



FMI masters silicone molding of critical medical components using Nikon Metrology iNexiv

iNexiv adds speed and quality to ultra-clean molding of silicone components that go into lifesaving medical devices

FMI in the Chicago area produces molded silicone components for medical applications. Intricate features and key dimensions of tiny silicone prototype and (pre-)production parts are measured optically using a Nikon Metrology iNexiv system. FMI engineers say that investigating parts under Nikon optics and illuminations result in superior digital imaging that guarantees high accuracy and R&R numbers, despite the typical light glow covering the transparent silicone material. Automatic iNexiv inspection jobs triple measurement productivity, slash operator overhead and eliminate human error, resulting in a payback time of less than three months. According to FMI, Nexiv's solid reputation in the medical device industry increase the trustworthiness of the qualification/validation reports they generate for the FDA and OEMs.

A world-class medical silicone company

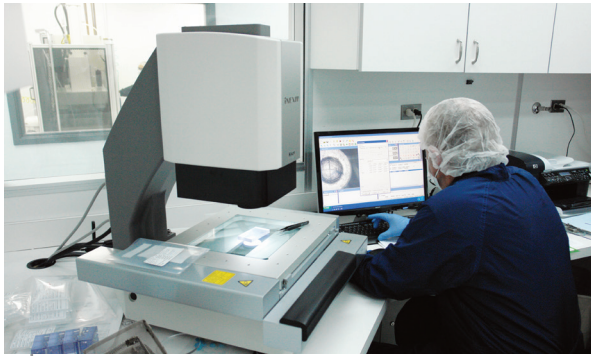
At its stand-alone manufacturing facility in Elk Grove Village, Illinois, FMI produces diverse implant grade and disposable molded silicone parts. Long-term implantable silicone parts are used in medical devices (pacemakers, defibrillators, heart

valves, etc.) designed for prolonged or extended service. Other silicone items are used in sealing systems, manifolds, connectors, stoppers and other devices. As 90% of FMI silicone products are implanted in the body, the FMI facility houses ISO 5, 6 and 7 clean rooms, fully equipped for silicone mixing, molding, inspection and packaging operations.

As a medical silicone company, FMI complies with qualification processes that ensure silicone material cleanliness, part shape integrity and the lowest failure rates. Important in this regard is FMI's choice for the table-top iNexiv system from Nikon Metrology, a high-performance CNC precision video measuring system. FMI demands an optical system because silicone parts are too soft to be measured using a touch



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probe. Fairly large specimens can be measured with the Nexiv system because it features a 250 x 200 millimeter stage and a 200 millimeter z stroke.

Clear and pinpoint sharp images

"It is night and day compared to our other vision system," said Harold Sant, Engineering Manager for FMI, Inc. in Elk Grove Village, IL, when looking at the first images taken by the iNexiv vision system. "The new Nikon inspection system generates overwhelmingly clear and pinpoint sharp images of difficult-to-measure silicon samples. Silica-based elastomeric rubber material attracts light and has a characteristic mystifying glow, but the iNexiv sees right through it. We have quickly come to trust the system, because it generates a superior digital image to measure from."

Inspection is key in FMI's Part Development & Prototyping (RPD) programs. Recently, FMI was contracted for a silicone header part of a pacemaker system to shorten the time between prototype and production. The header part goes on top of a pacemaker assembly and bundles all leads and connections. "Based on elaborate iNexiv measurements performed on different cuts, our engineers fine-tuned the header part concept to ensure optimum moldability. Low-distortion optics and high-intensity white LED illumination provide superb imaging that leaves no room for any operator misunderstandings. Even the header's intricate features could be investigated easily without requiring any re-checks. We used image magnification up to 20x, which is way below iNexiv's maximum magnification of 120x."

The economics of automatic inspection

Measurement throughput used to be the bottleneck when dealing with prototype qualification batches. Harold Sand says that instead of inspecting header parts manually, FMI

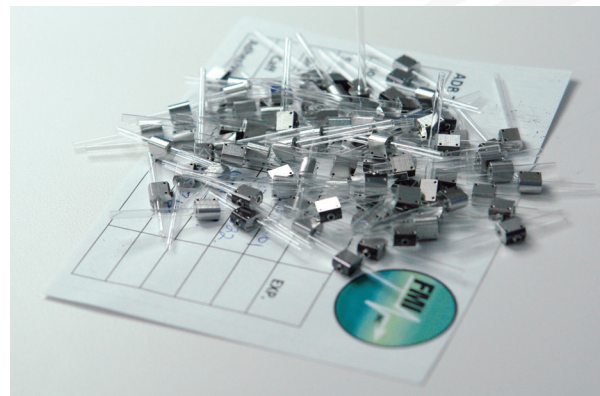


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Harold Sant, Engineering Manager for FMI, Inc

engineers teach the iNexiv system to perform a number of dimensional measurements fully automatically. "Defining an inspection job following our own measurement techniques is easy and very similar to setting up a macro. Automatic inspection takes a jump start with intelligent search capabilities and pattern recognition, which automatically spots the header part position and orientation. In the automatic inspection job we also included wall thickness measurements, a unique capability offered as part of the Nikon AutoMeasure software. Thanks to automatic iNexiv inspection using fast stage controls, we were able to reduce the start-to-shelf time for the pacemaker header part from 4 days to 1 day and a half!"

Sand says that pre-production and production operations at FMI probably benefit even more from automatic inspection. "iNexiv proves to be a major timesaver, considering the millions of silicone parts we produce every year. The shift from automatic to manual inspection led to a 3 month payback time for our system, just in labor alone."



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In addition to the iNexiv CNC video measuring system, FMI uses many stereomicroscopes from Nikon.

High-precision measurements you can trust

The complexity of the parts has increased tremendously. FMI invests in state-of-the-art processes and equipment to deliver the sophisticated ultra-clean silicone product required for surgical implantation. Based on expertise built up over the years, FMI is recognized as a leader in insert molding and bonding of silicone to various substrates.

“High precision is key in the medical device business, to make sure critical silicone parts can be confidently incorporated into lifesaving medical devices and state-of-the-art laboratory equipment,” remarks Sant. “The Nikon Metrology iNexiv system is ideal to measure any of our silicone molded parts, including micro-precision parts manufactured to the tightest tolerances. It outperforms our previous manual video measuring system in terms of measuring accuracy and speed as well as repeatability and reproducibility. We notice that leading medical device manufacturing firms trust our inspection qualification and validation reports better, because the majority of them are Nikon users themselves who know the system we are using.”

FMI is also a long time user of many stereomicroscopes from Nikon and NIS Elements software to characterize the detailed features of molding tools. The iNexiv CNC video measuring system was purchased after concluding a detailed comparison study including demos and benchmarks involving different brands. “All along, we felt that Nikon better understands our business, and that iNexiv hardware and software are better aligned for inspecting medical device components,” Sant clarified. “We would definitely recommend Nikon to any of our business partners, also because we are very satisfied with the provided training, support and advice.”

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