BIODERMIS SILICONE GEL SHEETING

INDICATIONS
Biodermis Gel Sheeting is intended for use in the management, control and prevention of old and new hypertrophic or keloid scars resulting from burns or surgical or traumatic injury of the skin.

CONTRAINDICATIONS
Do not use on open wounds or when any Dermatological conditions disrupt the skin (such as a rash).

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,
• Sheeting tack and thickness vary	

Rashes have been observed on skin under the gel sheeting, this has been attributed to poor or insufficient hygiene. Similar rashes have been attributed to gel sheeting being wrapped too tightly. Should a rash occur, stop using the gel sheeting for 12 hours followed by using the gel sheeting for 12 hours. 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 and thickness from sheet to sheet. Perception of tack is subjective and the adhesive characteristic of Biodermis Gel Sheeting may vary. These variations do not affect the function of the product.

Small bubbles may form after repeated washing and use. This does not have an impact on the function of the product.

Do not use creams, lotions, sun block or other silicone products on your skin when wearing silicone gel sheeting. These products will create a barrier between the scar site and silicone gel, preventing a proper healing environment.

For children under 5 years of age, use under adult supervision.

INSTRUCTIONS FOR USE
Biodermis Silicone Gel Sheeting

1. Wash both scar and hands per cleaning instructions.
2. Open the non-sterile pouch containing the Biodermis Silicone Gel Sheet.
3. Clear gel sheeting is covered on both sides by a plastic film. Fabric gel sheeting is covered on the tacky side by a plastic film. Remove plastic film 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.
6. If the product is worn during sleep, it should be secured. Use of medical tape (Epi-Tape) or other means is recommended to keep the product from falling off.

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, 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. Make sure the sheeting is completely dry before re-applying to the scar. 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.

Incident Notice: Any serious incident that has occurred in relation to this product should be reported to Biodermis and the competent authority of the Member State in which the user and/or patient is established.

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MD CE

6021 Rev X 00000000

Printed in the USA

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