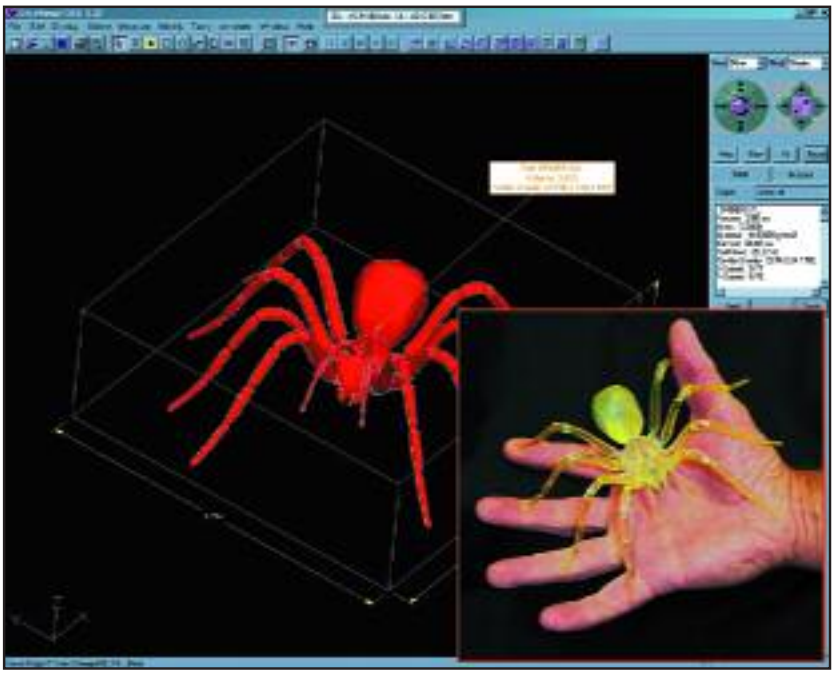
Perfecting the Process

New Rapid Prototyping Technologies Are Aiding Device Manufacturers Reach Market More Quickly



An illustration of the SLA process, this IGES file of a spider was created in Pro/E. The SLA process uses laser technology to solidify UV-sensitive resin in layers based on the parameters established in the CAD database. The resulting SLA prototype can be generated within two days, providing the customer with a workable unit for critical verification and approval processes. Photo courtesy of Mack Prototype.

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For decades, medical device manufacturers have jostled to be first to market with their innovations. In recent years, the bar has been raised: be the first to introduce a gold standard design that end users will embrace and can be produced efficiently and cost effectively. Advances in rapid prototyping are helping them reach their goals.

Consider a glucose sensor manufacturer that recently approached Potomac Photonics in Lanham, MD for help. The company was considering several product designs, so Potomac Photonics encouraged its customer's engineers to move from traditional tool die prototyping methods to laser technology. The traditional method would have resulted in a single prototype being produced in a six-week period. Using lasers allowed seven different product designs—including the version ultimately selected—to be created within the same time frame.

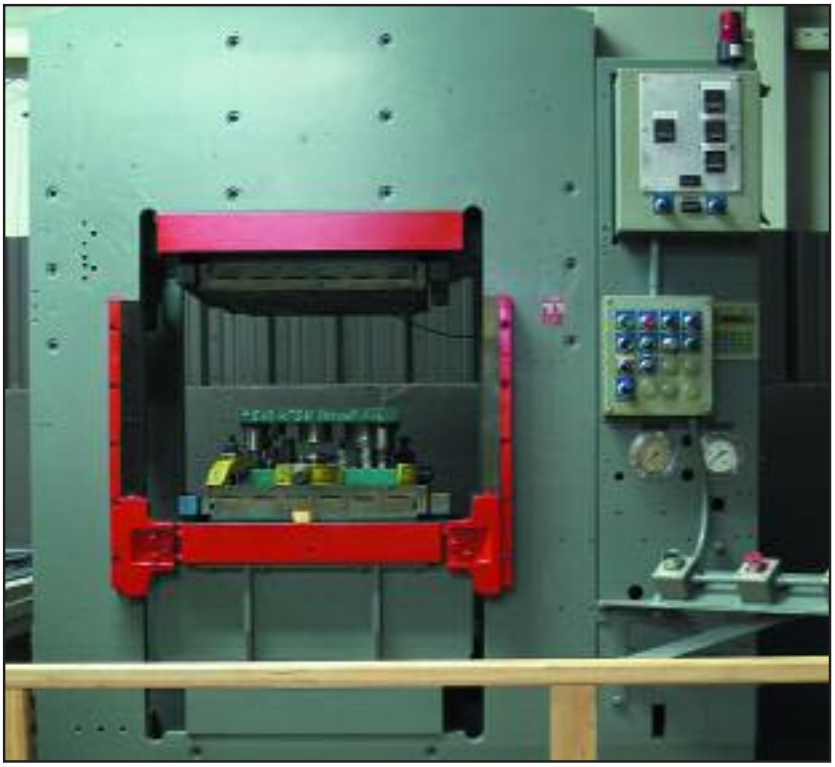
Like many other prototyping houses, Potomac Photonics, worked with its customer to ease the transition into manufacturing. By using multiple beam delivery and galvos, speed and throughput during production were increased, resulting in substantial cost savings for the client.

