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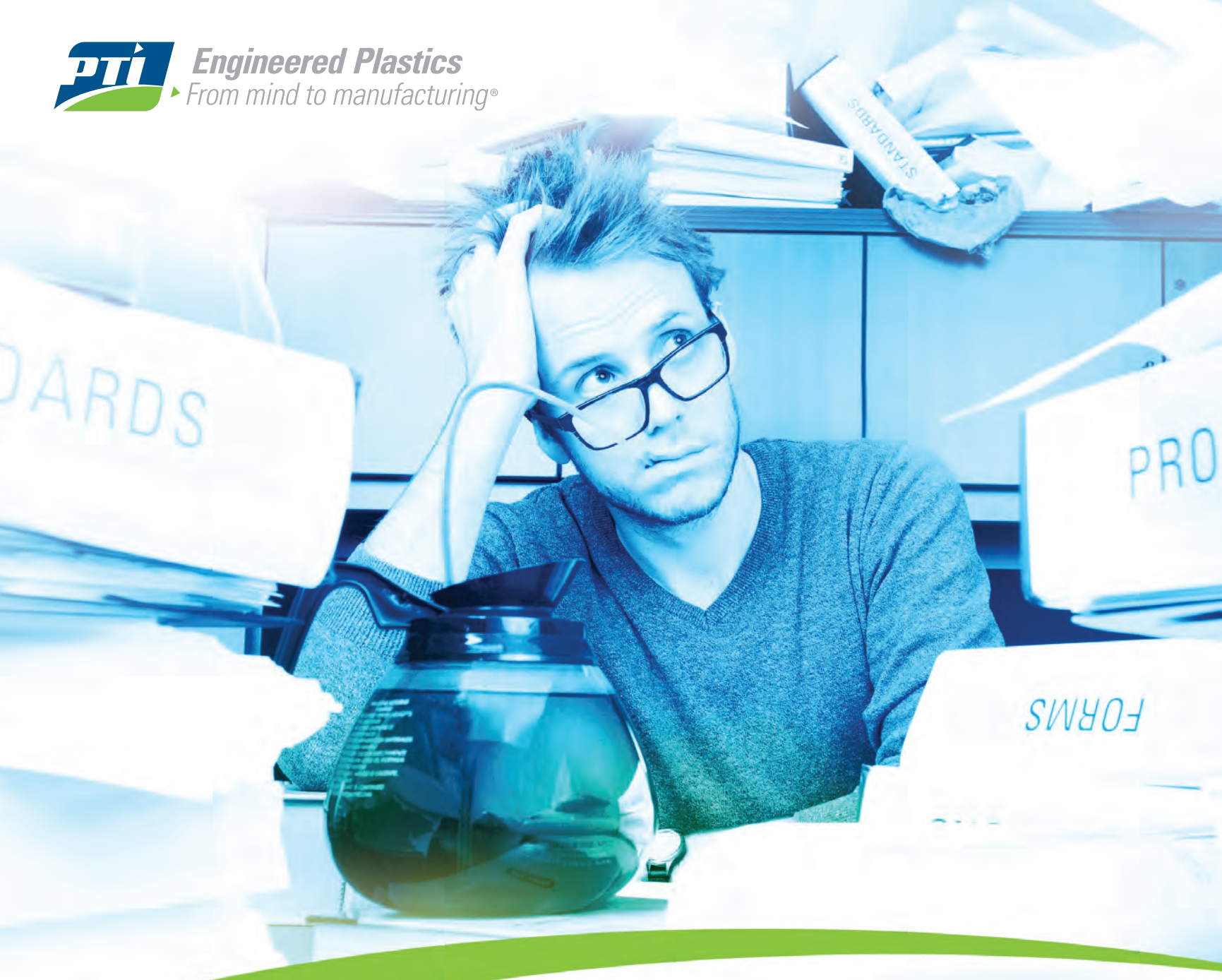

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7 things CMOs don't want you to know

We asked contract manufacturers to let us in on the things they don't tell their customers. Here's what they told us.

1. They really don't want to give you a fixed price
Jerry Melsky, VP of Engineering at CardioFocus, says CMO partner Minnetronix tried to work within a fixed price on one p oduct. "I think we both learned a lot from that experience. I'm not sure they'd be willing to do that again, but it was an interesting experiment." That's because in medtech, the goalposts always move. "There really isn't any such thing as a fixed pric contract, because there really isn't any such thing as a fixed deliverabl specification," Melsky explains

2. It will cost more than you think.
"In a startup, for example, when a mistake happens or a schedule slips or something goes wrong, the expectation is people double down or triple down on their efforts to fix it With a contract manufacturer, they'll do that work, but it also translates into them doubling down and tripling down on their billing. It can come as a shock to the people who are doing development work," Melsky says.

3. The big guys get the price breaks.
"If you're one of the big beasts in the industry, if you're Johnson & Johnson or Medtronic, your suppliers will be a little bit more willing to choke down some overruns for the sake of continued business," Melsky tells us. With smaller fi ms, CMOs have to factor in the risk that the client might not be around in a few years. "For those companies, CMOs have to get paid for the effort that they put in."

4. Their 1st price estimate "comes out of our a$$"
"The initial price we give comes right out of our a$$" because of the aforementioned moving goalposts, says one business development executive at a well-known CMO, who understandably asked to remain anonymous. "Probably the biggest problem is, unless you're in a business where everything you do looks the same, it's really hard to get data for how long and how much it's going to take something to do," Melsky explains. "Somebody says, 'Oh, yeah, we'll do this job for you, and the cost is' whatever. The cost is $75,000 or it's $3 million, and the timing is X. Those numbers and those dates are never the reality."

5. The margins are thinner than you think.
"OEMs underestimate how thin the margins have to get in certain areas, the level of effort it takes to bring a product into a quality system," according to the CEO of another prominent CMO, who agreed to speak candidly in return for anonymity. He also noted that being in candid and frequent communication with your CMO is essential. "Customers often don't realize that contract manufacturers don't know everything customers know about their product," he says.

6. They don't have – or need – the latest and greatest equipment.
"We aren't going to simply install the newest technology because it's cool. We use it when it makes sense for the business," Tegra Medical Vice President Mike Treleaven tells us. "Everyone has gaps in technology. Companies have to consider 95% of their business and purchase capital equipment based on those needs. Everyone has gaps in technology. That said, if there is a partner involved who needs the technology and there is a potential to strengthen our relationship and add to our capabilities, then we will make an investment."

7. The given wisdom on off-shoring is wrong.
Hans Lang, CEO of Wisconsin Tool & Mold, rejects the given wisdom that, if an OEM is going to be successful, it has to consider off-shoring. "Companies should take care of their people, but most CEOs care about stockholders more," Lang says. "We want to work with people who appreciate the American market. We have a responsibility to our people first, to o fer a decent and affordable life; we want to produce quality."

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3D printing: New life sciences technology and old product liability claims

Angela R. Vicari |
Kaye Scholer LLP |

3D printing's potential to revolutionize the medical device and drug industries also brings product liability risks. Just as 3D printing technology upends how devices amd drugs can be manufactured and delivered, future cases alleging injuries caused by 3D-printed products will present fact patterns and legal issues that challenge traditional notions of product liability.

3D printing and healthcare today

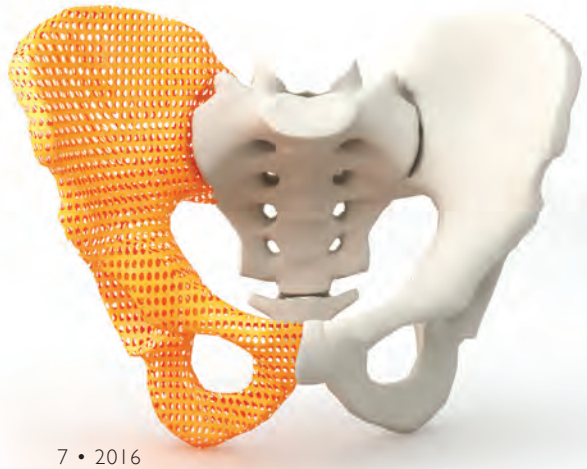
3D printing technology, *aka* additive manufacturing, begins with a digital design for an object, generally in the form of a computer-aided design (CAD) file that is transmitted to a 3D printer. The printer creates a final, th ee-dimensional product by consecutively applying thin layers of material, such as plastic or metal, one on top of the other, until the object is formed.

These techniques have been applied in the life sciences industry. The first 3D-printed drug approved by the FDA, in 2015, assembled the drug by thinly applying multiple layers of powdered medication without using compression forces or traditional molding techniques.

Although there is only one FDA-approved 3D-printed drug on the market, 3D printing has already been used to create medical devices such as prosthetics, dental implants, hearing aids, and bone grafts. An estimated 85 or more 3D-printed medical devices have already received FDA approval.

In addition, "bioprinting" is a particular type of 3D printing that uses cells or tissue as material in the printing process, instead of plastic or metal. This technology is already being used to generate liver tissue for use in drug testing.

Photo courtesy of istock.com



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3D printing potentially disrupts "product" defini ion and distribution

More than a mere manufacturing process, 3D printing's relative accessibility has the potential to turn the traditional chain of distribution for medical devices and drugs – from manufacturer to dispensing point (e.g., a hospital, pharmacy, etc.) to patient – on its head. 3D printing's ability to create and deliver highly customized medical products and services further adds to its potential to serve patients outside of the traditional chain of distribution.

As non-traditional distribution chains emerge to deliver devices and drugs created using 3D printing, the courts will be challenged with novel questions in what would otherwise be traditional product liability cases. For example, what will happen when device and drug companies sell a CAD file instead of a finished p oduct to hospitals and doctors, which then use it to print a personalized medical device or drug? Is the CAD file itself a "p oduct?" What theories of liability can be applied to the seller of the digital file? Can the hospital or doctor now be liable in strict liability?

While the language of product liability law reflects a focus on tangible items, courts typically examine whether they are tangible vs. intangible, as well as the context of its distribution when considering whether something is a "product." Given the complicated examination, the line between what constitutes a "product" and what does not can be blurry. Plainly, the medical device or drug that is actually created by a 3D printer is a "tangible" product, but what about the digital file that serves as the blueprint for making the final product? Is that a "product," for purposes of product liability law?

What is a "product" anyway?

In addressing the question of whether CAD files a e "products," it helps to examine where courts have historically drawn the line on what constitutes a product for purposes of strict liability. The patchwork of case law discussed below does not answer the question of whether or when a CAD file is

> ALTHOUGH THERE IS ONLY ONE FDA-APPROVED 3D-PRINTED DRUG ON THE MARKET, 3D PRINTING HAS ALREADY BEEN USED TO CREATE MEDICAL DEVICES SUCH AS PROSTHETICS, DENTAL IMPLANTS, HEARING AIDS, AND BONE GRAFTS.

product, but it does provide both plaintiffs and defendants with an arsenal of arguments as lawsuits involving 3D-printed objects become more common.

- ***Computer source code and software***
  Outside of the federal criminal statutes content – see *U.S. v. Aleynikov*, in which the Second Circuit reversed a criminal defendant's conviction of trade secret theft from Goldman Sachs' high-frequency trading platform under the National Stolen Property Act and espionage under the Economic Espionage Act, on the grounds that Goldman's system "was neither 'produced for' nor 'placed in' interstate or foreign commerce" – there are several cases that may bear on the issue of whether digital blueprints for 3D-printed products are themselves products.

  At least two courts have suggested that computer software might be considered a product for purposes of strict products liability in tort (*Winter v. G.P. Putnam's Sons* (9th Cir. 1991); *Schafer v. State Farm Fire & Cas. Co.* (E.D. La. 2007)). There is also a nuanced line of case law under the Uniform Commercial Code: Software that is mass-marketed is considered goods (*Systems Design v. Kansas City Post Offic* , (Kan. Ct. App. 1990); *Advent Sys. Ltd. v. Unisys Corp.* (3d Cir. 1991); *RRX Indus., Inc. v. Lab- Con, Inc.* (9th Cir. 1985)), while software that is developed specifically for a customer is a servic (*Data Processing Servs., Inc. v. L.H. Smith Oil Corp.* (Ind. Ct. App.1986); *Micro-Managers, Inc. v. Gregory* (Wis. Ct. App. 1988)). If these computer source code and software cases become the foundation for handling product liability cases involving 3D-printed medical devices and drugs, whether the creator of a digital blueprint can be held liable in strict liability may depend on how the file is marketed

- ***Information in navigational charts and maps***
  Inaccurate data in a navigational chart that is linked to an accident has been considered a product (F*luor Corp. v. Jeppesen & Co.* (Cal. Ct. App. 1985); *Brocklesby v. United States*, (9th Cir. 1985). The import of Fluor and cases like it for injuries caused by 3D-printed products is obvious. Fluor stands for the proposition that an injury does not have to be caused by impact from the physical properties of an item. Under this rationale, if a person is injured by a product created by a CAD file, the file could be consid ed a product.

- ***Content of video games and books***
  Courts have consistently held that the intangible thoughts, ideas, and expressive content in video games do not constitute products for purposes of strict liability (*Sanders v. Acclaim Entertainment*, Inc. (D. Colo. 2002); *Wilson v. Midway Games, Inc.* (D. Conn. 2002); *James v. Meow Media, Inc.* (W.D. Ky. 2000), aff'd 300 F.3D 683 (6th Cir. 2002); *Gorran v. Atkins Nutritionals, Inc.*). Like the video games and books in these cases, the CAD file used to c eate a 3D-printed medical device or drug will not itself physically injure a patient. However, unlike the video games and books, the CAD file is not an intangible thought or idea. Subjecting its creators to strict liability may not raise the type of free speech issues that are seen in the video game and books cases. Instead, the CAD file serves as a digital blueprint for a product that itself causes an injury. Although it may be tempting to apply the video game and book cases to the 3D printing paradigm, fundamental differences in their fact patterns may render them of limited import.

- ***Architectural drawings***
  Designs, technical drawings, and professional advice are considered "services" and not "products" for purposes of strict liability law (*Snyder v. ISC Alloys, Ltd.* (W.D. Pa. 1991); *City of Mounds View v. Walijarvi* (Minn. 1978)). Just as architectural drawings are literally the blueprints for a finished tangible p oduct, a CAD file to c eate a 3D-printed medical device or drug serves the same purpose. However, the relationship between an architect and her client is markedly different than the relationship that will likely be formed between a device or drug manufacturer and the purchaser of a CAD file. For that eason, although both are blueprints, courts may be more likely to impose strict liability on a drug and device CAD fi e "manufacturer" than an architect.

Are human tissue and organs "products?"
Although human blood and tissue fit the technical definition of angible property, they are specifically excluded f om the coverage of the Restatement (Third) of Torts: Prod. Liab. § 19(c). If technology continues

to advance at its current pace, it will not be long until courts start to see cases in which a plaintiff alleges injury as a result of defectively bio-printed tissues. Farther into the future, courts will have to address product liability cases involving 3D-printed organs. Whether courts will follow the Restatement approach of exempting such cases from strict liability or consider tissue and organs to be subject to the same rules as other tangible items remains to be seen.

Who are potential defendants?
In a future product liability case in which a patient alleges injury from a 3D-printed medical device, organ or drug, there are several potential defendants, including the 3D printer manufacturer, the device or pharmaceutical company, and the hospitals and doctors who treat patients.

- Imposing liability on the 3D printer manufacturer is unlikely, unless the alleged injury is caused by a defect in the 3D printer itself.

- If medical device and drug manufacturers no longer "manufacture" anything tangible at all, and become designers and sellers of digital files that contain the blueprint for others to print medical devices and drugs using their own 3D printers, would they be immune from liability under a strict liability theory? The answer could depend on how courts answer the question of whether a digital file is a "p oduct." If a digital file is not a product, then companies that design and sell digital blueprints are not "engaged in the business of selling or otherwise distributing products." But does it make sense to exempt such companies from strict liability? The same rationale that imposes strict liability on today's drug and device manufactures will be used by plaintiffs' attorneys in the future to hold commercial sellers of digital blueprints strictly liable for injuries allegedly caused by the 3D-printed products created from those blueprints.

- An overwhelming majority of jurisdictions refuse to apply strict liability principles to claims against hospitals and physicians involving the distribution of allegedly dangerous medical devices or drugs, reasoning that hospitals and physicians provide services rather than products. While these holdings may make sense when products are sold using a traditional distribution system, what if hospitals start to incorporate a 3D-printing center onsite? Is the hospital "engaged in the business of selling" the 3D- printed product? Is it more likely that a hospital is engaged in the business of selling the 3D-printed product if patients choose that hospital because they know that they can purchase custom-3D-printed devices there? How many devices would a hospital or doctor have to print to be considered more than a "casual" or "occasional" seller? In considering these questions, courts may part ways with the traditional rule that exempts hospitals and doctors from strict liability.

Regulatory considerations
A product's regulatory history and classification plays a major ole in device and drug product liability litigation. How the FDA regulates 3D-printed medical devices and drugs now and in the future will affect the merits and strengths of both claims and defenses. Although there is no formal FDA guidance for 3D-printed medical devices and drugs to date, the FDA is paying attention to the evolution of 3D printing. Two labs in the FDA's Office of Scienc & Engineering Laboratories are investigating how the technology may affect the manufacturing of medical devices in the future, and a recent (albeit unofficial) articl co-authored by CDER's James Norman concluded by saying "FDA encourages development of complex dosage forms and manufacturing processes, such as 3D tablet printing, using science- and risk-based approaches."

