

LONG-TERM WEARABLE MEDICAL DEVICES:

HOW TO AVOID GETTING STUCK WHEN SELECTING SKIN-CONTACT ADHESIVES



INTRODUCTION

Developing long-term stick-to-skin wearable medical devices is a challenging process. To develop a device that is both functional and wearable there are numerous requirements to consider—one of which is the adhesive that is chosen to adhere the device to the body. Often one of the last things product designers consider, medical grade pressure sensitive adhesives ultimately play a pivotal role in the success or failure of any stick-to-skin device.

Finding an adhesive that sticks and stays put for the intended duration of the device *and* can be removed without causing trauma to the skin is difficult as a balance must be struck between device functionality and the goal of doing no harm to the patient. Strong yet gentle can be a tricky combination.

The most important thing to know when selecting an adhesive for a long-term wearable medical device is that there is no one-size-fits-all solution. A systems approach that examines all design and performance variables is necessary to ensure components work together to achieve the desired outcome.

This paper will highlight the key points to keep in mind throughout the product development process and serve as a guide to assist with adhesive selection.



FACTORS TO CONSIDER FOR ADHESIVE SELECTION

A variety of factors must be considered when selecting the adhesive that will work best for any given long-term wearable medical device. Careful consideration of each of these factors and how they work together will guide the selection process.

Desired Wear Duration

The best place to begin the selection process is by considering how long the device will need to stick to the body. The answer to this question will significantly narrow down the options you have to choose from. It may seem like a good idea to select the longest wear adhesive available, however longer is not always better when it comes to adhesive selection.

“Avoid over-engineering your solution, cautions Del Lawson, Medical Materials & Technologies Laboratory Manager, 3M™ Medical Solutions Division. Placing a 14-day adhesive on a device designed to last for a few days will not give the adhesive performance enough time to degrade. The device could still be strongly adhered and may result in skin tearing or stripping if not removed properly. In terms of application design, selecting the adhesive with the longest wear duration for an intermediate wear duration may not actually help from a user experience perspective.”

Key takeaway

Wear duration is the key driver to determine the best adhesive for each application and sets the stage for further evaluation.

Device Design

Wear performance also depends on the design of the device, including its size, weight, and rigidity. The height of a device and how far it protrudes from the body can make it more likely to get caught on clothing, be bumped, or get in the way of daily activities. However, the larger the device the more surface area available to bond to skin. The less a device weighs, the better the bond can maintain that weight. Heavy, bulky devices make creating a reliable bond more difficult, yet smaller devices have their own issues. “As technology evolves, devices are becoming smaller creating yet another challenge with long-term wearables. You need a skin-contact adhesive that can stay on the body long-term, but with less surface area to form the bond” said Aditi Subramanian, Strategic Business Unit Manager – Healthcare, FLEXcon.

Key takeaway

Device size, weight, and rigidity demand different adhesion levels. Surface area, body location, and adhesive design all impact wear performance.

“We are not yet into flexible electronics that bend and move like skin. Since most wearable devices are still rigid, you need to rely on the layer between the skin and the device to hold and absorb that stress. It is a gradient of stress from the skin all the way up to the rigid wearable device. If you don’t take that into account, the device can pop or lift off leading to device failure. You often need an adhesive skirt that sticks out beyond the edge of the device to help manage that stress.”

-Audrey Sherman,
Division Scientist,
3M Medical Solutions Division

3M

End-User Demographics

A number of demographic factors influence adhesive selection. A neonatal or geriatric patient will have more sensitive skin that requires a low-trauma adhesive. Medical conditions such as diabetes can also create fragile skin that needs a gentler adhesive. Skin elasticity, body hair, sweat, oil secretion, and other skin characteristics affect adhesive performance. Adhesives that move and flex with the body are important considerations depending on where the device is placed on the body and patient activity levels.

Key takeaway

Skin variations across end-user demographics require different types of adhesives to ensure devices remain bonded, yet do no harm when removed.

