New Advancements in Silicone Adhesives for Wearable Medical Devices

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ABSTRACT

Material suppliers are developing new silicone adhesives to support the rapid growth of the wearable medical device market over the next few years.

INTRODUCTION

One of the growing shifts that will take place in the healthcare industry is a greater emphasis on preventive care and home health. This change will be driven by many factors, such as an increasing population of seniors, a surge of patients with diabetes and obesity and the long-term effects of the implementation of the Affordable Care Act. While these factors pose challenges to the industry, they also offer opportunities for reform. The goal to reduce costs while treating a greater number of patients will lead to innovative solutions in wearable medical devices that will ultimately benefit patients. Wearable devices have made a splash in consumer electronics, but it is in the healthcare industry that they will have the greatest impact on the user's quality of life. Wearable medical devices can empower patients by allowing them to take charge of their own health and enjoy greater mobility and freedom.

However, wearable devices can also become a burden for patients. They can be uncomfortable to wear and cause skin tears or irritation either during use or removal, which can result in patients being noncompliant with their treatments. Medical device manufacturers can solve many of these issues and increase the probability that their devices will be successful in the marketplace by choosing the right adhesive material.

This white paper details the healthcare megatrends that will drive the growth of the wearable medical device market and the benefits that silicone adhesives offer when used in these devices. It also describes the wide range of silicone adhesives that Dow Corning offers.

HEALTHCARE MEGATRENDS

The aging population in the United States (defined as over 65 years) will increase rapidly over the next few decades. By 2060, this group will have more than doubled in number since 2013.[1] Since seniors typically have more health issues than the younger population, this growth will pose a number of challenges to healthcare institutions and programs. Wearable medical devices can solve some of these issues by reducing trips to the hospital or clinic for patients in general and allowing more seniors to stay in their homes through remote monitoring and treatments.

Two other closely linked populations that are skyrocketing are patients with diabetes and obesity. In the United States alone, there are 1.4 million Americans diagnosed with diabetes every year.[2] More than two-thirds of American adults are considered overweight or obese, while more than one-third are considered obese.[3] Wearable devices have increased the quality of life of diabetes patients by simplifying both the monitoring and delivery of insulin, but their most significant impact could be in prevention of obesity and diabetes. Fitness and wellness monitors allow people to track their health and motivate them to make healthier choices.

Another challenge facing the healthcare sector is the pressure to reduce costs. In the United States, the implementation of the Affordable Care Act (ACA) is one reason for this, as one of its primary goals is to curb healthcare costs across all sectors — from health insurance to hospital bills. In Europe, similar issues such as demographic pressures and an increasing prevalence of patients with chronic diseases are straining the healthcare system. Since most healthcare systems in Europe are funded through taxes, public expenditure on healthcare and long-term care is predicted to increase by one third by 2060.[4] Lowering healthcare costs is therefore a top priority. Wearable devices can help with this goal by replacing in-patient or out-patient clinical care with the ability to monitor and treat a patient at home. They also play a key role in preventive care, and this may be where the real cost savings are ultimately realized.

While most patients would prefer home monitoring or treatment in theory, they may not comply if the wearable device is uncomfortable, irritating to the skin or difficult to remove. The use of the right adhesive material is therefore paramount.

Silicone adhesives offer many advantages that make them uniquely suitable for wearable devices. Medical grade silicones are biocompatible and have been used in medical devices for 70 years. Silicone is hydrophobic, so a device using silicone could potentially be worn in the shower.

Silicone adhesives also offer great flexibility in that they can be tailored to meet specific needs. For example, wearable devices for long-term use need different adhesives than those intended to be worn for just a few hours. Because of this, Dow Corning has developed several product lines of silicone adhesives suitable for different types of wearable medical devices.

SOFT-SKIN ADHESIVES FOR SHORT-TERM WEAR

A small, light-weight wearable device for short-term wear can utilize a material with high tack and lower peel adhesion, so the device can adhere to the skin with light pressure and be removed with a low peel force. This means that both the initial and subsequent applications are gentle for the patient, while the adhesion properties remain. Repeated use of certain non-silicone adhesives can cause skin irritation or even skin tears, if not removed carefully.[5]

The MG product line of soft skin adhesives (SSAs) from Dow Corning, initially developed for wound dressings, are gentle to the skin. Dow Corning currently offers four medical-grade SSAs: *Dow Corning*® MG 7-9700, 7-9800, 7-9850, and 7-9900 Soft Skin Adhesives. These materials are two-part platinum-catalyzed, cross-linked silicone elastomeric adhesives. SSAs bond quickly to the skin and can be easily repositioned, so they are suitable for wearable devices that need to be removed and placed back on the patient several times. SSAs are also a good choice for compromised or damaged skin and elderly care (since aging skin tends to be less elastic, thinner and fragile).[6] These two-part adhesives are solventless. Other benefits of these materials are that they are transparent and have low viscosity. They typically are processed with a knife over-roll coating process and can be paired with low-cost polyethylene release liners.