Conclusion
Because law often lags behind technology and science, the presence and impending proliferation of 3D-printed medical devices and drugs raise more tort-related questions than it answers. Although the questions addressed above are theoretical now, they will soon become reality; it's unclear how the courts will respond. One thing, however, is certain: Our legal system does not allow perceived "wrongs" to be left without remedy for long. As attorneys who defend medical device and drug manufacturers, we must prepare as diligently as we can to develop our best defenses and be prepared when the first p oduct liability cases involving 3D-printed products are filed.

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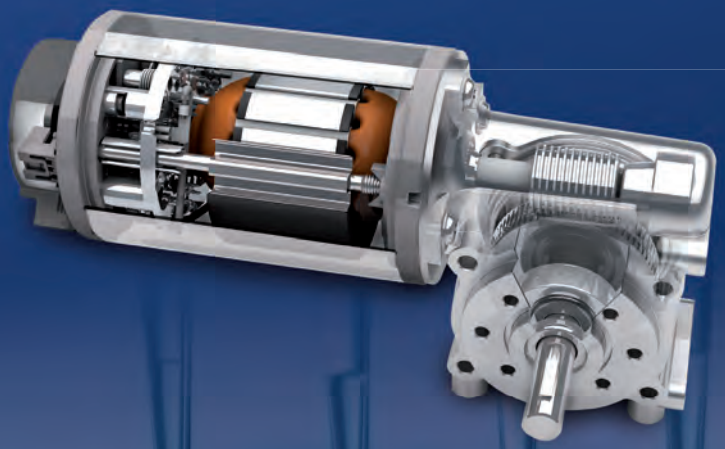

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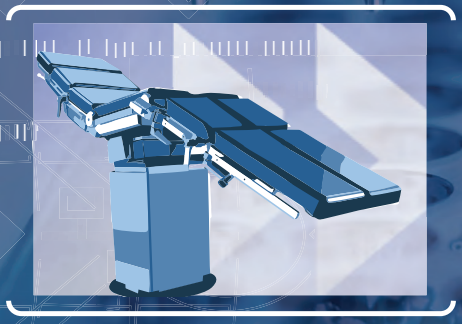

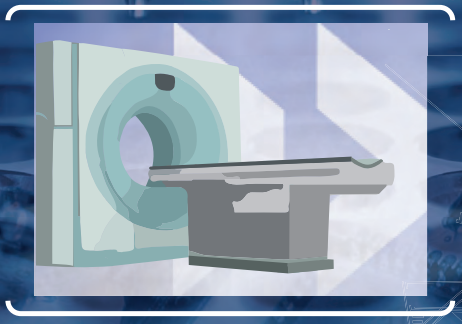

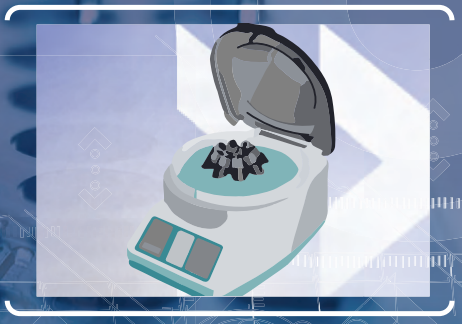

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New seal and catheter material may need new processors

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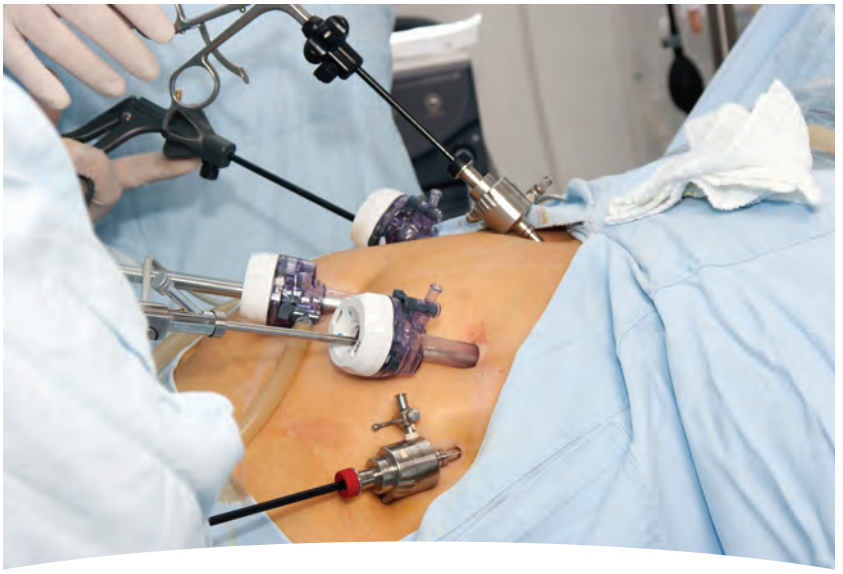

Lih Fang Chew |
Global Vice President Marketing |
Quadion, LLC |

Healthcare is a highly competitive industry that demands consistently high-quality,yet affordable products. That means the industry struggles with higher costs and decreased reimbursement. With these forces fi mly entrenched, the medical community has worked hard to enhance specialized products so they are more ergonomic and functional. Designers continue tweaking, redesigning, and improving their work. If the device is to be considered industry-leading, material selection becomes critical.

The right material often requires finding the right p ocessor

Just as material formulations differ, so do their processors. Finding the right material manufacturer can be a challenge, especially with increasing consolidation in the medical-design industry. However, certain experienced and more nimble companies offer the research & development-backed materials, along with the flexibilit , that more innovative medical device companies look for in a supplier.

Over the last 100 years, the molding of durable rubber and plastic devices has become highly precise and automated. But providing an efficiently molde component or assembly is no longer enough for most medical companies. For that reason, researchers and processors have designed rubber and plastic formulas with inherent characteristics built into the polymers. These characteristics include strength, durability, and flexibilit .

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Research and elastomer development by Minnesota Rubber and Plastics results in seals that may improve endoscopic procedures. These duckbill seals at left (named for their apparent shape) are molded from specially formulated Quniton compound. It is highly lubricious and pliable with good memory, so that it stretches properly and holds shape around the inserted instrument during the procedure. Catheter components are another potential application.

Medical syringe technology continues to evolve for better function, with plungers and caps molded of specially formulated Quniton by Minnesota Rubber and Plastics. These materials are highly lubricious and reduce stiction, allowing care providers to more easily administer services to patients. Quniton may offer longer shelf life than pre-fille syringes, thanks to the material's ability to maintain lubricity and sealing force throughout the product life span.

Research and elastomer development by Minnesota Rubber and Plastics has resulted in a particular seal that may improve endoscopic procedures (catheter components are another potential application). Duckbill seals (named for their apparent shape) are molded from a specially formulated Quniton compound. It is highly lubricious and pliable with good memory so it stretches properly and holds shape around the inserted instrument during the procedure.

Despite these advances, quality, clinical performance, infection-control liability, and other concerns begin to dominate. As a result, manufacturing technology pushes the limits on material design, including factors such as:

- Characteristics of the plastics and rubbers
- How the materials interact with fluid and chemicals in their environment
- Whether molding operations are done in FDA-registered facilities and clean rooms
- Temperature tolerance in extreme conditions, while maintaining all inherent characteristics
- How device design maintains integrity and performance during use.

What drives innovation

Industry demands drive innovation. Medical device manufacturers rely on component and assembly manufacturers to push the development envelope so they can offer healthcare professionals the best solution for their applications. This comes at a cost – sometimes a high one. It is no surprise that cost is a major factor in the medical device industry. Large and small suppliers struggle balancing the cost of research and development with the cost to the provider and patient.

As a result, material manufacturers are cognizant of this balance when it comes to assisting with device design. A more expensive design without a major clinical benefit will not be specifie

In the 1980's and 1990's, a large manufacturing transition pushed designs from metal to plastic-and-rubber alternatives due to the availability and relatively lower cost of the materials. With that transition almost complete, findin

new ways to make ever more affordable, better plastic and rubber formulations has been a priority. Investing in quality materials and manufacturer relationships can ensure a quality product. But over-investing can be problematic. On one hand, it generates cost drivers. On the other hand, using a lower quality or poorly developed product can lead to device failure that could compromise a supplier's relationship with a customer. Finding a middle ground in price, while ensuring quality and clinical performance, is every medical device manufacturer's goal. It's important to recognize, while making a new material decision with a new processor, the potential for a successful, long-term partnership.

A partner with material development expertise

A supplier will often have a design concept in mind, but lack the R&D expertise or the resources to finalize design specification Materials manufacturers, such as Minnesota Rubber and Plastics, are recognized as industry leaders for their commitment to research and design. Such leaders also have a long-standing commitment to developing molds and processes for these new materials that ensure long-lasting effectiveness in the medical industry.

Components from the company contribute to industry-leading devices and brands in the diagnostic, surgical, orthopedic and interventional markets. A critical part of meeting this demand is an ongoing mission to develop innovative materials; the most recent innovation is Quniton, a completely new compound.

Slippery material offers new possibilities for seals, catheters, and more

Every so often, a new material is developed that outdoes others in its class because it has multiple benefit beyond those already in the market. That is the case with Quniton, a low-friction material with obvious benefits for th medical device industry.

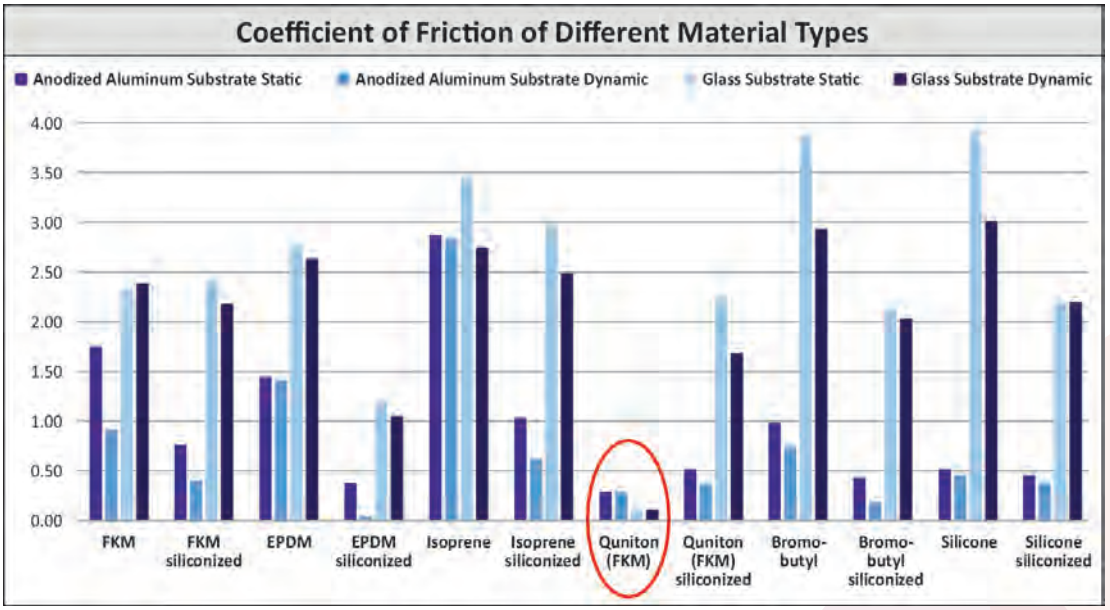
Medical syringe technology continues to evolve for better function with plungers and caps molded of specially formulated Quniton by Minnesota Rubber and Plastics.

The material is highly lubricious which reduces stiction and that lets care providers more easily administer services to patients. Quniton may offer extended shelf life to pre-filled syringes because it can maintain lubricity and sealing force throughout the product life span.

The material also makes the seals on plungers, vials and access devices more secure and smoother to operate. Additional benefits and featu es of Quniton are ideal for an industry with requirements including:

- A low compression set, meaning it will maintain its integrity and sealing force;
- UV resistance, a feature especially timely with an increasing number of UV disinfection technologies on the market;
- Stability in temperatures up to 500°F.

Compared to existing materials such as SBR and NBR, Quniton exhibits excellent resistance to UV aging, making it applicable in devices and equipment that use high-dosage UV light. Because Quniton is saturated (i.e., containing no double bonds) it is inherently protected from degradation caused by exposure to UV light. This is important because UV disinfection is becoming more widely used in the medical device industry, due to its ability to reduce hospital "superbugs" and because of its overall environmental friendliness compared to other sanitization methods.



What designers should know about processing metal tubing

Paul Dvorak |
Founding Editor |

Mention tubing in a medical context and most designers think of extruded polymers. But there is more to medical tubing than plastics. Metal tubes play a significant ole in most hand-held medical devices. A conversation with Al Carolonza, director of market research, and Steve Santoro, executive VP, at contract manufacturer MICRO reveals a few manufacturing tricks and capabilities for metal tube that may have eluded medical device designers.

For example, MICRO has a patented rolled-tube technology that is interesting because it starts by stamping a flat sheet of metal "That allows putting what would be secondary features in the flat blank," says Ca olonza. "Now it's possible to stamp and roll a finished tube o f a power press in one second, versus drawing raw tubing, cleaning it, cutting it to length, and putting in the secondary features afterword. The roll-tube method lends itself to high-volume applications, those that call for 500,000 devices a year. Single-use 5mm endoscopic instruments are one such device. Overall, between scissors, graspers, dissectors and babcocks (tissue-holding forceps), we produce over 700,000 units a year – and the backbone of that is the rolled tube method. Although this production method is economically viable for high-volume applications, many medical device quantities fall within the 10,000- to 300,000-piece range," he explains. Recognizing this, the company rounds out its offering with custom-drawn tubing and forming solutions.

Until recently, production equipment was relatively inflexible. new device feature or an adjustment to an existing feature involved an additional, time-consuming setup. "But working with the latest equipment available, be it laser cutters, Swiss screw machines, or combination, means a change to the design now requires a much simpler programming change, instead of a more expensive tool change. A design adjustment becomes more flexible, especiall if there is slight difference in the product." The production trend, Carolonza adds, is that CNC equipment and laser cutters are used more predominantly than stamping.

You can do a lot to a metal tube. Designers should consider device capabilities that include diameter changes, flanges, precise slots and holes, and sharpened surfaces. The first five tubes (om the left) are drawn tubes and the remaining five a e examples of the rolled-tube technology.

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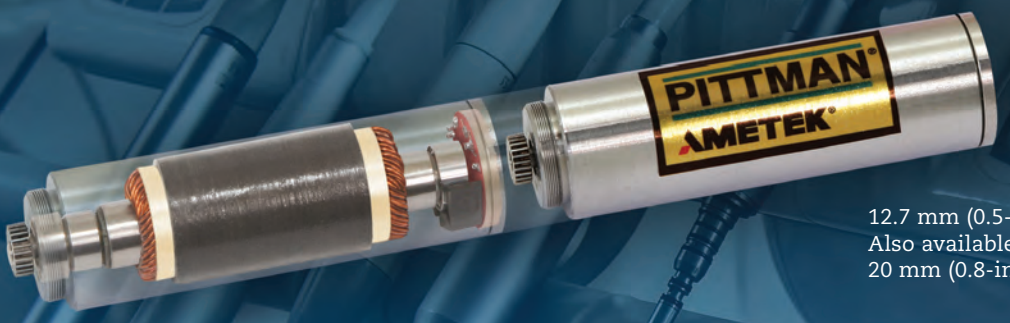

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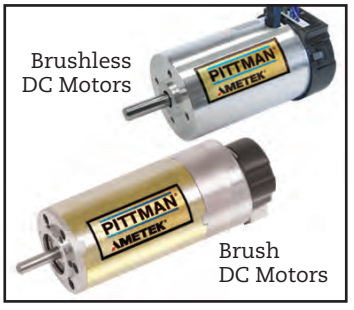

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The four tubes show the unusual and complex features capable with a laser-Swiss machine.

To get a designer's mind moving toward new possibilities and greater design flexibilit , consider that tubes need not be round. "Tube can be drawn in a range of profiles," Santo o says. "Our tube mill can draw many different profiles. Drawing efers to extruding a stock tube through a die to impart a particular cross section. A D-shaped profile is common, bu a octagon cross section is another recent shape, and the oddest appeared like a figu e 8. Of course, some shapes are more difficul than others, but the capability gives designers flexibilit , and because the mill is a dedicated facility, it is easy to develop a profile in lot less than the six-month lead time other companies may require."

