Nelipak®
healthcare packaging

White Paper

The Evolving Role of Thermoforming Suppliers in Medical Packaging Design

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Abstract

Today's medical device OEMs need a thermoforming supplier to take on expanded roles in packaging design, development and testing. The full-service capabilities provided by Nelipak Healthcare Packaging enable optimized sterile medical packaging fit for purpose, which may be more sustainable, and can even play a big part in the functionality of the device.

The Evolving Role of Thermoforming Suppliers in Medical Packaging Design

Thermoforming represents one of the main manufacturing processes used in the growing sterile medical packaging market. But today's thermoforming suppliers need to be more than simply manufacturers. Medical device OEMs are looking for strategic thermoforming partners that can become an extension of the customers' packaging development team, taking on expanded roles in design, development and testing. Furthermore, OEMs expect thermoformers to not only design around the product, but to fully understand how both the product and package are to be used within the clinical environment.

This increasingly results in device packaging not simply being used to get the device to the OR - in many cases the pouch or tray may be used as part of the actual surgical procedure.

Considerations for Choosing a Thermoforming Supplier

A smartly-designed product is no use to the customer if the product is difficult to manufacture, therefore design for manufacturability is an important consideration for the thermoformer. Prediction tools allow designers and tool makers to understand how a part will behave during manufacturing and to amend accordingly to maximize production runs. On the OEM side, automation is increasingly being introduced into the manufacturing setting so the design team needs to take account of the requirements of the process balanced with the needs of the end-user.

Thermoformers need to understand how packaging influences the customers' packing operations and supply chain. In addition to reducing the overall amount of plastic used, well-designed products have the ability to reduce labor and handling costs such as transportation, sterilization and storage through the supply chain.

Reduction in overall footprint of the end package should lead to less plastic finding its way into the waste stream in situations where recycling is not practical, such as hospital waste with risk of contamination.

Thermoformers and OEMs also need to collaborate to determine which materials should be used for packaging. The decision behind material selection is based on the product which is being packed, the sterilization method and material costs. Pricing can affect material choice if multiple materials can meet the same need for the package, but when there are no alternatives customers expect that package design will minimize the amount of material required to lower unit cost.

Additionally, thermoformers must have an intricate understanding of the factors which impact seal integrity, which is critical to the product efficacy of healthcare packaging, as the seal maintains necessary sterile barriers. Seals must always remain intact under the strains of shipping and handling, yet peel open quickly and easily for the end-user in a surgical environment.

Nelipak's Capabilities for Custom Thermoformed Healthcare Packaging

Nelipak Healthcare Packaging brings a thorough understanding of industry trends and end-user needs and challenges to every project, in order to create a product that can better serve its purpose and even minimize risk factors when used in critical healthcare environments. The company is 100% focused on products for the healthcare market, and produces sterile barrier packaging manufactured in ISO class 7 and class 8-certified cleanroom conditions across its operations.

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Neliapak's design teams, with access to model-making and tool-making shops across its global manufacturing locations, apply their skills in conjunction with unique freehand drawing capabilities and technology including CAD/CAM systems to custom engineer next-generation packaging optimized to ideally meet customers' specific product and packaging needs.

After designs and prototypes are approved, Nelipak's experienced CNC programmers, tool and die makers develop and produce production tooling in-house. All production tooling is produced of high quality material and precision machined to the highest tolerances. It is custom-made and consists of many parts such as the production mould, plug-assist, cutting knives, cutting plate, clamping frame and a robot handling plate.

Upon completion, tooling goes through a qualification process to ensure the tool is capable of producing the product for which it is designed. This, coupled with the team's expertise, supports constant innovation as Nelipak works with its customers to expand the boundaries of technology.

Double-wrapped raw material ships to production suites where in-line cleaning systems remove residual particulate prior to forming. Precision cutting tools eliminate angel hair presenting trays and blisters which are glove and pouch friendly. Practically all the production operations in the cleanrooms are carried out by robots to minimize manual intervention.

In line inspection and data recording provides documented evidence that the product conforms to agreed upon tolerances and checks. Machines and ISO class

7 and class 8 cleanrooms are duplicated across regions to ensure Nelipak can always meet supply needs and that tool transfers and revalidations are as quick and easy as possible.

Additionally, Nelipak offers a comprehensive range of services to specifically support package testing and validation analysis. Its team of experts has experience in problem solving and can offer counsel on all aspects of packaging design and regulation.

The dedicated validation team advises customers on applicable standards and test methods and tailors a test protocol appropriate for the specific situation. Work is carried out at an in-house validation center and Nelipak provides the raw test data, as well as interpretations and conclusions about the data which can be used as part of a submission to the OEM's notifying body.

Custom-built Cleanroom Sealing Machines

In addition to adding value during product design and manufacturing, Nelipak applies best practices during the heat sealing process. It uses custom-built cleanroom sealing machines designed to the specifications of a medical device, pharmaceutical thermoformed blisters, or trays which can result in better quality products that consistently have the necessary seal strengths and properties.

Sustainability for Healthcare and Pharmaceutical Packaging

By considering sustainability early on in the design phase Nelipak - a member of the Healthcare Plastics Recycling Council (HPRC) - can help OEMs create more efficient and environmentally responsible device packaging that reduces material waste during development and production and allows for products that can be used and recycled more effectively in hospital environments.

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Sustainability not only benefits the environment, but can also result in cost-savings and efficiency gains for the OEM, including:

- More efficient use of energy and material during manufacturing;
- Lowering packaging ownership costs to the MDM;
- Elimination of waste during production and optimal waste recycling for hospitals;
- Optimum functionality for all users;
- Optimum volume and efficient logistics in the supply chain.

What's Next for Medical Packaging?

Healthcare device and pharma companies are often conservative about changing their packaging materials, largely due to the regulatory scrutiny they face. Healthcare rigid packaging predominately uses PETG, APET, HIPs and Barex materials. OEMs will generally favor these packaging formats and materials already proven in the market, which can limit their ability to innovate for evolving market needs. But new packaging formats or material combinations require validation and preparation of documentation for submission, which is both time consuming and costly to carry out. New materials must address a critical market needs in order to get quick acceptance, otherwise penetration of the market can be slow. Choosing a thermoformer like Nelipak who is experienced in navigating these challenges can open the door to expanded possibilities for next generation packaging.

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Packaging also has the potential to play a bigger part in the functionality and use of medical device and have a larger role in educating home users in the device's proper use. Nelipak's expertise, technical capabilities and industry knowledge add value at the design and development stages which will be critical for OEMs looking to keep up with the needs of their end-users and capitalize on the opportunities of the growing healthcare packaging market.

About Nelipak® Healthcare Packaging

With facilities in Cranston, RI; Phoenix, AZ: Whitehall, PA; Liberty, NC; Venray, the Netherlands; Galway, Ireland; Juncos and Humacao, Puerto Rico; and San Jose, Costa Rica, Nelipak® Healthcare Packaging designs, develops and manufactures custom thermoformed packaging products that provide superior protection for medical devices and pharmaceuticals. The company offers medical trays and blisters, surgical procedure trays, pharmaceutical handling trays, custom built sealing machines and other value added services. Nelipak's customers consist of some of the largest and most reputable medical device and pharmaceutical companies in the world. Nelipak is focused on delivering superior quality and customer experience through world class manufacturing at each of its locations. More information about Nelipak can be found at **www.nelipak.com**.

Nelipak® Healthcare Packaging is a trade name of Nelipak® Corporation