Dip Molded Products Play Critical Role in Medical Equipment Design

Ed Sullivan

Dip molding may not be a term that readily comes to mind when surgeons begin complicated procedures. Yet, without this sophisticated, highly controllable process, many medical devices used daily in hospitals could not meet stringent certification requirements.

Dip molding defines any process where a mold is dipped into a polymer for molding a part. The process begins with aluminum or steel mandrels, or molds, on a handling rack. The rack is preheated then dipped into a substance, such as Plastisol, latex, neoprene, urethane, or other material for a specified amount of time. The newly formed parts are then cured, dip-quenched, and stripped off the mandrels and delivered to medical equipment manufacturers in the quantity required.

The wide range of

medical products made available through the dip molding process is growing and includes nasal cannulas, Y-connectors, dental dams, and tissue collection sacks. Quality stent covers, probe covers, tubes, diaphragms, and catheter balloons also benefit from this technique.

Tim Truitt, co-founder of Truer Medical Inc. [1], appreciates the critical role dip molding plays in the medical arena. His company supplies a proprietary line of products for airway management and temperature sensing used by anesthesiologists. One of Truer Medical's products is the esophageal stethoscope, which is used to monitor heart rate, breathing, and core body temperature during surgery.

These esophageal stethoscopes contain a critical dip molded component that is used to house the sensitive internal components and electronics required to monitor temperature and sound. The cuff also assists in the installation of the device into the patient by covering the sharp end of the extruded tubing and can be lubricated.

"It's important that the wall of the molded part is consistent and thin so that the temperature, as well as heart and breath sounds, can easily be picked up by the sensors inside the cuff," says Truitt.

The part is so critical, in fact, that Truitt says it receives 100% testing to ensure there are no pinhole leaks and the solvent bonding is secure so that upon removal, the cuff does not remain in the patient.

To meet these requirements, the cuff is dip molded in Plastisol, a liquid at room temperature that, once exposed to a specific elevated temperature, gels and remains a solid. It can range in hardness from 33 (softest) to 96 (hardest) Shore A scale durometer, and offers temperature resistance from -20°F to 160°F. It is also ISO 1099 certified and approved by the FDA.

Plastisol heads the list of dip moldable materials because of its long history of success, ease of processing, affordability, and prevalence in the industry. But latex, neoprene, urethane, and other materials may also be used.

"It's a long, difficult process to qualify a material for the medical device industry. That's why many medical equipment designers and manufacturers use Plastisol. It has successfully endured the testing process," says Truitt.

For medical device applications, the Plastisol must meet Class VI testing by the United States Pharmacopeia, a private non-governmental organization that promotes the public health by establishing state-of-the-art standards to ensure the quality of medicines and other healthcare technologies. The standards include six classes, of which Class VI is the most stringent.

For Truer Medical, a dip molded cuff made from Plastisol had one potential negative drawback. In the hands of inexperienced dip molders used to less stringent tolerance requirements, dip molded parts could contain minute drip marks if not handled properly.

From a medical standpoint, this is problematic as drip marks could affect the thickness of the cuff's double-wall, which, to be most effective, is limited to eight to 14 thousandths of an inch per wall. Any blemishes potentially diminish sound transmission and, as a result, possibly impede the physician's ability to accurately assess a patient's condition during surgery.

These types of medical devices are subject to the Code of Federal Regulations, Title 21, Part 11. The code defines the criteria under which electronic records and electronic signatures are considered to be trustworthy, reliable, and equivalent to paper records and transmissions.

Fortunately, Truitt has never had any kind of Medical Device Report from a quality standpoint because he has maintained a long-term relationship with Molded Devices Inc. [2] Over the years, the full-service, California-based firm has refined its dip molding process to eliminate drip marks and other similar flaws.

According to Truitt, Molded Devices is one of only a few companies in the United States that can offer dip molding, dip coating (a similar process in which a metal part is dipped directly into Plastisol or other material), and injection molding capabilities.

Truer Medical receives four different sized cuffs, including 9Fr, 12Fr, 18Fr, and 24Fr, as well as an injection molded cap for the other end of its esophageal stethoscope.

Through a key acquisition in mid-2012, Molded Devices has added latex, neoprene, and Dermosol dip molding capabilities. Latex, in particular, is ideal for molded parts for the medical industry as it is more robust than Plastisol and can tolerate a wider high-to-low temperature range. It also allows for more elasticity and the ability to withstand more chemical abrasion.

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