

Solutions for scar care

Skin care expertise for wound care applications



DuPont solutions

Endless possibilities for scar management

DuPont's leadership in the healthcare field is matched only by its 70 years of skin care formulation expertise.

By bringing the two together, we're unfolding countless possibilities for scar management therapies—and we know this is just the tip of the iceberg.

We want to put our know-how to use by collaborating with you. Starting with its unique silicone technology platform, DuPont will help you develop effective and aesthetically superior scar therapies in the finished product. DuPont offers cost-effective solutions to meet market demands, without sacrificing your need for more technologically advanced products.

Proven time and time again

An international panel of scientists and experts on scarring determined that the standard for preventing and treating abnormal scars are therapies using silicone gel sheeting and intralesional corticosteroids. (See Mustoe, T.A.: "International clinical recommendations on scar management," *Plastic & Reconstructive Surgery*, 2002 Aug; 110:560-71.)

Results from a meta-study of 27 separate trials demonstrate that silicone gel sheeting is more effective than other occlusive dressings (e.g. polyethylene, polyurethane) and showed no significant adverse effects.

DuPont proven solutions – keeping pace with your innovations

The proven ability of DuPont silicone materials to serve as delivery vehicles for the topical application of synthetic drugs and biologics provides possible synergies with known or emerging anti-scarring therapies.

Scar therapy devices on the market adhere to the skin with secondary dressings, films and non-wovens. DuPont offers a range of **adhesives** that remain constant for extended periods, even under high-humidity conditions. The safety of these materials is supported by laboratory testing, and by their extensive use in healthcare applications. DuPont's Soft Skin Adhesive technology (for example, DuPont™ Liveo™ 7-9800) is the basis for current gel sheeting therapy.

DuPont's line of silicon-based excipients (qualified for use in topical pharmaceutical formulations) may be used in drug delivery applications. These products have enhanced drug permeation properties to facilitate the loading, stabilization and release of actives on the skin.

DuPont's line of **Dimethicone NF (Liveo™ Q7-9120 series) Fluids** are well suited for our customers who use dimethicone as an active ingredient in their formulation and choose to make skin protectancy claims with their skin care product. Refer to the Code of Federal Regulations "21 CFR Part 347: Skin Protectant Drug Products for Over-the-Counter Human Use" final monograph for specific details describing the use of dimethicone for skin protectancy claims, or call DuPont to learn more!

A recent innovation from DuPont is referred to as **New Scar Technology (NST)**. NST is patented technology composed of silicone gum, silicone fluid, silicone wax and silicone volatiles. This film is non-tacky, substantive and semi-occlusive. Additionally, this technology can also be used to deliver pharmacological and cosmetic ingredients.

Additionally, DuPont supplies a range of **Silicone Elastomer and Dimethicone** product options that are appropriate for a range of skin care applications, including lotions and ointments for scar therapy products. DuPont silicone elastomers can improve the aesthetics as well as modify the rheology of your formulation. Our dimethicone products can improve spreadability, while providing substantivity and a soft skin feel.

DuPont offers you a full range of affordable scar therapy solutions available today, or customized to your specific needs tomorrow. We also help you invent the future when we innovate together. Give us a call—our global offices are listed on the back of the brochure—we welcome the opportunity to put our technology, material and formulation expertise to work for you.

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Performance-enhancing materials appropriate for healthcare innovation

DuPont, a long-term leader in the healthcare industry, continuously enhances the performance of its materials to optimize them to meet our customers' needs. Scar therapies can benefit from our experience with skin care formulations and the efficacy of silicones in delivering multifunctional benefits—including delivery of actives. DuPont has an FDA-registered and inspected facility dedicated to healthcare material manufacturing.

At DuPont, we believe that there are many uses for silicones in scar therapies—film forming, moisturizing, occluding, adhesion, sheeting, delivering actives, etc. Our expert resources can help you invent the future for scar management.

This paper reflects some of the uses we anticipate for silicones in the growing scar therapy market. However, where we've been most successful, is in collaboration with our customers, providing solutions that meet your needs.



