Perspectives on Manufacturing Technologies, Part I

The capabilities of manufacturers are growing to enable the fabrication of components that are extremely tiny, very complex, and incredibly intricate. These advances are leading to medical devices that could not have been developed just a few years ago. With this in mind, this months Perspectives asked about how these capabilities would impact future devices. While only a few are shared here, view all of the responses recieved online.

How will new(er) manufacturing technologies impact the design and/or capabilities of upcoming medical devices?

Murtaza Fidaali
Director of Business Development, Medical and Industrial Markets, ITT Interconnect Solutions

Connector manufacturers are utilizing different manufacturing technologies in the development of connector contacts. While contacts are traditionally either stamped or machined, new manufacturing techniques are allowing contacts to be wirewound together, resulting in a high reliability contact system that exhibits very low insertion force even with a multiple (highs in 50s) pin and socket design. While typical connectors that employ pin and socket systems often result in extremely high insertion force and less mating cycles, such wirewound designs not only exhibit extremely low insertion force, but are capable of more than 10,000 lifecycles as well. They also don't need any cam action or other system to mate and de-mate.

Such compact plastic connectors with new contact designs are being employed in self-care equipment and hospital beds where sealing is not an issue, but robustness

and cost-effectiveness are primary concerns. Multiple points of contact, positive wiping action, and a superior latching system further ensure reliability and are ideal for point-to-point electrical connections. The use of various medical-grade plastic materials increases robustness as well as cost-effectiveness, making these connectors unique and a better fit than traditional interconnect solutions for medical applications.

Luke Tankersley
Medical Team Manager, Chiron America

As a machine tool builder, we continually see our capabilities pushed to the limits with new and innovative medical device designs and material selections. Cutting edge dynamics, and the expanding world of six-sided machining allows design and process engineers to think "outside-the-box" of typical manufacturing limitations. This all-in-one capability allows greater complexity in part geometries while improving part quality.

The current demand for minimally invasive implants and instruments continues to push the envelope of manufacturing competency. While continually improving and updating our abilities, those strides are soon filled with greater demands, thus continuing the cycle of better, faster, and stronger.

Our unique approach to work holding and data transfer allow production type manufacturing of custom components. The custom market surely holds the greatest promise in the medical device industry. Three dimensional scanning technologies and modeling advancements have facilitated an automated manufacturing approach for even the most difficult geometries.

Continual pursuit of the latest and greatest will hopefully progress our efforts for everyone to live healthier, happier, and longer lives.

David Coughlin
Director of Operations, Industramark

A medical device is only as good as its markings! Be it safety messaging, product instruction, or even decoration, the markings on medical devices ensure their proper and safe use by medical professionals. In-mold labeling is not a new technology, per se; however, it is relatively new to the durable goods market, which includes medical devices. By inserting an in-mold label during the molding process of a plastic-based medical device, the markings on the device become permanent and completely resistant to peeling and fading. They hold up against harsh chemicals and cleaners that are commonly used in the medical industry. Plus, they increase the area or space on the actual device for product marking, adapting to the most complex shapes and taking on textures of the molded device. This enables manufacturers to include markings and messaging in spaces previously unavailable to pressure-sensitive labels, and it ensures that safety and warning messages are permanently a part of the device. Permanently bonding and labeling a medical device limits the improper or accidental administration of drugs, liquids, or other medical agents. This technology establishes a permanent marking on products that eliminates the risk of labels falling off through the lifecycle of critical products, which is particularly important in today's litigious society.

Kevin Quinley
Vice President, Risk Services, Berkley Life Sciences LLC

Incorporation of micro-machining and nanotechnology in medical devices will hasten a trend toward miniaturization in medical technology. These do not, however, necessarily imply micro-risks or miniature concerns. Indeed, there will be an even stronger need for device manufacturers to ensure that precise tolerances are observed in the manufacturing process to eliminate defects that could culminate in adverse patient outcomes. Product safety programs and risk management processes must also be able to stand up to the same level of rigor. Failure to design medical devices with a mind toward durability, reliability, and intended use could create mega-headaches from a product liability standpoint. The greater complexity of manufacturing processes also heightens the need to have on hand corporate representatives who can explain–in plain English–to juries the exhaustive processes in place to screen out defects. Micro-manufacturing and nano-tech doesn't necessarily translate into micro-liabilities or nano-risks!

Nader Fathi
CEO, SigmaQuest

Adopting new manufacturing technologies has one clear disadvantage, and that is starting the learning curve all over again. This means that companies must accelerate their learning to drive up reliability and yield, and lower cost and throughput times. Product quality management software is already playing an increasingly greater role in helping companies accelerate a new product introduction time to high yield on existing manufacturing processes. These same software tools can be applied to new processes as well, to accelerate any organization's learning.

Product quality management software solutions provide 24/7 monitoring and feature capturing production process steps that work the best. In steady state, these tools have powerful root cause analysis to help users find, fix, and avoid issues. Information is presented via easy to interpret views such as dashboards with drill down analytics. Also, warnings and alerts provide users with "at their fingertips" information when problems in manufacturing occur (i.e., yields falling below target specifications). By leveraging top product quality management solutions, users are able to increase production yields, lower their cost of goods sold, minimize the potential for product returns, and improve customer satisfaction. Medical device manufacturers are using third-party, On-Demand, product quality management software to capture and aggregate comprehensive manufacturing data in real time from globally dispersed manufacturing sites, suppliers, and product repair centers to reduce costs and risk of field failures.

Michael Hansen, Ph.D.
Senior Technical Development Engineer, Mack Molding Co.

Gas-assist injection molding is a technology that introduces nitrogen gas to the traditional molding process. There are two forms: internal and external. With internal gas-assist, nitrogen gas is injected into a plastic-filled mold cavity to partially displace the molten plastic and produce a hollow, lightweight, relatively inexpensive part. The external process is designed to yield sink-free surfaces over ribs and bosses by forming a blanket of nitrogen between the underside of the part and the mold, gently pushing out any sink marks and producing a cosmetic surface.

While popular in other markets for several years, gas-assist technology is now channeling its way into medical device manufacturing because it replaces metal, consolidates parts, reduces weight and cost, encourages design freedom, minimizes secondary operations like painting, and generally decreases wall thickness while increasing part size. And that is always the ultimate goal–to make a bigger part with less plastic.

Mechanically, a hollow tube structure is almost as strong, yet lighter, than a solid part, resulting in an excellent stiffness-to-weight ratio. Additionally, gas-assist produces a finished part right out of the mold, and the molded-in channel is integrated right into the part.

Right now, the gas channel usually doesn't do more than act as a flow leader that ultimately hollows out the part. But could it do more? Could it serve as a reservoir for fluids? Or perhaps become functional space for managing cables, transporting fluids, or monitoring air pressure? Combining this technology with advanced materials will produce integrated gas channels that go far beyond reducing part weight and cost.

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