Protecting Devices, Protecting Patients:

How Packaging Makes the Difference in Medical Device Safety

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In the medical device industry, manufacturers must balance numerous goals in product development and supply, but no objective is greater than patient safety. Medical devices of all kinds must be sterile, defect free, contaminant free, and delivered and ready when practitioners need them. Whether a device is new or established in the market, validation of safety is key to its usage. This imperative is the reason for strict regulations and safety standards in manufacturing the devices themselves, but what about when they leave the production line?

This is where packaging and safety coincide: packaging plays a key role in ensuring product safety from the factory to the patient, who is the ultimate end user. Packaging protects the product device in transportation, but also, it plays a role in maintaining a sterile and contaminant-free microenvironment for that device. For these reasons, it's vital that device manufacturers choose reliable, high-quality packaging materials that demonstrate proven and consistent performance.

Availability of supply is also a factor. If the approved and validated raw materials aren't available to device manufacturers, that can interfere with production or business continuity. Recent supply chain issues stemming from the COVID-19 pandemic, severe weather events, and economy-wide labor shortages have made this issue all too clear across the healthcare industry, from a lack of sufficient PPE to specimen collecting supplies and more.[1]

Lastly, medical device packaging must be easy for practitioners to use. There is no time for complexity when accessing a medical device while caring for a patient, and the packaging that protects a device must offer easy access to the device inside with quick confirmation for the medical professional that the package isn't compromised.

How can medical device manufacturers achieve these goals? By sourcing and utilizing packaging that meets the following needs:

- **Device protection**
- **Sterility**
- **Supply reliability**
- **Ease of use**

Ensuring that packaging has these attributes will provide manufacturers with the quality and safety their patients expect and require. Let's explore how each of these attributes come to life in today's packaging innovations.

Strong packaging for device protection

Medical device packaging must be strong enough to resist punctures, tearing and abrasion, as well as other stresses from extended shipping and handling. Simply put, the stronger a package is, the greater its ability to protect the device inside.

A package is only as robust as its weakest component. That is why both the forming film and lidding film of a form-fill and seal package must have excellent puncture resistance and tensile strength. The sealing strength of heat seal coatings on lidding materials such as DuPont™ Tyvek® and reinforced paper also plays a role.

[1] U.S. Food & Drug Administration, "Medical Device Shortages During the COVID-19 Public Health Emergency." https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/medical-device-shortages-during-covid-19-public-health-emergency

For example, CR27® heat seal coating has been a reliable standard for over 30 years, and with good reason. This sealant is used by over 25 of the top 30 medical device companies because of its consistent seal strength and the balance it maintains between ease of opening for the practitioner and a strong hermetic seal.[2]

New seal innovations have come to the market as well, such as **Amcor HealthCare™ AirPeel Technology ACT2100™, which has a seal strength that is 25% stronger than CR27®**. ACT2100's higher seal strength can prevent seal failures even for bulky, large, and heavy devices while still providing ease of opening the package in fast-paced surgical environments.

The heat seal coating application process matters for device protection as well. If the heat seal coating is inconsistently applied, then the seal strength and integrity can be impacted. Excellent control of application weight via state-of-the-art applicators, integrated with closed-loop coating weight control systems, deliver consistent coating thickness across the entire package seal area. Air-knife coating applicators smoothly and uniformly apply the coating. Also, high-resolution camera systems can identify potential defects in the base Tyvek® or paper while confirming a defect-free coating application.

In short, greater seal strength and consistency decrease the risk of a seal breach during distribution, particularly for large-pack items and heavier packages. Maintaining package integrity is vital for keeping devices sterile, yet as we'll see, strength is not the only way that packaging can assure a sterile environment.

Facilitating sterile microenvironments

The world has rightly been focused on COVID-19 over the past two years, but SARS-CoV-2 is just one of many pathogens that put humans at risk. Multidrug-resistant (MDR) bacteria have become increasingly problematic in healthcare settings and for medical devices in those settings.[3]

The FDA has also sounded the alarm about supply chain effects of sterilization facility closures, and how a shortage of sterilized medical devices is a detriment to public health.[4]

Thus, medical device manufacturers are acutely aware that medical device sterility is an ongoing and critical requirement for their patient customers.

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[2] Medical Product Outsourcing, "The 2021 MPO Top 30 Medical Device Companies Report." July 7, 2021. https://www.mpo-mag.com/top-30
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[3] Jonathan Josephs-Spaulding and Om V. Singh, "Medical Device Sterilization and Reprocessing in the Era of Multidrug-Resistant (MDR) Bacteria: Issues and Regulatory Concepts." Frontiers in Medical Technology, February 10, 2021. https://www.frontiersin.org/articles/10.3389/fmedt.2020.587352/full

[4] Norman E. "Ned" Sharpless, MD, "Statement on concerns with medical device availability due to certain sterilization facility closures," October 25, 2019. https://www.fda.gov/news-events/press-announcements/statement-concerns-medical-device-availability-due-certain-sterilization-facility-closures

How does packaging play a role? If unfiltered air enters medical device packaging headspace, it can lead to contamination by introducing microbes that compromise the device's sterility. Stronger seals therefore reduce the risk for an opened seal.

