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ORTHOPEDIC DESIGN & TECHNOLOGY

More Tools

Instrument suppliers get creative to meet medical device makers' demands.

Drivers of Design

New materials and cost are influencing implant designs.

Lean for Low-Volume

FDA and the 510(k)

Increased Orthopedic Dealmaking

More Tools in the Toolbox

Manufacturing partners leverage a creative network of product development to stay ahead of increasing OEM demands in the surgical instrumentation market.

Mark Crawford • *Contributing Writer*

It's a familiar story this year for orthopedic surgical instrumentation and delivery systems: Orthopedic device manufacturers want "more tools in the tool kit" that can outperform the competitors' tools in a way that justifies a premium price.

OEMs particularly are interested in instruments that are lighter weight, battery powered, and durable enough to withstand high pH dishwashers and hundreds of autoclave cycles. Others are intent on finding new finishing and coatings that will improve the longevity of the aluminum trays that are subjected to the stringent cleaning systems developed for the European market. Another growing area of interest is incorporating electronics into instrumentation.

Accelerating pricing pressures, along with a tough regulatory climate, continue to challenge contract manufacturers and suppliers. Aggressive design-to-price targets are being requested by OEMs more frequently and participation in the risk assessment and validation plans now are expected to be part of the initial proposal process.

"As a result of these pricing pressures, we find ourselves designing and developing devices with materials and or processes not commonly used in orthopedic instrumentation just a few short years ago," said Van Flamion, director of Paragon Medical's Orthopedic Instrument Global Design Center and Bioskills Lab. Paragon Medical is a tier-1, turnkey supplier of solutions for custom and standard cases and trays, surgical instrumentation, and implantable components based in Pierceton, Ind. "For example, we see the continued expansion of polymer, silicone, and metal injection molding (MIM) to satisfy the pricing demands, especially in disposable applications."

Of course, the ultimate challenge for medical device firms is producing these added features at a cost that is acceptable to OEMs. Contract manufacturers and suppliers constantly are looking for new ways to reduce costs and maintain margins. Sourcing offshore is one approach to reduce the cost of the instrument sets; another is reducing the number of instruments within a set. Stocking programs and consignment inventory are other methods that OEMs are using to reduce the total cost of providing instrument sets into the market.

Supply Chain Management

Nearly every OEM is scrutinizing the contract manufacturer's supply chain. Shortening the chain and spreading the compliance risk downstream is probably the most direct way to create cost reductions through improved quality, validation and speed to market.

"Major device firms are fully implementing their supplier development initiatives," said Joe Rotino, vice president of quality

Segment of an arthroscopic shaver system. Photo courtesy of Pro-Dex.

management and regulatory affairs for Pro-Dex, Inc., an Irvine, Calif.-based firm that specializes in the design, development, and manufacturing of powered surgical devices. "They are imposing much tighter supplier controls, resulting in required equipment and process validations, measurement system qualifications and detailed inspection control plans. For many contract manufacturers this now requires infrastructure and system changes to implement these necessary controls."

Chip Harvill, vice president of marketing for Cadence, a provider of surgical cutting, piercing, and delivery system applications in Staunton, Va., indicated more customers are extending their requests for quotation (RFQ) to include as many downstream operations as suppliers capably can manage—including final assembly, labeling, packaging, sterilization and finished goods management.

"In addition to the downstream operations," he noted, "customers are also extending their requests to include the upstream activities as well, such as product design and performance testing. These changes are pulling contract manufacturers in new directions and stretching their core processes and technologies."

Medical device manufacturers also are placing more scrutiny on the human factors and usability elements in the design and documentation process, including all user interactions such as screens, buttons, input devices, alarms, auditory, visual and physical interactions, and operating functions. They want to improve device performance and safety, and reduce use errors," said Marc Dubreuil, director of new business development at Farm Design Inc., a full-service, product development company based in Hollis, N.H. "New guidelines such as IEC 62366:2007, Medical Devices–Application of Usability Engineering to Medical Devices [from the International Organization for Standardization, or ISO], require developers and manufacturers to involve users in all stages of development—from start to finish—to determine usability requirements and verify and validate inputs/needs. Medical device manufacturers are playing catch up trying to demonstrate that all potential use-related hazards in their devices have been identified, tested, and mitigated."