Environmental Conditions

Environmental conditions the device is exposed to can have a big impact on adhesive performance. First, temperatures and humidity levels can vary widely depending on the end-user's geographical location. Next, sterilization methods can change adhesive properties leading to premature adhesive failure. And, finally everyday activities such as showering, and exercise will expose the device to moisture that can become trapped if materials prevent evaporation. This can lead to skin irritation, itching, maceration, or even trauma when the device is removed. Understanding how these conditions will impact adhesive performance will be vital to overall device performance and patient comfort.

Key takeaway

When working with your converter during the material selection process, be sure to clearly specify where and how the device will be used.

→ End User Demographics to Consider

- Skin type (sensitivity)
- Age
- Gender
- Race
- Body type
- Body hair
- Activity level
- Body placement
- Patient health

FLEXcon Featured Adhesive

FLEXcon dermaFLEX™ NNRU - Nylon Reinforced Polyurethane with Biocompatible Skin

Contact Adhesive is a high tack adhesive that is thin, lightweight, flexible, and breathable adhesive designed to move with body and provide long-term adhesion without irritation.

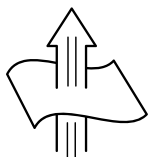
Check out the complete FLEXcon portfolio of [Skin-Friendly Adhesives](#) to learn more.



Performance Requirements

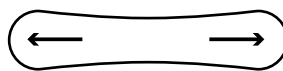
Skin contact adhesives need to stick and stay stuck for the intended duration without damaging the skin when it comes time for removal. Additionally, they need to meet the following requirements:

Breathability



Skin breathability through the adhesive is essential to prevent maceration and irritation during wear or removal. In general, the longer the device will be attached to the body, the more breathable the adhesive needs to be.

Flexibility



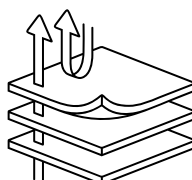
Materials need to be able to stretch and move with the body to prevent the device from popping or lifting off during everyday activities.

Durability



Devices that remain attached to the body for an extended period of time must be able to handle the wear and tear of day-to-day life. The adhesive that is used to attach the device to the body is no exception. In fact, it may be the most important component of all since if the adhesive fails, so will the entire device that's attached to it.

Reliability



A reliable bond is critical both in terms of ensuring the device stays stuck, and functionality through proper contact with the body to accurately collect data.

Berry Global Featured Adhesive

The Polyken 3621A Long-term Wear Medical Grade Non-woven Tape

is a highly breathable adhesive with bi-directional stretch for added flexibility and patient comfort.



Check out Berry's [complete line of healthcare adhesives](#).

Key takeaway

Long-term wear skin contact adhesives must be breathable, flexible, durable, and reliable to endure the stress incurred with everyday life.

SKIN CONTACT ADHESIVE MATERIAL OPTIONS

Once the above factors have been carefully evaluated, the next step in the process is to select the adhesive that meets those application requirements. The three most common skin contact base adhesive materials are acrylate, silicone, and synthetic rubber. There are pros and cons to each one based on their performance properties. It is helpful to understand those properties to select the one that best matches the application requirements.

Adhesion levels are typically measured in terms of peel, tack and shear. For long-term wearables, the desired combination of adhesion properties is typically high shear to keep the device in place, high initial tack to ensure quick adhesion to the skin, and low peel to limit skin trauma upon removal.

Material breathability is impacted by coat weight and moisture vapor transmission rate (MVTR). Lighter coat weights enhance breathability while heavier coat weights increase bond strength. Finding the right balance is key. With stick to skin adhesives, a high MVTR is desirable. The higher the MVTR the more breathable the material which maximizes adhesive strength and wear time.

➔ Adhesive Performance Properties Defined

- **Peel adhesion:** measurement of the force needed to break the bond between an adhesive and the surface it has been applied to
- **Tack:** a measure of how quickly an adhesive bond is formed when two surfaces are brought together with slight pressure
- **Shear strength:** maximum stress an adhesive sustains prior to failure
- **Coat weight:** material thickness, density
- **Moisture vapor transmission rate (MVTR):** the amount of water vapor that passes through a material over a specific period of time

Key takeaway

Daily life continuously exposes long-term wearable devices to forces that challenge the adhesive bond. Understanding the role peel, tack, shear, coat weight and MVTR play in adhesive performance is crucial.

