



## Engineered Material Solutions and Adhesive Expertise Improve Quality and Effectiveness of Body Worn Diagnostic Devices

Physicians and researchers continually seek ways to improve their quality of life for patients with chronic diseases, like diabetes, by using diagnostic and therapeutic devices that simplify daily treatment. These devices are becoming an increasingly complex combination of materials and electronics that often must adhere to a patient's skin.

Fabrico Medical is helping medical OEMs, designers, and contract manufacturers create comfortable, durable, and efficacious body worn devices by suggesting the best components and advanced fabrication and assembly techniques for the applications.

### What is a Body Worn Device?

Patch pumps and other body worn diagnostic "mechanized" devices are small, reusable or one-time-use devices that could be composed of a reservoir of a drug and/or a small needle on the side facing the patient for treatment. Patch pumps are used primarily for insulin therapy, which often requires patients to wear the device for extended periods of time based upon the severity of their medical needs.

Body worn devices adhere to a patient's skin, which requires balancing the need for a strong bond to hold the device in place for as long as the treatment requires, and the ability to remove or reposition it without causing skin trauma, such as skin tears or stripping. Constant skin re-adherence can cause irritation and potentially infection, especially if the adhesive is too aggressive.

### Material Partners

Fabrico Medical has formed strategic partnerships with world-class suppliers, such as 3M, who have developed proprietary formulations that provide a strong bond while being easily removed from skin. These partnerships, including another with DuPont, enable us to offer leading-edge materials to our customers and, where needed, work with suppliers to provide unique customer solutions. Whether adhesive films or liquid, all critical material properties are considered in any Fabrico Medical project, including chemical, thermal, and moisture resistance.



### 3M™ Hydrocolloid Adhesive Tape 9943J

*3M™ offers many adhesives, tapes, and films from which to choose when designing 'skin friendly' devices that attach to patients, including plastic films, foams, and other materials used to construct these devices.*

## Criteria for Body Worn Devices

According to the American Association of Diabetes Educators, body worn infusion devices have a variety of criteria that should be met prior to users deciding to use them. Top among the factors that need to be considered are adhesion strength and skin compatibility (skin features often vary among populations).

Based upon significant experience with stick-to-skin applications, Fabrico Medical's engineering team selects the right adhesive material based upon a variety of determinants, such as:

- Device design requirements
- Wear times
- Sterilization (which can degrade some adhesives)
- Specific patient activities (such as taking the device in the shower or pool)

Fabrico Medical works with premier suppliers of medical adhesive materials, such as 3M, who have developed proprietary formulations that provide a strong bond while being easily removed from skin. Skin adhesives used in these applications can include acrylics, hydrocolloids and silicones. Material bonding applications can include acrylics, epoxies, and rubber based adhesives. Additionally, Fabrico Medical is knowledgeable on specialized formulations, including blends, hydrophilic tapes and films, and thermally or electrically conductive adhesives.

## Quality Control

The manufacturing of the components for these sensitive devices must be done in a quality-controlled, clean room environment, where they can be produced, assembled, and packaged without contamination. Fabrico Medical has multiple Class 10,000 (ISO 7) clean rooms which ensure the proper, high-level quality required for medical appliances.

Additionally, Fabrico Medical upholds these certifications and standards:

- ISO 9001:2008
- ISO 13485:2003
- FDA Registration #3001032418

## Selecting the Right Converter

Fabrico Medical's design engineers can assist medical or contract manufacturers with building the flexible components for these devices. Various materials converting capabilities for body worn devices include custom design solutions for applications that require slitting, laminating, die-cutting, and more. Laser die-cutting, kiss-cut and water jet die-cutting are also available depending on the application requirements and materials being used.

With more than 30 years of materials experience, Fabrico Medical 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.

## About Fabrico Medical

Fabrico Medical is a leader in engineered material solutions for the medical market, with experience in a broad range of applications, including device and diagnostic equipment, disposables, wound care, microfluidics, body worn devices, and packaging. Fabrico Medical has developed a track record of solving unique challenges and providing sound customer solutions. The company offers a wide range of R&D, fabrication, prototyping, and converting services for medical OEMs and contract manufacturers.



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