Another recent trend is the increase in validations for special processes such as cleaning, heat-treating, passivation, welding and coatings.

"We are fully validated with all internal special processes," indicated Shawn Schafer, vice president of sales and market development for Oberg Medical, a full-service contract manufacturer based in Freeport, Penn. that specializes in implants, instruments and assemblies. "We also ensure that for any special process that we subcontract, that the supplier must also be fully validated and pass our supplier audits. Our supplier audits have increased both in frequency as well as in focus in the area of validations."

From a metal finishing standpoint, large orthopedic device manufacturers are asking manufacturers to employ validated processes for all metal finishing and coating operations.

"Our company has invested the time and effort to validate all our finishing processes," stated Jeff Boehmer, director of marketing and sales for Electrolizing Corporation of Ohio in Cleveland, which provides metal finishing for medical instruments, implants and medical devices. "A key area of concern is the stringent cleaning systems developed for Europe. Currently the United States market seems to be utilizing hardcoat anodizing for their trays and delivery systems; we are continuously researching and developing new products and coatings to improve the life of aluminum trays, from standard autoclaves to the harshest European cleaning procedures."

When applied correctly, coatings can be an inexpensive way to improve the durability of a medical product. Because a denser anodize coating offers benefits such as increased hardness, greater abrasion resistance, and enhanced lubricity, hardcoat anodizing is applied to cases and trays to increase lifespan and overall appearance of the product, instead of the standard sulfuric anodizing.

Color anodizing also can provide an aesthetically appealing look to a product. "Not only is it used to incorporate a company's color to the product, it is also used in color-coding applications," added Boehmer. "Color-coding instruments and/or implants to specific sizes is a common practice that simplifies the use of medical devices. Delivery trays or cases can also be color-coded to easily identify the products inside."

Pro-Dex has modified its current equipment qualification/validation processes to match the requirements of its customers.

"We have conducted standard gage repeatability and reproducibility studies under their acceptance criteria," said Rotino."

In addition, we could only use specific sub-suppliers that we validated according to the customer's quality system. In some cases this required in-house technical expertise and specific systems to implement and document these special controls. It's not so much that these requests change over time, it's that major device companies are not all on the same timetable and some are imposing these requirements after others have already implemented them."

Ultimately, the key to success for each project is getting absolute clarity on the customer's requirements for every step of the RFQ. Depending on the project, the situation could require installing the latest equipment and adding the labor that's needed to accomplish the process.

"Sterilization remains a part of the requirements set that we will continue to outsource because the effort needed to successfully install, qualify, and validate that process is high," said Harvill.

Communicate, Communicate, Communicate

It may sound cliché, but according to industry experts, excellent communication skills are important in developing surgical instruments. Designing and producing instruments is extremely demanding—usage is very specific and each surgeon responds differently to characteristics such as shape, form, balance, weight, materials, etc. Getting all the design details right the first time is essential for maintaining or gaining on market share (it doesn't take long for unhappy surgeons to spread the word). Therefore, it is imperative to stay in almost constant touch with end users and solicit feedback because, if you don't, your competitor may learn that one piece of information that makes the difference in surgeon satisfaction and win the next contract.

"We are seeing our OEM customers require suppliers take on more of the design ownership on instrumentation, or 'design authority' as more commonly termed within the industry, relating to co-developments," said Flamion. "Having suppliers that have the knowledge and infrastructure to support development activities at this level provides a tremendous value to the OEMs, which is why Paragon has invested heavily in being capable of providing full design and development services, including our recently opened Bioskills Lab."

Using a fully implemented, concurrent engineering approach keeps the device customer involved in all phases of product development, from initial concepts and product feasibility to the final design transfer into production. This keeps the design, validation, and production activities fully in line with customer requirements and prevents untimely product/design changes in the final stages of product release.

"The key is to really understand the customer requirements, convert that into a technical design input requirement, and evaluate the feasibility of the design," advised Rotino. "We do that under true concurrent methods to ensure inputs from all functional vantage points (engineering, quality and regulatory, operations, and materials management) are addressed and on the table as soon as possible. Once all these factors are evaluated, we know we can be successful in developing a design that is reliable and easily manufactured."

