

CASE STUDY

CLIENT

Vancouver, Washington-based, privately held medical equipment company seeking to manufacture first medical device product of its type

CHALLENGE

Client sought an expert contract manufacturer skilled in eliminating PVC yet keeping costs low

SOLUTION

- ▶ Radiofrequency welding of non-PVC materials
- ▶ Medical device materials selection
- ▶ Durable yet attractive welds
- ▶ Superior technical expertise
- ▶ Expert customer service

RESULTS

- ▶ Superior, long-lasting product
- ▶ Increased cost efficiencies
- ▶ Environmentally friendly partner



REDpoint StedLine IV Sleeve

REDpoint International

Medical device company outsources material research/development and manufacturing for infusion therapy product line

REDpoint International (www.redpointcorp.com), a privately held medical device company, is the producer of StedLine™ innovative infusion therapy products and Versatilt, a safe patient handling device for wheelchairs.

One of REDpoint's primary products is the **StedLine IV Sleeve**. It acts as a stabilizing device for an IV primary line set, providing greater patient comfort and reducing risk of IV failure. The StedLine IV Sleeve has proven especially beneficial for elderly and pediatric patients, as it absorbs yanks and tugs that commonly cause IV catheters to fail, and it does not involve any gluing or taping to secure the IV to the skin. When seeking FDA Class I, 510k status and bringing this device to market, one of REDpoint's primary production goals was to make manufacturing as cost-efficient as possible, while keeping production within the United States, both for quality standards and to retain jobs stateside. In addition, they wanted a high-quality finished product that was patient-friendly, safe, comfortable and PVC free. According to the American Medical Association, medical devices made of certain PVCs can leach DEHP, which has been found to cause organ damage in animals. In 2002, the U.S. FDA issued a Public Health Notification on DEHP warning health care providers to reduce DEHP exposure for certain vulnerable populations, including infants and other patients receiving multiple medical treatments.

With these facts in mind, REDpoint set out in search of an expert within the medical device manufacturing industry to provide product development and material selection guidance, along with quality manufacturing and innovative non-PVC RF heat sealing solutions.

REDpoint realized that Genesis had many phthalate-free and non-PVC material solutions, a team of knowledgeable and experienced engineers and the ability to manufacture high quality RF welded products at a lower cost.

REDpoint executives first met Genesis Plastics Welding experts at an industry tradeshow and followed up with additional information-gathering from the Genesis website, to further evaluate the company's RF welding expertise within the medical device contract manufacturing industry.

Genesis led REDpoint to lower-cost PE and PET materials that were well suited for single-use medical products such as their IV sleeve, but yet robust enough to provide the



REDpoint StedLine IV Sleeve



With our latest product — the StedLine IV Sleeve — it was important that we find an RF plastics welding manufacturing partner who understood the importance and potential of our product within the medical device industry. We found these qualities with Genesis, and we are thankful for their ability to help us find a non-PVC material that not only keeps patients safe but provides them a durable, comfortable and long-lasting product.



— Chuck Nokes
 Founder & President
 REDpoint International

desired product strength. In addition, with the help of Genesis' proprietary RF welding technology, ecoGenesis, the finished product features durable and attractive welds. In addition to providing phthalate-free material solutions for REDpoint, Genesis also assisted in finding aesthetically pleasing material color combinations and developing a low-cost printing option for the application of REDpoint's logo to the product.

REDpoint and Genesis worked closely through the entire development process, not only to improve the manufacturability of the product and to lower costs, but also to improve patient comfort and safety through material selection. In an effort to create a device that is exceptionally patient-friendly, REDpoint went through many focus groups to fine-tune their innovative IV sleeve and provide the highest quality finished device possible to their customers. After each of the customer's research rounds, Genesis' engineering team worked diligently with REDpoint executives to make needed changes to tooling and processes, while keeping manufacturing as efficient and low-cost as possible.



Thanks in part to Genesis' dedicated team of engineers, vast phthalate-free and non-PVC material solutions experience and lower-cost manufacturing options, REDpoint's Stedline IV Sleeve has been introduced to the market and is rapidly acquiring distribution within the disposable medical device arena. REDpoint also has already received several awards within the medical device industry in recognition of their innovative risk-reducing IV sleeve.

