing valuable solutions.

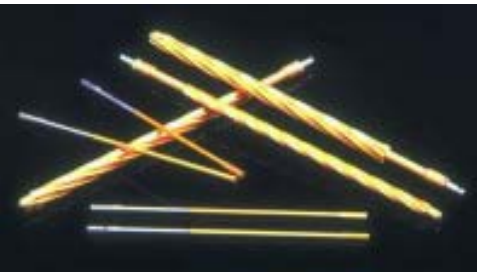
TiN (titanium nitride), the most widely used coating today, is an accepted biocompatible product. There are, however, many improved coatings beyond TiN that offer improved properties and characteristics that are better suited to a variety of old and new applications. Newer products improve wear and abrasion resistance, retain cutting edges, reduce friction, and provide hard, functionally decorative colors as well as coatings that provide a surface for biologic in-growth.

In addition, coatings provide chemical barrier layers to minimize fretting corrosion, reduce nickel sensitivity, and reduce corrosion while being inert to many acids. Only new products that have been tested in accordance with ISO 10993-1 standards and documented as biocompatible should be used. Numerous suppliers provide coatings, but not all of these coatings have been tested for biocompatibility.

Technical Overview

Coatings are deposited by Physical Vapor Deposition (PVD) technologies that are characterized by the melting of a metal to create a metal vapor that can be reacted with different gasses to form thin film coatings that are very hard and have exceptional adhesion characteristics.

There are three fundamental PVD technologies used to deposit coatings: Arc Vapor Deposition, Sputtering or Magnetron Sputtering, and E-Beam Evaporation. Each of these technologies generates metal and gas ions—neutrals and electrons that are collectively known as plasma. All of the technologies are referred to as 'line of sight' processes in that the part to be coated must be exposed to the plasma.



Each of these technologies generates plasma material but imparts different qualities to the plasma, resulting in coatings that are labeled the same, but have properties that can differ significantly.

This is because the coating process consists of three stages: evaporation, transportation, and condensation. The properties of the coating are dependent upon the energy level and ionization level of the plasmas developed. It is widely accepted that the process of Arc Vapor Deposition produces plasmas and coatings with superior properties that can be deposited at temperatures that will not compromise the properties of biomaterials.

Coatings can be applied to all accepted biomaterials, including 300 series, 400 series and 17-4-PH stainless steels, as well as to titanium and cobalt alloys. It is critical that the application temperature of the coatings be controlled so that even material with low tempering temperatures (450 degrees F) can be effectively coated. Only experienced suppliers of coating products should be consulted and used so that the material's initial properties of hardness and corrosion resistance are not compromised. The coating thickness and required properties can be determined after a thorough contract review process is completed in collaboration with the customer. The need to understand the material and how it is processed is critical to ensuring a successful coating.

Considerations

Issues that can impact the quality of the deposited coatings are related to how the substrates are processed. Heat treatments in poor vacuum cause oxides and discolored surfaces that need to be removed. Discussions should be held with the vendor providing the heat treatment to ensure that the process is controlled and certified. Materials can be given the same hardness in many ways, some of which will not provide the desired properties for the application. Glass bead blasting of surfaces, if improperly performed, can cause media to be imbedded in the surface that, if not removed, will cause voids in the coated surface.

Properly maintained systems that have fresh glass bead media and good air pressure controls should be used. Systems can be easily contaminated by the blast cleaning of other materials not related to the medical device product. Poor quality machining of surfaces can cause material to be *folded over*, trapping contaminants such as oils, causing poor coating adhesion. Excessive electro-polishing of surfaces, and poor or inadequate passivation of surfaces, can lead to exposed grains that act as porous cavities, trapping machining oils or other debris and releasing it back into the vacuum environment, generating coatings with poor adherence characteristics.

One of the best features of the PVD process is that it takes place in a vacuum environment and applies heat to the surfaces to be coated. If issues relating to surface contamination on instruments and implants have been incorporated into the material during fabrication and processing, they will be exposed by the coating process.

It is critical that the coating supplier maintains lot integrity during the coating process. Similar materials processed by different companies should not be coated together in the same batch. In addition, similar materials supplied by the same customer should also not be put together in the coating batch, as the device may have been processed in different ways. Cross contamination within the coating system can take place if strict guidelines are not maintained. These issues can be resolved to provide a safer product for the customer in a contract review process that is indicative of an FDA compliant and ISO 9000-certified facility.

Commitments for Success

The PVD coating of medical devices should not be taken lightly. Companies supplying PVD coatings to industry should have experience not only in the application of the coating, but also in the numerous processes that precede the actual coating of the product.

A coating facility should at minimum be ISO 9000-certified and employ controls such as specification development, documentation systems, and certification capability. This should be backed up by a materials analysis capability so that if issues arise, the root cause can be determined and eliminated. The products that are offered should have been biocompatibility-tested, and supporting documentation should be available for review. Coating processes that are computer-controlled to minimize human error, as well as other data should be logged so that the process can be reviewed.

Attention to these considerations, and collaboration with consulting services that possess an extensive history of experience, will lead to the successful application of surface enhancement technologies in our industry now, and will meet the challenges of the future.

Editor: IonBond LLC has provided surface enhancement products and services to the healthcare industry for over 15 years. IonBond conducts and publishes fundamental studies on the properties and performance of coatings and, with respect to the orthopaedic industry, is focused upon coatings that provide performance-enhancing solutions for surgical instruments, orthopedic implants, and spinal implant systems.



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