

**SCARCARE GEL-PAD KIT- elastomer, silicone, for scar management**  
**Blaine Labs Inc.**

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**SCARCARE GEL-PAD KIT**

**USES:**

**SCARCARE GEL-PAD KIT™** is intended for managing hypertrophic, hyperpigmented and keloid scar tissue.

**CONTRAINDICATIONS:**

Do not apply to open wounds or third degree burns. Never use on a sutured wound until sutures have been removed or when any dermatological conditions disrupt the skin (such as a rash or burn).

**HOW SUPPLIED:**

Non-sterile product is labeled as such and supplied in protective packaging and container.

**WARNINGS, PRECAUTIONS, ADVERSE REACTIONS:**

Possible complications include:

- Superficial maceration of the skin
- Skin discoloration
- Sheeting tack and thickness vary
- Rash
- Pruritus

Rashes may occur on skin under gel-pad due to poor or insufficient hygiene. Rashes may also result from wrapping gel-pad too tightly around skin. Should a rash or irritation of skin occur, stop use for a minimum of 12 hours before next treatment. Stop use and ask a doctor if rash persists.

Discoloration of skin covered by gel-pad may temporarily occur in patients with darker complexions.

Do not use creams, lotions, sun block, or other silicone products on your skin when wearing gel-pad. Only apply gel-pad to clean, bare skin.

**DIRECTIONS FOR USE:**

- 1) Wash your hands and the scar area with soap and water. Dry thoroughly.
- 2) Cut the gel-pad to fit the scar area as needed, so that the edges extend at least 1/4" beyond the scar on all sides.
- 3) Gently peel the gel-pad from the mylar release strip (it is normal for small bits of the gel to remain on the mylar release strip). Do not discard the mylar release strip.
- 4) Place the sticky side of the gel-pad directly onto the scar. For best results, wear the gel-pad 8-12 hours per treatment. Wait 8-12 hours without use before next treatment.
- 5) After removal of gel-pad, apply 1-2 drops of E-Sil™ onto the scar, massage gently until absorbed. Repeat as needed.
- 6) When not wearing the gel-pad, place the gel-pad (sticky side) back onto the mylar release strip. Place the gel-pad back into the original pouch for protection.
- 7) When the sticky side of the gel-pad appears dirty or worn, use your finger to gently wash the gel-pad with soap and water, as needed. Rinse with water and allow to air dry. The stickiness will return once dry. Do not fold while washing or drying.

\* Proper use, and gentle care of the gel-pad will be re-usable up to eight (8) days.

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been removed or when any dermatological conditions disrupt the skin (such as a rash or burn). In rare instances, silicone sheets may cause a rash on the skin. This condition may result from improper cleansing of the scar area where the gel-pad has been applied. Stop use and ask a doctor if product is applied properly and skin irritation still occurs. Persons with dermatological disorders should contact their doctor prior to using this product.

## **Product Label**

### **BLAINELABS**

NDC 63347- 150-01

MDA-K001608

US PATENT # 6,572,878

### **SCARCARE**

### **GEL-PAD MATRIX**

### **MEDICAL-GRADE SILICONE GEL MATRIX WITH VITAMIN E**

ONE (1) GEL-PAD - 3" x 5.5" (NON-STERILE)

ONE (1) E-SIL SOLUTION - 0.5 FL OZ (15 mL)

GUARANTEED TO FLATTEN AND FADE ANY SCAR  
OF ANY AGE, OR YOUR MONEY BACK\*!

MADE FROM THE FINEST MEDICAL-GRADE SILICONE MATRIX

EASY-TO-USE, COMFORTABLE TO WEAR  
WITH VITAMIN E

WASHABLE AND REUSABLE

CUT TO FIT THE SHAPE AND SIZE OF ANY SCAR

CUSTOM SIZES ALSO AVAILABLE

\*WHEN USED PROPERLY. PLEASE READ PRODUCT DIRECTIONS AND CONSULT A  
DOCTOR FOR APPROPRIATE USAGE.

SCARCARE GEL-PAD KIT™ IS BACKED BY BLAINE LABS®' 100 PERCENT, PATIENT-  
DIRECT,

MONEY-BACK GUARANTEE. CALL THE NUMBER BELOW FOR MORE INFORMATION.

QUESTIONS OR COMMENTS? CALL (800) 307-8818,

M-F, 8:00 AM-5:00 PM (PST)

MANUFACTURED BY:

BLAINE LABS, INC.

1 1 0 3 7 LOCKPORT PLACE

SANTA FE SPRINGS, CA 90670

BLAINELABS.COM

MADE IN THE U.S.A.

PLEASE RECYCLE! THIS  
PACKAGE IS MADE FROM  
RECYCLABLE MATERIALS.

04000-01-P-BOX

REV20190723

**DISPENSED EXCLUSIVELY BY PHYSICIANS  
NOT AUTHORIZED FOR INTERNET SALE**

Outer Box



Inner Foil



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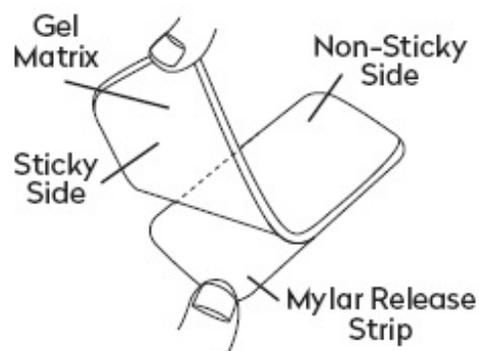
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## SCARCARE GEL-PAD KIT

elastomer, silicone, for scar management

### Product Information

<b>Product Type</b>	MEDICAL DEVICE	<b>Item Code (Source)</b>	NHRIC:63347-150
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:63347-150-01	1 in 1 BOX		
1		1 in 1 POUCH; Type 4: Device Coated/Impregnated/Otherwise Combined with Drug		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
premarket notification	K001608	10/01/2018	

**Labeler** - Blaine Labs Inc. (017314571)

**Registrant** - Blaine Labs Inc. (017314571)

**Establishment**

Name	Address	ID/FEI	Business Operations
Blaine Labs Inc.		017314571	manufacture

Revised: 7/2019

Blaine Labs Inc.