#### ScarEase<sup>®</sup> Silicone Gel Occlusive Sheeting For the management of keloid

and hypertrophic scars

Doctors around the world have long recognized Silicone Elastomers to be safe and effective in the management of hypertrophic and keloid scars. Applied over a scar daily as directed, ScarEase softens, smoothes, and flattens scars and restores skin to a near normal surface and color. Results may vary with scar density, age, size and from person to person.



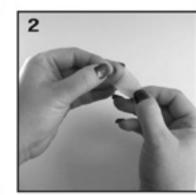
Before applying Scarease gel sheeting wash the scar area with mild soap and water. Rinse and dry the area completely with a clean towel.

- Step 1 Trim a piece of the ScarEase Sheeting to the approximate size and shape of your scar, it should be large enough so that there will be some overlap of the scar area.
- Step 2 Peel off the blue plastic backing to expose the adhesive surface.
- Step 3 Press to apply the now exposed adhesive side against the scar.
- Step 4 For best results wear the sheet as much as possible and apply a fresh sheet when material becomes soiled or loosened.

How long must I wear ScarEase?

ScarEase should be worn for 8-12 weeks.









Topical devices applied directly to the skin's surface can cause minor skin rashes. Generally, such rashes are caused by sweat and rarely occur, however, if you experience a reaction, stop using

Do not use on open wounds. Use only under the supervison of an adult. Keep away from children and pets. Do not use in, on or around eyes or mouth. Do not reuse sheet on another user. Keep product away from sunlight









## Formulated and Manufactured in the USA











## Formulated and Manufactured in the USA





























### **PRODUCT** INFORMATION

#### Indications

ScarEase occlusive scar dressings are indicated for the management of hypertrophic and keloid scars.

#### **How Supplied**

#### ScarEase Gel

Liquid Elastomer Gel 15g / 4g / 2g tube

#### ScarEase Sheet

Durable, Soft-Solid Elastomer

5 x 6cm

10 x10cm

12 x 14cm

7.5cm circle

3.5 x 15cm

3.5 x 30cm

#### **Product Overview**

ScarEase is a uniquely formulated silicone elastomer dressing for use on closed wounds, as well as on advancing and developed scar tissue. ScarEase is available in two different forms:

#### ScarEase Gel

Liquid elastomer gel, available in a 15-gram tube for easy apportion to all skin areas requiring management. Ideally suited for application to skin folds, joints, and facial features that challenge elastomer sheeting.

#### ScarEase Sheet

Durable, soft-solid elastomer sheet, individually packaged. Suited for application to flat skin surfaces with raised or thickened scar tissue. Especially effective where pressure is required, following intralesional injections or revision surgery. A single sheet can be used for the duration of scar management.

#### **Directions For Use**

#### ScarEase Gel

Apply to affected scar areas twice daily and again after bathing or showering. Wash the scar area with mild soap and water, then pat dry. Using fingertips, apply only a small amount directly onto the scar area. In a circular motion, from the center of the scar outward, cover the scar evenly, overlapping by 1/4 inch or so in all directions. Wipe away excess to avoid staining of clothes and undergarments. To maintain coverage, reapply after exercise or rigorous activity. Use continuously for 8 to 12 weeks or as directed.

#### ScarEase Sheet

Wash the scar area with mild soap and water. Rinse thoroughly and dry completely with a clean towel. Remove the clear plastic film and apply sticky-side down on the scar. For best results, wear ScarEase at least 12 hours each day, reapplying twice daily: once in the morning and once every evening. Use continuously for 8 to 12 weeks or as directed.

#### **Contraindications and Warnings**

ScarEase Gel: contraindicated for use on mucous membranes or open wounds. Avoid contact with the insides of eyes, ears, and mouth. Discontinue use if unexpected redness or swelling occurs.

ScarEase Sheet: contraindicated for use on mucous membranes or open wounds. Sensitive individuals may experience a minor, localized skin reaction (sweat rash). Discontinue use if unexpected redness or swelling occurs.