Abnormal scarring

Hypertrophic scars and keloids are fibrotic conditions that result in an over-deposition of collagen in the skin. They can be caused by minor cutaneous perturbations such as ear piercing or acne, or by traumatic injuries such as burns. Visually, these scars are raised reddish nodules that can cause pruritus, pain, restricted movement, and cosmetic disfigurement. The principal difference distinguishing keloid from hypertrophic scarring is that a keloid progressively invades the surrounding healthy tissue. In contrast, a hypertrophic scar only increases in dimension by pushing out its margins; there is no expansion into the surrounding tissue. Whether the scar is hypertrophic or keloid, the scar tissue rarely extends deep into the dermis.

It is well documented in published literature that various factors including ethnic background, hormonal status and injury location can contribute to a heightened incidence of scarring. Keloids are more prevalent in individuals with darker skin pigmentation, with an incidence of 4.5 - 16% in African and Hispanic populations^{1,2}. Of note, data from the National University of Singapore indicates that keloids are three times more common in Chinese patients than among Caucasian patients. Another study in the published literature suggests that Chinese are slightly more prone to keloids than the darker-skinned Indians and Malays³. Hypertrophic scars are more common and occur with equal frequency in all racial groups.

The average age of onset for keloids has been estimated to be approximately 22 years for both men and women⁴. Others report a higher incidence in young women relative to age-matched males, which may reflect a higher frequency of ear lobe piercing among women. Specific body sites that are more prone to scarring are areas with oil-secreting sebaceous glands or areas of increased skin tension. They include the shoulders, upper back, upper arms, chest, ears, cheeks and neck. Hypertrophic scars can regress over time, whereas spontaneous regression of keloids is rare.



Overall benefits of silicone

Among qualified materials used in healthcare applications, silicones are clearly recognized for their biocompatibility. DuPont's healthcare products have a long history of clinical use to support their biocompatibility.

Additionally, silicone chemistry offers a broad range of performance characteristics that make DuPont materials suitable for use in many types of processes and applications, ranging from multifunctional excipients and active pharmaceutical ingredients to medical device components.

Silicone solutions for scars

A variety of techniques have been utilized to prevent, as well as treat, abnormal scars. The standards for preventing and treating abnormal scars are therapies using silicone gel sheeting and intralesional corticosteroids⁶. Clinical studies have proven that silicone gel sheeting is safe, and is superior to polyethylene, polyurethane and other occlusive dressings⁷. Although less studied, formulations of silicone fluids have also demonstrated efficacy on minor hypertrophic scars⁸⁻⁹. Whether this beneficial response is due in part to silicone-induced skin hydration is at present unknown.

A number of other treatment modalities have also been explored (e.g. topical or intralesional steroid applications, ultrasound, cryotherapy, compression therapy, radiotherapy, and laser therapy), but few have been supported by controlled clinical studies. Surgical excision can result in recurrence, as the new surgical wound is prone to the same mechanical, immunological and biochemical forces as the original scar. In general, hypertrophic scars appear to be more responsive to treatment than keloids⁵.

DuPont skin care heritage

For more than 70 years, DuPont silicones have been formulated into skin care applications. In the early 1950s, silicones were used in diaper rash creams and hand protectants. Today, silicones are used in one out of two personal care products on the market, because they provide such unique aesthetic and delivery benefits, such as:

