

Creating Quality Medical Packaging by Working With an Experienced Materials Converter



Fabrico helps medical OEMs and contract manufacturers determine which materials and adhesives have the required strength and durability for a specific package application.

One packaging related recall can have a negative impact on business for a medical OEM or contract manufacturer. The possibility of a letter from the FDA, especially if it is a Class 1 recall due to poor seals, pin holes, tears or other packaging defects, underscores the importance of building quality into every package. As medical device OEMs and contract manufacturers look to improve efficiencies and reduce manufacturing costs, it is important to investigate new processes and materials without sacrificing quality in the end package.

Quality begins in the design phase, with a package design that will meet all specifications and can be consistently manufactured to meet quality and cost requirements. Selecting the right materials, adhesives, and packaging processes affects the success of a product package. Testing materials, adhesives, and processes is critical for ensuring that all the components are suitable for the application.

To ensure packaging quality while investigating new materials, adhesives, and processes, medical manufacturers are looking to partner with experienced medical converters, like Fabrico.

Fabrico offers everything manufacturers require for medical packaging:

- Numerous materials, adhesives, and manufacturing capabilities
- Extensive medical packaging experience
- A commitment to a team approach to improving design and solving materials and manufacturing challenges
- Compliance with ISO, FDA, and other relevant standards
- Commitment to quality throughout the organization

Keeping Up With Advances in Packaging Materials

Materials for medical packaging are constantly changing to meet market needs. Currently, the marketplace is minimizing packaging materials and costs by using thinner and less expensive materials. Fabrico can help medical manufacturers by determining if these materials will have the required strength and durability for a specific application.

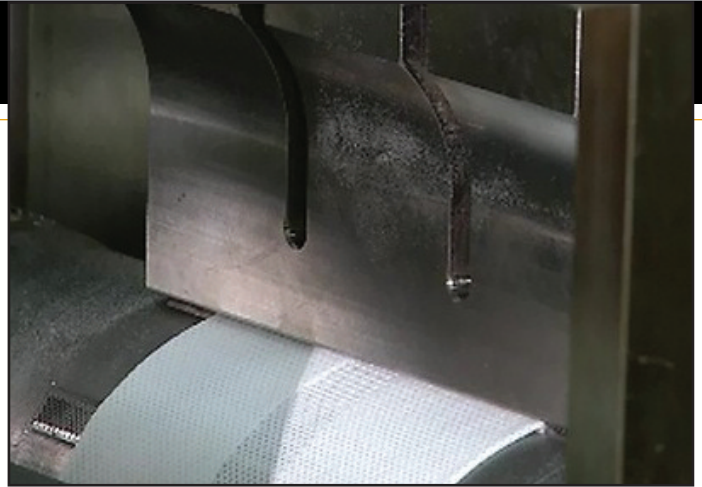
Most medical packaging includes some combination of materials, such as single or multi-ply laminated materials, that provide specific characteristics such as improved barrier performance. The material may combine paper and film, including Tyvek® film from DuPont™, and foils. Plastic films are generally seen by the industry as cleaner and stronger than medical papers.

Where the medical package is designed for impermeability and low moisture vapor transmission rate (MVTR), multi-layer films that combine two polymers are often used. Polyethylene terephthalate (PET) is an example of such a combination film. Polypropylene and polyester are also popular substrates for high barrier films.

Where permeability is desirable, for example in wound care products, polyurethane and thermoplastic elastomers have good “breathability” or MVTR characteristics. In addition, nonwoven composites are also being developed for these applications.

Fabrico is familiar with EN ISO 11607 on packaging for sterilized medical devices where porous materials are used and provides an adequate microbial barrier to assure the integrity of the sterile barrier system and product safety. The medical industry is expressing a strong interest in anti-microbial materials to counter healthcare-acquired infections (HAI).

At the same time that anti-microbial safety is a major concern, manufacturers are also looking for materials that are recyclable. Some packaging that was previously considered disposable is now being looked at for re-sterilization.



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This will require more durable materials that can stand up to the rigors of multiple sterilization processes.

There is also a trend in medical packaging to be able to see the medical device. This has led to materials that combine advanced barrier capabilities in a clear format – what-you-see-is-what-you-get in a medical application.

Adhesives for Medical Packaging

In addition to materials expertise, Fabrico is also knowledgeable about advanced adhesives for medical packaging. Adhesives are used both in the construction of the medical package and also in the manufacture of films for medical packaging. They can be liquid or tape, with pressure-sensitive adhesive (PSA) tape a favorite for sealing medical packaging to prevent theft or contamination.

Adhesive characteristics for laminating films include bond strength, heat and chemical resistance, and barrier properties. Laminate adhesives can include acrylic polymers and copolymers, natural and synthetic rubber, vinyl acetate/vinyl chloride copolymers, and polyvinylidene chloride. Films using these adhesives typically exhibit low permeability.

