Indispensable Software Operations

Traceability in Medical Technology. Over the past years the technological hurdles and risks of liability have grown increasingly high with respect to medical technology. For medical molders who must quickly and consistently manufacture high quality parts using difficult-to-mold resins, as well as complex tooling that hold extreme tolerances, this leaves no room for error. Process control in real time and consistent documentation are fundamental issues.

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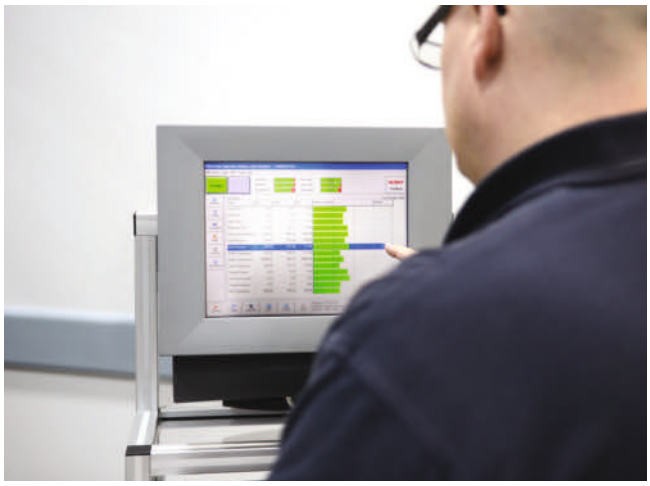
An aging population and increasing demand for disposable medical devices present significant short and long-term opportunities for medical manufacturers of plastics components. But while medical molding is a growing market, it is also a challenging industry characterized by lengthy product development processes, many clinical trails, demanding documentation practices and greater regulation within the industry. For this reason, part traceability has become a critical factor in producing medical parts and manufacturers are increasingly required to adhere to the highest levels of quality.

Pioneer in Processing

Polymer Conversions Inc. (PCI) located in Orchard Park, New York, is a specialist in the production of high quality thermoplastic molded products for medical applications. PCI has more than 20 injection molding systems in production, as well as portable cleanrooms according to the ISO 5 standard, where no more than 3,520 particles of 0.5 µm may exist in one cubic meter.

PCI offers a wide variety of products ranging from respiratory care equipment via oxygen concentrators and infusion pumps, to drug delivery systems. "PCI considers strong relationships with OEMs as a crucial issue. We virtually work with them throughout every stage of the process. This begins with upfront design, developing and testing the prototype, and ends with turnkey capability and sealed package," says Tom Rybicki, PCI's Director of Operations who has been with the company for 16 years.



The Shotscope NX software enables real-time monitoring of the production process and re-adjustment of the process parameters
(photos: Husky)

As an early adopter in the field of process monitoring, PCI has had a monitoring system in place for almost two decades. However, they recently decided to upgrade their process and production monitoring system throughout their injection molding facility when they found their existing software no longer met their needs. "We were looking for a system that focused more on the injection molding process rather than on simply counting parts. Our goal was to monitor our molding processes to improve quality, as well as meet the needs of the medical industry and its high demands on technical design and process documentation," explains Rybicki.

After researching different software suppliers, PCI moved ahead with the initial implementation of the Shotscope process and production monitoring system. Shotscope had previously been offered by Moldflow Corporation, the production branch of which was acquired by Husky Injection Molding Systems, producer of injection molding units and hot runners from Canada, in 2007.