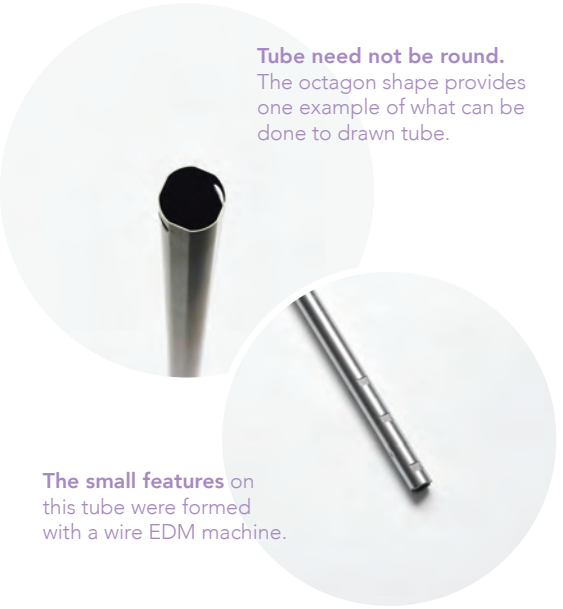
Santoro also suggests that designers think about the tolerances of the tube they might be considering. He says company equipment and operators are capable of holding ID and ODs to within 0.0005 in. "Normally designers spec ± 0.001 in., but we can tighten that up, especially when a design calls for over-molding with plastic, such as a hand grip, over the tube. The tighter tolerances are necessary to avoid flashing. If the diameter varies too much the molding operation will cause flas and tooling may need changing to avoid flash. Flash a ound critical features must be minimized to avoid fit and function issues i the final device assembl ."

A tube's wall thicknesses depend on the application. "A lot of medical tube is thin-walled, meaning 0.010-in. thick," says Santoro. "But if the tube surface requires machining, consider a much thicker wall, such as 0.030 or 0.040-in."

The company recently acquired a Swiss CNC screw machine with laser-

cutting capability to improve its tubing production. "It allows laser cutting and machining in one setup. Previously, two machines were needed for turning and laser cutting, and the transfer from one machine to the other increases the likelihood of misaligned features." The recently added capability also means it's possible to put features into a thicker-wall tube as well as cut through it. Designers should be aware of value in a single setup, especially when a part will include machined and laser cut features with critical orientations. "That is now possible in one setup, so you get registration capability within 0.0005 in. In the end, it saves cost when you can do things in one setup instead of two or three. You get a better part and in a shorter cycle time." Santoro adds that although a machine such as the $500,000 laser Swiss cutter has great potential, learning to coax out that potential takes a lot of learning and experience.

Wire Electro Discharge Machining (EDM) brings other capabilities to cutting tube features. "First of all, the machine uses a taught wire carrying high voltage to remove metal in a way that milling cannot. That allows for unusual features, such as window shapes not attainable with laser cutters. This is useful when the angle of the cut in the tube wall must mate with other components. Although wire EDM is considered a relatively slow production process, creative fixturin of multiple stacked parts can streamline the process and in fact make it cost competitive."



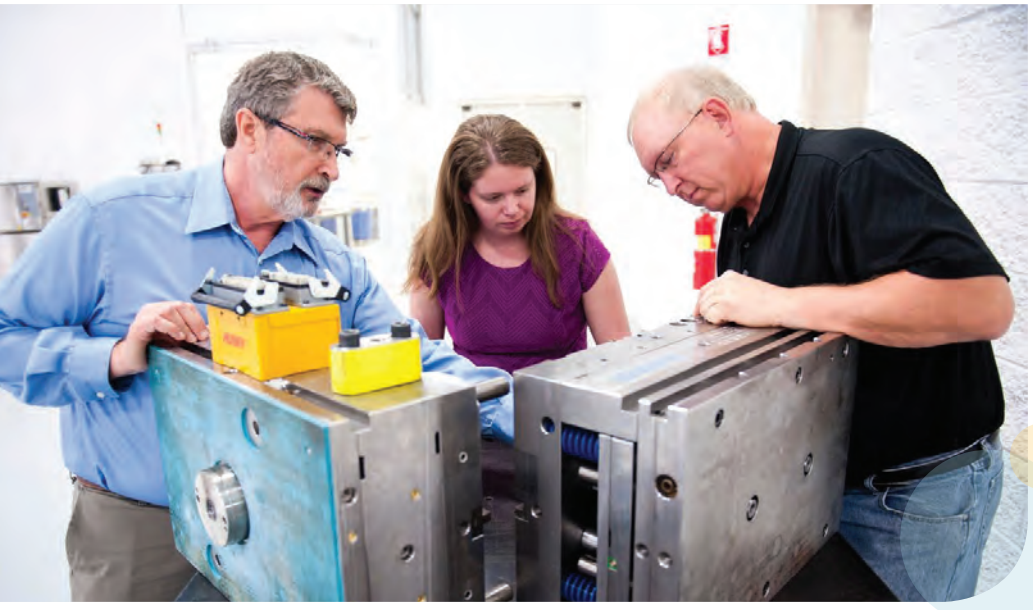
Tube need not be round. The octagon shape provides one example of what can be done to drawn tube.

The small features on this tube were formed with a wire EDM machine.

Redesign challenge shows two teams are better than one

Darren Bjork |
Vice President, Medical |
Metro Mold & Design |

Manual-assembly methods for a particular part made scalability difficult, while a long supply chain made for slow deliveries of critical components. But development teams from client and supplier found solid solutions to both problems.



The MMD team discusses the next steps after inspecting molded parts from a development tool. The relatively inexpensive prototype mold showed what could work and how well. The production mold then incorporated all lessons learned with modifications for a more automated production.

Narrowing the gap between design requirements and what's possible is always a major challenge for medical-device manufacturers. When only eight to nine months are available to transition from a manual assembly process to a more scalable method, a successful transition calls for drastic measures.

This was the case for a major medical device manufacturer when it was looking for a more efficient way to manufactu e a 6-French subassembly for an atherectomy device, designed to remove plaque from arteries. A significant portion of this part s manufacturing process was done by hand, inhibiting scalability, increasing risk, and raising costs.

Design for manufacturing

The previous design included a small machined scoop connected to a clear tecothane tube housing a lumen. A platinum marker band was crimped around the top to let a surgeon clearly identify the device's location under fluo oscopy during surgery. The tube geometries were not conducive to a robust molding process, so a piece of cellophane-like plastic was wrapped by hand around a wire holding the lumen, marker band, and scoop. When heated by a flame, the plastic shrank compressing it tightly to the wire. This was repeated with additional layers until the part was built up to a proper size.

Although the process resulted in acceptable parts, it involved substantial labor and a high risk of failure. Because

the subassembly had to mate to another machined part, any variation created through the manual process meant a "trial and error" fitting was needed to match components perfectly during assembly. Countless hours and dollars were expended through this inefficient manufacturing process.

When asked for assistance, our team at MMD Medical began by looking at this challenge holistically. This method was derived from our combination of skill sets and perspectives, based on our experience with multiple manufacturing disciplines. The approach led us to believe that injection molding was a possible alternative to the manual process.

Knowing that the part geometry could not be changed, two distinct challenges stood in the way of injection-molding the plastic over the lumen, marker band, and scoop:

1. **Alignment of multiple complex components:** The gate location would be critical; high pressure from the injection-molding process could deflect the lumen, c eating an unacceptable part. Gate and tool design were the keys to minimizing this effect.

2. **Robust process window:** Because the molded plastic had to shut off on the scoop without flashing, an the wall was extremely thin, it was difficult to avoid ending up with short-shot, or overcompensating and creating flash

Each team brought significant ski ls to the collaboration table. One team knew the design while Metro Mold & Design provided the expertise in manufacturing.

Our team began collaborating with the customer's engineering team to the point that we became extensions of one another. Working quickly to identify what was going to work and what wasn't, we worked side-by-side, making decisions and significantl shortening the time frame.

Getting started

To understand how to design a more efficient, epeatable solution, the teams

With the in-house capabilities to machine a previously outsourced component that was often delivered late, it became clear that we should make it ourselves.

began to consider the possibilities. Ultimately, the discussion led to the creation of a development tool -- a test mold. Given the complexities of the application, it was more efficient to c eate a low-cost prototype tool than conducting a mold-flow analysis. We believed we would learn far more about the viability of injection molding from the tool's performance.

Based upon this decision, we built a proprietary development tool to better understand how the subassembly could be molded. Normally, development tools are used to test and tweak geometry, gate location, and other performance factors, but we knew we had to make sure this initial bare-bones tool would work at a basic level. We built it of steel to ensure the part would fill; once it was built and tested, we confi med our hypothesis that we could develop an injection-molding solution to replace the existing manual process.

Our team then developed a second tool to test how it would work in production, given the complex geometries of the subassembly. Based on what we learned from the first tooling iteration, we we e able to further optimize gate size, gate location, and molding parameters. We also made sure to use the same mold base for both development tools to maintain overall cost savings.

When building the second development tool, a main consideration was making sure we could move the gate location 180° if necessary. This would let us manipulate the tool to determine exactly how to maintain the proper positioning of the lumen within the subassembly during the molding process.

The ability to move the gate around, along with other minor tool adjustments, gave us crucial insight into enhancing repeatability and scalability, and to predict component wear patterns. This information would ultimately lead to the development of a more durable and efficient p oduction tool.

After developing the second tool, the teams working on the subassembly were ready to hit the aggressive product launch date with a more efficient p ocess. The collaboration of both teams provided a shortened learning curve and led to the development of a reliable production tool – built for optimized efficiency and longevit .

The next generation

With the new, reliable, scalable process and design in place, it was time to address a significant supply chain challenge. A supplier for the subassembly's machined scoop was proving unable to keep up with product demand. Due to lack of capacity, it didn't have the machine time to keep up with the aggressive lead times for the development process.

Because we have the in-house capabilities to machine the component, it became clear to the customer that we should make it ourselves. This would streamline the supply chain, drastically reduce lead times, and let us maintain the quality control needed to ensure consistent, successful runs. Leveraging our vertical integration let the customer get the part machined in weeks rather than months.

We were able to further drive out costs by eliminating additional components on the next-generation design. For instance, making the previously clear tube out of a radiopaque material meant that the marker band was no longer needed. The entire component would now be visible with a fluo oscope. Eliminating a single component resulted in reducing both inspection and material expenses, slashing cost and making the device more competitive in the marketplace.

Final thoughts

By seeing what was possible in a difficul situation, a talented team forged a relationship that led to increased business and success for both companies. A broad range of in-house capabilities and perspectives led to the manufacturer's willingness and capacity to take on multiple challenges for its customer as well as find ways to st eamline production, reduce costs, and provide a higher quality product. This relationship inspired innovation from both parties and resulted in capturing market share that would have otherwise escaped.

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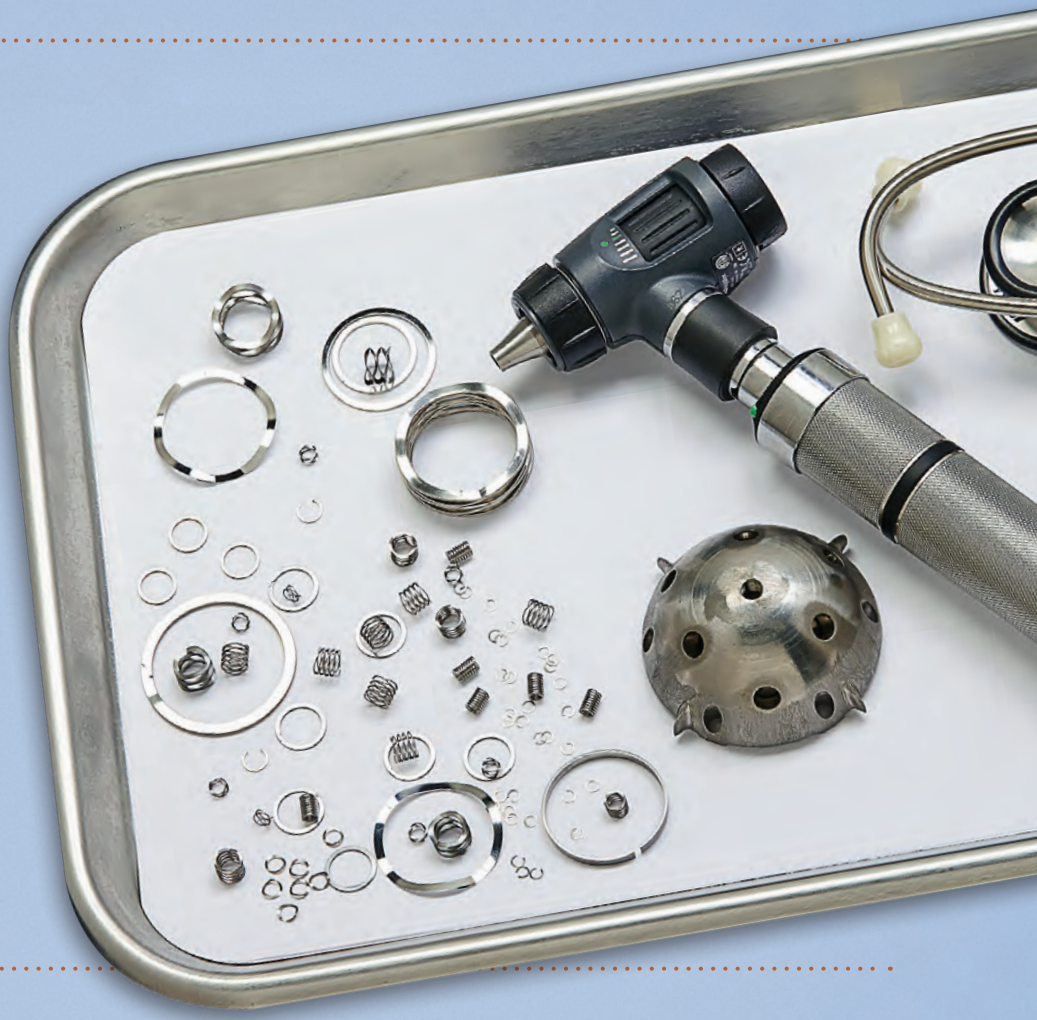

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Stuck in the middle?

It's not a bad place to be when it comes to molding

Jim Jarrett |
Founder & President |
AIM Plastics' Tech Center |

Need more than a prototype, but not ready for a high-volume production mold? Take a look in the middle. Hybrid or bridge tooling may be your answer.

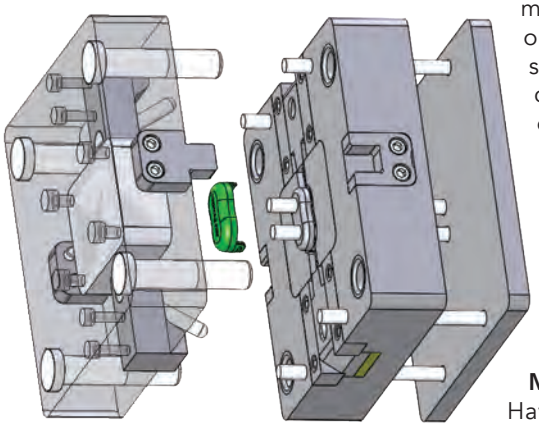
Over the past decade, there have been significant advances that g eatly affect traditional prototype and low-volume mold construction. It's not a one-key-fits-all solution anymo e, so here's some clarification and di ection to help navigate through the mold maze. First things first Address the basics.

1. What is the estimated yearly volume?
2. What is the lifespan of the program?
3. What resin will be used?

With this information, along with a 3D CAD file and printout identifying all critical dimensions, a reputable mold builder or molder can quote a best-fit tooling solution that will achieve quality requirements and provide a tool life that doesn't fall short of the program lifespan. Companies don't want to pay for a 1-million-part tool life and incur a 12-week lead time when only 150,000-tool life is required with a much faster lead time.

A prototype or low-volume molder should have all the protocols and procedures of a production molder, so audit and select one carefully. The molder should offer in-house mold construction and have experience with hybrid and bridge tooling. In most cases, this can fill p ototype requirements, allowing engineering changes to move on through validation and meet production needs.

A Solidworks image of a single-cavity hybrid showing the options and benefits o this type of tooling.



Mold construction

Having the tooling built in-house (where the mold builder and molder are the same entity) is preferable, as it eliminates finge -pointing and helps keep to tight timelines.

Mold design software has come a long way, with draft analysis and parting line split tools allowing quick, efficient desig for manufacture. Additionally, tools such as quick split and electrode creation save the designer time, enabling a quick and efficient 3D mold to be placed on the sho floor for construction within days

Shops with high-speed machining centers have two major benefits:

(1) They can cut hard steel, eliminating many post-heat-treat procedures while maintaining a superior surface finish, whic reduces benching and polishing time.
(2) With high spindle RPMs, small cutter diameters can be used in many cases, omitting the need for Electrical Discharge Machining (EDM) procedures, both decreasing deliveries and cost. Current CNC EDM machines offer benefits fo quick-turn mold construction as well. Their metal removal rate is much faster than older manual machines and leaves a better surface finish, educing or eliminating the need for benching or polishing procedures. In most cases, light texturing such as MT11020 is achieved with an equivalent EDM finish, eliminatin the need for costly texturing procedures and reducing deliveries as well.

Molding

The molding equipment should have gone through an install qualification/operational qualification p ocess, and some type of standard validation procedure should be in place. Scientific molding practices should also be followed. All basic production procedures should be in place as well as all employees following the cGMP guidelines.

