# Prototyping Via Innovative Customization

Device makers adapt traditional manufacturing techniques to rapidly create cost effective prototypes.

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New York City, 2009. A virulent plague has struck, spreading through Manhattan faster than it can be contained. The infected turn into terrifying monsters of unpredictable, varied forms, with one sole mission: kill the uninfected. The plague is Blacklight, and a military operation dubbed Blackwatch is created to contain the infection to the island of Manhattan. At the center of the operation is Alex Mercer, the secret weapon warrior who can consume whole beings and shape-shift as needed. A mysterious, hooded figure, he has no memory of his past. He swoops through the city changing forms as he goes, a mask over his face, on a mission to save humanity.

City unknown, circa 2013. A scientist studying the so-called "singularity," a hypothetical moment in the future where artificial intelligence will supersede human intelligence and radically change society as we know it, finds himself at the mercy of a fatal disease. To survive, he "programs" his human brain into the "brain" of a military robot, and escapes (in the body of the robot) from the military facility. Roaming the city as a hooded, masked figure, he seeks freedom, both physical and intellectual.

The former scenario is from a 2009 video game called "Prototype," and the latter from a film not yet released called "The Prototype." The trailer for the film shows the hero darting about city streets and alleyways almost exactly like the hero does in the video game, leading scores of fans to think this trailer promised a translation of their beloved game to the silver screen. In reality, the film's producers just tacked a "The" at the beginning of their film title; it has nothing to do with the game—even though the game came first—confusing audiences (perhaps intentionally, to draw views) and effectively squashing any chance the game's developers Radical Entertainment and Activision had of making money off a film adaptation.

The situation with the two "prototypes" presents an interesting look inside what it actually means to be A Prototype (not "The Prototype.") A prototype, of course, is a model on which a final product is based. Therefore, it comes first, before the product is created. It serves as a foundation, a visualization of design and what the product eventually will be capable of. The final product that makes it to market may look and function almost exactly like the original prototype, or may have changed quite significantly after design goals prove unattainable in practice, or if unforeseen demands make themselves known in the process. A company or design team sometimes may go through dozens of prototypes, all of which are different in seemingly insignificant ways, before settling on one that satisfies needs and demands. Like "The Prototype" the movie versus the original "Prototype" game, the final product may (or may not) have anything (or everything) to do with the original version.

*Bone Models+ often has "Skinny" on display at trade shows, a full-size model skeleton made up of vacuum metalized plastic parts made to look like real metal. Image courtesy of Bone Models+*

Prototyping broadly serves two main purposes: as proof-of-concept and as form study. A proof-of-concept prototype is used to test some of the more functional aspects of a product or device without adhering to exact intended appearance, material or manufacturing process goals. A form study prototype provides an interface for exploring the basic dimensions, appearance and tactility of a device without concerning itself with actual function or exact appearance of the product.

Prototyping for orthopedic and other medical devices has and always will present unique challenges because some of these devices, particularly in the orthopedic space, go into the body and stay there.

"We are essentially creating tools similar to everyday household tools such as a screwdriver or ratcheting driver, but for use in the medical field," Mark Bakula, director of research and development at Bradshaw Medical Inc., a Kenosha, Wis.-based company that makes orthopedic and spinal instruments, told Orthopedic Design & Technology (ODT). "This poses interesting challenges because the instruments must be created only with materials that are biocompatible with the human body.
These drivers also must be manufactured ergonomically with comfortable gripping features and light components to ensure surgeons can use them for extended surgical procedures. The instruments we manufacture also must be able to withstand sterilization and manual cleaning cycles which takes the instrument up to 275 degrees Fahrenheit and exposes it to multiple cleaning solutions."

Rapid prototyping is the go-to solution for quick, cheap models, especially in the orthopedic industry where a modular implant, sometimes with complex geometries, is the device in question. The technology rapidly is advancing and companies such as Stratasys, which is projected to represent 21 percent of the 3-D printing market by next year through a string of acquisitions, are growing rapidly as well. The medical device space is the most exciting one for 3-D printing, Pete Basiliere, research vice president of the Stamford, Conn.-based information technology and advisory firm Gartner Inc., said at a recent Stratasys press event in New York, N.Y. Opening up manufacturing speed and cost reduction potential for medical devices literally has "life altering potential," Basiliere said. However, at least right now, medical device manufacturing still is heavily reliant on large-volume, traditional manufacturing techniques such as injection molding. These traditional processes offer economies of scale in the long run when producing large product volume; they become important in the prototyping stage, where only a few devices are being made, when it is important that the prototyping stage prove that the device or component can be made via the intended end-stage manufacturing process. Prototypers have become inventive in finding ways to use techniques such as injection molding or CNC machining in early stages in order to meet this need.

