

# The Silbione™ difference

Medical grade Silicones for Healthcare &  
Biomedical applications



# Medical grade silicones utilized in life-saving and life-enhancing medical technologies

## Medical & Biomedical Grade Silicones for Healthcare applications

Medical grade silicones have long been used in Healthcare, Medical and Pharmaceutical applications as a result of their biocompatibility, chemical inertness, hypo-allergenicity, high performance physical properties and stability across a wide range of environmental conditions. Our global fully integrated silicone manufacturing infrastructure, extensive range of medical grade silicone materials, capability to customize solutions, and 65+ years of silicone formulation expertise, make us the partner of choice for Medical Technology OEMs and CDMOs. Learn more about the benefits of our materials used in a wide array of segments:



### General and advanced surgery

Biocompatible silicone technologies meeting the strict medical and regulatory requirements of medical devices used in an operating room, ranging from disposable valves and catheters to long-term implants.



### Orthotics and Prosthetics

Comfortable, lightweight and durable medical grade silicones for the manufacturing of medical devices like orthopedic inserts & prosthetic liners.



### Diagnostics and monitoring

Safe silicone technologies for in-vitro diagnostics, wearable devices manufacturing and attachment to the body.



### Pharmaceutical and drug delivery

Wide range of medical and pharmaceutical grade silicones used in drug delivery devices or siliconization of parteral packaging



### Wound management

Soft Skin Adhesives for a gentle and atraumatic adhesion to skin, promoting healing of hard-to-heal wounds but also providing greater quality of life to patients and consumers.



### Dental

Proven tailor-made silicone dental technologies for private labeling in the fields of dental impression (VPS) and laboratory duplication.

## Our range of Silbione™ technologies include:

**Liquid silicone rubber (LSR)** including general purpose LSRs, biomedical LSRs utilized in long-term implant applications and LSR Select™ for enhanced liquid injection molding

**High consistency rubber (HCR)** including general purpose HCRs for extrusion and molding and biomedical HCRs utilized in long-term implant applications

**Silicone Adhesives** for high strength bonding of medical device parts including general purpose and biomedical adhesives utilized in long-term implant applications

**Silicone Skin Adhesives** for gentle, non-irritating adhesion to skin

**Room Temperature Vulcanizing (RTV)** biocompatible, low viscosity silicones curing at room temperature into soft and durable elastomers

**Silicone Gels** very soft silicone elastomers for the manufacturing of cushions and breast forms

**Silicone Fluids** providing lubrication and hydrophobic properties

**Our Silbione™ brand of products offers the highest quality medical grade silicone solutions, produced in a clean environment, and supported by biocompatibility testing to meet your application needs.**



# 1

## General and Advanced Surgery



## Biocompatible silicone technologies meeting the strict medical and regulatory requirements of Medical devices used in an operating room

Medical grade silicones have long been used in medical applications as a result of their biocompatibility, chemical inertness, hypo-allergenicity, high performance physical properties and stability across a wide range of environmental conditions. Manufacturers and OEMs who serve the healthcare industries use a wide range of Silbione™ Silicones to make medical parts and devices supporting care givers and patients in the operating room, including:

### Medical Valves

Fluid management in medical devices – such as tubing, catheters and valves – plays a critical role in healthcare and patient wellbeing. Elkem Silicones provides a standard and a self-lubricating range of Silbione™ Liquid Silicone Rubber, enabling manufacturers to design and produce safe and reliable medical valves including needle-free access valves.

### Cardiac Resynchronization Devices

More and more patients need to be implanted with Cardiac Resynchronization devices (e.g. pacemakers), which quickly adjust abnormally high heart rhythms or other life-threatening cardiac anomalies. The silicones used in these critical and very precise devices must meet the strict requirements for long-term implants to efficiently ensure patient safety over time.