More, More, More

Medical device manufacturers are embracing the importance of the prototyping process like never before.

"In the past, the prototype cycle often was undervalued and overlooked in the development of a medical device or instrument," said Debra Van Sickle, vice president of sales and marketing for Peridot Corp. in Pleasanton, CA, "Today, manufacturers are considerably more savvy about the roles materials and manufacturing techniques play in a product's ultimate success, so we're being brought in earlier and earlier to dialogue with our clients."

Van Sickle noted that her company often advises medical device manufacturers of materials they may not have considered for a particular application. Peridot's metallurgists and engineers stay current on which materials



By adding a hot forming press at its facility, Okay Industries can now turnaround prototypes using exotic materials in a day compared with one week or longer when forms must be outsourced to a heat treater multiple times for annealing in between forming operations. Photo courtesy of Okay Industries.

are most cost effective and what new technologies can most enhance a material's physical properties. They make recommendations that can save customers thousands, even millions, of dollars over a product's life cycle.

For example, significant cost reductions can often occur simply by changing from nitinol or other higher-priced metals to a more moderately priced material. Said Van Sickle, "Our people always look at a project as if we were spending our own money."

Jason Howey, business development manager for Okay Industries, Inc. in New Britain, CT, said clients often ask for his involvement earlier on in the design process as well. "We're using new processes in prototyping that are more representative of the production environment, which prevents future production delays and excess costs and eliminates unknowns," he noted.

These new processes are enabling manufacturers to more quickly and cost-effectively get more of everything: more designs for a single product being prototyped concurrently, more iterations of each design and more copies of each prototype.

Medical device companies increasingly are seeking parallel development of different product designs, reported Sidney Wright, technical lead for contract manufacturing for Potomac Photonics' MicroFabrication Center. "More customers are saying, 'Here are four designs. Make all four, and I'll see which one I like the most.' They want to find the right path quicker versus following a serial process in which they pursue one design, then modify it and modify it again," Wright said.

More Iterations

Increased numbers of iterations also are common. Ric Perry, president of Mack Prototype in Gardner, MA, noted that because prototype houses today often are working off of engineering CAD databases, they are able to turn around prototypes much faster than in the past, which allows additional time for more revisions. He added that he often sees customers asking for one or two more rounds of prototypes before finalizing designs.

"Customers are putting more prototypes in the hands of the end users—in the hands of surgeons or whoever will use the product—to make sure it meets all criteria, which is leading to better functionality and ergonomics," he said. Further, he noted that customers want more copies of each iteration to distribute. In the past, a prototyping house might have produced just two to 10 parts. Today, in many instances, companies want 20 to 200 parts.

Also, high-speed machining and improvements in materials and programming software are speeding the process. "Three or four years ago, it would take two to three days to program a machining center," Perry said. "Today, it takes two to three hours."

Indeed, prototype houses report that they've been adding new services and capabilities to better meet customers' expectations. Mack Prototype offers full-service prototyping and a low-volume manufacturing facility so that it can meet the needs of a range of medical firms. Perry said that companies increasingly are seeking to simplify their supply chain so selecting a house that can provide stereolithography

(SLA), selective laser sintering (SLS), CNC machining, polyurethane molding, liquid injection molding, custom injection molding, painting, and myriad other technologies under one roof is becoming a higher priority for some industry players. Not only can one company meet all of their needs internally, which simplifies project management and can save significant amounts of time, but also numerous projects and processes can be run concurrently.

Howey noted that Okay Industries has also seen the same trend of customers asking for more sets of prototypes, although he theorized that his customers are using the extras to perform more tests. Okay Industries and other companies also are performing more testing on prototypes for customers as well as offering value-added services such as cleanrooms, assembly, supply chain management and the like.

New Technologies

During the past year, Peridot has added screw machines, laser cutting and welding to its offerings and currently is incorporating a cleanroom facility and more contract manufacturing space. Van Sickle noted that one of the company's—and the industry's—increasing focuses is on microfabrication.

"Our customers have asked us to become more efficient at doing smaller and smaller size envelopes—meaning the products are getting smaller and smaller," she said.

In late August, Peridot installed a Rofin-Sinar Precision YAG laser system to address those requests. The new Rofin machine performs micro-laser tasks such as cutting slots in tubing and medical instrumentation. Prototypes can be turned around in a few days to two weeks, depending on how closely processes must match the final production environment (the closer the match, the more time required).