Rotino cited an example where Pro-Dex was developing a powered handpiece using a lithium ion battery for high power requirements. Once the battery was spec'd out from a technical standpoint, the design team realized the handling and transportation of such a battery would have been highly prohibited and interfered with distribution and general use. "We quickly switched to an alkaline solution and continued the design process," said Rotino. "The crisis was averted before it happened—this is the kind of outcome that results when all functions are involved at the earliest stages."

It's important to have the opportunity to provide feedback to customers in the design stage, especially when companies find ways to improve on the part design and determine their impact on manufacturing, said Peter Browne, sales engineer for PMI Medical Instruments, a Madison, Ala.-based contract manufacturer that manufactures medical devices and implants for the orthopedic industry.

"This is one of the best ways to cut cost out of manufacturing prior to the part being finalized and submitted for FDA [U.S. Food and Drug Administration] approval," he said. "It is always best for us to understand the part we are working with as well as any other devices or implants it will come in contact with. This helps us focus on helpful suggestions without altering the benefits of a new design."

Farm similarly strives to be an extension of its clients' teams and serve as a resource by sharing concepts and ideas, from sketches to proof-of-concept prototypes that are then assessed and selected by the collaborating teams.

"Our process is based on user interaction," said Dubreuil. "Farm does not depend solely on marketing information or engineering's view of what users need. It is our belief that users can and should be the primary focus in establishing new product requirements. We can further develop these ideas and concepts into working, fully functional prototypes that can be used for bench testing and/or preclinical (animal) studies."

Talking with Surgeons

The most sophisticated OEMs have their own surgical training and development centers where new products are designed and tested, with a direct line of communication between product development teams and surgeons.

"As a key partner to OEMs, they prefer that we leave the direct interaction with the surgeons to them," said Harvill. "They have already invested in the people and facility infrastructure to enable that interaction to be very efficient and productive. The OEMs end up with ownership of the design of the product and the related intellectual property. They interact with the surgeons to define the functional requirements needed for the product. We then develop performance testing methods to assure functional conformance."

Consulting firms also can be hired to solicit surgeon feedback—not only do they have broader industry perspective, companies like Farm conduct research directly with doctors, surgeons, nurses, patients and administrators. These sessions often involve live surgical observations, one-on-one interviews, and competitive analysis. "We conduct deep-dive research to uncover unmet