### Neurostimulation Devices

Neurostimulation devices are typically surgically implanted in the patient and function through thin wires or leads. Implantable grade Silbione™ Biomedical can be used for making gaskets, seals, adhesives, lead insulators, and drug delivery systems in active implantable neurostimulation or neuromodulation devices and applications, including Cochlear Implants and Chronic Pain Treatment.

### Stents

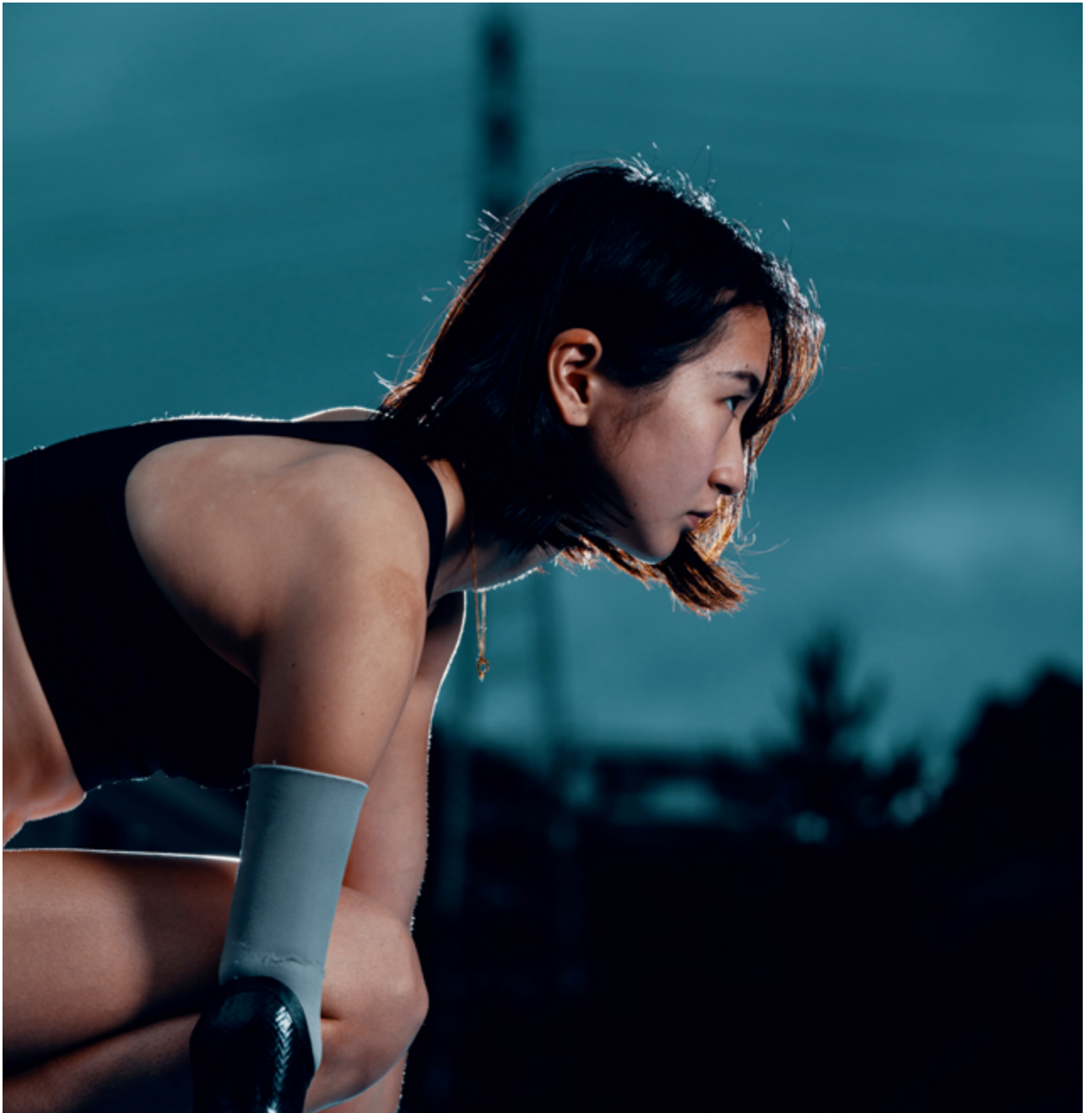
Stents are designed to keep pathways open within the human body and often require additional biocompatible silicone coating to provide corrosion resistance and to decrease the amount of tissue ingrowth. Biomedical grade silicones can also be used as drug eluting matrices to release specific APIs from the stent.

