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MIM and 3D Printing: Precision Cleaning and Product Finishing of Medical Devices

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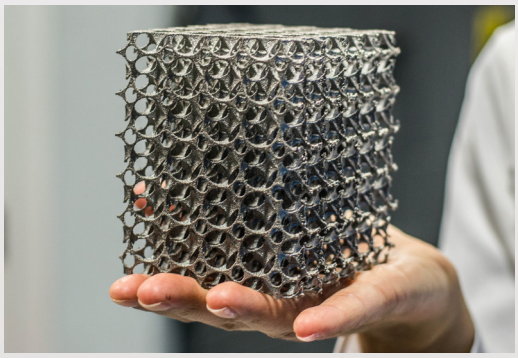

3D printing allows easier design of complex, intricate parts.

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As the miniaturization trend continues to take the medical device world by storm, manufacturing with metal injection molding (MIM) and additive manufacturing processes such as 3D printing are gaining widespread acceptance, allowing designers more options for creating parts economically that would otherwise be impossible to manufacture. In many instances, these state-of-the-art MIM and 3D printed processes are not possible without the use of special cleaning and or solvent-based process treatments.

For example, with the MIM process, binding agents required during the manufacturing process to bond powdered metal into a specific shape must be removed before the part can be exposed to the high heat required for sintering. In many cases, the binders require a specialty solvent that is engineered to selectively remove most, but not all of the binder. Up to 80 percent of the binder is removed to avoid contamination of the metal during sintering, but it is essential that some of the binder remains so that the part maintains dimensional accuracy during the sintering process.

With 3D printed processes, printers dispense special polymers to build a component progressively one layer at a time, often leaving a surface that is terraced. The part surface is subsequently chemically smoothed with a fast evaporating solvent vapor so that surfaces can be smoothed precisely to remove the terraces without damaging the finished part. This article examines how specialty solvents and precision cleaning fluids are specifically designed for the innovations in state-of-the-art medical device design and manufacturing, and how these types of chemicals can address different challenges in these new manufacturing processes.

New Manufacturing Process Considerations

Advances in manufacturing options such as MIM and 3D printing have opened up the possibilities for new and innovative medical device designs. For example, in the past, design compromises had to be made for parts that were too complex or small, but today, new processes using MIM for high-volume metal, and advances in additive 3D printing technology for low-volume specialty polymer parts allow design possibilities that are almost limitless.

MIM

Materials advances in MIM technology allow manufacturers to produce large quantities of parts with complex geometries, often eliminating machining completely. The quality and precision of parts made with MIM often results in parts requiring minimal subsequent machining to create a finished part with excellent dimensional repeatability. The MIM process is capable of creating complex and precise structures by blending metal powder with various binding agents. Metals available include stainless steel, tool steel, and many other ferrous and nonferrous alloys. The actual process combines a polymer or wax known as a binder with a fine metal powder to form a moldable admixture that then is formed or molded into the desired structure.

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MIM combines a polymer or wax binder with a fine metal powder to form parts.

Solvent extraction of up to 80 percent of the binder is done in a vapor degreaser.

Common types of binding agents are typically paraffin wax, carnauba wax, and specialty polyethylene waxes. The binding agents serve a critical purpose in the forming process but are ultimately sacrificial and must be removed once the structure is formed. Selection of a debinding method is a balance of removing the binder in the shortest amount of time and with the least amount of damage to the structure because as the binder is removed, the structure becomes fragile.

Solvent extraction of up to 80 percent of the binder can be done in either the solvent vapor or liquid phase in a vapor degreaser. Both rely on the solvent flowing through the pores of the structure to dissolve the wax. This is where the physical properties of the solvent become important. The ideal solvent will be nonflammable, have a low surface tension to work its way into the part structure, and be 100 percent volatile so the solvent can be easily removed before sintering. Once the debinding solvent is fully removed from the part structure, the parts are then thermally sintered under high heat to bond the metal powder into its finished solid mass state. The remaining binder in the part is essentially burned off at sintering temperatures.