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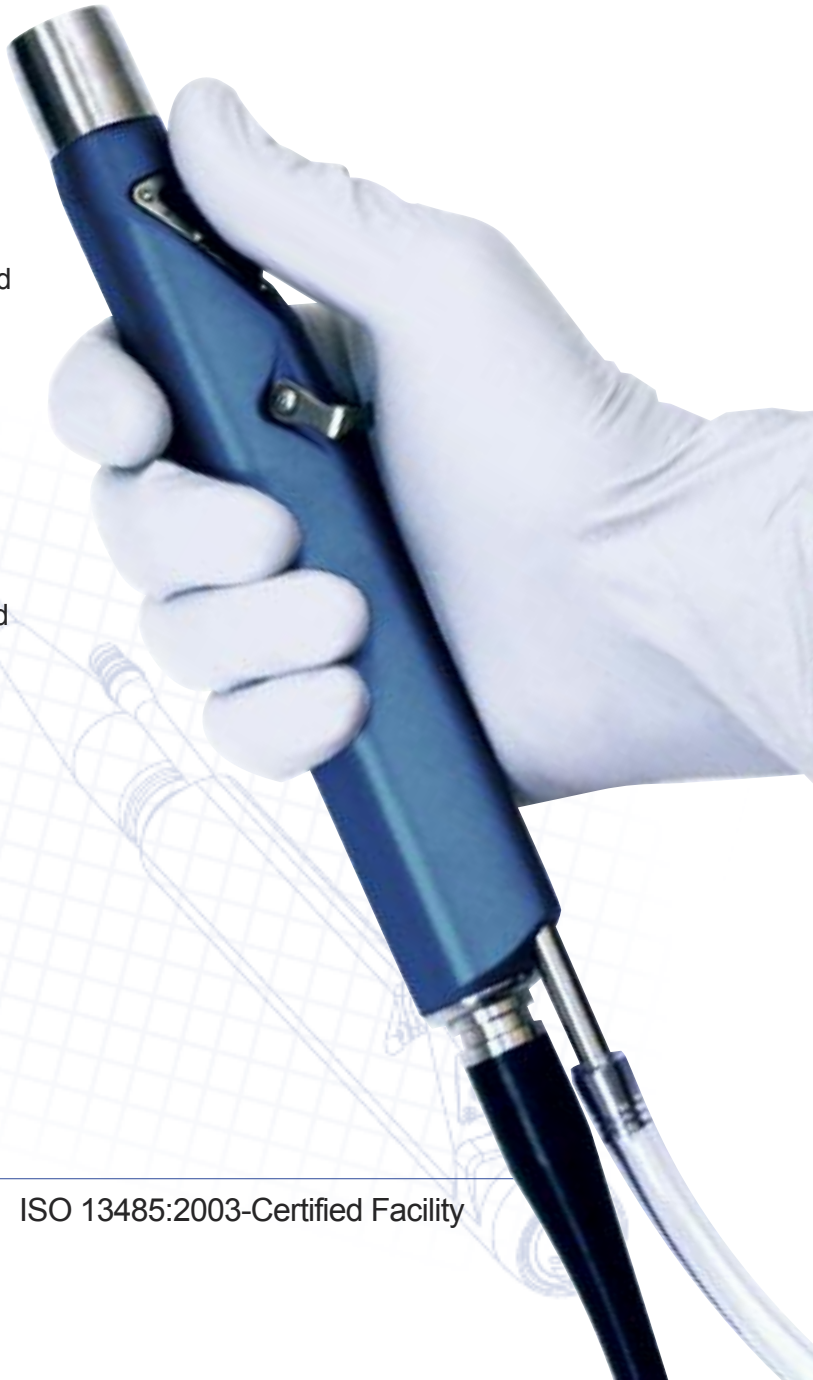

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and unarticulated needs," said Dubreuil. "These needs drive product strategies, product features, product innovations, and intellectual property."

Farm's process begins with user research: identifying what users really want, need, use and will buy. User preference testing and usability testing is incorporated throughout the development process to verify that user needs have been met. This is an effective way to identify new product ideas and features that have resulted in increased user adoption and marketplace success.

There are three steps in the process:

1. The user research is designed to target the most appropriate participants.

2. The research is conducted with the appropriate number and diversification of participants—including thought leaders, academia, and less-experienced users—to achieve the range and significance of results. The number of participants is proportional to the homogeneity/diversity of the users and environments, and the type of research. Generative research requires more data points, preference testing can rely on fewer data points, and usability validation may require 25 more or less to achieve the statistical validity.

"The research specialists determine the appropriate numbers against the deliverables," said Dubreuil. "The key is not so much the numbers as knowing how to design, conduct and analyze the data. So many times companies use a questionnaire being delivered by marketing or engineering types who don't have the training of conducting deep research to uncover unmet needs. The diversity of research recruits is usually more important than the number."

Research includes segmentation of participants by such factors as demographics, geography, specialization, training, experience, and skill levels. The process also uses proven techniques in ethnographic research to understand the environment and context of the device's use. "This means being in the operating room, the catheter labs, the intensive care unit, or even a patient's home in order to completely understand all of the elements that contribute to the device's usability and safety," said Dubreuil.

3. Lastly, the process involves careful and thorough analysis of video, photos, and interview data to uncover those elements that are not readily apparent nor articulated by users, but valuable for uncovering trends, understanding the relative importance of product features, and determining how best to implement those features. "It is extremely important that the analysis culminates in design inputs, recommended product strategies, product features, and overall product recommendations to drive innovation and new product growth," concluded Dubreuil. "The research must uncover actionable results for the development and marketing teams."