Silbione™ medical grade silicones meet the highest quality and manufacturing standards, complying with the Elkem Silicones Quality Management System. This includes:

- Inhouse clean operation standards, applying the principles of Good Manufacturing Practices
- Certified ISO 9001
- Application of the Responsible Care Management System™
- Biocompatibility

# 2

## Orthotics and Prosthetics



## Comfortable, lightweight and durable medical grade silicones used in the manufacturing of orthotics and prosthetics

**Manufacturers of prosthetics devices, such as artificial limbs, use silicones for their mechanical properties and for the comfort they provide for end users. Prosthetics devices made with silicones are lightweight and feature outstanding feel and appearance features.**

Elkem Silicone's range of medical grade Silbione™ Soft Elastomers (RTVs) and Gels provides a variety of benefits in the following applications :

### Prosthesis & prosthetic liners

In the case of prosthetic liners, silicones are used to create soft and flexible materials that can be shaped over the patient's residual limb for protection against contact with a prosthetic device. Silicone liners reduce swelling, avoid skin abrasions and lessen the pain that amputees often experience. Compared to other carbon-based materials, silicones are known to be more durable and provoke less skin irritation.

Silbione™ Soft Elastomers allow designers and manufacturers of prostheses and artificial limbs to :

- Create end products with a life-like feel
- Optimize comfort for the end user thanks to a wide range of hardness (starting from Shore A 1)
- Improve the durability of the final piece with exceptional mechanical properties
- Increase their productivity with easy to mix and degas low viscosity silicone RTVs

### Breast Forms & Cushions

Elkem Silicones has been developing over the years a wide range of very soft silicone gels for the manufacturing of pressure ulcer preventing cushions and breast forms. Our offering includes :

- A wide variety of visco-elastic properties for a realistic feel and rebound
- Low density gels for lightweight external breast prostheses
- Tailor-made grades matching specific needs

