

CASE STUDY

CLIENT

Cleveland, Ohio-based, privately held medical equipment company

CHALLENGE

On-shoring the contract manufacturing of a neoprene therapy device and improve quality control

SOLUTION

- ▶ Thorough testing of existing product to eliminate bladder leakage problems
- ▶ Stringent testing and sampling plan to ensure product integrity
- ▶ Superior communications and customer service
- ▶ Cost-effective domestic production and manufacturing

RESULTS

- ▶ Consistently reliable end product
- ▶ Satisfying collaboration and partnership
- ▶ Collaborative relationship resulting in ongoing product engineering and development



ThermaZone™ Neoprene Pain Relief Knee Pad Wrap

Innovative Medical Equipment (IME)

Medical device manufacturer on-shores production of RF-welded Neoprene pain relief pads

Innovative Medical Equipment, LLC (www.imeconcepts.com), a privately held manufacturing, licensing and distribution company located in Cleveland, Ohio, manufactures a portfolio of FDA approved medical devices.

ThermaZone™ (www.therma-zone.com) is an Innovative Medical Equipment (IME) product line that offers continuous and targeted heating and cooling therapy and drug-free pain relief. In response to ongoing design, quality control, supply chain and manufacturing issues with their overseas manufacturer, IME sought to on-shore the product line's production, and began the search for a domestic manufacturer.

Of utmost importance was to partner with a company who understood and could meet the specific engineering and plastics welding intricacies required as well as provide a cost-effective and consistently high quality end product.

Innovative Medical Equipment began conversations with several U.S. companies and it quickly became apparent that Genesis Plastics Welding had the considerable medical device knowledge and contract manufacturing experience for the type of production IME's product required.

Genesis developed a collaborative relationship with the IME design and engineering team and utilized strong project management and ISO 13485:2003 quality controls to troubleshoot historical quality issues and ultimately provide a product that met IME's expectations.

Adherence to ISO 13485:2003 quality controls were key to Genesis remedying prior quality issues with the ThermaZone™ product.

Through a detailed engineering study that included analysis of tensile testing, weld thickness and life cycle testing data, Genesis was able to identify and then engineer solutions to remedy prior quality issues. Genesis also worked with the IME team to establish a cost-effective testing and sampling plan for continuous monitoring of product integrity and conformance.



ThermaZone™ Neoprene Pain Relief Shoulder Pad Wrap



Genesis has become a true consultant for us — identifying new methods to make our products better, leveraging prior experience to ensure higher quality standards, finding new materials that we hadn't thought of, and developing innovative solutions to problems with our initial designs.



— Brad A. Pulver
President / COO

Innovative Medical Equipment, LLC

Genesis manufactures a product that stands up to repeated use by IME's end users at a total per unit cost that is comparable to overseas manufacturing. Since working with Genesis, IME reports they no longer are challenged by the same design, engineering, supply chain and manufacturing issues they were experiencing previously.

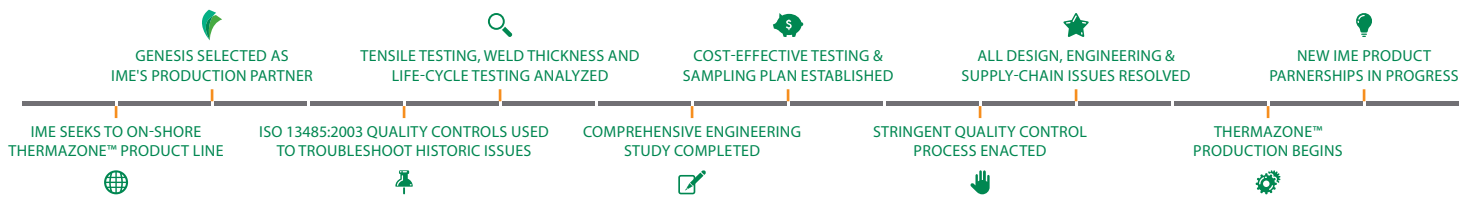
Additionally, IME has not received one report of their product leaking since their product has been outsourced to Genesis — testament to Genesis' stringent quality controls and systems utilized and the capability to produce a superior end product.

IME was inspired by the productive collaboration with Genesis and engaged the company in the research, development and manufacturing of a disposable version of the neoprene therapy wrap devices to support the healthcare industry's demand for single-use products in clinical settings.



A disposable, extremely lightweight therapeutic wrap, engineered through the IME and Genesis partnership, will offer a low-cost, single-use disposable alternative to surgery centers and hospitals.

By on-shoring production with Genesis, IME has realized greater product integrity at a total cost per unit comparable to overseas manufacturing.



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Genesis Plastics Welding is an ISO 13485:2003 certified contract manufacturer providing radio frequency (RF) welding and heat sealing applications of plastic products for military, medical and other industries. Products include military helmet pad systems, blood pressure cuffs, inflatable bladders, hot and cold therapy devices, compression therapy sleeves, disposable heating blankets and drainage bags. Genesis' proprietary heat sealing technology, ecoGenesis™, allows RF plastics welding of very thin gauge (down to 0.001 inch) polyethylene, polypropylene and low-loss polymers and

can facilitate polyvinylchloride (PVC) and polyurethane (PU) replacement with phthalate-free plastics. For more information visit www.genesisplasticswelding.com.

For more information on Innovative Medical Equipment products, visit www.imeconcepts.com

For more information on ThermaZone™, visit www.therma-zone.com

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