

Flexible Materials Converting and Adhesive Expertise in Surgical and Ostomy Applications



Steri-drapes provide a barrier to reduce infection and facilitate the handling of skin around an incision.

The growth of the medical device market is fueled by population demographics (the aging boomer population), product innovation, and increased market potential within and outside of the United States.

Two areas experiencing related growth are steri-drapes (sterile drapes) and ostomy device components. For medical OEMs and medical contract manufacturers, the design of a medical device can require the materials and adhesive expertise of a flexible converter, like Fabrico.

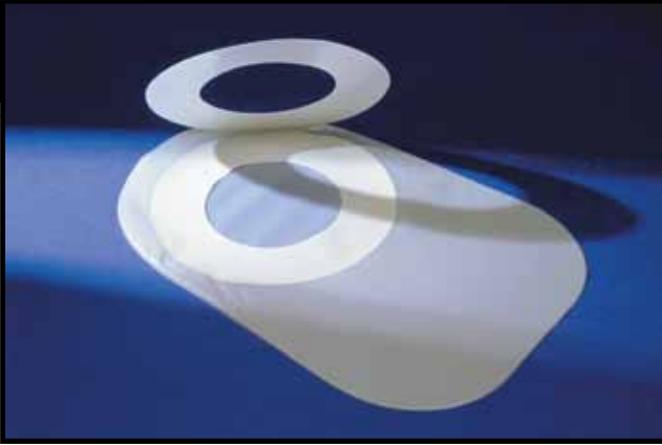
Steri-drapes are used during operations to reduce infection and facilitate the handling of skin around an incision. Typically, these drapes are manufactured using adhesive-coated, plastic film. The drapes come in all sizes and shapes and contain an opening for the surgical procedure.

Steri-drapes need to be designed for “skin friendliness” on one side, yet they may be required to adhere strongly on a second side to a different substrate, perhaps another surgical drape, or a different surgical device.

Fabrico can help a medical OEM or one of the growing number of medical contract manufacturers to develop a workable design, select the appropriate materials, identify and use the most appropriate adhesives, and manufacture the part.

Different materials and adhesives

There are a wide range of materials that can be used in the manufacture of medical devices, with a trend in the industry towards the increased use of polyolefins. Materials can include polystyrene, polycarbonate, acrylics, silicone rubber, polyethylene, polypropylene, and synthetic rubbers. Each material will have its own challenges and must be carefully matched with the appropriate adhesive. For example, “non-stick” Low Surface Energy (LSE) plastics such as polyethylene and polypropylene will require the use of new adhesives specifically designed to form strong bonds with these materials. These adhesives may be required in different formulations for different applications. Access to a wide range of innovative adhesive manufacturers can be critical in designing and manufacturing the medical device component.



A critical property for ostomy devices and similar medical device pouches is secure attachment.

The primary types of adhesives used in medical device applications include:

- Acrylics;
- Epoxies;
- Silicones;
- Styrene block co-polymers.

Fast curing acrylics are available in one-part anaerobic adhesives that cure in the absence of oxygen, one-part light-cure adhesives that set up in seconds, and two-part formulations with improved viscosity and handling characteristics. Cyanoacrylates are also popular. They include one-part formulations that cure within seconds and are well-suited for joining LSE and other difficult to bond materials.

Epoxies are also extensively used especially with film adhesives that can be die-cut to intricate custom shapes. Thin film bonding systems such as these are a good choice when the bond line geometry presents a gap that must be filled. This is crucial in ostomy applications, where a strong seal is required to prevent leakage.

Selecting the proper material and adhesive is an important decision for both the design engineer and the manufacturing engineer, who is responsible for the efficient manufacturing of the device to specification and within overall cost parameters. Both engineers can work with Fabrico to identify the distinct advantages and disadvantages of different materials and adhesives.

Double coated and single coated film tapes and transfer tapes can provide tensile strength, conformability, and breathability.

Steri-drapes

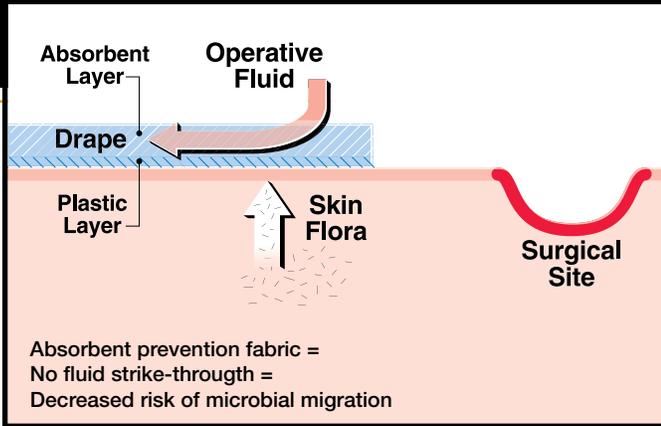
Steri-drapes consist of flexible plastic film which is adhesive coated or uses pressure-sensitive adhesive coated tape and is applied to the area of an operation prior to making an incision. The drapes are typically three-layers with a polyurethane film laminated to a releasable layer and a strengthening layer of thicker plastic material, such as polyethylene.