This approach can be expensive—surgeons and other healthcare practitioners must be scheduled, observed, and interviewed, which sometimes involves international travel. The data must be analyzed. Clients can help reduce these costs by providing more help in recruiting and scheduling, using known and friendly doctors and users. Because this user research is invaluable to identifying their true needs as opposed to relying solely on personal opinions of marketing and engineering individuals, the cost of the study is recovered through the design of better-selling and higher-value products.

Customized Instruments

Surgeon interaction also is critical in the rapidly developing field of custom instrumentation—building orthopedic instruments for a particular surgeon or group of surgeons who want special features on an instrument for a particular procedure or need. "Sometimes we are asked to accomplish this in as little as three to five days," said Schafer. "This is a fairly unique service because of the complexity of the instrument and the short lead time. As OEMs look to convert surgeons over to their platforms, often the ability of the OEM to provide a modification of their instrument set could be the deciding factor. We have been asked to lengthen, shorten, and bend at varying degrees everything from a single instrument to a family—just to satisfy the surgeon's desire and help the OEM complete the conversion to its platform."

Schafer also has observed an increase in demand for patient-specific instruments and implants over the last few years. "While standard implants and instruments will be used in the majority of surgeries and provide patients the intended results, there is a growing need for patient-specific products for trauma, cancer, etc., where the patient-specific products are clearly a better choice for the patient," said Schafer. "This is also a great opportunity for our engineers to work closely with the design engineers of our OEMs in understanding the design intent of the patient-specific item, as well as engaging our manufacturing managers in the design phase to ensure the patient-specific item can be made in the most economical manner from a manufacturing standpoint."

Paragon Medical's project engineers at the firm's design center are fully engaged upstream in the development cycle with its customers. Paragon interacts with their cross-discipline project teams, which allows information pertaining to the overall scope of the program, as well as the design inputs from their engineers and/or their designing surgeons, to be delivered first-hand.

"Full prosthesis system developments with our customers can span years and has taken our team throughout the U.S. and Europe to perform cadaveric studies with the designing surgeons," said Flamion. "New development programs have also afforded our team to participate in live surgery evaluations seeing first-hand the challenges the surgeon may be facing with a particular surgical technique, allowing us to offer up new instrument designs and techniques to overcome those challenges. Having the on-site Bioskills Lab is a convenient and cost-effective tool to enhance the speed at which ideas and innovations are tested."

OEMs are getting better at defining their patient-specific platforms and approach to servicing the market. The challenge, of course, is making the process cost-effective. Because these products are so unique, the traditional manufacturing methods that normally help minimize costs (such as the batching of parts, standardization of design,

Surgeon feedback, interviews and live surgical observations are among of the most important tools in new instrument development and design.

setup or fixturing) cannot be applied. "Thus the contract manufacturer is more reliant on sophisticated advancements in rapid prototyping capabilities (SLA/MIM), and what we call 'MRI to Solid Model to Machining Center' to keep costs down and speed up product delivery to the surgeon," Schafer indicated.

"As designers and manufacturers," added Rotino, "we constantly strive to simulate product use in the field during our design verification testing. The more information we receive from end users (surgeons), the better we can anticipate field-related concerns, design for those features, and develop internal testing protocols to conduct our simulation tests. This includes the cutting of simulated or animal bone, introducing saline irrigation solutions, cleaning with medical disinfectants, autoclave sterilization with industry parameters, and now disinfecting and cleaning with high-pH dishwashers. These tests are repeated hundreds of cycles to ultimately measure field reliability."

Another way to receive surgeon feedback is to reach out locally and talk with surgeons, even if they aren't end users of your products.

"We meet quarterly with local orthopedic and spine surgeons to discuss a variety of relevant market topics such as new legislation, patient volumes, reimbursement, and new technologies and procedures," said Schafer.

"Careful, insightful research is the key to designing instruments that surgeons really want," said Dubreuil. "Companies such as Apple and Ethicon have large budgets and teams to conduct user research to identify user needs and wants. They have demonstrated success in full and differentiated product lines. Other medical companies are just starting to understand the value of these processes. It's not easy to get healthcare workers to find the time and interest to participate in these activities, but the results can be startling to the users who have to depend on the safety and performance of medical devices."

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