

## CASE STUDY

### CLIENT

Medical device manufacturer specializing in infection control and oncology solution products

### CHALLENGE

Client sought expert contract manufacturer to provide heat sealing for disposable surgical instrument covers

### SOLUTION

- ▶ Superior heat sealing expertise
- ▶ Adherence to regulatory compliance and quality control standards
- ▶ Flexibility and responsiveness to production changes
- ▶ Innovative cost-saving solutions

### RESULTS

- ▶ High Quality Product
- ▶ Increased Cost Efficiencies
- ▶ Just In Time (JIT) Delivery
- ▶ Solid Business Relationship with Partnership Approach



## Medical device company outsources heat sealing and contract manufacturing of disposable surgical instrument covers & oncology products.

### Collaborative partnership allows medical device company to maintain growth while reducing costs and risk to the supply chain.

A medical device manufacturer specializing in instrument covers and oncology solution products faced a unique challenge when they recognized the need for a second source for their oncology line of products to minimize risk to the supply chain.

The OEM's contract manufacturing source at that time held oncology product raw component information that they were not openly disclosing to the OEM, so the medical device company sought out an expert partner in reverse engineering and heat sealing.

An online search led the medical device company to Genesis. With 25 years of experience as a contract radio frequency welding manufacturer specializing in heat sealing thermoplastics of all types, Genesis quickly gained the company's confidence. Upon receiving a sample of the product to be produced, Genesis' skilled engineering team was able to successfully reverse engineer the product.

### THE CHALLENGE

Several years later, the OEM found itself once again needing a heat sealing expert with a strong focus on quality, this time for production of disposable surgical instrument covers.

Typically made from polyurethane or polyethylene, covers are a high performance, low maintenance product used in a variety of medical procedures, including surgeries.

Instrument covers require air tight and water tight seals with precise folds in order to ensure ease of use in the surgical setting. Since they provide hygiene and infection control and reduce cross contamination risks, strict attention to quality standards is a critical part of production.

After years of making the disposable surgical instrument covers in-house, the OEM began experiencing growth in demand and could no longer keep up with production. The company struggled to hire enough qualified staff to support production and faced high overhead costs. They needed a way to continue growing without raising costs in order to remain competitive.

### THE SOLUTION

The medical device company was looking for an outsourced manufacturing company that could go beyond just building parts. They needed a complete partner. Genesis had already proven once to be a competent partner.



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**Genesis' technical expertise, strict adherence to quality and industry knowledge has enabled us to maintain growth and keep up with market demand. More than that, they've become a complete and collaborative partner for us, leveraging their experience to provide us with innovative solutions that allow us to continuously improve our processes and products.** ”

— Medical Device Company,  
VP of Strategic Communications

Additionally, Genesis' quality systems were designed to be compliant with ISO 13485 and Medical Device Quality System Regulation 21 CFR 820.

True to the collaborative nature of the relationship, Genesis and the OEM even worked together to plan and qualify Genesis' Class 7 Medical Clean Room.

Genesis also provided weekly shipments and just in time delivery which enabled the company to maintain inventory levels, as well as have a constant production flow in and out.

### THE RESULTS

By outsourcing a portion of production to Genesis, the company maintained costs while increasing production and reducing risk to the supply chain. Genesis' responsiveness to scheduling and order changes has helped the company quickly respond to customer feedback.

Over the years, the innovative partnership has continued. Genesis has acted as a consultant during each phase of production, offering ways to improve cost-effectiveness and efficiency on everything from material choices to logistics. Genesis also connected the company with multiple new film suppliers and resin experts that helped substantially save on costs.

“Genesis' technical expertise, strict adherence to quality and industry knowledge has enabled us to maintain growth and keep up with market demand, without increasing costs or sacrificing the integrity of our products,” said the medical device company's president and CEO. “More than that, they've become a complete and collaborative partner for us, leveraging their experience to provide us with innovative solutions that allow us to continuously improve our processes and products.”