New solvent blends have been developed to speed the debinding process without the use of n-propyl bromide, methyl pyrrolidone, polyethylene glycol, heptane, or trichloroethane, which all carry health and or environmental baggage. The new debinding solvents boast low viscosity and surface tension ratings, are nonflammable, and are engineered for selectivity so the right amount of binder is removed without damage to the part structure. The debinding solvents are distilled and reused in the debinding process, and as an added bonus, the solvents are hostile to the growth of bacteria, so manufacturers can rest assured that the risk of bioburden is almost entirely eliminated in this process. Because solvent cleaners do not allow bacterial growth, they simplify quality controls associated with process validation and good manufacturing practices (GMP) and provide a convenient way to validate bioburden out of the manufacturing process.

3D Printing

The surge in popularity of 3D printing, a type of additive manufacturing process, is transforming the medical device research and development process, allowing for rapid mechanical design and development, as well as quicker testing and prototyping of complex plastic parts. It offers more flexibility and significantly reduces lead times, all at a lower cost than traditional prototype manufacturing methods.

The flexibility of 3D printing allows designers to make changes and test those changes easily without setting up additional equipment or expensive tools. It also allows manufacturers to create individual custom devices, perhaps even including features that are matched to a patient's unique anatomy. 3D printing is very well suited to smaller production runs, as well as more complex devices with intricate geometries. Because many 3D printers build the devices progressively one layer at a time by extruding a thermally heated plastic filament, the surface finish of a part consists of layered terraces that must be removed to smooth the surface of a part.

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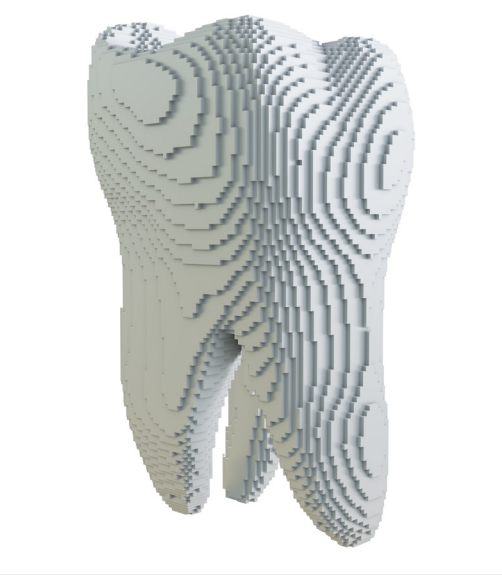

Plastic additive manufacturing often results in a terraced part requiring smoothing.

Traditional methods of removing the terraces have historically been extremely manual, but today, solvents have been developed for use in a vapor degreaser to chemically smooth out ridges without damage to the overall part by liquid or vapor immersion. Manual smoothing processes that include sanding or buffing would leave behind particles — this is not an issue when addressing the issue chemically. In order for this process to work, it is necessary to understand the chemical composition of the 3D printed polymer and find the correct chemical solution for the application.

While 3D printing today is largely limited to plastics, the commercialization of economical 3D printing of metals is just around the corner and promises to change manufacturing in ways that are almost limitless. In many instances, as with MIM production, the successful development of 3D metal printing will be directly linked to the availability of safe, appropriate solvent-based debinding agents. Trained vapor degreasing experts have experience selecting smoothing fluids for specific types of 3D printed polymers and can guide designers through this process.

One Thing Always Remains the Same

The medical device industry continues to evolve with innovative device design and manufacturing processes. Advances in device design is in a constant state of flux, but one thing will always stay the same: Even state-of-the-art designs and manufacturing processes can benefit from unique chemistries that make process advancements possible. It is essential to work with a partner with specialized experience and expertise in solvent technology that can keep up with innovation in cutting-edge medical device design and manufacturing.

About the author:

Jay Tourigny is Senior Vice President at MicroCare which offers precision cleaning, lubricating and debinding solutions. He has been in the industry more than 30 years and holds a BS from The Massachusetts College of Liberal Arts. Tourigny holds numerous U.S. patents for cleaning-related products that are used on a daily basis in medical, fiber optic and precision cleaning applications.
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