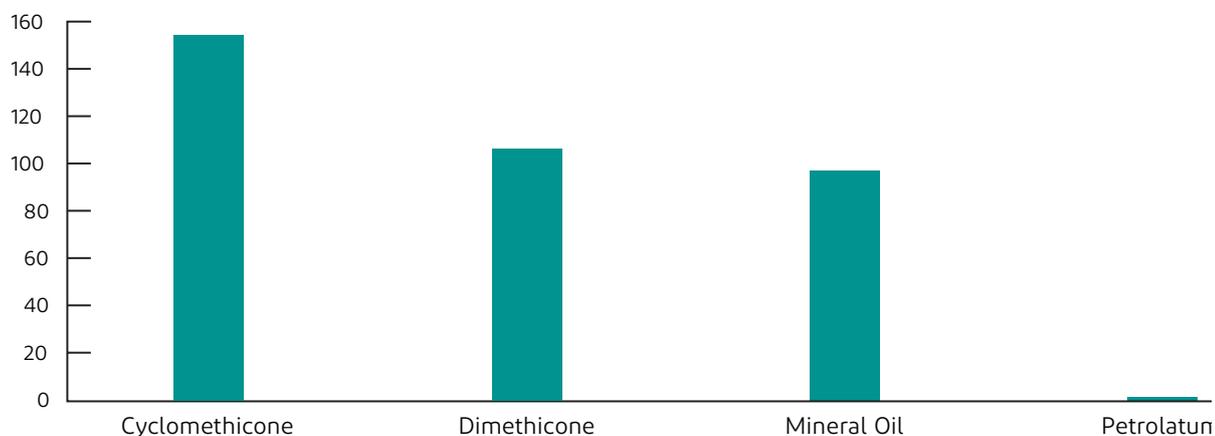
- Moisturization
- Humectancy
- Occlusivity
- Emolliency
- Water barrier and improved wash-off resistance
- Improved aesthetics

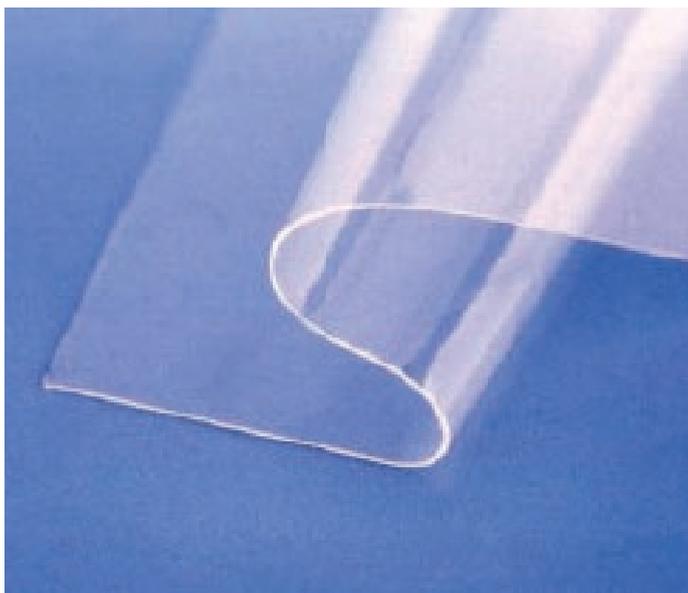
Customers around the world choose DuPont for our formulation expertise, our regulatory expertise, our dedicated FDA registered healthcare facility, our Good Manufacturing Practices, our Responsible Care[®] policies and our global supply chain.

Here's an example to demonstrate a scar therapy application with an existing DuPont product that's used widely in topical applications. Silicone materials provide multifunctional benefits including improved substantivity, lubricity, and detackification—qualities often sought in scar therapies.

You can also use Silicone materials to formulate lotions and ointments. Call any of the locations listed on the back on the brochure; our customer service representatives are happy to provide you with formulations or any other needs.

Water Vapor Permeability





New product development: synergies with other anti-scarring therapies

The proven ability of silicone materials to serve as delivery vehicles for the topical application of synthetic drugs and biologics provides for possible synergies with known or emerging anti-scarring therapies. Recently developed anti-scarring therapies include actives such as hyaluronic acid, interferon alpha-2b, decorin, tamoxifen, manose-6-phosphate and imiquimod¹⁰⁻¹¹.

Delivery of actives

Silicones have historically demonstrated their utility as delivery vehicles. DuPont has commercialized a line of products to provide enhanced drug delivery. These products are silicon-based excipients qualified for topical pharmaceutical formulations and provide drug substantivity, drug release and distribution of active ingredients on skin (stratum corneum, epidermis and dermis).

Gentle skin adhesion

Today, there are scar therapy devices on the market that are attached to the body with secondary dressings. Other commercial scar therapy devices, films and non-wovens, are adhered directly to the skin. DuPont offers a range of adhesives to meet this need.