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Service Description	Traditional Prototyping	PROTOTYPE Plus™
Customer owns tool	In some cases "NO"	**YES** Customer owns tooling, fixtures and 3D design
Ability to modify (engineering change)	In most cases "NO" May need to purchase new tool	**YES** Allowing adjustment of critical areas
Cut from your CAD without limitations	NO If it can't be cut on CNC	**YES** Sinker EDM, wire and high speed CNC limitless
Ability to run Hi Temp Engineered resins	NO Typically mold temp cannot exceed 250° F	**YES** Can run resin such as Peek (450°F)
Ability to run custom colored resins	NO Or limited selections	**YES** Limitless, AIM will work with customer supplied material or purchase material
Ability to overmold	Hit or Miss	**YES** In vertical or horizontal
True two shot availability	NO	**YES** In as little as 2 weeks
Full material traceability	Typically Limited	**YES** Robust ERP system offering full traceability
Provide gate freeze study	NO	**YES** AIM's regimented process includes this
Fill customers production demand	RISKY	**FULLY CAPABLE**
Provide process validation	NO	LEVEL 1, 2 or 3
Ability to provide aluminum, mild/hard tool steel	NO Typically limited to soft tooling	**YES**
Tool life warranty	NO	**YES** Tell us what you need and we will get you there
Full secondary operation including pad printing / light assembly / thermal inserting	Typically NO	**YES**
Material moisture analysis	Typically "NEVER"	**YES** Material moisture analysis provided on every job "it's just what we do"
All manufacturing equipment has gone through EIOQ (Equipment Install Operational Qualification)	NO How do you know are processing within "manufacturers parameters" if the machine has not received EIOQ	**YES**
All employees are trained in cGMP (Current Good Manufacturing Practice)	NO	**YES** Documented training
Prototype-Plus™ tooling can be ran in our class 100,000 Cleanroom	NO Typically not available	**YES**
SPC quality checks	NO	**YES**
Continuous Process Improvement through-out operation (mitigating risk)	NO	**YES** Always making ourselves better
Make inspection fixtures as req'd (same fixture used for incoming)	Perhaps Typically involves 3rd party	**YES** AIM builds inspection fixture (no 3rd party needed)

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Assessing Compliance for 3D Printed Devices

Chris Krampitz | Strategy and Innovation for AM Technologies | UL |

Additive manufacturing (AM) is a complex process when it comes to compliance. It's a specialized one, with a lot more sources of variability than traditionally manufactured devices. This variability comes at every stage of development: Design, materials selection, processing, and post-processing. And those sources of variability are less understood than traditionally manufactured devices. As such, there are singular challenges with compliance to make sure those devices are manufactured consistently against the regulatory requirements, industry standards, and even the customer-specifie requirements.

Another factor complicating the compliance of 3D-printed products is that the test methods for assessing the performance of the devices or implants are used a bit differently, or applied differently, than in traditional manufacturing. For example, non-destructive techniques, like CT scanning or ultrasonic scanning, have been applied to traditionally manufactured devices and additive. AM manufacturers and compliance bodies are still testing to see limitations of non-destructive tests, as well as when those tests are suitable and when they're not. That adds a bit more complexity in assessing compliance.

A major factor in 3D printing is that the prime benefit of the p ocess, in terms of compliance, is also its greatest difficult . It seems obvious, but design changes can put devices out of compliance without the designer fully understanding the ramifications. In te ms of compliance, change is not good, and variability is bad. In traditional manufacturing, the rule is that you have to reduce variability, but in AM the variability is the source of benefit. That means finding ways to embrace that variability and learn to harness, control and direct it.

FDA guidance

To harness those benefits and mitigate th risks of variability, FDA released a guidance document called Technical Considerations for Additive Manufactured Devices. The guidance is a major step forward in adding clarity to manufacturers of medical devices that are trying to use the technology.

The guidance outlines the technical considerations associated with additive manufacturing processes, provides recommendations for testing and characterization of the devices, as well as factors that occur during the development stages. This is for devices manufactured exclusively with addititve processes, as well as devices in which AM is used in one or more steps. Devices don't necessarily have to be entirely produced with additive manufacturing to fall under the guidance's purview.

The guidance is broken up into two major sections. The first section i associated with design and manufacturing considerations. FDA focused on providing recommendations around controlling design and the different aspects of the manufacturing process. It assesses the steps that need to be considered, and what happens during those steps.

The second area, device testing considerations, provides information on the type of data that should be submitted during 510(k) or the pre-market approval applications. It helps a device manufacturer or device designer who's developing a device to figu e out what information they should be submitting.

The document tries to answer the question, "How do I need to think about the design and manufacturing of these medical devices, and what type of information I need to submit for the FDA to even review the applications?" Manufacturers should be thinking about that right now as their number one priority.

> A MAJOR FACTOR IN 3D PRINTING IS THAT THE PRIME BENEFIT OF THE PROCESS, IN TERMS OF COMPLIANCE, IS ALSO ITS GREATEST DIFFICULTY.

One thing the guidance does not address is point-of-care device manufacturing. If you're trying to manufacture at a hospital or specifi location, this guidance doesn't really talk about those situations. It also doesn't address any biological, cellular, or tissue-based production using the technology, such as bioprinting.

With point-of-care manufacturing and bioprinting, there's still a lot more research & development to be done. As those options mature, those ideas will be incorporated into the guidelines. I expect point-of-care manufacturing to happen sooner than bioprinting, because there's still quite a bit of R&D to be done on bioprinting.

Embracing variability

Medical manufacturers should understand that the process to design and manufacture medical devices using AM technology is complicated, requiring a holistic view of the supply chain. Partnering with a service provider can help throughout the entire process. There are variables in the manufacturing process that need to be examined, which don't correlate with decision-making processes in traditional manufacturing. Topics such as software workflo , imaging resolution of patient scans that are transferred into CAD files, have not been part of traditiona manufacturing, but they are a significan part of the benefits of AM technolog .

But those benefits also ad complexity, and having a partner that understands the variability is important to successfully move from development through production, and achieve FDA approval.

Reimbursement thinking for medtech designers and engineers

Heather Thompson |
Senior Editor |
Medical Design & Outsourcing |

Reimbursement is a dreaded topic for designers and engineers, says Mike Drues, president of Vascular Sciences. "It can be boring because people approach it like it is a box to check." But, he says, it's not just about the money and checking boxes. "Engineers have to care about reimbursement, because it's fundamental to ensuring that the products developed actually get to the patients that need the technology."

In the U.S., we think we have the best medical technology money can buy, says Drues. But that's not entirely true. "We have the best medical technology that money is willing to buy."

That's not necessarily a bad thing, he adds, just the result of dealing with the system that's in place. And, as such, there are fundamental considerations, such as reimbursement, that need practical consideration even from a design standpoint.

Reimbursement is the principle of establishing or aligning technology with a code. Those codes (e.g., ICD-9, ICD-10) are used in documenting diagnoses and procedures in a healthcare setting. And those codes and the path to getting those codes must be part of the design and development discussion, says Drues. "It's not sufficient to design a bette mousetrap, especially if a product is expensive," he says. "There are plenty of innovative devices that could be designed, but they aren't in development because there's no business case for them."

In fact, Drues says, one of the fundamental innovation questions designers should ask is, "What are we NOT developing, and why?" The answer might be that the business isn't worth it.

This might be particularly true if you are trying to fit your technology into an existing code. Drues explains that existing codes can be a double-edged sword. "I'm often asked whether it's better to fit the eimbursement code or to create a new one," he says. The advantage of an existing code is that it works within an established framework – it's easily understood by all stakeholders. The disadvantage is that if you get existing coverage, you get existing payments. "So if a treatment is on the market for $19 for an office based procedure, you really can't make a business case of why you should get more for treating the same disease in a similar way."

And, he says, although no one gets to pick their code, if companies are prepared they can suggest proper codes to CMS.

Think early, but don't act until you're ready

"One of the most common questions I get is, 'When should I start thinking about regulation or reimbursement?'" says Drues. His response to that question is always, "You can't think about it soon enough." He advises companies to integrate and time regulations and reimbursement together.

Thinking about it is one thing. Taking action, however is another, says Drues. "You can't think about it too soon, but you shouldn't go to FDA or CMS one day sooner than you are able to present your plan and strongly defend it."

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> "THERE ARE PLENTY OF INNOVATIVE DEVICES THAT COULD BE DESIGNED, BUT THEY AREN'T IN DEVELOPMENT BECAUSE THERE IS NO BUSINESS CASE FOR THEM.

This is a delicate part of the strategy, he notes. "I won't go to FDA or CMS until I've able to say, 'This is what we need to do and why we should do it.'"

Don't ask, present

"The most important thing is not to ask FDA (or CMS) what to do," says Drues. He says the agencies are directional, not dictatorial. The earlier you consider reimbursement, the better chance you have of figuring out what course of action makes sense for the product. It also helps if companies conclude that they might need to deviate from the normal process – and have a good reason why.

For example, he says that sometimes reimbursement can come first. "I've gone to CMS befo e FDA in order to get the details about what clinical evidence CMS needs to see for reimbursement." He explains that for a particular product he was working on, the 510(k) was a simple process. So instead of going to FDA, he went to CMS to come to agreement on the study the agency needed to see to get the proper code. "Then I went to FDA and told them the clinical trial we were planning (based on CMS input). We looked like heroes."

Ultimately, he says, you have to be able to sell the agency on your strategy. "It is your job to think about what you are doing, and come up with the best strategy for regulation and reimbursement, not FDA or CMS." Then you go to the agencies and say, "this is what makes sense." He says companies should be definitive and convinc FDA or CMS of the correct path, and that can only come if that strategy has been thought about from a design perspective.


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What'd you say?

Pressure relief valve improves removal of patient earwax

Koren Huskins | Smart Products |

A custom-manufactured pressure-relief valve has improved the operation of an earwax removal device. The valve Model #130 valve with 3/8-in. OD from Smart Products is customized with a plastic body, special O-ring material, and precise opening pressure. The customized components ensure the valve works precisely within the Earigator. Pressure control is critical, so the Model #130 valve is the first line o security within this system. Should the water pressure reach a certain point, the Model #130 activates to divert pressurized water back to the reservoir. For additional safety, a pressure switch shuts off the Earigator system completely if needed.

The original device was invented in the 1990s by otologist Dr. Irwin Ginsberg. He and others noted that too much earwax – cerumen – can lead to ear pain, ringing, itching, or loss of hearing. Because ears are delicate sensors, it's often a good idea to seek professional treatment. Formerly, this involved irrigation with a syringe. This manual procedure puts a stream of pressure from three to more than 110 psi depending on the applied force. There is also a lack of precise temperature control, general messiness, and patient discomfort. Ginsberg noted other drawbacks, such as a risk of injuring the ear's external canal or the eardrum itself. Medical device manufacturer Nupur Technologies acquired rights to the unit and improved it in several ways.

"We have re-engineered the Earigator to a state-of-the-art design, with improved features. We have also significantly reduced costs. The product today will sell at less than half of the previous design," Nupur Technologies CEO Joseph Priest explains.

Cleaning earwax is a common procedure. "But no one ever thought about improving the control and speed with which the procedure could be accomplished," adds Priest.

The newly launched

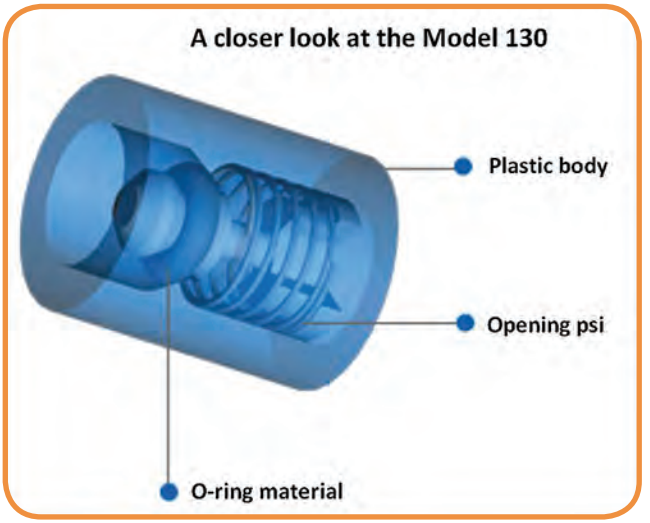
The Earigator's base unit houses the electronic control board, water reservoir, heater, and water delivery system. This assembly includes the pump, a pressure relief valve, pressure switch, and water delivery tubing.

"NO ONE EVER THOUGHT ABOUT IMPROVING THE CONTROL AND SPEED WITH WHICH THE PROCEDURE COULD BE ACCOMPLISHED.

Earigator controls the temperature of the irrigating solution at 98°F (37°C) and holds the pressure at 10 to 12 psi. The design now combines the functions of an otoscope and irrigation device in one product. The otoscope lets users clearly view and pinpoint the cerumen buildup before and during the procedure.

The hand piece includes a flow control trigger, water nozzle, magnifying glass, and LED lights. A procedure usually lasts three to five minutes. The Earigator makes earwax removal safer, faster, less messy, and lessens patient discomfort.

The valve Model #130 is a part of the Series 100 Standard Cartridge line of products. it comes in a manual relief bleed style, check valves, or pressure relief valves, and in sizes from 0.25 to 0.75-in. and opening pressures from 0.09 to 20 psi.



The U.S. Food & Drug Administration's list of PMAs and 510(k) clearances granted in May 2016

510(k) final decisions

TOTAL 510(k)s THIS PERIOD: 213

TOTAL WITH SUMMARIES: 205

TOTAL WITH STATEMENTS: 8

PMA Monthly approvals from 5/1/2016 to 5/31/2016

SUBMISSION NUMBER	FINAL DECISION DATE	REVIEW TRACK	TRADE NAME	APPL/SPR NAME	APPROVAL ORDER STATEMENT
P160002	5/18/16	PMAO-PMA Origi	VENTANA PD-L1(SP142) CDX ASSAY	VENTANA MEDICAL SYSTEMS, INC.	Approval for the PD-L1(SP142) Assay. The device is indicated for the following: VENTANA PD-L1 (SP142) Assay is a qualitative immunohistochemical assay using rabbit monoclonal anti-PD-L1 clone SP142 intended for use in the assessment of the PD-L1 protein in formalin-fi ed, paraffin-embedded (FFPE) othelial carcinoma tissue stained with OptiView DAB IHC Detection Kit and OptiView Amplifcation Kit on a VENTANA BenchMark ULTRA instrument. PD-L1 status is determined by the proportion of tumor area occupied by PD-L1 expressing tumor-infiltr ting immune cells (% IC) of any intensity. PD-L1 expression in >= 5% IC determined by VENTANA PD-L1 (SP142) Assay in urothelial carcinoma tissue is associated with increased objective response rate (ORR) in a non-randomized study of TECENTRIQ (atezolizumab).

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the FDA says CONDUCT HUMAN FACTORS STUDIES, or else

Patients and caregivers adapting to new equipment may use them in error. But applying human factors principals and conducting usability studies early enough in a design project can minimize mistakes.

PAUL DVORAK
EDITOR

The idea of a human-centric design is not new. It may have gotten its start in WWII, when aviation psychologists suggested a standardized instrument layouts for all U.S. aircraft. Before implementing HCD, pilots transitioning from aircraft to aircraft had to relearn the location of instruments and controls, and those that did not adjust quickly often suffered fatal mishaps.

Today, applying the principles of human-centric design to a bewildering array of medical devices is one way to minimize errors in hospitals and homes.

"About a decade or so ago, the FDA began paying more attention to the increasingly complexity of medical devices," says Debbie McConnell, human factors lead at Battelle Laboratories. "In 2007, the FDA wrote guidance that said, in effect, if a company wanted a successful submission, it had to demonstrate its product was likely to be used as intended – and the medical device manufacture could not use the justification that, 'The user did not follow instructions.'"

In response, the Association for the Advancement of Medical Instrumentation (AAMI) provided guidance. The standard, ANSI/AAMI HE75:2009, describes the type of summative evaluation a medical device must undergo. "For example, you must have at least 15 individuals of a kind who will use the device in the study that comes at the end of the development cycle. Otherwise, the FDA will not approve the submission."

A monster flop

For those who think a usability study is unnecessary, consider the promising diabetes drug, Exubera, and the delivery device that allowed taking it by mouth – no more needles. "The product got all the way through testing and then failed in the field," says Battelle Program/Project Manager Carol Stillman. "It passed from the product performance standpoint, and it was a safe device. What the developer did not do was [consider] the user-experience side."

The pharmaceutical company's plan was that a person just about to eat – seated at a table – would take the drug as soon as they saw the food. But the device was large and conspicuous. Worse, it looked like the user was taking a hit off a bong, an impression some thought too embarrassing. And taking the drug early, say before entering a public space, did not provide the therapeutic effect. Users found the product to be too inconvenient and chose not to use it.

"Insulin pens have been designed to look like ball-point pens, not a medical device, and so people can use them in a restaurant without drawing attention to themselves," said Stillman. One solution to the Exubera design, she suggests, might have been to make it look more like something that everyone has in their bag.

Bottom line: After 11 years of development, the device was pulled from the market. The *Wall Street Journal* reported that the insulin flop cost the company $2.8 billion

Early user research and formative usability studies

During early user research, human factors engineers go into the field to watch people work with exiting products and figu e out where gaps are, such as how today's medical devices are inadequate, or how people accommodate for a design's shortcomings. "It's fascinating to watch people find a way to use a product. What people put in place to fill usability gaps are big indicators of what should be present in the next generation of the device. We watch people work with a device in a natural setting and then interview them, taking lots of notes about the environment, such as the noise, lighting, complexity in the space, and the likelihood of being interrupted, or how mobile the device might be, and how conspicuous or inconspicuous it must be. For example, if a home is the setting, we might ask who else lives there besides the patient who might use the device? If the device is used in a surgical space, how will the surgical team use it, and how does the surgical team interact with one another? That's a huge part of the design. This type of research takes place early in the product design lifecycle. It helps the designers understand the context of use. Hence, it's called contextual research," McConnell explains.