#### Mechanisms of Action

ScarEase is an occlusive scar dressing that changes skin pressure, moisture and temperature. Larger, thick and very raised scars may benefit from the pressure of ScarEase Sheets, whereas smaller scars on facial features and skin folds may receive greater benefit from ScarEase Gel. Using a practical, three-phase model of wound healing, (inflammatory, fibroplastic and remodeling) it is unclear which phase is most affected by the application of ScarEase. The bulk of current scientific study proposes that occlusive dressings may affect surface pressure, increase moisture, slightly increase skin temperature, or create static electric charge, thus altering the biochemical process within the keloid. It is therefore likely to be a combination of effects rather than a single effect that diminishes the keloid. However, heavily fibrous keloids may require additional treatments (i.e. intralesional injections of triamcinolone, radiation, surgical revision, and/or pressure garments) and may be unresponsive to ScarEase. A bibliography of scientific material on these subjects is available upon request.

#### \*Results may vary







After ScarEase Gel

#### ScarEase Gel 2 gram tube ScarEase Gel 4 gram tube

Size

ScarEase Gel 15 gram tube ScarEase Sheet 5 x 6cm Patch ScarEase Sheet 10 x 10cm Sheet ScarEase Sheet 12 x 14cm Sheet

Product

ScarEase Sheet 7.5cm (pair) Round Areola ScarEase Sheet 3.5 x 15cm Strip ScarEase Sheet 3.5 x 30cm Strip







#### ScarEase is Effective

ScarEase is generally effective on all scar types, but results vary. Patient compliance and skin conditions may limit the effectiveness of ScarEase.

#### Clinical Classifications

Although there is no perfect clinical classification for scar tissue. ScarEase Inc has categorized scars into 3 groups: normal, keloid and hypertrophic. Normal: a "normal" scar is usually a linear structure, often hypopigmented, and only slightly raised above the surrounding skin. Keloid: in the "keloid" scar, however, there is a disproportionate proliferation of fibroblasts, giving rise to excessive collagen in the corium during tissue repair. Aside from their obvious characteristics, keloids are distinguished by the presence of numerous proliferating fibroblasts including the accumulation of dense, deeply eosinophilic-staining collagen. Thus, the "keloid" scar progressively enlarges during the healing process. Hypertrophic: a "hypertrophic" scar is formed by exuberant cicatrization, giving it the appearance of a "keloid," but without the tendency to progressively extend.



For the management of keloid and hypertrophic scars

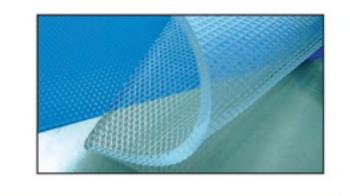
ScarEase

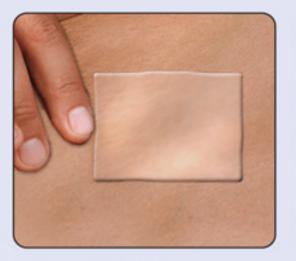


# Sheeting

For the management of keloid and hypertrophic scars

ScarEase™ is a soft silicone gel sheet which is tacky on the back and easy to apply. ScarEase silicone gel sheeting is the most effective, proven method of scar management available today. All ScarEase sheets can be trimmed as needed





Silicone Gel Patch

For preventing and managing small hypertrophic and keloid scars.

SEGS5.6 Patch 5cm x 6cm



Standard Silicone Gel Sheet

For managing mid-sized hypertrophic and keloid scars.

SEGS10.10 Sheet 10cm x 10cm SEGS12.14 Sheet 12cm x 14cm



Silicone Gel Areola Circles

For small hypertrophic and keloid scars resulting from areola reconstruction and breast augmentation surgery.

SEGS7.5 Round Areola 7.5cm



#### Silicone Gel C-Strip

For C-section and hysterectomy scar treatment sites.

SEGS3.15 Strip 3.5cm x 15cm



#### Silicone Gel Strip

For surgical scars resulting from C-section, tummy tuck and cardiac procedures. SEGS3.30 Strip 3.5cm x 30cm



A072011 Rev. 0003 VR.SEINFO 08