Engineered Coatings Minimize Downtime, Improve Sanitation in Medical and Pharmaceutical Applications



Applying Magnaplate coatings to pill chutes maximizes throughput and minimizes downtime.

Processing and packaging applications in the food and drug industries have many criteria in common, because both industries must meet stringent standards developed to guarantee the utmost safety of products intended for human consumption. Production methods must also be as efficient and cost-effective as possible, maximizing throughput and minimizing downtime. To meet these dual objectives of high product integrity and efficient production, engineered coatings are increasingly being used to protect machine components, improve sanitation and solve performance problems in the packaging and processing of pharmaceutical and medical products.

Specialized coatings that enhance the surface of metals and other substrates are used in the medical and pharmaceutical industries to provide FDA compliance and solve wear, corrosion, lubrication, mold release and other production issues. Magnaplate Corporation, a pioneer in surface enhancement coatings, is continually developing specific product families that can withstand the rigors of pharmaceutical sterilization and production. Depending on the application, product families may be mixed and matched to meet several design objectives. For example, several coatings work excellent for applications reaching temperatures as high as 1,000°F and is compliant for food contact applications. These coating technologies are combined with our coating families such as Nedox® and Tufram® to meet specific medical and pharmaceutical application requirements.

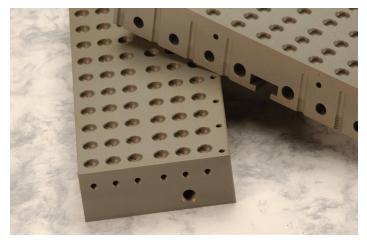
WHITE PAPER



Understanding Synergistic Coatings

Before delving into the issues involved in medical and pharmaceutical production, it's important to have an understanding of how surface-enhancement coatings work. The basic idea behind engineered coatings is to enhance the surface of metals and other substrates, imparting performance attributes such as corrosion resistance, hardness and dry lubrication. Used in applications from undersea to outerspace, synergistic coatings from Magnaplate transform plentiful and inexpensive metal parts into chemical-resistant, super-hard, dry-lubricated products that last longer, perform better and are more cost effective than components made of expensive and rare metals.

Coatings are applied to substrates in a multi-step system that begins with specialized cleaning processes. Next, the substrate's surface is enhanced by applying a base coating using plating conversion, deposition, thermal spray or a mix of these techniques, depending on the specific coating formulation. The process then continues with a controlled infusion of various proprietary polymers or other dry-lubricating particles or metals. For example, on some metals, a hard layer of nickel alloy is deposited on the surface. The micro pores are enlarged, and polymer particles are then infused into the surface layer. A secondstage treatment ensures thorough integration into the top layer.



HCR was used on this forming tool for form/fill/seal blister machines because it is highly resistant to gases emitted from PVDC laminates film.

The major advantage of Magnaplate coatings versus other types, such as paint-on varieties, is that the materials in the Magnaplate coatings become an integral part of the substrate. Particles are mechanically bonded and the resulting new surface layer resists chipping, flaking, peeling or rubbing off. Because these coatings create metal surfaces that offer superior performance to both the original base metal and the conventional coatings, these surface enhancements are said to be "Synergistic". Further, because the engineered surfaces either duplicate or surpass the performance characteristics traditionally provided by metals such as chromium, cobalt, cadmium and manganese, use of these expensive, scarce or environmentally hazardous materials can be reduced.

When selecting an engineered surface treatment, it is important to consult with the coating supplier early in the design process so that the most appropriate formula may be matched to the intended application. Several families of Magnaplate coating systems are available, each developed to protect a certain metal or group of metals or to solve a specific problem. For example, the widely used Nedox family is a nickel-alloy-based coating that protects most metals, including aluminum, against wear, corrosion, sticking and galling. Within the Nedox family are many subvarieties that employ various polymers and dry lubricants to achieve different properties, such as FDA compliance, enhanced hardness, superior mold release or excellent release at high temperatures. Similarly, the Tufram family of coatings for aluminum and aluminum alloys also features a range of specialized formulations depending on the intended use. The ability to customize product families with our proprietary polymers holds true across most Magnaplate coating families.

Coatings Enable Safe, Efficient Pharmaceutical Packaging and Processing

Engineered coatings are used for a wide range of purposes across many industries and in various stages of production and design. For example, existing parts are often coated to improve wear and performance, damaged parts are repaired, coated and returned to service, and newly fabricated parts are coated to provide optimal performance on new machinery. What should design engineers and those in the MRO community be aware of when specifying coatings for medical and pharmaceutical applications? Following are several criteria that apply to both industries.