Some wearable devices require a higher degree of adhesion than the traditional SSAs provide. For these devices, Dow Corning will offer a new material called *Dow Corning*® MG 7-1010 Soft Skin Adhesive. *Dow Corning* MG 7-1010 Adhesive will also be available in a two-part, platinum-catalyzed form.

HIGH-ADHESION SILICONES FOR EXTENDED WEAR TIME

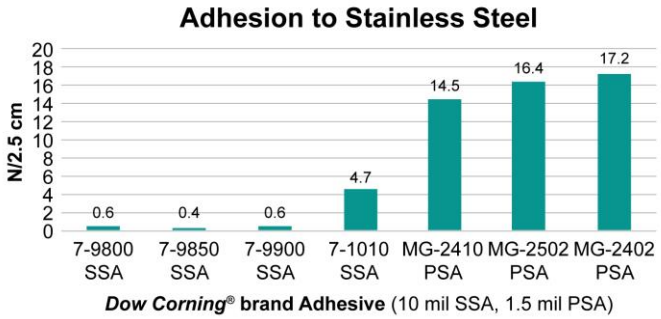
Wearable devices for longer-term use require strong and stable adhesion and high shear strength, but comfort for the patient is still paramount. To meet these requirements, Dow Corning offers the MG series of pressure sensitive adhesives (PSAs), which includes the *Dow Corning*® MG-2401, 2402, 2410, and 2502 Silicone Adhesives. These adhesives are especially suitable for longer-term patient monitoring devices. To resist environmental demands over time, they have high gas and moisture permeability. They are available in a range of tack options, solvent types and solid contents to enable use in various applications. This product line consists of three one-part, solvent-based silicone adhesives which can be processed using conventional tape coating equipment and one hot-melt silicone adhesive. All have passed cytotoxicity, skin irritation and skin sensitization according to U.S. FDA regulations.

PERFORMANCE OF *DOW CORNING*® BRAND PSAs AND SSAs: A COMPARISON

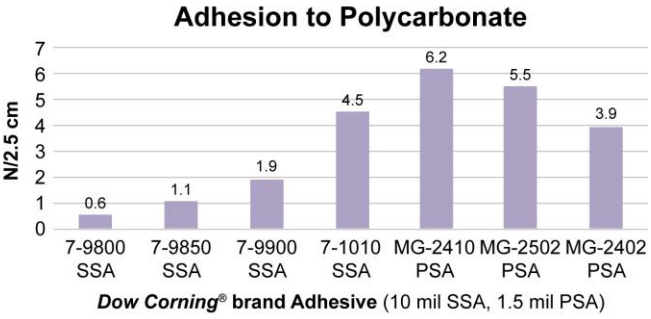
Until recently, it has been difficult to compare the performance of specific PSAs to SSAs because the techniques used to test them were different. Dissimilar test methods were utilized in the past because the basic compositions, properties, and applications of the SSAs and PSAs are so unique. A new study conducted by Dow Corning provides a direct comparison of the adhesive characteristics of the two product options. In order to obtain a

representative comparison, Dow Corning prepared laminates of each technology that were coated at the typical thickness corresponding to the recommended material coat weight. For SSAs, the tests were performed with an adhesive thickness of 0.010', while the PSAs were coated at a thickness of 0.001-0.002'. The four measures chosen for this study were peel adhesion to polycarbonate, peel adhesion to stainless steel, dynamic shear and probe tack, as they represent the characteristics most associated with the ability of the adhesive to be applied to and adhere the substrate. These are the results of that study.

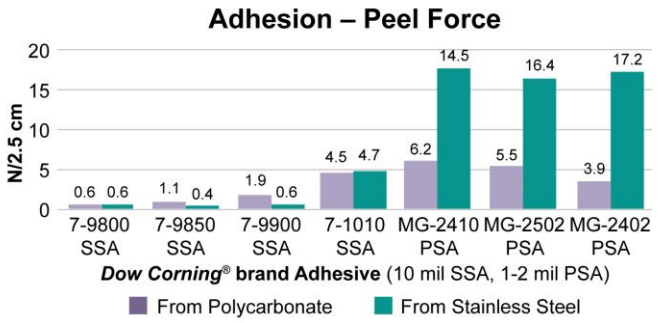
Peel Adhesion: *Dow Corning*® brand SSAs have traditionally been measured on a polycarbonate substrate, while PSAs were measured on a stainless steel substrate, making it difficult to compare/contrast each technology. In this study, both product lines were tested on both substrates.