Battelle human centric design staff members Andrew Sweeney, Annie Diorio-Blum, and Neha Kalra participate in a brainstorming session to generate product concepts.

After early concept sketching takes place, a group of intended users can be brought into an observation room and asked to react to a picture, 3D model, or a collection of possible future designs. "Non-function models can include 3D-printed components. During all our usability studies, we create an environment that's as close as possible to one that represents where the device will actually be used. Then we put nonfunctioning components in the environment and say to a subject, 'Imagine you want to accomplish a particular task. Walk me through what you would do. Pick things up, move them around, and tell me what you are thinking and how you would use these components.' It's astounding what you learn watching someone use an early approximation of a product. This is referred to as formative work," she says.

Collaborative design session takes place at the Battelle uLab

McConnell tells of working on a device that had a predecessor that was already commercially available. The study's goal was to find if a change to the physical form would differentiate it enough so that people would use it as intended and without confusing it with the commercially marketed predecessor. "We were interested in watching people pick up the model and move it around, to determine whether the design alone would be sufficient to

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The clumsy insulin dispenser was so embarrassing to user they became nonusers. The developer conducted no user studies before production.

indicate its use. For instance, we watched to see if the device was held the right way. You learn a lot just by asking folks to pick up a non-functional prototype," she notes.

A recent FDA requirement

The FDA must see value in such studies, because it's recently required them in submissions. "Now we have a whole other side of requirements. It was hard enough to design a device when companies had functional requirements and biocompatibility," McConnell says.

"But we hope that over the next decade, people understand that the new user interface requirements are not just an extra assignment. When we have early versions of the device in design, we conduct formative studies to see if the user interface requirements are met and if the users will be able perform the tasks they need to do. When started early, the study makes the rest of a design process much easier because it answers usability questions such as, 'How will the alarm be perceived?'" says Stillman.

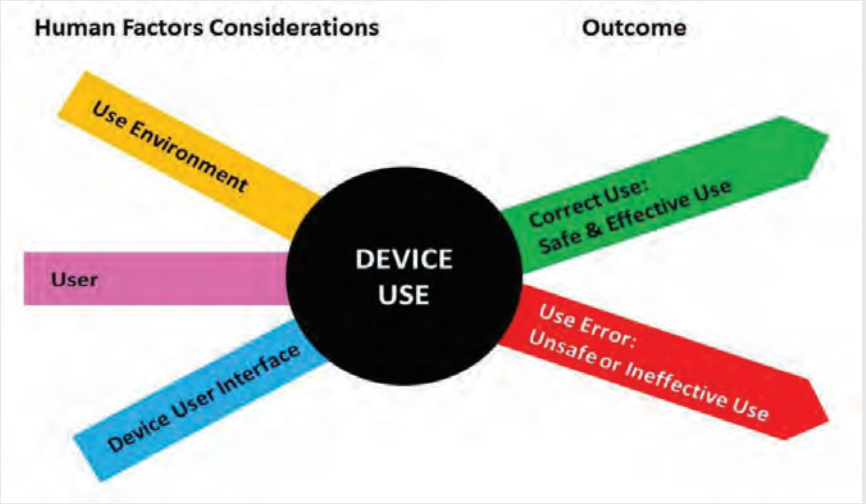
Alarms are a subject of constant debate, she adds. Consider: How can a device issue a warning without sounding alarming? Stillman recalls one device that issued frequent alarms that were so annoying, ER nurses kept the device off. "Its designers hadn't thought

THE FDA HAS A LOT TO SAY ABOUT HUMAN FACTORS

FDA has developed a guidance document, Applying Human Factors and Usability Engineering to Medical Devices, to assist the industry in following appropriate human factors and usability-engineering processes. Its intent, says the agency, is to maximize the likelihood that new medical devices will be safe and effective for the intended users and use environments. Recommendations in the guidance document are intended to support manufacturers, to improve a device design, and to minimize potential use errors and resulting harm.

The FDA adds that it believes that these recommendations will let manufacturers assess and reduce risks associated with using medical devices. FDA's guidance documents, including this one, do not establish legally enforceable responsibilities.

Instead, guidance documents describe the agency's current thinking on a topic and should be viewed only as recommendations unless it cites specific regulatory or statutory requirements. The use of the word "should" in FDA parlance means something is suggested or recommended, but not required. The full 49-page document is here: http://tinyurl.com/fda-humanfactors.



Interactions among HFE/UE considerations result in either safe and effective use, or unsafe or ineffective use.

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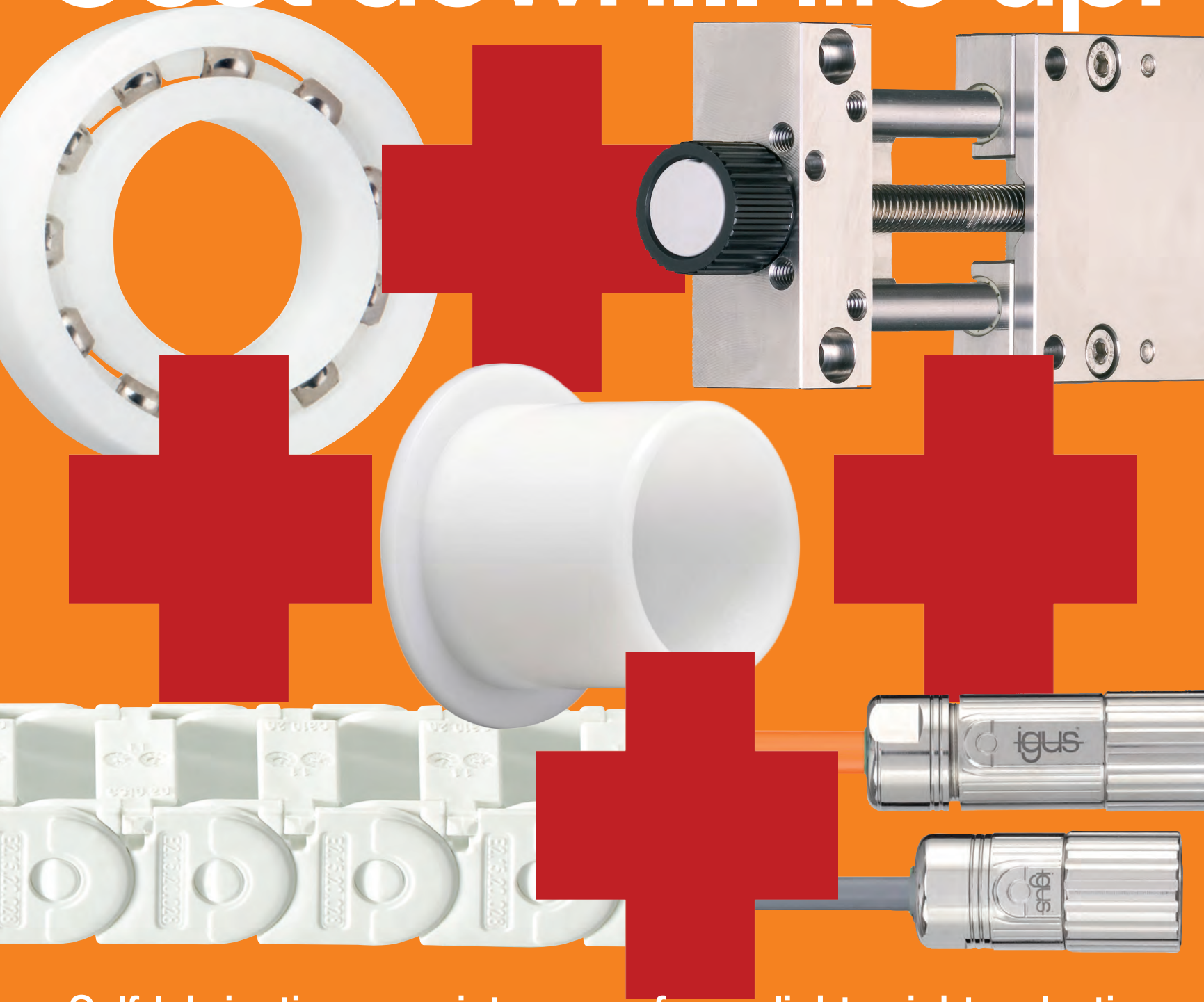

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To evaluate an initial medical device prototype, a Battelle human centric design staffer uses it on a mannequin as part of an early formative study.

how distracting the alarm would be in a busy emergency room. It became easier to just turn the darn thing off and check it every once in a while than to have it going off all the time," she said.

What could possibly go wrong?

Lest you think conducting usability studies is an exercise in excess, consider this: "I was working on a system that delivers a drug, an implanted system with an implanted pump," says McConnell. "We were doing an evaluation of that system, close to the summative study, and realized that when the nurse held it to enter the prescription from the physician, the field whe e the nurse would enter a value for the amount of drug was constructed in such a way that the nurse could misinterpret where the decimal point fell. That meant the nurse could unintentionally program the device to deliver much more drug than intended. Fortunately, the flaw was caught and cor ected before the system went to production."

In a final instance, a device intended to deliver a medication through an injection could be used incorrectly and in a way that people could inadvertently poke themselves. "That's pretty common. Anybody who has a story about an injection device can tell you what happens when you use it wrong, and what part of your body gets the injection," says Stillman.

10 USABILITY GUIDELINES FOR DESIGNING A USER INTERFACE

Jakob Nielsen and Don Norman, sometimes called the grandfathers of heuristics, may have been one of the first to codify several general principles for the best interaction with a design. Nielsen calls the principles "heuristics" because they are broad rules of thumb and not specific usability guidelines. Here are their first three:

Clear system status: The system should keep users informed about what is going on, through appropriate feedback and within a reasonable period.

Match the system to the real world: The system should speak the users' language, with words, phrases and concepts familiar to them, rather than system-oriented terms. This is important especially when there are preconceived ideas from existing devices.

User control and freedom: Users often choose system functions by mistake and will need a clearly marked "emergency exit" to leave the unwanted state without having to go through an extended dialogue. A good example: A computer program's "escape" button.

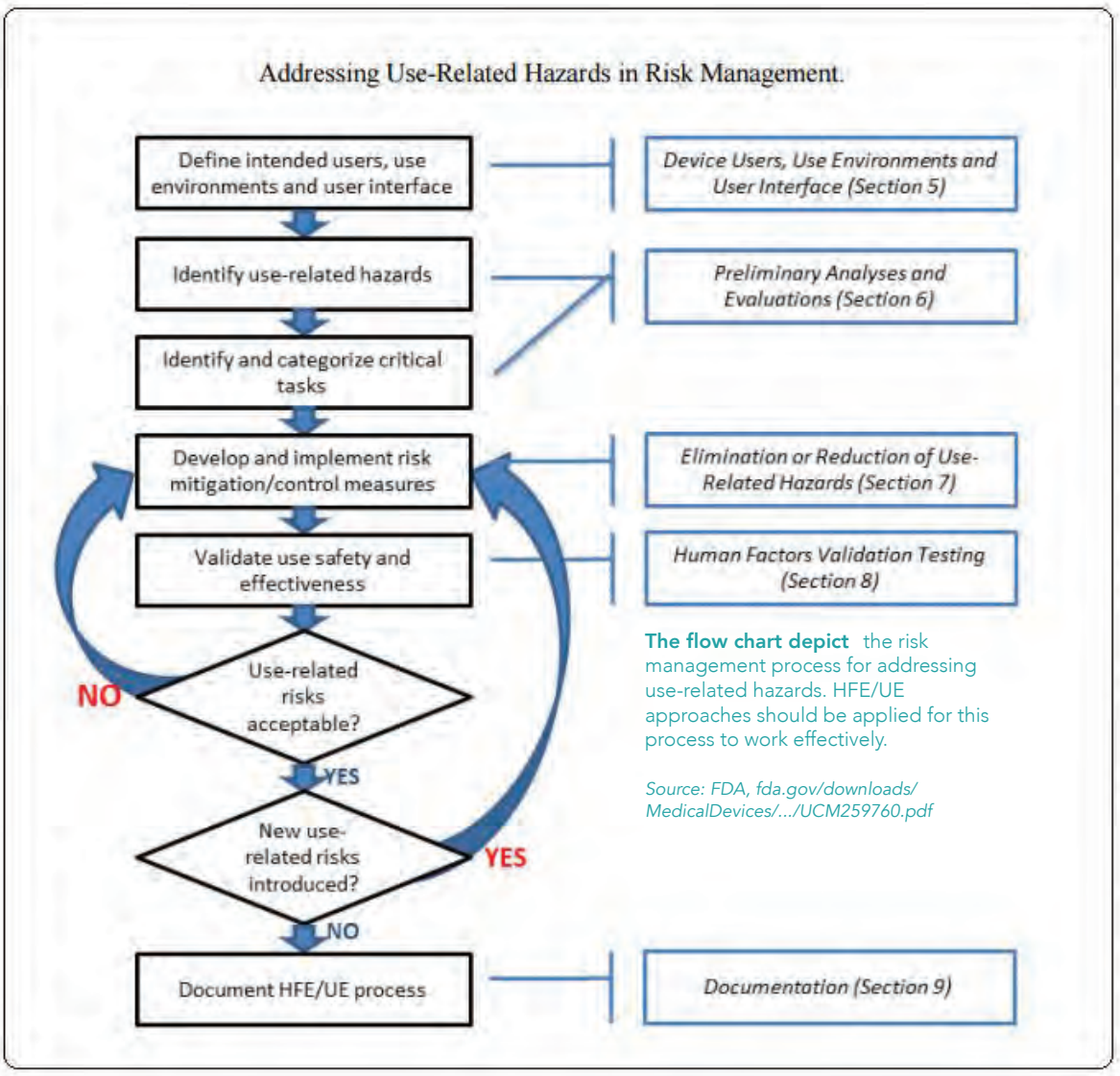
Find all 10 at http://tinyurl.com/human-centric.

Good enough or perfect? When to release a device

"What's the minimum we need to do to earn FDA approval?" is the wrong question, say McConnell and Stillman. The answer varies, depending on the device. Developers naturally ask because they have a limited budget and a schedule. "We bring value to the process by knowing what the FDA expects of medical device manufacturers and fitting this into the context of a particular business's needs," says McConnell.

FDA guidance talks about acceptability. "The people who wrote the guidance understand that at some point, you have to launch the device and make money for the company to stay in business." Users want the device when it's good for them, meaning reasonably usable and always safe for use. They don't want to wait until it's perfect. The idea of 'good enough' to be safe and reasonably useful is universal. A medical device manufacturer wants to make it good enough, the users want it to be good enough, the FDA expects it to be good enough. All these parties know that there will be an evolution in the product design. 'Good enough' is kind of the 'secret sauce' to brining a product to market which is safe and useful, but not perfect," says McConnell.

So the right question is, "What is acceptable?" McConnell adds that her team and others can do as much refinement as one has time for, but at some point, there has to be that trade-off of, it's good enough to be safe and effective, and that's what it needs to be.



The flow chart depict the risk management process for addressing use-related hazards. HFE/UE approaches should be applied for this process to work effectively.

Source: FDA, fda.gov/downloads/MedicalDevices/.../UCM259760.pdf

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CONTRACT MANUFACTURING

Medical Design & Outsourcing takes a look at contract manufacturing:

- *Secrets of a CMO: The 16-year relationship between CardioFocus and Minnetronix*
- *Five tips to surviving supplier consolidation*
- *Molding manufacturers: Standing out in a crowd*
- *The hidden costs of multiple-vendor contract manufacturing*

the hidden cost of multiple-vendor contract manufacturing

Thomas Black
Vice President • OEM • International Divisions Sales and Marketing
B. Braun Medical Inc. • us.bbraunoem.com

The process of bringing a medical device to market is extensive. One consideration is whether to choose multiple independent service providers or one contract manufacturer.