New Scar Technology (NST)

Another innovation from DuPont is New Scar Technology. This combination of silicone materials leaves a film on the skin that is non-tacky, substantive and semi-occlusive. Consider the opportunities for using this technology to deliver actives, such as pharmacological and cosmetic ingredients as well. If the commercialization of this technology interests you and your company, please contact us to further discuss future collaborative activities.

Product Classification	DuPont™ Liveo™ Product Nomenclature	Delivery of Actives Potential	Film Forming on Skin	Moisturizing/Occlusive	Adhesive	Solid Devices/Sheeting
Dimethicone	• Q7-9120 (20, 100, 350, 1,000 and 12,500 cSt)	X	X	Non-occlusive		
	• TI-1050 fluid (5, 10, 50, 100, 200, 350, 1000, 12,500, 30,000 and 100,000 cSt)		X	From non-occlusive to semi-occlusive		
Dimethicone Fluid and Gum Blend	• ST-Dimethiconol 40	X	X	Non-occlusive		
	• Dimethiconol Blend 20	X	X	Non-occlusive		
	• Silmogen Carrier	X	X	Non-occlusive		
Volatile Silicone	• Q7-9180 Silicone Fluid (0.65 cSt and 1.0 cSt)	X		Volatile		
	• ST-Cyclomethicone 5 – NF	X		Volatile		
	• TI-1050 fluid, 1,5 cSt			Volatile		
Elastomer	• Class VI LSR • Class VI HCRs	X		Semi-occlusive		X
Elastomer Blend	• ST-Elastomer 10	X		Semi-occlusive		
	• TI-3021 Silicone Elastomer Blend			Semi-occlusive		
Fillerless Elastomer	• 7-9600 Soft Filling Elastomer			Semi-occlusive	Slightly	X
Fast Cure Elastomer	• MDX4-4210 Medical Grade Elastomer	X	X	Semi-occlusive	Slightly	X
Cured Elastomer Film	• 7-4107 Elastomer Membrane			Semi-occlusive		X
Skin Adhesive Elastomer	• 7-9800 SSA	X		Semi-occlusive	X	X
Pressure Sensitive Adhesive	• MD7-4502 Silicone Adhesive (medium tack) • MD7-4602 Silicone Adhesive (high tack)		X	Semi-occlusive	X	X
	• Bio-PSA Silicone Adhesives	X	X	Semi-occlusive	X	X

You can count on DuPont for:

- **Trustworthy Regulatory Practices:** We strictly adhere to current appropriate manufacturing practices and specifications—Pharmacopoeia certifications, U.S. Drug Master Files, European Drug Master Files, ISO 10993-1 standards.
- **Reliable Source of Supply:** DuPont's integrated supply chain and comprehensive documentation ensure complete traceability of our materials.
- **Consistent Quality:** Our healthcare materials are manufactured in a dedicated, FDA-registered (CFN 1816403) and inspected facility that meet cGMPs and Responsible Care® policies.
- **Supportive Regulatory Practices:** In addition to delivering on the performance and the purity level your application requires, DuPont also manufactures and tests materials so that they comply with the industry's—and your geography's—stringent regulatory demands. We also offer Drug Master Files, European Technical Files and FDA Material Application Files for some materials, to help speed and simplify the regulatory process.
- **Supportive Services:** DuPont is available to help you make informed choices for a current product or custom formulated material. We offer a worldwide network of technical assistance centers, toxicological testing and analysis, material analysis, chemical engineering services, and more.
- **A Range of Beneficial Materials:** DuPont products have a long history of biotesting and clinical use to support their biocompatibility. Silicone chemistry also offers a broad range of performance characteristics that make DuPont materials suitable for use in many types of processes and applications, ranging from multi-functional excipients to active pharmaceutical ingredients to wound management therapies.
- **Innovative Solutions:** DuPont is meeting the market's need for excipients that improve the aesthetics and bioavailability of topical pharmaceuticals, while collaborating with customers all over the world to expand the use of elastomers and adhesives for wound care. What will tomorrow bring? Countless opportunities to build upon the proven technology of our materials and our expertise, in the context of your product needs.





To learn more about DuPont's healthcare solutions visit:
www.dupont.com/healthcare.html

For country-level information, visit:
www.dupont.com/corporate-functions/our-company/global-locations.html



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