Even tried-and-true technologies are seeing improvements. Van Sickle explained that EDM prototyping has become hugely popular at Peridot. "It used to be that many parts were photo etched first, but this was done out of house and required a two-week lead time to get the blank in."

"Today, we stack layers of material in a form and put it into a wire EDM, blanking it and forming it in-house. This lets us shave one week off the total time required, so EDM is playing a more vital role in rapid prototyping."

Advancements in Lasers

Potomac Photonics' laser processing technology allows for prototypes to be made within 24 hours, and the company noted that lasered models are real parts that can be tested and assembled, as opposed to some SLA samples, which often are simply mockups or models. Mike Adelstein, vice president of microfabrication for Potomac Photonics, said that a better understanding of how materials react with lasers as well as improvements in materials and lasers have combined to cut turnaround times.

"Advancements in laser technologies continue to be made in all wavelengths, which allow many different materials to be processed," he said. "Costs are coming down so it's easier for companies like us to integrate them into our systems and produce prototypes faster, easier and more

When Designing a Prototype, Experts Advise OEMs To Consider Myriad Manufacturing Parameters

Medical device manufacturers' increasing attention to detail when producing product prototypes can pay off big when those products go into production—but only if they've also spent time considering manufacturing parameters.

Larry Noble, president of Norman Noble, Inc. in Cleveland, said that while overall the product designs his company sees today are cleaner than they've been in the past, too often companies have not thought about how manufacturing details will affect a chosen design. In fact, he said, drawings that come into his company often require significant modifications.

"Too often engineers don't have practical background, so frequently they over-tolerance dimensions," he said. Other common mistakes? Using the wrong materials or the wrong heat treatments.

Fortunately, manufacturers can make corrective recommendations that benefit all parties involved. There is a world of difference between design engineers and manufacturing engineers, Noble explained, and to get the best product, both sides need to work together, ideally from the beginning of a project. After all, it is much less costly to correct problems at the stereolithography stage than to have to rework building tools or scrap out parts later in the process.

Noble reported that his firm's suggestions sometimes can save a company substantial sums over a product's life cycle. Norman Noble also can recommend manufacturing processes or finishing techniques that will streamline production or help improve a product's final appearance and, thus, performance in the marketplace.

cost-effectively."

In the past, prototyping houses often used excimer lasers to machine materials because they are compatible with numerous materials. However, because of its slow processing speed, excimer technology did not provide a cost-effective solution for certain applications once the product moved into production. Some companies are now using solid state lasers that offer the power and repetition rates necessary to significantly speed up the machining process. Using lasers with a wavelength of 355 nm, Potomac Photonics was able to successfully machine many of the same materials previously limited to excimer, but the new technology is still unable to achieve an acceptable cut quality for some materials due to the higher wavelength.

Potomac is considering making the move to 266 nm lasers, which are able to machine a wider variety of materials, including glass, polyester and PEEK. Widespread use of the 266 nm lasers will not be achieved until its price tag is comparable to those of excimers and the 355 nm lasers, though.

Wright pointed out that today's lasers, coupled with software-controlled galvanometers, offer more precision and faster results. Laser microfabrication of features as small as one

Views from a Long-time Prototyping Veteran from the Front Lines

As principal of Antocci Engineering Co. in Leominster, MA, Joe Antocci has personally been involved in the prototyping efforts of medical device and instrumentation companies for more than 30 years. During that time, he's noted several new developments:

• More prototypes for clients means more input. Antocci said human factors, especially with handheld instruments, are more important today, so companies often want at least 15 prototypes so they can get simultaneous feedback from numerous sources on a product's design, style and feel. These models help to optimize a design and to accelerate product release schedules.

In addition, more companies are acquiring prototypes for three or four competing product designs concurrently because lower prices are making parallel prototyping more affordable while also speeding time to market.

"You can get an SLA (stereolithography) for $200 to $300 for a modest-sized part since you can make several design concepts at the same time on the same plate. You can quickly obtain a group of rapid prototype models for competing designs at once for a relatively low price. It's a very effective design tool," Antocci said.

• The falling costs of prototyping machines are enabling more companies to buy their own. One of Antocci's clients recently purchased its own prototyping equipment so its designers would have exclusive access to the machine, further speeding the prototyping process.