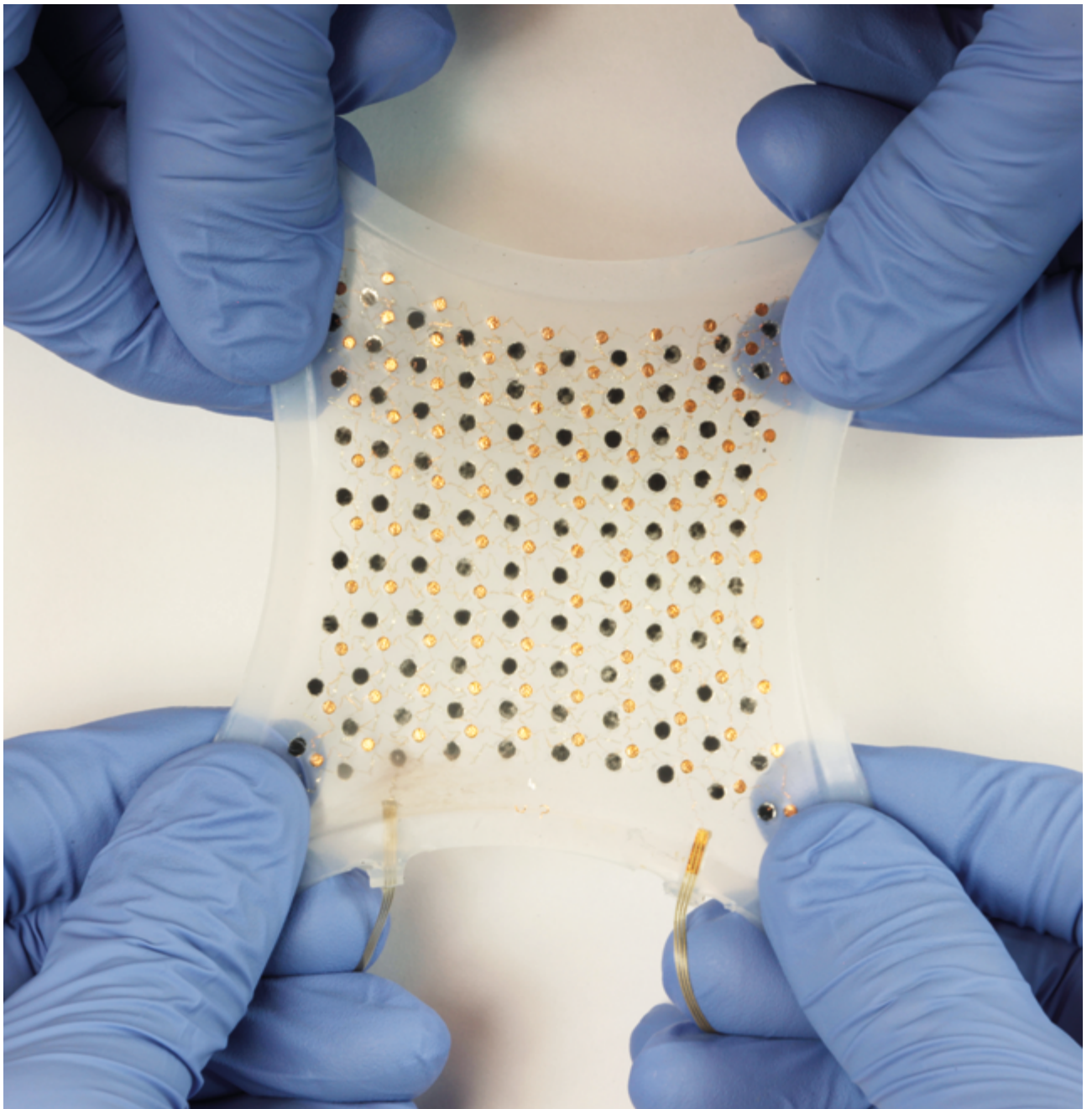
### Podology & orthoses

Modern insoles and orthoses typically use soft silicone elastomers (RTVs) to absorb some of the bodyweight or pressure and prevent further damage to the limb. Our range of Silbione™ RTV offers:

- Extremely soft materials (down to 11 durometer in Shore 00) for sensitive limb parts
- Proven damping and rebound properties for such applications
- Outstanding compromise between low viscosity and mechanical performances

# 3

## Diagnostics and Monitoring





## Medical grade silicone elastomers for the manufacturing of diagnostic and monitoring devices

Constant health monitoring is not only important to track progression of an illness, it has also become a lifestyle trend to follow various health parameters on a daily bases. Innovative wearables solutions like watches, implantable sensors, smart textiles and many other devices enable healthcare professionals to have on-demand access to health data like oxygen, stress, blood glucose, or fitness level.

Manufacturers of diagnostic or sensory devices use medical grade silicones in the production of disposable and home-health devices, microfluidic chips, gaskets and cushioning pads not only because of their inertness and ease of processing, but in particular due to their superior biocompatibility.