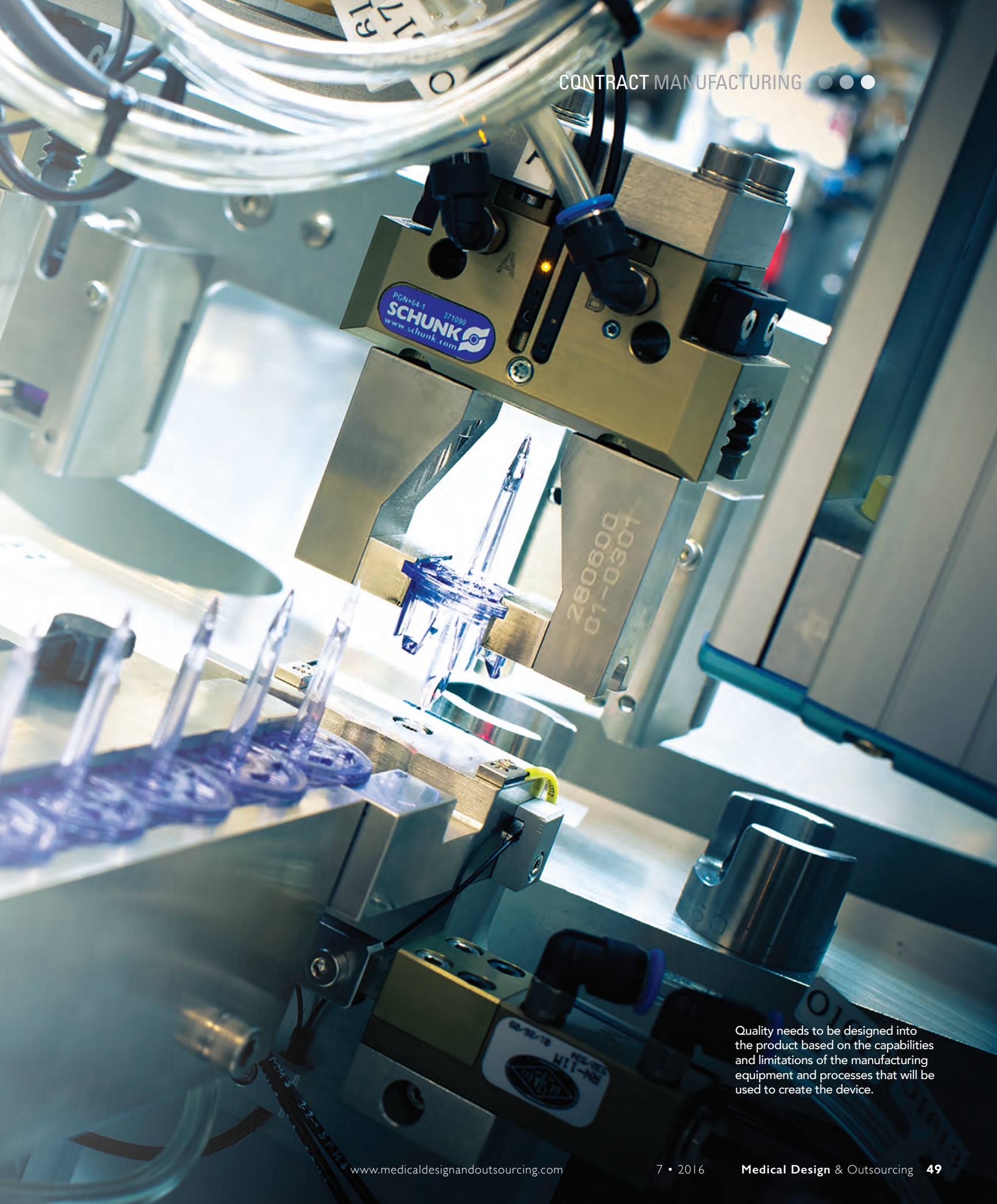
It can be challenging to pick among the thousands of industry resources. From the beginning, companies looking to outsource medical device manufacturing face a major strategic decision. Should we opt for a selection of independent service providers or a single-source contract manufacturer that can handle every step of the process?

Piecing together a collection of resources has its advantages, in finding companies that specialize in p ocesses and techniques that are particularly well-suited to a specific device – a d eam team of partners who are the leaders in their respective disciplines. Companies may opt for a collection of suppliers that share a focus on speed or cost savings, for example. Another option is to simply work with established vendors out of familiarity.

More often, however, the decision to use multiple suppliers on a medical device can have a variety of unintended consequences. These could delay the project timeline, increase costs and lower finished qualit , in addition to creating undue workload and stress for the internal project team. The movement toward a vertically integrated, single-source contract manufacturer has many benefits

Reduce supplier audits and validation

Consolidating design and engineering functions with manufacturing provides significant syne gies. The design team will lean heavily toward materials and components from suppliers who have already been audited and are part of the company's existing supply chain. Auditing and qualifying new suppliers can take weeks or longer, and consume hours of time. Three professionals each spending 20 hours on an audit account for a total of 60 hours



Quality needs to be designed into the product based on the capabilities and limitations of the manufacturing equipment and processes that will be used to create the device.

that could be allocated more productively, not to mention the cost of their salaries and the expenses associated with the audit. Similarly, engineers typically design devices with pre-validated components and materials from these suppliers, eliminating the time and expense required for the validation process.

Although multiple vendors can all be ISO-certified and follow similar quality protocols, there is no assurance that their data monitoring, collection and storage systems will be compatible. Proper documentation is essential if a quality issue occurs or an FDA inquiry is made. Continuity of data is just as critical as the continuity of engineering or manufacturing processes.

Minimize variability

Engineers intimately familiar with their manufacturing processes understand how to optimize the design to make the most of their equipment and processes while minimizing manufacturing variability. Quality needs to be designed into the product based on the capabilities and limitations of the manufacturing equipment and processes that will be used to create the device. Even the most automated pieces of equipment have variations, and even the most rigorously controlled assembly operation has idiosyncrasies. Thankfully, engineers can account for limitations with smart design. After all, quality can't be inspected into the product. It needs to be designed and built in.

Another example of design-manufacturing cooperation involves designing for sterilization. Without meticulous coordination, a separate design team might select a valve and tubing configuration that would not permit ethylene oxide to flow completely th ough the device. Alternatively, an engineer could select a component that would discolor under gamma sterilization. Complete communication and understanding of all phases of manufacturing among all team members mitigates the likelihood of downstream problems.

Furthermore, it's essential that all parties involved with the process have the same interpretation of the user requirements document. An engineering team that writes the document one way and a manufacturing team that interprets it differently could mean a final p oduct that's inconsistent with the desired function. A comparable problem can occur with quality specifications. And measu ement capabilities vary from manufacturer to manufacturer. Are they using the same equipment and is it consistently calibrated? The more entities involved in the process, the more unpredictable the outcome.

Reduce management time

Compiling a team of separate vendors places the responsibility for coordinating them with the internal project management team. Each vendor must be aware of its role in the process and when it will occur. Working with an integrated contract manufacturer eliminates the need to manage multiple vendors. One project manager is responsible for the entire timeline from the earliest design stages through assembly and sterilization.

Additionally, the development of an integrated project timeline minimizes delays between stages of the manufacturing process. A seamless transition is critical. If parties are not talking to one another, they will never understand the upstream requirements of the product. It's analogous to having adjacent conveyor belts. If they're too far apart,

items will fall through the crack. If there's an overlap, items will pile up.

The issue of accountability is a final benefit. If the e is a product failure or quality issue with a device that involves multiple vendors, it's unlikely that one of them will step forward and take ownership of the problem. The more likely scenario is a round of finge -pointing followed by a call to the lawyers. Centralize the entire process with an integrated manufacturer and there's no question about who is responsible for resolving an issue. As one client expressed, he likes having "one throat to choke."

Prepare for a long product lifecycle

Although a collection of multiple vendors could occasionally prove advantageous in the short term, the use of an integrated contract manufacturer delivers benefits over a product lifecycle. For example, a contract manufacturer that also provides sustaining engineering capabilities will be better able to address improvements and changes to the product as feedback returns from the field. Does tubing length need to be changed? Or do pressure requirements need adjusting to ensure proper device operation? An integrated team can evaluate options from a sustaining standpoint, rather than starting anew. As with initial design, they can work as a team to update components and processes without triggering the need to conduct additional auditing or validation.

Likewise, the longer an integrated team works on a medical device from design through production and sterilization, the more institutional knowledge they can provide. Rather than acting as a disparate collection of independent vendors, a vertically integrated contract manufacturer acts as a full extension of the customer's team to provide critical insight and history about everything from material selection to engineering. They also have a holistic understanding of how and why the product has evolved to the current state, providing knowledge that offsets employee turnover or corporate restructuring on the customer side.

Finally, the extent of the partner's experience should also be considered when evaluating a product lifecycle. Should a product prove successful in one country, is the contract manufacturer prepared to provide engineering guidance, change packaging, or obtain regulatory approvals to enable distribution outside of the original country of manufacture? Can they use components that have already been validated by each country's regulations? Once again, an integrated multi-national team provides meaningful, fruitful guidance where individual service providers might struggle.

Which model works best?

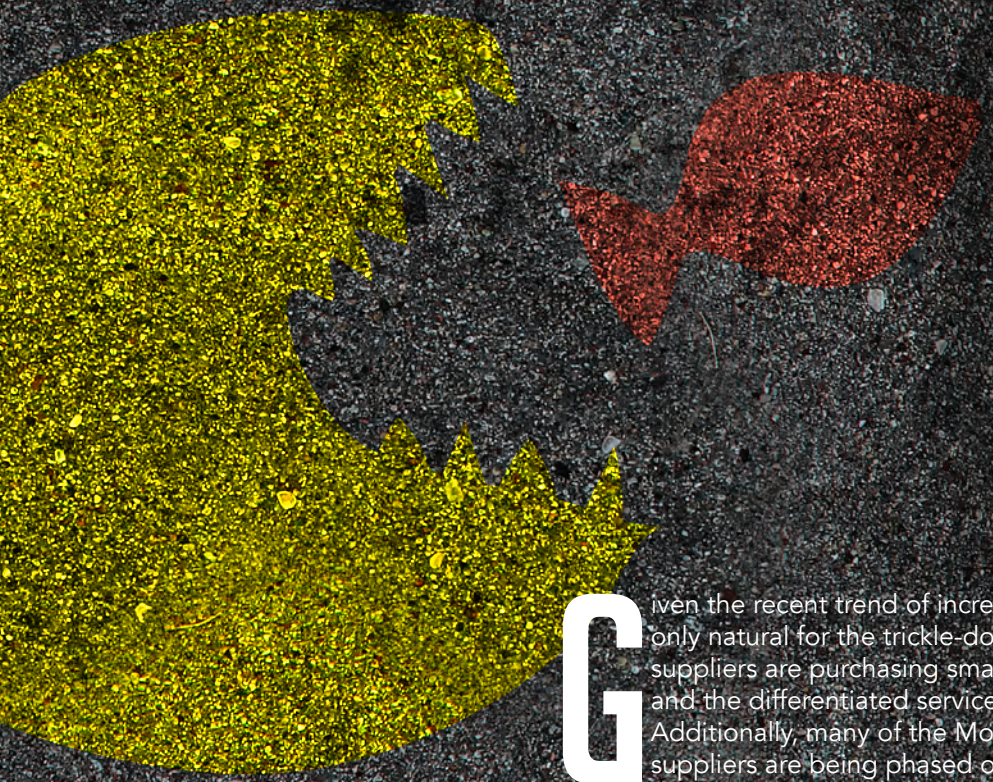
Of course, no one model works best for every company. Some might opt for an approach akin to selecting a group of "All Stars" to play together on the same field. Individual aptitude, howeve , doesn't always lead to excellent team performance, which is essential for something as involved and critical as a medical device.

As the design, production and distribution of medical devices become increasingly complicated and regulated, there's tremendous value in consolidating resources with a single contract manufacturer that provides an integrated team to steward a product from conception through many years of production. The long-term benefits in terms of time to market, overall quality, thoroughness of documentation and accountability typically will outweigh any perceived short-term benefits of a multiple-source approach. M

Measurement and testing capabilities can vary from company to company. Multiple vendors may use different testing equipment or procedures that could cause issues with quality control.

FIVE TIPS to SURVIVING SUPPLIER CONSOLIDATION

Marissa Fayer • President • Fayer Consulting



Given the recent trend of increasing consolidation at the OEM level, it's only natural for the trickle-down effect to hit suppliers as well. Large suppliers are purchasing smaller suppliers, both for increased capacity and the differentiated services offered, but also to eliminate competition. Additionally, many of the Mom-and-Pop single-component or service suppliers are being phased out, as the large OEM conglomerates face market and investor pressure to consolidate supply chains.

The consolidation effect on suppliers is directly related to OEM consolidation, similar to the aerospace consolidation that occurred years ago. Once the OEMs merge, suppliers are forced to merge to gain economies of scale, pricing advantages, depth of services, and capital for investing in technology.

The only suppliers that are able to survive are mid-size shops that offer a wide range of services, including several vertical capabilities and heightened customer service; suppliers that are so specialized that they're "the only game in town;" or suppliers that have the largest footprint, so that their prices are the most competitive (yet they suffer in customer service responsiveness). Each has its place in the consolidated medtech market and offer value to the OEM, depending on their core principles and mission.

"After 12 to 18 months of organizational integration and strategic planning, the 'new OEMs are now positioned to reduce COGS via the supply base," says Matt Jordan, VP/GM of operations at Providien LCC. "The supplier consolidation process is under way – which means that single-production line, single-portfolio, outsourced operations are getting bundled together and auctioned off as larger opportunities. In the end, the winners will be mid-sized contract manufacturers that have a strong quality system, a diverse & vertically integrated offering, and an ability to leverage capital for cost-reducing solutions."

Here are 5 things you need to know to survive in the era of supplier consolidation:

A WORLD APART IN A WORLD OF PARTS

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1. A robust Quality System: ISO 9001 is mandatory and ISO 13485 is highly recommended, as it demonstrates that as a supplier you take your business seriously, are a solid force in the medical device space, and have higher-than-average quality standards. It also shows that you monitor the effectiveness of your supply chain, which is increasingly important to large OEMs as their supply chains are consolidated and they have less control over them. And it demonstrates that the traceability related to the regulation of material and finished devices is in place, i compliance with FDA scrutiny.

2. Value-added capabilities: In addition to creating singular components, providing a service that creates value for the OEM beyond what they can do in-house increases your value to them. Additional assembly capabilities, inventory management, testing capability, and quality inspection have become standard requirements for OEMs – they are no longer optional. Invest in the time, training, and equipment required to add those offerings and you'll be competitive in today's marketplace. OEMs want to do less and continue to pay less, and will only partner with a supplier who can help them save time, resources, and money beyond what they can do themselves.

3. Responsive customer service: A key differentiator between large and mid-size suppliers is their level of customer service. As consolidated OEMs continue to get larger, their demand for customer service increases. Large contract manufacturers and suppliers might be responsive to their top two customers, but what happens to the others? They get lost in the shuffle and a e treated like second-class citizens. Mid-size suppliers value all of their customers, as each one represents a larger percentage of their business. Providing excellent problem-solving and responsiveness will ultimately lead to an increase in business. Issues happen, regardless of where manufacturing occurs, and it's most importantly about how you deal with it and communicate that back to the OEM that matters. A mid-size supplier will be more collaborative and pro-active than a large, bureaucratic supplier.

4. Breadth of scope: In the age of market consolidation, the supply chain must also consolidate, including the capabilities of each supplier. Compressing a supply chain to one company with four verticals is easier for the OEM to manage and justify than four distinct, smaller-spend suppliers. Increasing your offerings and capabilities through either supplier consolidations or investment in additional technology, or both, makes you a more attractive option than a sole-technology supplier. Having multiple verticals allows a supplier to leverage their own in-house capabilities and assets to reduce costs for OEMs, which will continue to be the ultimate goal in consolidation.

5. Relationships with key strategy- and decision-makers: Regardless of the technology offered or its costs, relationships are still one of the most valuable assets in the age of consolidation. The movement of executives and decision-makers is fluid as result of the churn, so your relationships are with both the company and their decision-makers. Continuing relationships based on trust and quality will serve your company over the long term and continue a cycle of new business even after consolidation changes the landscape. You never know where someone will be tomorrow.

A supplier that's positioned itself with these imperatives in mind will be more profitable, with increased market share and new business, regardless of market shifts in the opposite direction. Quality certifications and a diversified business a e best-practice positioning tools that will serve future growth and success.

secrets of a CMO

What CardioFocus and Minnetronix learned over 16 years of partnership

Earlier this year, CardioFocus wowed the market when it won pre-market approval from the FDA for its HeartLight system, an endoscopically guided light energy device for the treatment of atrial fibrillation. The minimally invasive ablation therapy is considered a major advance in treating afib because it allows su geons to see the actual tissue they're ablating. To date, more than 3,400 patients worldwide have been treated using the HeartLight device.

"We're still somewhat of a small company," vice president of engineering Jerry Melsky says. "Our core technology is delivering laser energy to the body in unique ways."

That core tech is employed in HeartLight as a continuous, near-infrared laser light projected by the catheter, which heats the atrial tissue around the heart's pulmonary vein, forming scar tissue that results in electrical isolation. The catheter works to create "conduction block" by allowing the physician to place overlapping arcs of laser light into the atrial wall around the vein. Complete isolation is often obtained with several 20-30 second energy deliveries, promising a great advantage in accuracy, speed and effectiveness in comparison with other catheter methodologies.

Such state-of-the-art advances don't happen overnight. In fact, CardioFocus has been working on the technology for more than 20 years, and found a partner in Minnetronix 16 years ago. You could say the two companies grew up together, sharing successes and challenges. What happened behind the scenes holds lessons for start-ups and established companies on the CMO and OEM sides of the aisle.

In the beginning

Minnetronix co-founder Dirk Smith says the relationship has been quite a journey. "CardioFocus hired us initially as a design company, and then they had to wait and see how things played out," he says. "It's very much evolved into a full design-to-manufacturing-to-service-and-field-support elationship."

Melsky says CardioFocus was founded on the idea of making modifications to optical fibers, so that light-base energy could be put into various parts of the body for a few therapeutic outcomes. "Way, way back, we were doing a lot of different things with laser energy, and in the mid-'90s we got very focused on making a device to treat atrial fibrillation and making the gadget that goes inside the body [the catheter and the laser fiber] as a single piece."

