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

By Corey Wesnitzer, General Magnaplate Corp.

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, provide antimicrobial properties 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



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

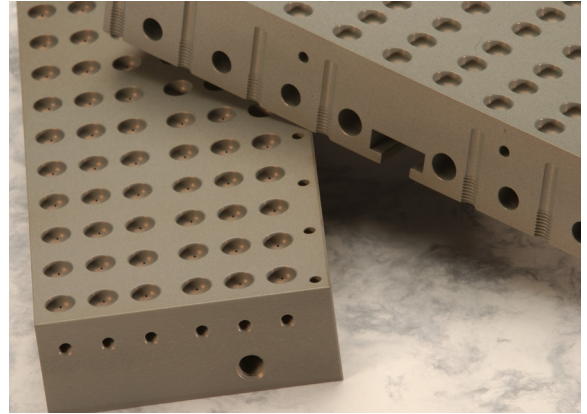


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used in the medical and pharmaceutical industries to provide FDA compliance and solve wear, corrosion, lubrication, mold release and other production issues. General Magnaplate Corporation, a pioneer in surface enhancement coatings, is continually 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, a new antimicrobial coating technology called MAGnanoSHIELD® offers microbial resistance in addition to other beneficial properties, while the new Magnaplate 10K™ Series is now available for use in applications reaching temperatures as high as 1,000° F and is compliant for food contact applications. These new coating technologies are combined with other coating families such as Nedox® and Tufram® to meet specific medical and pharmaceutical application requirements.

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 General 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.



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.

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 second-stage treatment ensures thorough integration into the top layer.

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.



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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 sub-varieties 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 all 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

MAGnanoSHIELD Antimicrobial Coatings

MAGnanoSHIELD has been subjected to extensive third-party testing by Antimicrobial Testing Laboratories LLC. Test results show that it inhibits microbes on different types of metal surfaces, even when implemented as part of a broader coating system. Here are some of the places antimicrobial coatings are being successfully used:

Pharmaceutical Equipment	Medical Diagnostic Equipment
<ul style="list-style-type: none"> • Pill Chutes, Pill Shoes 	<ul style="list-style-type: none"> • Carousels
<ul style="list-style-type: none"> • Fill Tubes, Fill Plates, Fill Box 	<ul style="list-style-type: none"> • Sample Platforms
<ul style="list-style-type: none"> • Freeze Dry Equipment 	<ul style="list-style-type: none"> • Chute Guides
<ul style="list-style-type: none"> • Capsule Indexing 	<ul style="list-style-type: none"> • Dilution Wells
<ul style="list-style-type: none"> • Tamping Pins 	<ul style="list-style-type: none"> • Centrifuges
<ul style="list-style-type: none"> • Dosing Discs 	
<ul style="list-style-type: none"> • Segment Blocks 	



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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, FDA and CFIA 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. Ask your supplier if antimicrobial formulations are available for extra insurance against microbes and fungus. Coated surfaces should also be non-stick 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.

Engineered Coatings Solve Pharmaceutical Packaging Issues

To gain an understanding of how engineered coatings can increase efficiency and solve

High-temperature 10K Coatings

10K 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

specific production issues, it's helpful to look at a few examples from the pharmaceutical industry:

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 or for 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.



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Solution: General 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: General 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 General 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 non-stick properties and resistance to hydrogen chloride fumes given off by the laminate in the pre-heat station.

Specialized Coatings Protect Against Microbes, Resist High Temperatures

Beyond protecting parts from wear and corrosion and providing excellent release, surface enhancement coatings can also impart other useful qualities to their substrates. Two new formulations especially well suited to medical and pharmaceutical applications include MAGNanoSHIELD

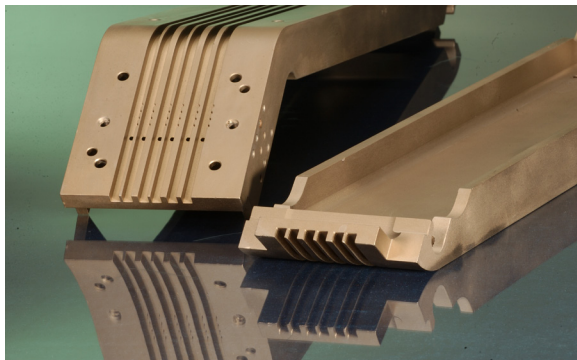


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coating technology for antimicrobial protection and the 10K series of high-temperature coatings. Let's take a closer look at each of these advanced coating families.