In high permeability films, adhesives can include acrylic, silicone, polyvinyl ether, polyvinylpyrrolidone, and polyurethane.

In addition, for those medical devices that will have a stick-to-skin application, Fabrico can suggest adhesives that exhibit low trauma, skin-friendly characteristics, for example, silicone or acrylic PSAs.

A Range of Medical Packaging Process Capabilities

From identification and selection of the appropriate materials and adhesives, to slitting, layering, laminating, precision die-cutting, and packaging of the finished product, Fabrico provides the design, prototyping, testing, and manufacturing knowledge required for success.

Fabrico provides the converting and advanced assembly capabilities OEMs and contract manufacturers require:

- Precision die-cutting, multi-layer laminating, and slitting to tight tolerances
- Clean room capabilities for both converting and assembly
- Access to medical grade adhesives
- Testing capabilities

Fabrico selects from servo driven rotary die-cutting, CNC die-cutting, laser cutting, and water jet cutting to meet the complex specifications of medical packaging components. For example, a servo driven rotary die-cutter can maintain tight tolerances ranging from 0.015" to +/-0.005" at speeds up to 500 fpm, and is ideal for the complex, multi-layer die-cutting and lamination that a medical device package might require.

For complex foam tape die-cutting, water jet technology provides clean edges with no distortion. Fabrico also offers laser cutting, kiss-cutting, slitting, and laminating for medical packaging.

Fabrico has three Class 10,000 clean room facilities for medical packaging converting and assembly.



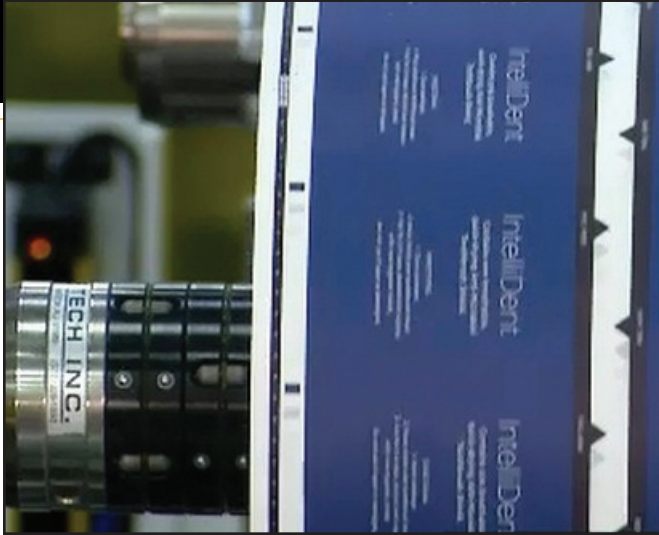
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Testing Before Manufacturing

A fully equipped test laboratory ensures that customer materials meet designed-in specifications before they move to the factory floor, often eliminating the need to test materials at the customer's facility. Fabrico's test lab provides:

- Accurate and precise part dimension measurement and verification;
- Adhesive/release liner testing to determine converting properties and high speed application characteristics;
- Strength measurement to ensure that material meets application requirements;
- Static shear testing to measure the cohesive strength of the adhesive to withstand a fixed load over time;
- Material weight measurement to determine adhesive coating weight;
- Microscopic imaging to determine differences between adhesive and material over time;
- Dielectric testing to determine a material's electrical insulation properties;
- Resistance and voltage testing to provide a complete profile of the electrical properties of an adhesive.

Testing can help predict the performance of a package in the field. By testing for tensile strength, puncture force, abrasion resistance, and other packaging characteristics, Fabrico helps the OEM or contract manufacturer explore alternatives before even investing in a prototype.



Cold seal adhesive can be used to keep adhesion at a minimum during processing, but allow for a strong, durable seal when finally assembled.

Expert Advice

Fabrico has invaluable suggestions to make at every turn in the medical packaging development process. For example, in a healthcare packaging application, use of an ultrasonic welding process was suggested for an anti-microbial material, resulting in a much sturdier package. In another example, cold seal adhesive was used for packaging to keep adhesion at a minimum during processing, but allow for a strong, durable seal when finally assembled.

For medical packaging, Fabrico's printing capabilities include:

- Package printing
- Tamper resistant and tamper evident labeling
- Bar code serialization and labeling

Certifications and Registrations

- FDA compliance and Current Good Manufacturing Practice (CGMP) standards
- ISO 13485 certification
- ISO 9001:2008

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Material Partners

Fabrico has strategic relationships with world-class materials suppliers, such as DuPont, Saint Gobain, Isovolta, 3M, Loctite®, and Adhesives Research to assist its customers in selecting the best material for the intended use and to expedite materials sourcing. For adhesive films or liquids, all critical material properties are considered in every Fabrico project, including chemical, thermal, and moisture resistance.

With more than 30 years of materials experience, Fabrico engineers also understand the impact of a material selection on the overall manufacturing process, and design material systems that optimize production efficiency and improve overall cost-effectiveness.



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