First, surface hardness should be adequate to guarantee long service life for parts by protecting against wear, abrasion, corrosion, friction and galling. Be sure to ask your coating manufacturer if formulas comply with USDA and FDA codes. Ease of cleanup is also extremely important: Sanitary cleanup must be thorough and easy to accomplish. Further, surfaces must be dense, have low surface finish values and non-porous to prevent growth of mold and bacteria. Coated surfaces should also be nonstick to prevent product hang-up and ensure efficient substance release. Finally, coatings must not contaminate products and coated surfaces must be non-reactive to the atmosphere and potential spills. For best results, it's important to discuss application requirements with your coating provider early in the design stage. Experts in material science and coating formulations will then be able to recommend the best combination of base materials and processes to meet specific requirements.

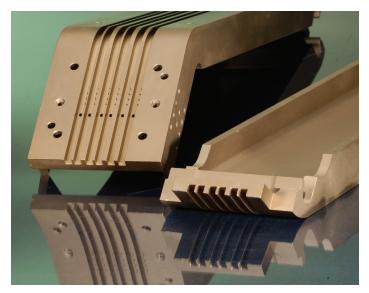
HIGH-TEMPERATURE COATINGS

Several Nedox and Tufram coatings are suitable for use in many medical and pharmaceutical packaging and processing applications, such as coating metal seal jaws, platens, and dies for quick release and easy cleanup, and heat-staking tools, blades, extrusions and tooling faces for wear resistance and quick release.

- Withstand temperatures to 1,000° F
- FDA compliant to Title 21 CFR175.300
- · Low surface energy, highly water-repellent
- Provide anti-stick, easy-clean surfaces
- No fluoropolymers, no PFOAs
- Will not degrade at high temperatures
- Protects Nedox-treated substrate from oxidation
 at high temperatures

Engineered Coatings Solve Pharmaceutical Packaging Issues

To gain an understanding of how engineered coatings can increase efficiency and solve specific production issues, it's helpful to look at a few examples from the pharmaceutical industry:



Pill guide plates used in pharmaceutical form/fill/seal machine. NEDOX prevents product hang-up keeping flow rates steady.

Mold Release – A contract packaging company produces thermoformed plastic sheets with multiple cavities for individual tablets, capsules and caplets. After the cavities are filled and sealed with foil, sheets are cut into strips and packaged for sale orfor use as drug samples, hospital doses or clinical study packages.

Problem: The films tend to stick to the aluminum tooling after thermoforming. Because each sheet of thermoformed film contains numerous cavities, if just one cavity is ruined because tooling sticks to it and tears it, the entire sheet must be discarded.

Solution: Magnaplate's Nedox coating provides a dry lubricating property that solves the problem. Nedox creates a dense, non-porous surface, which also eliminates the potential growth of mold and bacteria.

Friction – A packaging equipment supplier to the pharmaceutical industry makes extensive use of Magnaplate coatings for improving wear characteristics, reducing friction and providing inert surfaces where chemically active material might contact equipment components. One application is a filler designed to handle irregularly shaped containers; its reciprocating head is timed to move with the conveyor belt so that the filling nozzle can enter, fill and leave the container without touching it.



Problem: The packaging OEM wanted to use aluminum for the filler heads, but was not able to because of friction and wear issues.

Solution: Magnaplate applied a Tufram coating that allows the aluminum heads to withstand the friction created by its moving parts.

Corrosion — When engineers at one pharmaceutical equipment manufacturer began reassessing their manufacturing facilities, they focused on an 8-ft-diameter center slung centrifuge featuring a perforated basket that holds in-process pharmaceuticals.

Problem: The engineering team anticipated corrosive attack from acids, bases and solvents.

Solution: To prevent the attacks, the centrifuge was treated with a corrosion-resistant Lectrofluor[®] coating.

Speed – A packaging equipment manufacturer supplies a variety of pharmaceutical companies with vertical and horizontal form-fill-seal machines for pouch packaging of viscous and aqueous liquid products, tablets, pre-moistened applicators and sterilizable hospital disposables in sealed and peel-open pouches.

Problem: The machines feature sealing head components and other key parts susceptible to corrosion, wear and product release issues.

Solution: Parts are coated with a variety of Magnaplate coatings to increase operating speeds without excessive part wear.

Sticking, Chemicals – A manufacturer needed to protect a three-piece mold that thermoforms blisters from PVC/ PVDC laminates in form-fill-seal machines.

Problem: The three-piece mold was facing issues with difficult product release and exposure to chemical fumes.

Solution: Magnaplate HCR[®] provides the desired nonstick properties and resistance to hydrogen chloride fumes given off by the laminate in the pre-heat station.