

Overcoming Challenges in Medical Device Manufacturing

How Precision Converting is solving problems and empowering new products





The medical device manufacturing market in the U.S. was estimated at around \$186 billion in 2021, and is expected to reach nearly <u>\$262 billion by 2028</u>.

Much of that growth is being driven by demand for consumable medical devices, consumer-ready test kits as well as OTC diagnostics. Healthcare leaders are looking to improve care both inside and outside of traditional clinical settings in the wake of the COVID-19 pandemic. At the same time, enterprising companies are making advancements in Al technology, 5G capabilities and other innovations that will shape the future of healthcare.

To address market trends and provide innovative designs, medical device manufacturers require reliable partners that can help them solve complex manufacturing challenges. At Precision Converting, we have extensive experience in developing solutions for highly technical medical products. We use our converting services and capabilities coupled with highly trained technical teams to enhance the production process and streamline manufacturing. We help engineers and designers overcome some of their biggest challenges and deliver exceptional outcomes.

Challenge #1 Stick-to-Skin Performance

Adhesive medical products have been around for more than 100 years and as technology continues to evolve, so must medical adhesives. Today, products like glucose monitors, transdermal patches, wound care products, ECG wearable devices, negative pressure wound therapies, and insulin delivery devices are driving innovation in this product category. There are a number of inherent challenges when trying to define effective stick-to-skin products. This is where our 50+ years of experience will help you find the right materials for your product.

One challenge is adhesion to skin wherein patients present with a variety of skin types and skin conditions oily, hairy, rough, damaged, broken, sensitive or fragile, etc. Devices must adhere to a majority of skin types and stay adhered under a variety of environmental conditions.

Product developers must also consider moisture management needs. The device adhesion may become compromised when the adherent surface of the device comes in contact with external moisture sources such as soap and water, lotions, medical ointments, and natural oils secreted by the skin or in contact with internal moisture sources such as wound exudate. The device adhesion to the skin may lessen and overall product performance may be greatly reduced or the device could fail.

Different types of devices also have different intended wear times, making adhesive selection critically important. Medical manufacturers work to assure devices will stay on for the specified period but can also be removed without damaging or significantly irritating the skin or surrounding tissues.

Precision Converting can address challenges with our materials science expertise and expansive network of material solutions. At any point of the product development process, we can guide material selection to help identify the adhesive best suited for the intended patient population, skin or wound conditions as well as the product's intended use. For example, as a 3M Preferred Converter, we have access to 3M's design and technical expertise to assure you're using the most optimal components for the application—no matter how complex or specialized. As healthcare companies continue to innovate and create new medical devices, Precision Converting is uniquely positioned to help with solutions that can improve device reliability and enhance performance.

Challenge #2 Bonding and Sealing

Bonding of a medical device—whether the external housing, internal components, or actual device has become more complex in recent years. As devices have gotten more ergonomic—smaller and lighter product engineers have had to find new ways to achieve strong bonds without adding significant weight or expanding device footprint. That has led more manufacturers to explore a variety of material options, including VHB tape, liquid adhesives, silicone-acrylic tri-laminates and pattern or zone coated adhesive solutions.

At Precision Converting, we have a long history of determining custom bonding solutions that provide both optimal bond strength and lasting durability under a range of conditions. Our experience with bonding applications allows us to help guide materials selection using a variety of different elastomers and custom formulations. Our inventory management programs allow us to provide JIT inventory, decrease inventory turnaround and accelerate delivery of your product to the market.

Challenge #3 Material Selection and Process Efficiencies

How an adhesive performs in different situations and how it interacts with other device materials influences the device's overall functionality and accuracy. Adhesion is part of a system, so it's important to understand how each layer of the system contributes to the overall adhesion performance. An incompatible stack-up of materials or adhesives can result in materials shifting or the device falling apart.

In material selection, if a selected adhesive is very soft, it can gum up equipment during converting and down-line production processes. This may lead to unforeseen costs and delays due to unscheduled stops and clean-down of equipment. Additionally, softer adhesives may require manufacturing equipment to run at slower speeds, which adds to the run times and the overall cost of goods.



Typical solutions are precoating/pretreating the converting dies with durable release surfaces, protecting contact rollers with low adhesion wraps, chilled rollers/air blowers and using thread-up designs that avoid contact with the adhesive surface.

Partnering with Precision Converting, a manufacturer that has expertise and is knowledgeable in working with a wide variety of materials, can help ensure the right materials and adhesives for your design, as well as optimized manufacturability with maximized yield.

Precision Converting – better partnerships lead to better business results

By partnering with Precision Converting, your company extends its resources with a partner who understands the particular needs of the healthcare industry and has the capabilities to execute projects at the highest performance level. We have a proven record of success helping medical device makers enhance products and find ways to increase manufacturing efficiency. We take a consultative approach to understand your projects' requirements in detail and how we can best add value to your operation.

As a division of Hisco, we are a part of a vast distribution network with 23 ISO 9001:2015 stocking locations. This helps our customers not only source difficult-to-find materials, but also maintain minimum stocking levels as well as just-in-time stock to keep projects on schedule. The Hisco business solutions offering culminates with the five Precision Converting sites to deliver exceptional value to our customers. Our teams of problem solvers are dedicated to creating custom solutions that advance the strategic aims of our partners.

Our healthcare converting is equipped with ISO certification and FDA registration, Class 7 (Class 10,000) cleanroom, controlled environment manufacturing and storage, along with additional cleanroom capabilities. Site-to-site redundancies in equipment and process prevail at all our ISO-certified locations. This allows redundancy in process and a second source for products with a unified quality system.

At every stage of product life cycle, we will help you determine the right materials and processes for your product to get your design to market faster. As the healthcare industry expands and new innovations lead to new possibilities for patient care, we are ready to help manufacturers develop the next generation of life-changing medical devices. Ready to start your next medical device project? Connect with us today to see how we can solve your biggest manufacturing challenges.



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