Newly developed MAGnanoSHIELD coating technology offers antimicrobial protection for metal parts while simultaneously delivering a low coefficient of friction, hydrophobicity, wear and corrosion resistance, and release properties. The coating technology offers a bacterial reduction greater than 99.9999%, protecting against the risk for contamination to equipment during the manufacturing process that can lead to diseases and contaminated drugs.

The combination of MAGnanoSHIELD with coatings such as Nedox and Tufram offers extensive functionality to design engineers. Applications for the new coating technology include food processing and packaging equipment, pharmaceutical and nutraceutical packaging, medical devices and cookware manufacturing. Magnaplate coatings in conjunction with MAGnanoSHIELD prolongs part life by protecting against wear and abrasion. In addition, the low coefficient of friction also ensures an easy-to-clean surface, which reduces the need for caustic and acidic chemical washdown solutions.

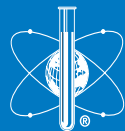


Pill guide plates used in pharmaceutical form/fill/seal machine. NEDOX prevents product hang-up keeping flow rates steady.

Here's how it works: Incorporated as a nanoscale dispersion within a coating matrix, MAGnanoSHIELD inhibits the growth of microbes by interfering with DNA replication, damaging cell walls, altering cell membrane permeability or combining with bacterial proteins in ways that disrupt normal cell functions. What makes the new antimicrobial technology especially useful is that it can be implemented as part of a more broadly useful coating. For example, MAGnanoSHIELD has been successfully combined with FDA compliant coatings such as Nedox for use on any non-ferrous or ferrous alloys, or Tufram for use on aluminum. It is also compatible with General Magnaplate's other coating technologies.

MAGnanoSHIELD has successfully been incorporated into coatings that offer low coefficient of friction (< 0.2), hydrophobicity ($> 120^\circ$), and wear and abrasion resistance. Imparting antimicrobial properties to medical devices, healthcare equipment and imaging machines provides clear advantages for product safety and integrity. An added benefit for these medical applications is the hydrophobic properties of the coating, which makes the equipment much easier to clean. As with medical applications, microbe resistance and cleanliness are of critical importance wherever pharmaceuticals are involved. Pharmaceutical manufacturing and packaging machines, which include many rotating and sliding components, will likewise benefit from the increased wear resistance and low friction provided by surface-enhancement coatings.

In packaging and processing applications where high temperatures occur, the Magnaplate 10K Series protects parts to minimize downtime and keep production



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up and running. Prior to the introduction of the 10K Series, coatings from major manufacturers featured product release temperatures to roughly 450° F. However, end users from across a range of industries were consistently requesting product release coatings that could handle temperatures of 700° to 1,000° F. The 10K Series was developed in response to these needs and offers three formulations:

10K1 — Solvent-based formula, withstands temperatures to 1,000° F

10K2 — Water-based formula (no VOCs), withstands temperatures to 1,000° F

10K3 — Solvent-based formula, withstands temperatures to 850° F, best release

Each coating formulation features low surface energy and is therefore highly water-

repellant, or hydrophobic. 10K coatings also feature a low coefficient of friction (COF), retain their properties at high temperatures, provide easy release at high temperatures and are FDA compliant to Title 21 CFR175.300. The 10K family is used in conjunction with any of General Magnaplate's coating families, such as Nedox, Tufram, Plasmadize® and many others. Typical applications for 10K coatings are found across a variety of industries — including medical and pharmaceutical packaging — and are especially beneficial in settings where a quick-release coating is required in a high-temperature environment.

To contact technical representatives at General Magnaplate Corporation, call (800) 852-3301, e-mail info@magnaplate.com, or visit www.magnaplate.com.