Silbione™ medical grade silicones meet the highest quality and manufacturing standards, complying with the Elkem Silicones Quality Management System. This includes:

- Inhouse clean operation standards, applying the principles of Good Manufacturing Practices
- Certified ISO 9001
- Application of the Responsible Care Management System™
- Biocompatibility

### In Vitro Diagnostics (IVD)

In Vitro Diagnostics (IVD) point of care test (POCT) are an emerging trend in the field of diagnosis as they include disposable and home health options for the patient. POCT devices are convenient since they are easy to use, eliminate the need of traveling to medical facilities and provide the test result within minutes. Among others, microfluidic cartridges are the heart of POCT devices. Condensed on a few centimeters, these chips enable sample drawing, sample preparation and parallel analysis of various parameters. Silicones facilitate the fabrication on a micrometer scale and integration of valves, micropumps and other components. Utilizing Silbione™ silicone materials will provide various benefits to manufacturers of In vitro diagnostic point of testing devices including biocompatibility and application-specific solutions to limit absorption of both proteins and drugs.

### Wearable Solutions

Wearable devices such as activity trackers and continuous glucose monitors or blood pressure monitors allow users to keep track of their health and wellness data. Direct access to this data can help to initiate appropriate care measures if necessary. Since these devices can be worn directly on the skin for extended periods of time, the material used must provide comfort and offer hypoallergenic qualities. For skin-worn patches, Silbione™ Soft Skin Adhesives are the perfect alternative to traditional acrylic based adhesives, since Soft Skin Adhesives can be removed painlessly and repositioned multiple times.

# 4

## Dental



## Silicone materials used for dental impression and laboratory duplication

### **A wide range of silicone materials used for high fidelity dental impression and laboratory duplication applications**

Dental silicone materials are about high fidelity, reliable reproduction and impressions made in a very short period of curing time. With more than 20 years of experience in dental industry, Elkem Silicones offers tin-free innovations and tailor-made silicones solutions manufactured in a state-of-the-art environment.

Elkem Silicones is exclusively a private label and B-to-B supplier. We develop and manufacture high-quality dental materials using our own technology, which ensures high fidelity, reliable impression and reproduction in a short period of time. By sourcing internally some key raw materials, we bring a high level of hydrophilicity, high thixotropy but high fluidity under shear, and friendly handling during use.

Our products are manufactured in controlled environment workshops, under the control of internal and external quality assurance, such as ISO 9001.

Elkem Silicone's range of silicone Elastomers (RTVs) provides a variety of benefits in the following applications :

### **Dental impression (also known as VPS)**

Our large range of Silbione™ impression materials offers a very high level of hydrophilicity, high thixotropy but are very fluid under shear, which makes them easy to handle during use. We cover all VPS technologies ranging from kneadable putties for the first impression to light bodies for an accurate second impression.

In addition, our silicone experts are able to develop tailor-made grades matching your performance or brand requirements (adjusted kinetics, viscosity, color, etc.)

### **Dental Laboratory duplication**

BLUESIL™ RTV Silicone Elastomers are widely used in dental laboratories to duplicate dental gypsum models and feature :

- Low viscosity for easy molding and degassing
- Complete range with wide variety of hardness
- High elasticity and tear strength
- Tailor-made grades matching specific needs

# 5

## Pharmaceutical Manufacturing and Drug Delivery



Whether the application requires the transfer of critical pharmaceutical fluids or for a material to act as an excipient for a drug, medical grade silicones are chosen for use in Pharmaceutical Manufacturing and Drug Delivery applications due to their biocompatibility, chemical inertness, thermal stability, flexible physical properties and environmental stability.

## Flexibility in Product Range

**Silbione™ medical and drug delivery silicones are available in many forms to support the best manufacturing method for a given component design: from High Consistency Rubbers (HCR) for extrusion to Liquid Silicone Rubbers (LSR) suitable for molded components to silicone Fluids for packaging siliconization. Each product line has an array of physical properties to choose from. Applications utilizing silicones related to pharmaceutical and drug delivery include :**

### Pharmaceutical Manufacturing

Silicones have been used for handling critical fluids in the pharmaceutical manufacturing arena across a wide range of applications: peristaltic pump tubing, transfer tubing, high pressure reinforced hoses, gaskets and seals. This flexibility in use coupled with the ability to be sterilized by a wide variety of methods (steam, heat, radiation) without undergoing major changes make them a good choice to prevent imparting leachables or extractibles into a critical fluid.