Minnetronix started working with CardioFocus around 2000, already armed with the core laser ablation technology in an early lab stage, explains Smith. "They came to us very much as technologists, asking us to help design and build a human-use laser." The core technology, however, is all from CardioFocus, says Minnetronix's Smith. "They have a good team of optics experts and systems engineers."

That initial project involved an instrument to power and control the laser, Melsky adds. "We needed an electronic box that had a diode laser in it as part of the system. We had a choice of whether we were going to build up in-house capability to do that, or whether to go to a supplier to help us with that. It seemed to make more sense, from a value proposition, for us to stay focused on the devices that go in the body and to bring in this other expertise at building an electronic box with a user interface to actually supply the laser energy to our device."

Minnetronix was brought in and spent a number of years working on getting CardioFocus into pre-clinical and clinical studies. For several years thereafter, CardioFocus continued advancing its technology, adding imaging and other advanced optics. Then it came back to Minnetronix for the next step. From there, says Smith, "We worked with them on the current product, basically, to do requirements through design of the product and then on into production of pre-clinical, clinical, and for-sale production devices.

Melsky says the relationship has been a good one for both sides. "We were able to tap into a lot of their expertise," he says. "One of the things that was really important to us was they had capability not just to do product development work, but also to do the manufacturing piece, and even beyond the manufacturing piece to do fulfillment of this piece of capital equipment."

What Minnetronix brought to the table, Smith notes, was experience with integrating complex medical devices, electronics and software expertise, plus systems engineering

and the regulatory and Quality System experience to go with it.

The technology is fairly complex, notes Jim Reed, vice president of new business development & marketing at Minnetronix. "A lot of things are happening at the same time: A balloon displaces the blood out of the atrium of the heart, a visible laser shows where the ablation will occur, and an invisible laser does the ablation, which you can't actually see. The system therefore has to create an artificial visual line on that display to show where you have ablated. That allows you to get a complete annular ablation around that vein to make sure it's completely isolated." Both lasers, the feedback loops for safety, the expanding and vacating balloon, visual signal processing, and visualization all have to operate in concert.

Reed says Minnetronix was able to develop a system that performs all of those functions simultaneously, in an intuitive, user-friendly and – importantly – safe way, "because you've got lasers and fluid and pressure, and temperature controls, all being handled at the same time."

The challenge for both companies was huge, says Reed. "CardioFocus was a startup and now, after years of development, clinical trials, and the regulatory processes, they have this game-changing PMA device."

Rising to the challenge

Smith points to the safety of the laser as a key focus during development. "This is a high-powered laser, and safety is really critical. They can burn tissue very quickly with this device." One of the first steps was matching CardioFocus's patented technology with the thermal safety of the laser.

Melsky likewise praises Minnetronix's technical team. He says the electrical hardware and software design was integral to the product, but even more than that, he says the CMO showed strength in creating a unified p oduct.

For example, he says "Their team was deep enough and capable enough that they were willing to go outside of their core competencies in certain areas, and we were pushing them into doing certain things with regard to integrating a laser into the electronic box. And they were able to rise to the challenge and to do that piece."

The optics integration was another big step, Smith says. The team worked to implement the imaging system to make sure it could display both still images and video quickly enough for surgeons to use.

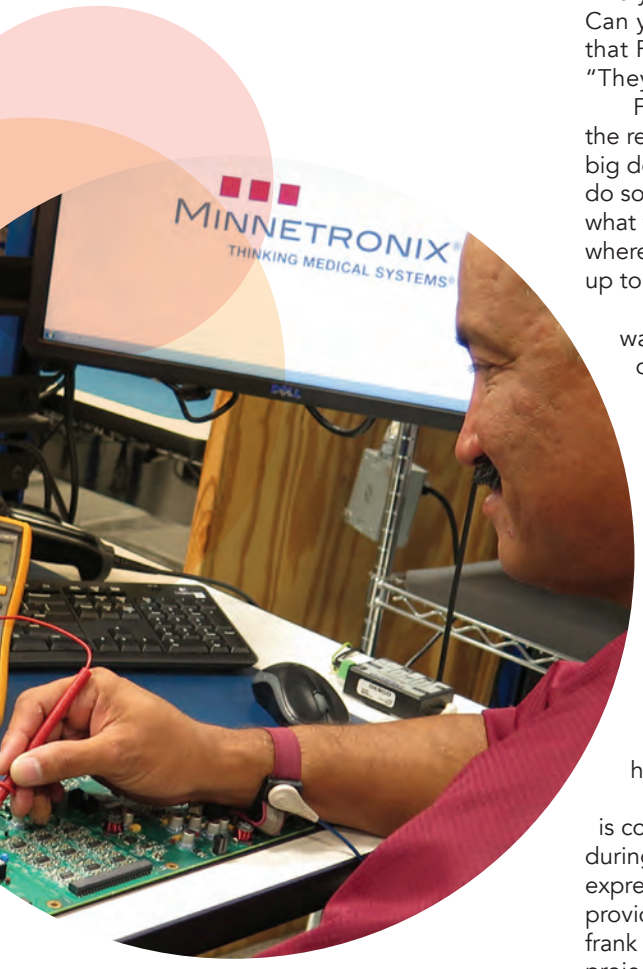
Melsky also recalls the development of the optics, which he says wasn't in Minetronix's core competency. "We had asked them to integrate this piece of optics into the system. The optics really needed a little bit of an alignment or an alignment check at the end of the manufacturing process. Initially Minnetronix said it didn't have any expertise for the alignment."

But CardioFocus insisted it was a key step, critical because Minnetronix was responsible for putting components together; there was no good way to get a good output other than to do the alignment once it's all put together, says Melsky. "They were able to rise to the occasion in putting procedures together so that they could do the alignment." And it turns out Minnetronix was able to improve on the original requirements by streamlining the manufacturing. "So they're not doing the alignment anymore, they're doing an alignment check."

An additional challenge was the user interface. "When you put as complex a system as this is together, the user interface has to translate that complexity to intuitive use for the user," Smith says. The goal was to create a simple user interface to control a complex system.

Another story highlights how Minnetronix was able to go above and beyond. "The endoscopic visualization system in HeartLight requires a specialized light source that delivers light to the optical fibers in the cathete ," Melsky explains. CardioFocus had been buying a xenon arc light from a supplier that discontinued the product. "There was nothing else on the market even remotely like this light source," Melsky says. The company asked Minnetronix to build the light source "almost from scratch;" Melsky admits it was an unusual request, but says Minnetronix rose to the occasion and built a replacement light source.

Smith attributes many of these achievements to Minnetronix's dedication to



quality and design controls. "An important focus area with this and other products is the technical file and documentation." Minnetronix managed the technical documentation on the instrument and the capital equipment through verification testing (although, Smith notes, a third company worked on catheter design). It also managed usability requirements.

Product quality was high on the list of attributes that made Minnetronix a good partner, Melsky says. "The stuff that they've delivered to us has always been high-quality, both in the development and in the manufactured items."

Melsky says CardioFocus felt comfortable with Minnetronix precisely because of its familiarity with quality management and FDA regulations. "Sometimes the first questions we ask suppliers a e, 'Are you FDA registered? Have you been audited? Can you show us your recent audits?'" It was critical that FDA and other bodies had vetted the company. "They had top-notch systems in place."

Finding a partner who knows medical devices and the regulated nature of the medical device industry is a big deal. "We've looked at other suppliers where they do some medical, and maybe some military, and often what we find is they have certain aspects of their system where the level of scrutiny and quality control really isn't up to snuff for the medical device industry."

Minnetronix prides itself on the fact that it was able to hand CardioFocus the subset of documentation needed to apply for the PMA, "essentially complete and ready to go to FDA," says Reed.

Lessons learned

All of this is not to say the relationship never had ups and downs. Both companies went through trials and errors, something inevitable with long partnerships. As Smith says, "There's definitely a g owth curve, and our company grew up through this process. Industry has seen regulatory changes and technology changes. For example, the electronics and software – the microprocessors – that we put in that first laser have changed so much in the last 15 years."

One of the hardest issues in any relationship is communicating disappointment. At one point during the companies' long relationship, CardioFocus expressed frustration over Minnetronix's ability to provide accurate timing and cost proposals. "We were frank with them," says Melsky. "It seemed like every project that we had done with them had run over."

They were looking at about a $2 million dollar project to redesign the whole box, he explains. According to Melsky, Minnetronix surprised the company by offering to do the project on a fixed-cost basis.

"They might shoot me for saying that," laughs Melsky. "I think we both learned a lot from that experience. I'm not sure they'd be willing to do that again, but it was an interesting experiment."

The reality was that the fixed cost proposal proved to be a poor decision. "There really isn't any such thing as a fixed-price contract," says Melsky, "because there isn't any such thing as a fixed deliverable specification.

Melsky says CardioFocus started out thinking they knew what they wanted, but eight months into the program, the company realized that the user interface wasn't working. "We needed to change our thinking." And, he says, it's perfectly legitimate that that as expectations change, as the specs change, the supplier will need to update their quote.

From the Minnetronix side, Smith says the development cycle for complex PMA devices is by nature long and always includes unanticipated challenges and opportunities. "While we follow a standard methodology for every design, each product and each company we work with is unique and every development effort has its own challenges and critical elements. Part of the fun and reward of working with companies like CardioFocus is that they're doing something that no one has done before, and developing a totally new therapy requires flexibility and adaptability.

"Developing safety-critical devices is complex, particularly for PMA devices which evolve over many years; working closely with our customers to help them identify and focus on the most critical and

necessary objectives is essential," he adds. The combined team had to adjust not only to changing specifications and p e-clinical testing results, but also with the evolving processes around testing and verification, including human factors and usability. "The way that we perform usability testing on this product now, and really how we conduct overall verification testing, is significantl more sophisticated than even 10 years ago, based largely on new regulatory standards and guidance documents," Smith says.

What makes a good OEM?

Smith says that when Minnetronix started with CardioFocus, it was one of hundreds of startups around the country. "We had no idea of their probability of success."

And yet, being able to provide long-term support is critical for Minnetronix as a CMO that works with some of the largest medical device companies in the world.

As Reed says, "We do a lot of work with startups as well as operating companies. We hope those startups will eventually become a company like CardioFocus and our goal is to help them cross that finish line.

Over time, says Smith, you develop a sense of what good startups bring to the table. Essentially, Smith says, OEMs that know what they need and when they need it are in a better position. CardioFocus is the same company it's been for more than 16 years, he says, but what they need from a CMO has changed dramatically along the way. That's very common, he says, particularly in the medical sector, where timelines and product lifecycles can span decades.

A good partner is one that looks beyond its immediate needs, as well as what fits at the moment. "It's important to play chess, not checkers," he notes. Smith advises companies to look at today's needs as well as next year's – and then 5 years down the road. "They're almost for sure going to change over time." It's important for companies to think about that and pick partners who can accommodate them for their whole company life cycle, not just the particular problem they face in the moment.

What makes a good CMO?

Melsky says an outsourcing partner should have specific technical capabilities, but the e's more to it than that. "I get a call every day from somebody who's seen our box, saying, 'That looks like the kind of stuff we make.' They say, 'Hey, why don't you consider us?'"

It was critical to Melsky to find a company that could cover development at a very early stage, from ideation for the new product all the way through to a manufactured product – and one that could actually do the manufacturing.

"Over the years, we've talked to different folks about being a supplier for us, doing things similar to what Minnetronix was doing." Many of them, he said, had development capabilities and were willing to make a few units, but they weren't able to do full manufacturing. Alternatively, others were highly capable in manufacturing but couldn't cover the development side.

"Having somebody that was going to take it all the way through from the concept state into full production, that was very important for us," Melsky explains, noting that a lot of issues occur at the hand-off from development into production.

"Another big thing for us is their response to problems that come up," he adds. "They've always been very responsive when we've had a new issue that we've discovered. They've always been very responsive in trying to help us sort through what the problems are and giving us rapid proposals for addressing problems." M

MOLDING MANUFACTURERS:

Standing out in a crowd

Economical micro processing of absorbable tack materials require minimum runner sizes to reduce waste. Absorbable tack materials degrade with shear generated in small flow paths. Designing a bioresorbable tack solution that balances these conflicting needs is a challenge we have learned to conquer.

Photo courtesy of MTD Micro Molding

The days of siloed manufacturing in the medical device industry are all but gone. No longer can OEMs find a contract manufacturer that just does one thing. A case in point is the medical molding industry – almost all molding companies have moved beyond the "we just make parts" mentality. Most offer design assistance, and other pre-work, plus after-mold services up to and including packaging and sterilization.

More than one molder tells *Medical Design & Outsourcing* that the drive to offer expanded services is always based on meeting customer needs and trying to stay ahead of the bigger contract companies. Many have built strong reputations based on years of experience in the medical technology market. These experts have responded to customer needs in multiple ways.

IP protection

MRPC is an ISO 9001 and ISO 13485 custom manufacturer of silicone, medical rubber, and thermoplastic components and assemblies. The company specializes in two-material molding, micromolding, silicone molding, and long-term implantable molding.

"We do it all in our facility. We want to be thought of as high-quality build for molds and molded parts, and a short-run production source," says Mark Brandstaetter, VP of sales and marketing, noting that MRPC is privately held.

"There is a lot of uncertainty in IP protection and ownership, but with privately held companies, that uncertainty is diminished," he says.

MRPC has recently expanded its services to include pouch packaging. "We are doing more of those downstream activities," to better serve clients, Brandstaetter explains.

Above all, Brandstaetter says his company puts an emphasis on quick turnaround. "Fast manufacturing is very important to industry. We can bridge the gap from prototype to production."

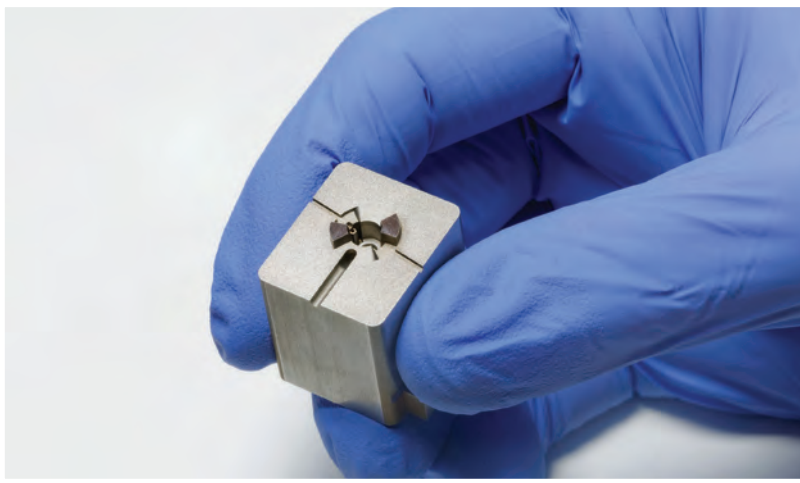
Micromolding to the rescue

MTD Micro Molding is a specialty house in the truest sense, says Director of Marketing Lindsay Mann. The company is solely focused on the micromolding of advanced medical products.

"We serve clients best that have projects that possess a level of 'impossible,'" says Mann. Her challenge is different from other molders because of the specialized requirements of micromolding technology, she explains. "Micromolding requires a significant level of know-how," she says. "We need to have a thorough, up-front view of the project to make sure we are putting our potential clients on the right path."

If a client's design doesn't meet the criteria that MTD's specialized process requires, Mann says, "it's better to be honest about it." MTD takes its role as an educator seriously. And it also sees itself as a

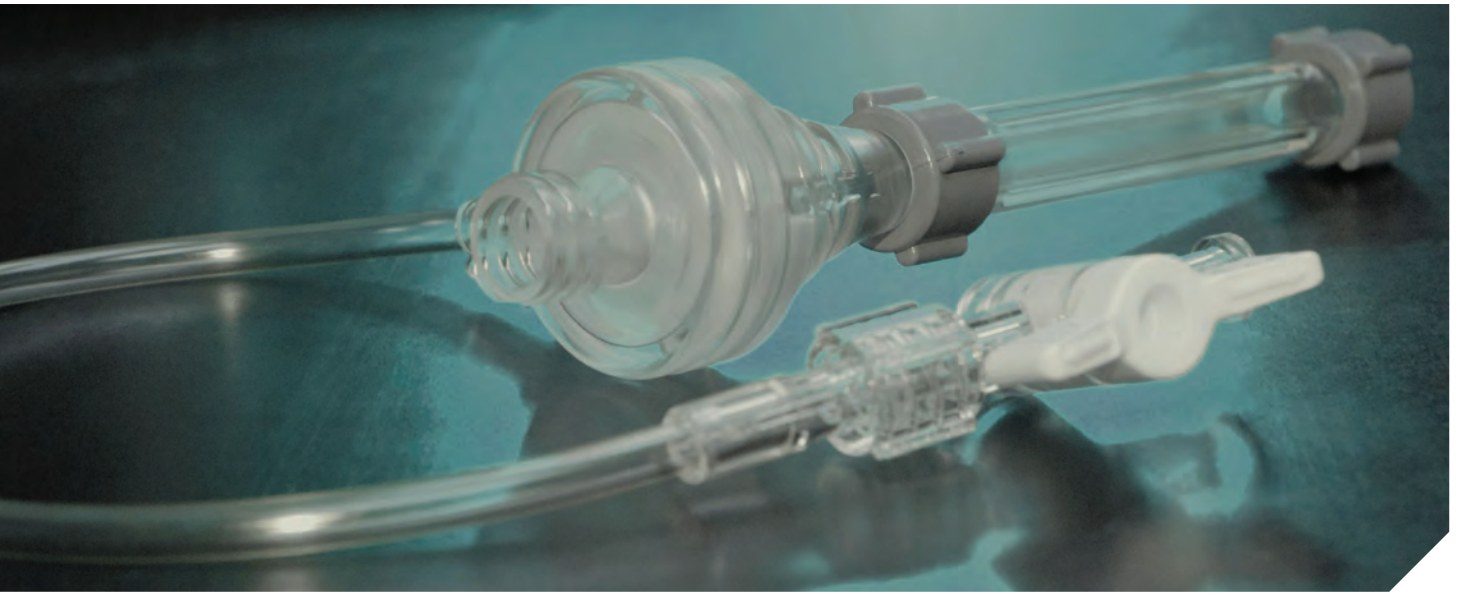
Ultra-precision tooling inserts created at MTD. Successful micromolding begins with exact tooling execution.



problem solver. "Because we are a specialty house, 25 percent of our business is rescue projects from companies that failed with another molder," she notes.