Each Single Cycle is Recorded

Husky's Shotscope system helps manufacturers characterize and report on produc-

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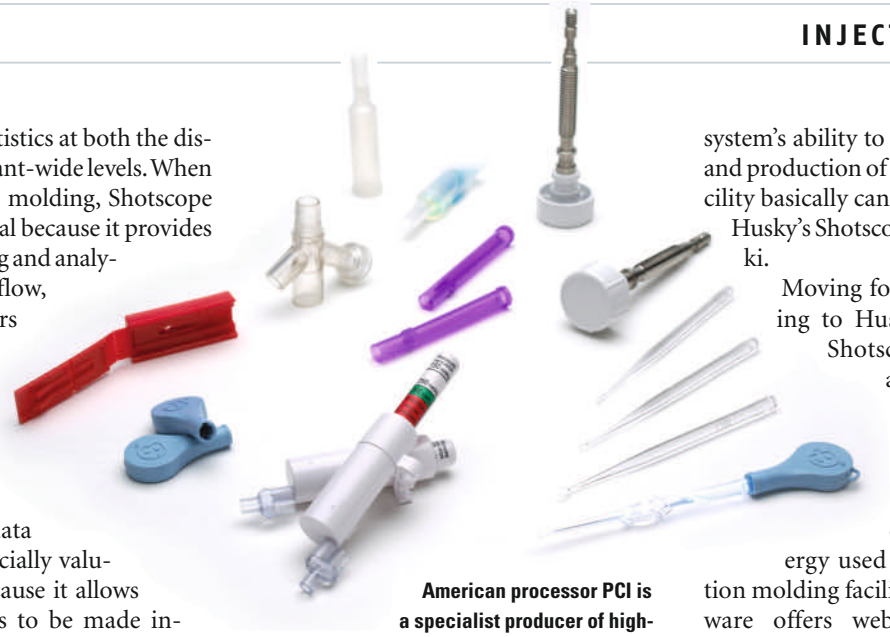
tion and process statistics at both the discrete systems and plant-wide levels. When it comes to medical molding, Shotscope is especially beneficial because it provides real-time monitoring and analysis, improves data flow, records all parameters relevant for process documentation, and facilitates more efficient plant scheduling. The ability to look at data immediately is especially valuable to molders because it allows production changes to be made instantly, which results in significantly less scrap and reduced part variability.

Rybicki states that, by using Shotscope, PCI has been able to facilitate qualification, documentation and traceability. These capabilities mean a great benefit for PCI in complying with Food and Drug Administration (FDA) regulations because they are able to confirm their system adheres to the required process parameters – after all, Shotscope monitors all process limits deduced from the machine settings.

Tom Rybicki, Director of Operations at Polymer Conversions Inc.: "Each cycle on every single part is recorded. This level of traceability is critical for suppliers of medical devices."



American processor PCI is a specialist producer of high-quality thermoplastic injection molded parts for medical applications

"In principle, the Shotscope software distinguishes between good parts and bad parts," Rybicki says. "It does this by aligning each step of the cycle with the set process data. Each cycle on every single part is recorded. This level of traceability is critical because healthcare companies need a supplier who can verify exactly under what conditions and environment a product was manufactured."

Connected to the In-House ERP System

Husky's Shotscope software is now a vital part of PCI's daily operation. It has been officially validated to meet guidelines for ISO 13485, an international standard that validates a quality management system's ability to provide for the design and production of medical parts. "Our facility basically cannot run today without Husky's Shotscope system," says Rybicki.

Moving forward, PCI is upgrading to Husky's next generation Shotscope NX software. In addition to process and production monitoring functions, this latest version enables enhanced monitoring capabilities of the energy used throughout an injection molding facility. Moreover, the software offers web-based functionality therefore reducing implementation and maintenance costs. In addition to an improved bar-coding capability to reduce paper pushing on the floor, PCI also plans to expand the system's use. It is due to interact with their ERP system to eliminate manual tracking.

As a side note to conclude this article: To help assess where it might be possible to increase efficiency in the production, PCI also commissioned Husky to perform an audit, which consists of Husky's team providing operational consulting, design and project management services. The calculations to show the merits of Shotscope NX were quickly done. After a day and a half audit, Husky experts also made the recommendation of replacing the lighting and air compressor in PCI's facility, which has since resulted in significant cost and energy savings. Obviously, it can be worthwhile to take a look also at the factory hardware equipment. ■

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