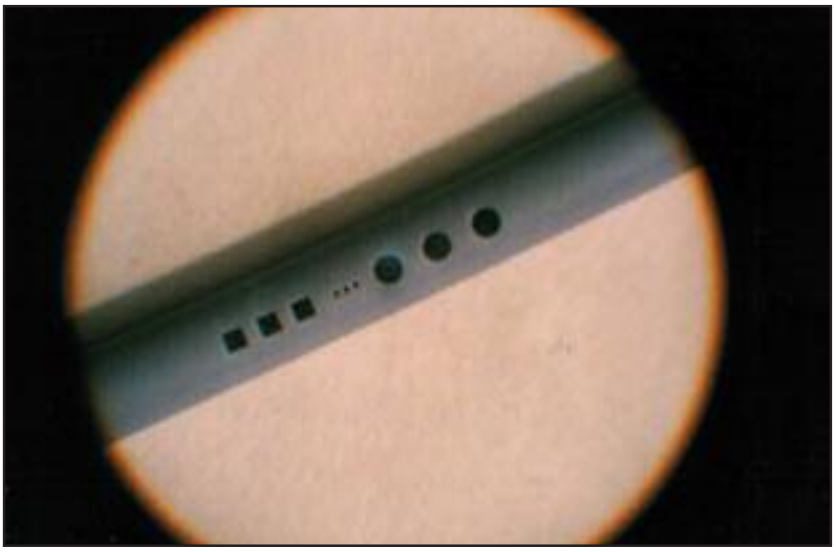
"It's great to have a machine in-house to aid in mechanism work," Antocci said. "Everything looks good in CAD, but once you have moving parts moving against other moving parts, it can be another story. If you have your own machine, you control the machine and you control the schedule." Before, a medical device company may have had to wait two to three days to get an SLA. By bringing the equipment in-house, it now can go from a 3D CAD model to an SLA in several hours.

• Rapid prototype model materials are more robust. This allows more functional testing. Today's materials are improved, which leads to better prototypes. In years past, Antocci said, if a model was dropped, it probably broke, precluding further testing. Models were used more simply to see how a device looked. Today, models can withstand higher stress, allowing parts to be tested for functionality and incorporated into existing assemblies.

• Full-service capabilities are valued by customers. Antocci said his customers want not just the part but the assembly and other value-added services. He noted a recent job in which the client's project required the testing and integration of a new paint system on a set of cast urethane front panels. The prototyping house had an onsite paint shop that was able to work out the paint application issues for the client and perform the work much more quickly than outsourcing it.

"The project would have been an abject failure if [the prototyping house] hadn't had an in-house paint facility that could work with the paint supplier and the client. We didn't want to have to ship the parts two towns away, wait in queue when we got there, and then have to go through more layers of people," Antocci explained. "I like working with one house that can meet all of the project's requirements. We get better service and responsiveness, which contributes to successful project completion."

Prototyping houses say that improved material properties are aiding prototype development in some instances because less processing is required.



By employing laser technology, very fine prototypes such as this one made by Potomac Photonics can be produced dramatically faster than using traditional methods, enabling OEMs to ask for more iterations. Photo courtesy of Potomac Photonics.

micron is common, and a prototype that might have taken two to three hours to create with an excimer may take just 1/25th of the time using solid state lasers, he added.

Okay Industries also has incorporated technology to streamline the prototyping process. This past February, the company added a hot forming press that can heat exotic metals such as titanium, different types of stainless steel, Inconel and other specialty materials to 1300˚F. Prototypes using exotic materials now can be turned around in a day compared with one week or longer when forms must be outsourced to a heat treater multiple times for annealing in between forming operations. "It's a better way for forming complex material, and it reduces lead time substantially," Howey said.

He noted that quick-change modular tooling also is becoming more popular. A lot of companies have similar prototype parts that can benefit from sharing common tools, shortening the lead time on the tooling end.

The Impact of Materials

Prototyping houses say that improved material properties are aiding prototype development in some instances because less processing is required. However, shortages in some materials are requiring advanced planning.

"The metals market is very challenging and uncompromising right now. Lead times and costs are going up. It can take months to get materials," Howey lamented. He said that Okay Industries has grown its inventory of materials to ensure its customers won't be adversely affected.

Indeed, medical manufacturers should be aware that titanium prices have more than tripled in the past year, with lead times to obtain titanium pushing out to six months or longer. Stainless steel prices have risen 30% to 35%, and it takes at least four weeks to obtain steel currently. Nitinol prices have increased by about 5% over 2004 levels, and lead times are running at about 10 weeks.

Some prototyping houses are working with medical device companies to refine current materials or develop new ones. Mack Prototype is currently testing new resins. "Because we're an engineering development company, we can work directly with medical device companies and plastics suppliers to develop higher-performing materials," Perry said.

The volume of prototypes being produced—both in number of new products coming online as well as the number of prototypes being created for each product—has been increasing dramatically, and the outlook for 2006 continues to be healthy. Most prototyping houses expect to see gains of 15% to 20% over 2005 levels next year on top of significant gains of as much as 50% this year. This can be attributed to continuing refinements in technology and materials, which are making more iterations—and more perfect products—possible. ❖

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