No surprises

Sil-Pro is a contract manufacturer specializing in the design & development, manufacturing, assembly, and packaging of silicone and thermoplastic devices, components, and machined parts. Marketing Coordinator Rebecca Talbot says the fi m's sweet spot is that it offers total manufacturing & assembly and post-assembly services from a single location, what Talbot calls "downstream processes and uses."



Contract manufactured custom vascular introducer assembly. The part comprises molded silicone, molded thermoplastic and was assembled and sonic welded by Sil Pro.

Sil-Pro's best clients come in with a design and work closely with the fi m to flesh it out, albot says. "The one thing no one wants is surprise," she says, remembering a client with a complex molding design. The group agreed on a material and process, but the client wasn't able to convey that the final part needed to withstand a certain temperature. Such detail is important and can influence the material selection and the geometry of the part. "We can do complicated geometries and cavitations, but we need realistic expectations," says Talbot.

The best way to avoid such a scenario is to have an open, communicative relationship, she says. Collaboration comes down to ensuring you have good technical people and that both sides ask the right questions. "The more you inform the CM, the better the manufacturing and the better the product. You don't want to waste money, so you have to be ready to collaborate."

Location, location, exchange rate

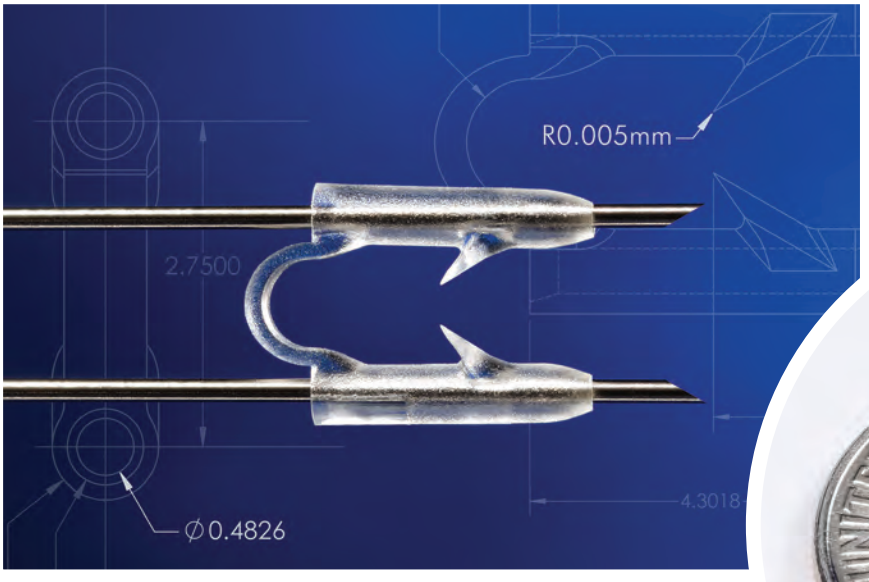
Freudenberg Medical is a complete silicone and plastic injection-molding fi m with assembly, cleanroom and R&D support. All of the processes happen under one roof in either Gloucester, Mass., or at Freudenberg's headquarters in Carpinteria, Calif., says Don Durand, business development manager. He says keeping individual projects together improves the company's internal process in order to improve the quality of the part.

Moore Med Tech is a custom injection molder that develops and optimizes plastic medical products. Jerome Mercier, sales coordinator at Plastiques Moore, touts the company's 44 years of experience in injection molding. The company has ISO 13485 certification and p oduces parts in an ISO 8 cleanroom. Sometimes it's not only the quality of the services you offer, but the ability to offer something others might not. In Moore's case, Mercier says the company's Quebec City location is an additional incentive because of the exchange rate between the U.S. and Canadian dollars (at the time of this writing, $1 was worth nearly C$1.31).

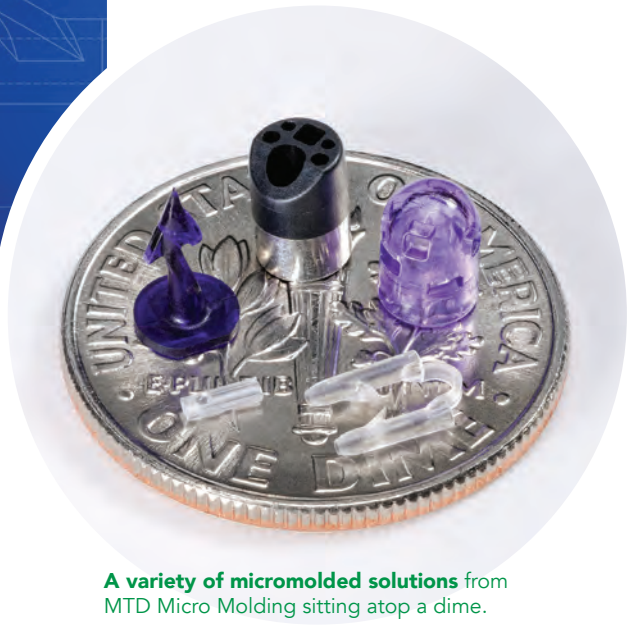
Thinking big and early

Nypro is an example of a traditional medical molder that has moved on to bigger ideas. The company, which provides metal injection molding and silicone molding services, was acquired by Jabil in 2013. The new resources provided by the merger support Nypro's expanding view; senior business unit director Alex Privert says the company is focusing on connected health with a "blue sky" innovation center and a pipeline for 3D scanning and ideation.

"Many of our competitors have small R&D departments, but our sweet spot is the front-end innovation," Privert says. "You can give us your tough jobs." M



A client approached MTD with a suture device design, seeking a product with minimal inherent viscosity loss and crisper features to improve functionality. While most competitors had difficulty ealizing less than a 20% IV loss, MTD developed a superior fastener with an IV loss of less than 4%.



A variety of micromolded solutions from MTD Micro Molding sitting atop a dime.

DeviceTalks:
A conversation with John Klein, Chief Procurement Officer, Medtronic

As the largest pure-play medical device company in the world, Medtronic has more suppliers than most companies have employees.

Although we were unable to get an exact number out of him, John Klein, Medtronic's new Chief Procurement Office , told us the company managed a growing universe of "tens of thousands" of suppliers. With each acquisition the company makes, and they've made many in the past two years, the more suppliers Medtronic has to either onboard to its way of doing business, or cut to reduce costs.

Managing that vast universe falls on the broad shoulders of Klein, who joined the company late last year after spending seven years with adhesives giant Avery Dennison Corp.

In his new role, Klein runs all strategy for Medtronic's supply management functions, focusing on "developing functional best practices across Medtronic, while also pursuing combined spend opportunities across the divisions," he tells us.

We asked Klein to give us an inside look at how Medtronic looks at managing and picking the suppliers it works with. The following interview was conducted via email to accommodate Klein's busy schedule.

○ DEVICETALKS: As the largest pure-play medical device company in the world, about how many suppliers is the company dealing with at any one time, and what is the process for vetting and securing new vendors such, as contract manufacturers?

● JOHN KLEIN: We currently have tens of thousands of supplier partners, and our primary focus is on optimizing our supply base and those partnerships. We evaluate new supplier capabilities and competencies on a number of critical areas such as cost, quality, service and innovation performance. We then evaluate how these potential suppliers might best fit with ou current and future business needs.

○ DT: How large a team is required to understand and manage these suppliers? Is it done from a central office or is it up to eac division to manage their own suppliers?

● JK: We have an extended staff of employees in Supply Management around the globe who are responsible for supplier quality management, technical sourcing, advanced sourcing, continuity engineering, contracting, purchasing, and process excellence, to name some of the predominant areas of functional concentration. We deploy a center-led approach for direct materials and contract manufacturing, and then a centralized structure for indirect goods and services.

○ DT: The automotive and aviation worlds are often said to be analogous to medtech, in the relationship of suppliers to the manufacturing process. But both of those industries have changed dramatically as a result of consolidation; now airline and car companies carry very few suppliers. Has the current system helped or hurt medtech, in that companies continue to support a vast constellation of suppliers and vendors?

JK: Medtronic is focused on delivering medical technologies that foster better patient outcomes while maintaining or reducing costs. That focus extends into how we manage our supply base. In some cases, our patients and customers are better served through strategic consolidation of our supply partners. However, Medtronic also partners with many smaller suppliers who have unique technologies and play a vital role in advancing our mission and strategies.

DT: You said Medtronic has tens of thousands of suppliers; about how many contract manufacturers is the company working with at any one time?

> IN SOME CASES, OUR PATIENTS AND CUSTOMERS ARE BETTER SERVED THROUGH STRATEGIC CONSOLIDATION OF OUR SUPPLY PARTNERS.

JK: We work with several hundred contract manufacturers who are strategic partners in our efforts to lower costs while improving quality, service and innovation.

DT: Before the Covidien merger, roughly how many suppliers was the company working with?

JK: The Covidien merger nearly doubled the global footprint of Medtronic, which increased our supplier base by roughly the same proportion.

DT: What is the SRM (Supplier Relationship Management) Program and how will it change the way the company does business?

JK: Medtronic's Supplier

> THE COVIDIEN MERGER NEARLY DOUBLED THE GLOBAL FOOTPRINT OF MEDTRONIC, WHICH INCREASED OUR SUPPLIER BASE BY ROUGHLY THE SAME PROPORTION.

Relationship Management program aims to create the strongest possible relationships with our most critical suppliers, and encourage efficiencies throughout our global supplier network. It allows all parties involved to maintain focus on our strategic priorities, while creating alignment internally and externally on those programs.

DT: Your background is not in medical devices. What drew you to the industry and Medtronic specifically?

JK: I am not entirely a newcomer to the industry. My last employer, Avery Dennison, had a medical division called Vancive Technologies, so I was familiar with supply management in a regulated environment. As a material scientist and engineer, the vast majority of my 25-year career has been with both manufacturing and material science-based companies that are innovation leaders in their fields. Medtronic fell right into this comfort zone for me. I'm excited to become more involved in a dynamic industry on the verge of tremendous growth and opportunity. The Medtronic Mission has been a strong driver of allegiance and commitment combined with a compelling corporate strategy that made it extremely attractive for me to join.

DEVICETALKS

STEPHEN MARSH
Founder & Inventor, Airing

SAMUEL F. STRAFACE, P.H.D.
President & CEO, MedRobotics

PATRICK WEST
Partner, Mirus Capital Advisors

NANCY BRIEFS
President, CEO & Co-Founder, InfoBionic

MARTHA SHADAN
President and CEO, Rotation Medical

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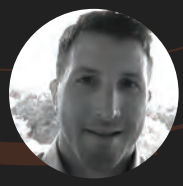

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DEBORAH DISANZO
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Join us on September 28th for a special 5 year anniversary show of DeviceTalks Boston, as we celebrate half a decade of bringing you the best in medtech conversations. We've expanded our program to bring you nearly a full day of insight, networking and thought provoking workshops and panels.

And, at dinner we'll be unveiling this year's *Medical Design & Outsourcing* **BIG 100** list of the top medtech manufacturers. Join us as we celebrate the best of this incredible industry in the mecca of medical technology.

WHEN:
Wed., September 28, 2016
from 1:00 PM to 8:30 PM (EST)

WHERE:
Boston Marriott Long Warf
296 State St., Boston, MA 02109

Questions? Contact:

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Event Coordinator
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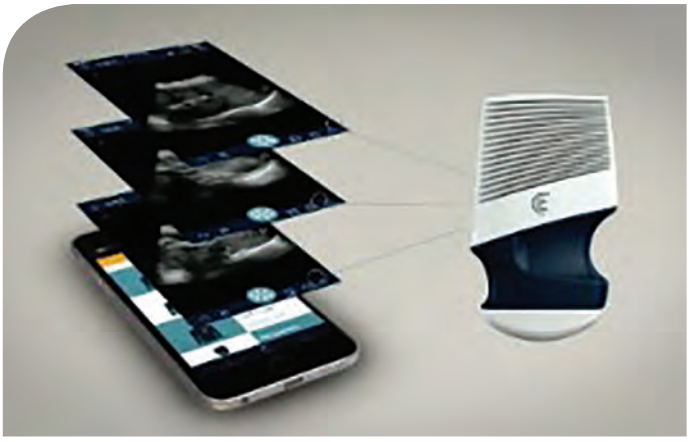
The Clarius ultrasound scanner for iOS and Android is world's first



Clarius Mobile Health has developed the world's first handheld ultrasound scanner with a mobile application f r iOS and Android smart devices. The Clarius ultrasound scanner is wireless and works with a mobile app that's compatible with most smart devices. With automated adjustments and an intuitive interface, the personal ultrasound device is designed to be carried around for quick exams and to guide procedures such as nerve blocks and targeted injections. Compact ultrasound systems for use at the bedside have become the norm in most hospitals and many private clinics.

Clarius Mobile Health
www.clarius.me

Next-gen touch buttons with 'smart' electric field sensing

Banner Engineering introduces next-generation touch buttons for its industry-recognized K30, K50 and K70 multicolor indicators and pick-to-light sensors. Using smart electric field sensing, the next-gen touch buttons p ovide better immunity to false triggering caused by the buildup of detergents, oils and other foreign materials, as well as exposure to direct water spray.

The next-gen K30, K50 and K70 indicators are ergonomically designed to eliminate hand, wrist and arm stresses associated with repeated operation, requiring no physical force to operate. The indicators can also be easily actuated with bare hands or in gloves. All models feature fully encapsulated IP67/IP69K construction for optimal performance in high-pressure wash-down environments.

Banner Engineering
bannerengineering.com

Foster introduces ProFlex SEBS polymers for soft touch medical devices

Foster Corporation debuts ProFlex styrene-ethylene butylene-styrene (SEBS) for medical device applications. These polymers offer a low-cost alternative to other thermoplastic elastomers with superior elastomeric properties.

Soft-touch over-molding of ProFlex SEBS onto rigid thermoplastic or metal components provides a high-friction, ergonomically friendly surface. Vibration-damping and insulative properties make ProFlex SEBS ideal for over-molding of instrument handles and grips. And ProFlex SEBS polymers also have 20% lower specific gravity than other engineering thermoplastic elastomers, yielding more parts per weight.

Foster
fostercomp.com

Tubing connections made easier for home users

The DTLD Series couplings better manage dual fluid lines in app ications such as cold therapy devices. The DTLD Series is the first in the category to allow connecting two lines either simu taneously or individually by a single, easy-to-use, patent-pending thumb latch. Conventional dual-tube connectors make users depress multiple latches to insert or disconnect tubing or contend with one tube inadvertently disconnecting when the other is inserted. The DTLD Series connectors solve these problems for device makers and end users.

Colder Products Co.
www.cpcworldwide.com

GRI's Magnetic Drive brushless DC circulation pumps run on 9-24 Vdc

Designed for the circulation and transfer of fluids, GRI s Integrity Series Magnetic Drive Circulation Pumps offer a flexible and obust pumping solution to OEM fluid applications. By manufacturing th motors and most of components in-house, GRI has the flexibilit to precisely configu e an Integrity Series pump to meet an OEM's specific flow and essure requirements. GRI's 9 to 24 Vdc, brushless and variable-speed circulation pumps are ideal for OEM applications where a small footprint is needed and high performance is expected.

Gorman-Rupp Industries
www.gripumps.com/products/brushless-dc-circulation-pumps/

New barbed check valves eliminate the need for bonding

Eight new barbed check valves were recently added to Qosina's extensive line of stock components. The valves are available in three different configurations, have a lo , 0.087 psi cracking pressure, and are made of SAN, MABS and silicone. Ideal for infusion, drainage and irrigation applications, they provide controlled directional flo , and eliminate the need for bonding. All versions are ETO and gamma sterilization compatible. The valves are also Reach and RoHS compliant as well as Class VI and ISO 10993 approved.

Qosina
qosina.com

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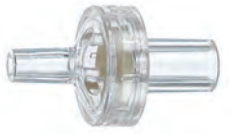
If you're looking for a single-source supplier, how about one that has a full range of parenteral



pharmaceutical solutions? Or one with a catalog of valves as thick as a phone book? Or one that



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