Double coated and single coated film tapes, as well as transfer adhesives can be used with steri-drapes. The tapes adhere well to skin but can be removed gently and completely. Double coated tapes can feature a low tack medical grade adhesive on one side and an industrial strength adhesive on the other. Fabrico can help a medical device OEM or contract manufacturer to investigate a wide variety of carriers that can be tailored for other properties, such as tensile strength, conformability, and breathability.

Fabrico has experience in adhering other surgical device components to a drape using a precision die-cut part that could create an airtight seal. Fabrico designed a die-cut part with double-coated tape for secure adhesion and a liner for easy handling in the operating room.

Ostomy Medical Devices

Ostomy and continence devices are another area of medical device manufacturing that's experiencing rapid growth. Applications in this area focus on securability. There is a wide variety of adhesive options for securing ostomy bags and similar medical device pouches, including nonwoven tapes, film tapes, foam tapes, and hydrocolloid adhesives. Each adhesive has particular characteristics that make it suitable for different applications.



Steri-drapes are commonly composed of polyurethane, polyethylene, and adhesive.

Converters can deliver a range of die-cut capabilities as well as expert advice in selecting materials and adhesives.

Nonwovens are a good choice for extended wear ostomy devices as they are highly conformable and breathable. The nonwovens are very elastic and provide excellent adhesion. Nonwovens are used with steri-drapes, pads, dressings, and filtration materials.

Film tapes offer secure adhesion and are easy to clean. They provide a translucent barrier film. Films such as PE, PET, PP, PVC, and PU can be used. Applications include thin film dressings, steri-drapes, or tape strips. Film tapes can also be used to attach electrodes.

Foam tapes have a soft feel for cushioning as well as insulating characteristics. They deliver a waterproof, antibacterial barrier and an easily cleaned surface. They are often used in applications where support films or papers are not desirable. Medical foam tapes are typically non-sensitizing and non-irritating with good initial adhesion that will last for extended wear – perhaps as long as one week. These tapes can be used as backings or protective coverings in passive and active transdermal applications.

Hydrocolloid adhesives are the most “skin-friendly” alternative and are body fluid resistant. They represent a special type of pressure-sensitive adhesive with both fast adhering characteristics as well as fluid absorbency. They are often used in ostomy applications and wound dressings. These adhesives are available in different formulations for different applications depending on the need for skin-friendly and absorbent properties. They can also be formulated for extended wear.

The Role of the Converter

The importance of working with an experienced converter in the medical device industry, especially with steri-drape and ostomy applications, can't be overstated. Converters, such as Fabrico, can deliver a range of die-cut capabilities, advice in selecting the most appropriate materials, and the ability to identify the best adhesive for the application.

Fabrico can select from servo driven rotary die-cutting, CNC die-cutting, laser die-cutting, and water jet die-cutting to meet the complexity and specifications on sophisticated medical components. For example, our Delta servo driven rotary die-cutting can deliver high repeatability and tight tolerances down to 0.015” to +/-0.005” at speeds up to 500 fpm. It is ideal for complex, multi-layer die-cutting, and lamination.

For complex foam tape die-cut components water jet die-cutting can provide a solution that delivers clean cut edges with the foam material. Laser die-cutting, kiss-cutting, slitting, and laminating can also be used in converting for medical applications.

With access to a wide range of materials, Fabrico can custom convert:

- Diagnostic test strips and carrier frames;
- Composite wound-care dressings;
- Die-cut medical foam tape;
- Woven and nonwoven biocompatible pressure-sensitive adhesive tapes;
- Steri-drapes and ostomy components.



Die-cut surgical parts can include hydrocolloid tape formulations.

In many instances, Fabrico can provide extensive label printing capabilities for tamper-evident and custom pressure-sensitive labeling of medical devices.

Fabrico is also able to suggest the appropriate adhesive alternatives for a specific application, such as single- or double-coated tapes, the best liner for the application, whether a foam tape is well-suited for the application, and what might be available in hydrocolloid tape formulations.

Recommendations could include adhesive alternatives, the best liner material, or whether to use foam tape.

Material Partners

Fabrico has strategic relationships with world-class materials suppliers, such as 3M, to assist its customers in selecting the best material for the intended use and to expedite materials sourcing. Whether adhesive films or liquids, all critical material properties are considered in any 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.



Fabrico Headquarters

4175 Royal Drive, Suite 800, Kennesaw, GA 30144

Phone: 678-202-2700 | Fax: 678-202-2702

Toll Free: 800-351-8273 | E-mail: info@fabrico.com



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