Table 1 from 3M compares and contrasts the features of each adhesive type

Summary Table of Medical Grade Adhesives			
Feature	Synthetic Rubber	Acrylate	Soft Silicone Gel
Peel Adhesion	High	Low to high	Low to medium
Sterilisation Compatibility	EtO, Gamma, Steam	EtO, Gamma, Steam	EtO
Breathability	Low	Tuneable	Medium
Repositionability	×	×	✓
Initial Tack	Good	Low to high	Good
Skin Trauma on Removal	High	Medium	Low

Table 1: Summary table of the features of synthetic rubber PSA, acrylate PSA and soft silicone adhesive gel.

Matching Adhesive with Carrier/Backing/Liner

After the adhesive material has been selected, it is essential to match the adhesive with the carrier. The carrier can affect the breathability, flexibility, and wear duration of the device, and each carrier material has unique characteristics. "PET nonwovens, polyurethane nonwovens, polyurethane film, and polyethylene foams are the four most common materials in the wearable device space. It is important to consider how these materials will bond and interact with the adhesive. For example, if MVTR is really important for the application, a polyethylene foam may not be a good choice because it is often not breathable. Foam tapes are soft, and easily conform to the body, but are typically not breathable. Nonwovens are soft, flexible and breathable with a high MVTR.

Key takeaway

The carrier plays a critical role in adhesive performance properties such as breathability, flexibility, wear duration and removability.

3M™ Featured Adhesive:

3M™ Medical Tape, 4576

- Polyester Spunlace Nonwoven
- Ideal for extended wear medical and retail applications



Check out the [3M™ product selection tool](#) to help find the right adhesive solution for your device.

DermaMed Coatings Featured Adhesive:

DM 2278 - A white stretchable 90gsm polyurethane nonwoven with a long term wear acrylic adhesive.

Check out [DermaMed Coatings](#) to learn more about their innovative adhesive solutions.

Manufacturing Process Compatibility

Finally, manufacturing processes expose adhesives to heat, friction and other stresses that can alter the adhesive properties and performance. Working with an experienced adhesive manufacturer and converting partner will ensure the adhesive is compatible with all aspects of the manufacturing process, as well as, assist with producing prototypes for crucial wear studies.

Key takeaway

Knowing how the device will be manufactured when selecting an adhesive is an often overlooked part of the process. It is important to know that not all adhesives and carriers are suitable for every manufacturing process.

CONSULT ADHESIVE AND CONVERTING PARTNERS EARLY AND OFTEN

"One of the biggest mistakes made when selecting adhesives for long-term wearable medical devices is waiting till the end of the design process to bring adhesive partners into the discussion, said Nathan Pierce, Regional Sales Manager, DermaMed Coatings. Failing to consider all the variables that direct adhesive selection early can lead to costly product delays and redesigns." Mark Swanson, Territory Sales Manager with Berry Global agrees, "Bringing the designer, engineer, adhesive manufacturer, and die-cutter together to have a discussion is key. Simply talking and answering questions can save a lot of time, money, and frustration heading down a path where it is hard to turn around."

Key takeaway

Avoid costly redesigns delays by consulting adhesive manufacturers and converting partners early and including them in discussions throughout device development process.

CONCLUSION

No single adhesive exists that performs as needed across all applications. Therefore, when selecting adhesives for long-term wearables careful consideration of all the variables a device will encounter is crucial. A multi-step evaluation process narrows down the available options to arrive at the best product for a specific application. Partnering with experienced adhesive and converting manufacturers early in the design build process will streamline development and production.

JBC Technologies is a leader in providing the highest-quality die-cutting and material converting solutions for the medical industry. Whether you need remote monitoring patches that employ a long-term wearable adhesive, medical diagnostic kits that rely on precision filter media, pulse oximetry bandages, health and beauty patches, or something else entirely, we'll work with you to produce precision die-cut parts that match your high standards—converting your concepts into reality.

And, when you choose to work with JBC during the early stages of your project, you're able to leverage our unparalleled network of industry suppliers and manufacturers from the very beginning, essentially making our connections your connections. We are proud to be a Solventum Preferred Converter and have strong relationships with the best adhesive suppliers in the industry.

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