### Transdermal Drug Delivery

A Transdermal Drug Delivery System (TDDS) is an adhesive patch that contains a drug or medication which is placed on the skin to deliver specific doses over time transdermally into the body, at a defined release rate. Silicone adhesives are widely used to manufacture TDDS because they provide many advantages compared to other traditional adhesive technologies, including a reduced skin irritation and a good compatibility with the main drugs used in this field.

### Drug Eluting Devices

The key advantages for using drug eluting devices include targeting drug delivery to specific locations (lowering systemic toxicity and minimizing drug dosage) and eliminating reliance on patient compliance (through sustained release over a given time). Silicone is selected as an excipient for active pharmaceutical ingredients (API) because it represents the highest standard for biomaterials and forms a permeable matrix structure when cured, creating space for API to reside and pass through over time.

Silbione™ medical grade silicones meet the highest quality and manufacturing standards.

# 6

## Wound Management



## Medical grade Soft Skin Adhesives gels to facilitate wound healing and provide a gentle, non-irritating adhesion, even to the most delicate skin.

Manufacturers of wound care products use silicones as a Soft Skin Adhesive (SSA) in the production of skin-friendly, low-trauma bandages, dressings and surgical tapes. The goal is not only to alleviate pain when removing the dressing, but also to avoid exacerbating existing wounds and ulcers or creating skin damage.

Beyond hospital use, SSA are used more and more in consumer applications (Over-The-Counter) because they provide maximum comfort, are easily repositionable and are proven to significantly reduce scars.

### Advanced Wound Care

The burden of chronic wounds on healthcare systems is increasing throughout the world. Silbione™ Soft Skin Adhesive are materials of choice for the production of wound contact layers, because they have demonstrated their inherent benefits :

- Proven biocompatibility according to ISO 10993 and reduced skin irritation versus traditional adhesives
- No trauma upon removal on the peripheral skin and the wound itself, improving patient comfort and compliance
- Compatibility with other materials in the dressing (Polyurethane films, Non-wovens) and with efficient manufacturing processes

### Adhesive Bandages

Consumers are familiar with the unpleasant feeling of removing traditional bandages, typically based on hot-melt and acrylic adhesives. Using Silbione™ Soft Skin Adhesives in the production of Over-the-Counter (OTC) products like bandages and orthoptic patches will allow consumers to :

- Reduce irritation and sensitization linked with traditional adhesives
- Remove pain and trauma upon removal of the bandages
- Reposition the dressing up to 10 times

### Medical Tapes & Drapes

Many self-adhesive products can be used during surgical procedures, including surgical drapes protecting the patient or adhesive tapes to temporarily attach something to the body. The typical wear time can range from minutes to several days, during which the adhesion to skin should be maintained while maintaining a high level of comfort for the patient. Medical grade silicone adhesives can be considered in such applications to :

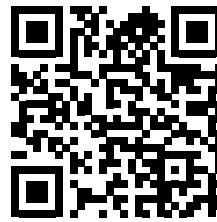
- Reduce occurrence of Medical Adhesive Related Skin Injury (MARS) thanks to the superior biocompatibility of silicones
- Reduce the pain experienced by the patient during the adhesive tape or drape removal
- Provide repositionability features to the adhesive product

### Elkem supports you

We focus on developing state-of-the-art application expertise to help our customers challenge their boundaries. At Elkem Silicones, we're more than just high quality silicone products.

We are dedicated people located around the globe committed to your success. From technical support to customized formulations and regulatory support, Elkem Silicones has the people in place when and where you need them.

### Contact us



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