On stainless steel, the PSAs demonstrate a much stronger peel adhesion.

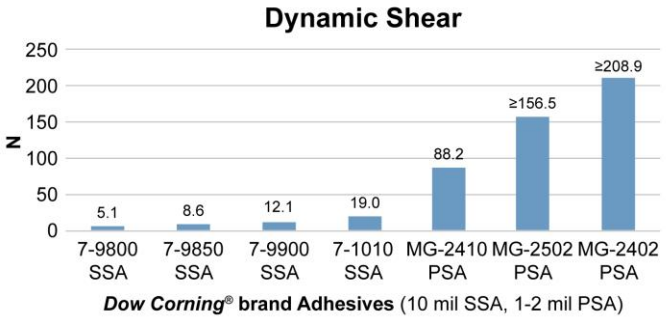


On polycarbonate, *Dow Corning* MG-2410 and MG-2502 Pressure Sensitive Adhesives adhere the strongest, but there is also some overlap between the two technologies.



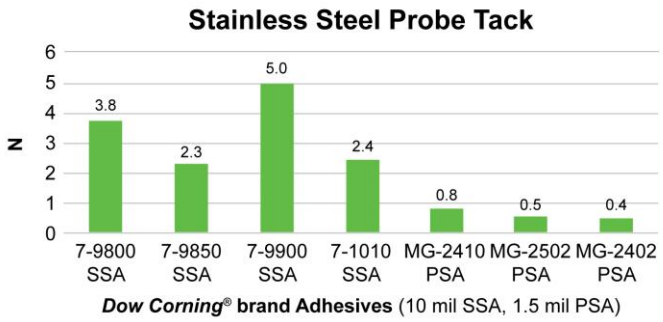
The differences in adhesion values between the two test substrates may be attributed to inherent characteristics such as substrate flexibility and interfacial properties like surface tension and roughness. However, the overall trend indicates stronger peel adhesion with the PSA materials, regardless of substrate.

Dynamic Shear: Test specimens were prepared by coating the adhesive onto an untreated polyester film at typical coat weight for each product. The devolatilized/cured adhesive was then covered with a second sheet of untreated polyester film. The shear force was measured as the two polyester films were pulled apart at a constant rate. The test indicated that a significantly higher force is required to separate the PSA material in this arrangement. In fact, the tests for *Dow Corning* MG-2502 and MG-2402 Adhesives showed that the polyester film started to deform before the material separated. Therefore the measurements for these may not represent the full shear strength of either material.



Tack: There are various methods of measuring tack. For this study, Dow Corning chose a method of using a stainless steel probe and integrating the area under the curve, because this method showed the

least variability between both technologies. This test technique lowers a steel probe onto the surface of the adhesive with a constant force for one second, then measures the force on the probe as it is removed from the adhesive. The study found that SSAs are tackier than PSAs.



While there are many variables to consider, choosing the right product for an application can be best achieved by understanding the demands that will be placed on the adhesive. If gentle adhesion, instant tack and the ability to reposition are key needs, then SSA technology is recommended. If the intended application warrants higher adhesion for secure, long-wearing applications, then PSAs will be best suited.

FUTURE OF WEARABLES

In consumer electronics, next-generation wearable devices are pushing the envelope when it comes to size, weight, appearance, and capabilities. In the medical device field, however, wearables are at their infancy stage. The same technological advancements that are making consumer electronics lighter and thinner are enabling wearables in medical devices by making them small enough to be comfortable. Great growth is expected in this field over the next few years. One report forecasted a CAGR of 17.7 % in the global wearable medical device market from 2015 to 2020. This is despite current challenges such as a lack of reimbursement and high prices for some of these devices.[7] As the technology matures, these devices will be less costly.

Meanwhile, both government programs and health insurance companies are focusing more on preventive health because of the long-term financial benefits. This will remove some of the roadblocks to reimbursements of wearable medical devices.

As the technology develops, there will also be more wearable devices that not only monitor health issues, but treat them. One recent example is the proof-of-principle study of a painless patch to dispense insulin to diabetes patients on demand.[8] While newer insulin delivery systems today may provide continuous insulin delivery and allow patients to avoid injecting themselves multiple times a day, such systems typically still require a person to program them with insulin doses and use blood glucose test strips for monitoring. Future systems such as the wearable patch would further integrate monitoring and treatments. While this study was released in 2016 and the wearable patch has a long journey ahead to the market place, it is expected that there will be many similar examples in the future of wearable devices that offer a full control loop from monitoring a condition to treating it.

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