While seal strength is critical to quality, porosity, or breathability, of the material is also required for ethylene oxide (EtO) gas to enter the package headspace, sterilize the device, and allow for the EtO to be completely drawn back out of the package.

As the FDA notes, approximately 50 percent of medical devices requiring sterilization are sterilized with EtO[5]. Manufacturers must ensure their packaging provides sufficient porosity so that their products complete this process reliably and thoroughly.

Combining sealants that offer porosity and strength with breathable materials that are also suitable for fast and aggressive EtO cycles allows medical device manufacturers to supply safer products to their customers

Facilitating sterilization during production and maintaining a sterile environment are vital, but they also underscore the importance of sourcing validated materials reliably.

The need for stable supply chains

We've seen supply chain issues become the norm across industries as the COVID-19 pandemic upended global commerce. The medical device industry is in the throes of these challenges—whether grappling with PPE shortages, a lack of raw materials, or shipping and logistics problems. Addressing and overcoming these difficulties is important for healthcare practitioners who need critical medical supplies. A recent McKinsey study found that over a 10-year period, supply chain shocks could cost the average medtech company 38% of annual earnings[6], and overall in our healthcare system, a lack of medical device supplies can impact the ability to adequately treat patients.

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To ensure safe and consistent supplies, manufacturers will have to evolve their processes to diversify sourcing and choose suppliers that have redundant production capabilities. This can be challenging because only certain materials and sources are validated and, as the McKinsey report notes, supply chains are optimized to assure regulatory compliance.[7]

[5] Ibid.

[6] Mohammad Behnam, Tacy Foster and Tony Gambell, "The resilience imperative for medtech supply chains." December 18, 2020 https://www.mckinsey.com/business-functions/operations/our-insights/the-resilience-imperative-for-medtech-supply-chains

[7] Ibid.

It's therefore imperative that medical device manufacturers partner with suppliers who can meet strict local regulatory requirements while also providing manufacturing redundancy that can overcome supply shortages.

Redundancy with validated packaging suppliers is preferable for manufacturers because they can be assured of receiving the same fully validated packaging their products require, while also overcoming supply bottlenecks in the case of weather issues, labor shortages, or shipping delays. Amcor, for example, has multiple manufacturing sites for their ACT2100 heat seal coating, with factories in both North America and Europe. This allows Amcor's customers to receive critical packaging materials more quickly from the plant based closest to their location or have the backup facility address any supply issues that may be happening in the customer's primary location.

Evaluating suppliers based on their geographies, number of locations, and even their list of tier-2 or tier-3 suppliers can help medical device manufacturers ensure that if factory shutdowns or transport back-ups happen in one region, they can still source necessary materials. This is fast becoming the gold standard for supply chains and allowing them to become more resilient.

Practitioners need easy-to-use packaging

The final component of safe packaging is making it easy for practitioners to access the device inside. **In a medical setting, there is no room for error and no time for doctors, nurses and other healthcare professionals to wonder if a package has been compromised.** Ease of use involves quick opening of packages, meaning seals must have a clean, easy peel and cannot tear when opening. It also means that practitioners can be confident in the package's integrity with just a quick look.

For example, some heat seal coatings can turn yellow with age, leading practitioners to wonder if the seal is failing and the device inside has been compromised. Relatedly, if those seals stick and tear when a package is being opened, the end user may be unsure if fibers or particles are being generated that can contaminate the device. Medtech companies should source heat sealable materials that maintain an easy-to-see, bright white or medical blue color. These characteristics aren't just aesthetic—they convey vital information to practitioners, providing confidence that medical devices packaged this way are safe to use.

Delivering the best quality for patients

Throughout the entire life cycle of developing, manufacturing and delivering a medical device, the top priority will always be patient safety. It's the driving force behind the regulations and precautions built into every step of the production process. But the keys to maintaining patient safety don't end with the device production line—the packaging process must stay focused on this goal as well.

First, device protection is vital for packaging. Breathable materials providing strong seals are necessary components to ensure package integrity and protection of the device inside, including large-pack and heavy devices. Sterility is crucial as well, and seals and packaging materials must facilitate EtO sterilization cycles and maintain a sterile microenvironment so that patients are treated with safe, uncontaminated devices. Ensuring a stable supply of validated and approved materials is necessary to meet those packaging requirements, and the final packaged product must be easy and reliable for practitioners to use.

By meeting these objectives with the highest-quality packaging, medical device manufacturers can be confident they're delivering the best products for their customers and patients.

To learn more about Amcor's solutions in healthcare packaging, visit **www.amcor.com/healthcare**