## Molding Models

Albright Technologies, a Leominster, Mass.-based company that that provides custom silicone prototypes and volume production, deals purely in silicone materials when prototyping for orthopedic devices. President Jeffrey R. Thumm explained to ODT that its custom prototyping services involves a rapid CAD to CAM to CNC (computer aided design, computer aided manufacturing and computer numerical control) process to produce molds quickly that can withstand the high temperatures and pressures of silicone

processing.

“The benefits of our process are a three-week standard delivery of custom prototypes, in-house process and material expertise, high-grade silicones from major suppliers, micro-molding (reproduction of sub-millimeter features), iterative product development support and processes that are scalable to volume production,” Thumm listed. Indeed, speed is the key word when speaking about medical device prototyping, as getting to market first is imperative in a space where intellectual property and first-mover-advantage can translate into millions of dollars lost or gained.

“With injection molding, material availability is the key benefit,” said Ric Perry, president of Mack Prototype Inc., a rapid prototyping and low volume manufacturing services company based in Gardner, Mass. “Prototypes can be molded in specific medical grade materials that will be specified for large-scale production. Multiple tooling strategies can also be employed to cut cost and time out of a project, including modular unit dies (MUD), aluminum and conventional stand-alone tooling in pre-hard or fully hardened steel construction.”

Mack Prototype is a subsidiary of Mack Group, which also owns Mack Molding. Perry pointed out the specific benefits of molding for orthopedic device manufacturing, saying that many orthopedic components must be produced in materials able to withstand high temperatures and that can be sterilized.

“Depending on where the OEM is in terms of product design and development, the prototypes may have to be produced in end-use materials, which is more challenging,” Perry added. “This typically drives the prototyping process toward machining and/or injection molding.”

There is a reason, however, that prototyping often is most easily done with rapid prototyping methods. It’s cheap and easily alterable, whereas with injection molding processes, tools need to be fashioned for each individual component of a device, which drives cost up. But the advantages of molding in the prototype stage should not be dismissed, as specialist providers such as Albright Technologies and Mack Prototype attest. Rapid prototyping as well as rapid CNC machining are quick, but they do not offer economies of scale as production volume grows. This is the forte of injection molding. Once the mold has been made, though one mold can easily run thousands of dollars, the cost per molded part drops significantly if the volume of production is high. This makes the process ideal for producing hundreds of prototypes for functional or market testing. As a prototyping method it is ideal because it can produce parts in virtually any of hundreds of injection moldable resins. And most importantly, it tests moldability. If the part in question is going to be produced via molding when finalized, testing moldability is an invaluable step.

“One of the most interesting and challenging projects we’ve worked on involved manufacturing a high part number mix at low volumes for a tibial trial project,” said Steve Fidrych, director of molding operations for Mack Prototype, recalling a recent project. “Tibial trials are the plastic instruments used during knee replacement surgery. They mimic the final implant and help surgeons determine the proper size and thickness needed for a correct fit. The size varies, of course, from patient to patient. Traditionally CNC machined, the customer was looking for a more cost-effective method for producing the required 420 tibial trial configurations.

“First, the OEM designed a spacer unit that allowed them to stack parts to create multiple thicknesses. This reduced the part number count to 258. Still, developing injection molding tools for such a large number of parts in a cost-competitive way was going to be a big challenge. Individual dies were needed for each of the top surface parts, because they had various articulating surface conditions. The bottom surfaces, however, were virtually identical for all parts of a particular size group. So to reduce the overall part count, they took advantage of this commonality by using the master unit die (MUD) tool concept, where standard prefabricated bases are inserted with custom core/cavity units. Working in partnership with Mack Prototype, they were able to produce 24 different part numbers using only four complete modular dies, five additional cavities, and two core sub-inserts.

“Using combinations of trials and spacers, the two companies were able to cover the entire breadth of the program (420 tibial trial configurations) with 258 unique molded part numbers, including 48 spacer molds, 48 complete tibial trial molds, and an additional 162 cavities. This approach reduced the total number of complete modular inserts by 210 and cut total tooling costs in half. Additionally, by converting from conventional CNC-machined trials to injection molded replacements reduced part cost by nearly 75 percent.”

With inventiveness, medical device manufacturers can use traditional manufacturing methods in a cost-effective manner to create varieties of components at once. And using the intended final manufacturing process provides the added advantage of validating the process in the prototyping stage, and testing whether the device can withstand the rigors of such processes.

