

BIODERMIS SILICONE GEL SHEETING

INDICATIONS

Biodermis Gel Sheeting is intended for use in the management and control of old and new hypertrophic or keloid scars resulting from burns or surgical or traumatic injury of the skin. Consistent use of Gel Sheeting can reduce hypertrophic and keloid scarring.

Biodermis Gel Sheeting may be used to aid in the prevention of hypertrophic and keloid scarring when used on closed scars following surgery, trauma, or burns

CONTRAINDICATIONS

Biodermis Gel Sheeting is contraindicated for patients with medical conditions that might render them unable to use the dressing properly. The use of this product is also contraindicated for patients with dermatological conditions which disrupt the integrity of the skin in areas of coverage. Silicone Gel Sheeting is not intended for use on open wounds.

HOW SUPPLIED

Non-sterile product is labeled as such and supplied in a protective package within a protective outer container.

WARNINGS, PRECAUTIONS, ADVERSE REACTIONS

Possible complications include:

- Superficial maceration of the skin
- Rash,
- Skin Discoloration
- Pruritus,

Meticulous care must be taken to insure proper hygiene. Clinical evaluators have observed rashes on skin covered by gel sheeting which have been attributed to poor or insufficient hygiene. Similar rashes have been attributed to gel sheeting being wrapped too tightly, as well as wrapped with an occlusive cover (e.g. ace bandage). Should a rash appear, apply the gel sheeting for a 12 hour period, followed by 12 hours of rest. If the rash persists, a physician should be contacted and gel sheeting use should be discontinued.

Discoloration of the skin covered by Silicone Gel Sheeting has been reported, particularly in dark skinned patients. This effect appears to be transient, and may be similar to the discoloration experienced whenever an area of skin is covered for extended periods of time.

Some patients report differences in Gel sheeting surface tack from sheet to sheet. Perception of tack is subjective and the adhesive characteristic of Biodermis Gel Sheeting may vary.

INSTRUCTIONS FOR USE

Biodermis Silicone Gel Sheeting

1. Wash both scar and hands.
2. Open the non-sterile pouch containing the Biodermis Silicone Gel Sheet.
3. The gel sheet is covered on both sides by a plastic film. Remove both sides of plastic prior to use.
4. The gel sheet may be cut into smaller pieces using scissors or a scalpel. Once you have determined the appropriate size of sheeting to use, apply tacky side to the scar. The gel sheeting should fully cover the scar and extend ¼ inch all the way around the scar border.
5. The exposed surface of the gel sheeting may be covered with surgical tape or bandage to help hold in place and to prevent sticking to other surfaces.

CLEANING INSTRUCTIONS

Remove the gel sheet every 12 hours to wash both the scar and the gel sheet using SilqueClenz™ in a basin of warm water and work up a small amount of lather with the soap. Gently wash the piece of gel sheeting in the soapy water, rinse, and then air dry. After washing, rinsing and drying the scar site re-apply the piece of gel sheeting.

WEARING TIME

Optimal wearing time for Biodermis Silicone Gel Sheeting is 24 hours per day.

If it is not possible to wear the gel sheet for the recommended 24 hour period, a minimum of 12 hours per day is required, washing per the instructions above once in that period. Follow this procedure each day, washing and re-applying the gel sheeting to the scar for 1 to 2 weeks. At that time the piece of gel sheeting will begin to lose its adhesive quality and/or may become embedded with surface dirt. When this occurs, discard the piece of gel sheeting and apply a new piece.

The overall optimal period of use is usually 8 to 12 weeks.

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