“Orthopedic prototypes often relate to an orthopedic problem unique to a patient or a patient set,” James Fentress, director of engineering for Gilero Biomedical, a provider of pharmaceutical and medical device design and development services based in Durham, N.C., told ODT. “This means that accurate prototyping of the device often requires accurately modeling the orthopedic injury as well as the device. However, extra care needs to be taken on pairing rapid prototyping material selection to the intended use of the prototype. Although a fair subset of orthopedic prototypes are used simply to verify device shape for the surgeon or the device spatial relationship to device user or underlying patient morbidity, occasionally devices need to better approximate the behavior of the expected final device. In such cases a material or set of materials needs to be selected for a prototype to better ensure that the prototype behaves as if made from the final expected device materials.”

## The Trust Factor

Orthopedic implant prototypes don’t usually make it inside a patient’s body or into a clinical setting—for that, the final, validated, tested, sterilized product is required. However, there is a lot of capital in prototyping companies providing their medical device OEM clients with assurances that they know the name of the medical game. The U.S. Food and Drug Administration, as well as every other regulatory body worldwide in charge of medical device regulation, imposes very strict guidelines on how a medical device can and should be manufactured for the maximum safety of the patient. Medical device OEMs are used to adhering to these guidelines, and prototypers do best when they acknowledge and work within these parameters too.

“Albright has found the challenges of prototyping for orthopedic devices to be similar to other product prototyping,” Thumm said. “One advantage in silicone molding is that major silicone suppliers (such as Wacker, Bluestar, Nusil and Shin Etsu) certify certain silicone materials for human implant. With the confidence of working with pre-certified biocompatible material, Albright molds medical products for our customers in our hard-walled, ISO 7 compliant clean room. All of Albright's molded silicone products are produced under the oversight of our TUV-certified [the German designation for a product certified to be safe for humans and the environment], ISO 13485 quality management system.”

Bone Models+ (Bone Models Plus LLC) is a custom anatomical models company based in Kingsford Heights, Ind. The company makes all manner of orthopedic (and other) components intended for educational, instructional, display and sales use. As such, the devices have to look right (for the buyer or trade show attendee), feel right (for the surgeon), but do not have to be sterile or biocompatible. However, the company is ISO 13485 certified, which certifies that the quality system used to manufacture devices satisfies the extremely high requirements for medical device manufacture.


*Bone Models+ makes anatomical models for instructional, educational, display and sales use. Image courtesy of Bone Models+*

“We have a quality system that parallels any medical device company that we work with or engage,” Founder and President Jeff Maki told ODT. “So there’s no falsification or misrepresentation of the quality of the implants we produce, because they are made just like a regular knee implant. Our customers value that. In the medical world, that ISO 13485 certification is cultural capital. It’s a significant investment for the company, and it represents the fact that we take quality seriously and we’re professional. ‘Do you have a quality system?’ is always a question that’s asked when you want to become a qualified vendor for an implant company. It is an easily recognizable tool that shows we run the same quality system our clients do.”

Bone Models+ is hard to miss at trade shows, where they often have Skinny on display (pictured). Skinny is a full-size model of the human skeleton made up of plastic parts that have been vacuum metalized. The process creates low cost parts made from various polymers, but metalized to look like a metal implant if the application calls for that. The high-shine, chrome finish closely replicates polished cobalt chrome, stainless steel, and titanium. The parts are prepared with a base coat of paint that is cured onto the surface with ultraviolet light. The parts are then placed in a large vacuum chamber. The metal applied is in the form of wafer foam, electrically charged, and is atomized to cover the parts. According to Maki, it imparts durability, clarity and looks exactly like metal. The process, also known as PVD (physical vapor deposition), allows for a much lower cost option for making metal orthopedic models.

Make no mistake, however. Bone Models+ doesn’t just make toys. Recently, the company completed a project with Orthosensor Inc., a maker of smart technological devices in the field of musculoskeletal digital health based in Dania Beach, Fla. Orthosensor’s Verasense sensor assisted surgery system combines a single-use, intelligent tibial insert trial with an user interface designed to enable evidence-based decisions regarding component position and soft-tissue releases to achieve balance and stability through a full range of motion during surgery. Bone Models+ developed a femoral component model for the company for use with Verasense that enables the simulated application of bilateral condylar pressure (around the knee) during use of the system. This allows a surgeon to feel exactly what it would feel like to use Verasense in a real surgical setting when s/he performs soft tissue modeling to balance pressure on the femoral condyles.

“It’s tactile,” Maki said. “Surgeons are all about touch. It’s cool to be able to present them with a model that gives a great explanation for the performance of what that product is, and also for them to be able to get their hands on it, adjust pressures, and observe in real time the computer screen showing the digital readout of the psi on each condyle.”

When a model or prototype instills trust in the first user, whether it’s an OEM seeking to sell a medical product or a surgeon seeking to use a product, it has done its job. Once this trust has been established, the manufacturer can move on to the next phases of development, validation, production and finally commercialization.

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