



11220 Grader Street · Suite 100
Dallas, Texas 75238
April 4, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 02N-0555 General and Plastic Surgery Devices; Classification of Silicone Sheeting

Dear Staff:

This letter is in response to the above Docket No. regarding the Classification of Silicone Sheeting.

Silimed is in complete support of your proposal to classify silicone sheeting intended to manage hyperproliferative (hypertrophic and keloid) scars on intact skin into Class I (general controls) and to exempt the device from premarket notification.

We have done a review of the history of silicone sheeting and its extensive application for treatment of hyperproliferative scars on intact skin. Silicones have definitely proven beneficial in a variety of forms as effective topical products including modifying scarring.¹⁻³² The attached bibliography supports treatment of hyperproliferative scars on intact skin.

Medical grade silicones have now been used in topical skin care products over the past 50 years. Medical grade silicone is the most biocompatible material available. The non reactivity of silicone prevents most other materials from interacting with it. They are in fact so non-reactive that they are used to establish the base line for all materials compatibility. It is used to coat all medical grade tubing, blood storage bottles, needles and syringes as it is one of the only materials that will not damage blood cells. Silicones have repeatedly demonstrated that they are versatile, non-toxic and beneficial as a topical product.

We appreciate the opportunity to provide comments regarding this issue. If you have any questions for us, please feel free to contact me.

Sincerely,

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PEER-REVIEWED LITERATURE

- ¹ Ahn S.T., Monafo WW., and Mustoe T.A. Topical Silicone Gel for the Prevention and Treatment of Hypertrophic Scarring. *Arch. Surg*, 126:499.
- ² Beranek JT. Silicone gel sheeting for the management of hypertrophic and keloid scars: the mechanism of its action. *Dermatol Surg* 1997 23:401-405.
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- ⁴ Carney SA, Cason CG, Gowar JP, Stevenson JH, McNee J, Groves ATR, Thomas SS, Hart NB, Auclair P. Cica-Care gel sheeting in the management of hypertrophic scarring. *Burns* 1994 20:163-167.
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- ⁷ Gibbons M, Zuker R, Brown M, Candlish S, Snider L, Zimmer P. Experience with silastic gel sheeting in pediatric scarring. *J Burn Care Rehab* 1994 15:69-73.
- ⁸ Katz BE. Silicone gel sheeting in scar therapy. *Therap Clinic* 1995 56:65-67.
- ⁹ Kavanagh GM, Page P, Hanna MM. Silicone gel treatment of extensive hypertrophic scarring following toxic epidermal necrolysis. *Br J Dermatol* 1994 130:540-541.
- ¹⁰ Knothe B, Merkel JL, Rawlings LSM, Hensell DO, Hughes WB. Alternative silicone gel sheeting application methods to improve burn scar outcome. ABSTRACT *J Burn Care Rehab* 22:S141.
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- ¹² Musgrave MA, Cartotto RC, Fish JS, Gomez M, Umraw N. The effect of silicone gel sheets on perfusion of hypertrophic burn scars. ABSTRACT. *J Burn Care Rehab* 22:S45.
- ¹³ Mustoe TA, Cooter RD, Gold MH, Hobbs FD, Ramelet AA, Shakespeare PG, Stella M, Teot L, Wood FM, Ziegler UE; International Advisory Panel on Scar Management. International clinical recommendations on scar management. *Plast Reconstr Surg* 2002. Aug; 110(2): 560-71.

ADDITIONAL PUBLICATIONS

- ¹⁴ Luria LW, MD. A Discussion of the Role of Silicones in Topical Therapy on the Skin. *Skin Wisdom* white paper.
- ¹⁵ Dockery G, Nilson R. Treatment of Hypertrophic and Keloid Scars with Silastic Gel Sheeting. *The Journal of Foot and Ankle Surgery*, 33: 110-119, 1994.
- ¹⁶ Ahn ST, Monafo WW and Mustoe TA. Topical Silicone Gel: A New Treatment for Hypertrophic Scars. *Surgery*, 106:781-787. 1989.
- ¹⁷ Gold M.H. A Controlled Clinical Trial of Topical Silicone Gel Sheeting in the Treatment of Hypertrophic Scars and Keloids, *Journal of the American Academy of Dermatology*, 30:506-507. 1994.
- ¹⁸ Gold M.H. Topical Silicone Gel Sheeting in the Treatment of Hypertrophic Scars and Keloids. *Journal of the American Academy of Dermatology*, 11:912-916. 1993.
- ¹⁹ Quinn KJ. Silicone Gel Scar Treatment. Controlled Therapeutics (Scotland) Ltd., East Kilbridge. *Burns Include Therm Inj* (England) OCT 1987, 13 SUPPL S33 40.
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- ²¹ Mercer NSG. Silicone Gel in the Treatment of Keloid scars. *British Journal Plastic Surgery* (U. Kingdom) 1989, 42/1. 83,87.
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- ²⁴ McNee J. The Use of Silicone Gel in the Control of Hypertrophic Scarring. *Physiotherapy* (United Kingdom), 1990, 76/4. 194-197.
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- ²⁷ Sproat Janet E et al. Hypertrophic Sternal Scars: Silicone Gel Sheet Versus Kenalog Injection Treatment. *Plastic and Reconstructive Surgery*, (1991) Vol. 90, No. 6.
- ²⁸ Hirshowitz B et al. Silicone Occlusive Sheeting (SOS) in the Management of Hypertrophic Scarring, Including the Possible Mode of Action of Silicone. (1993). *European Journal of Plastic Surgery*. 16:5-9.

ADDITIONAL PUBLICATIONS (cont'd)

- ²⁹ Gold JH. A Controlled Clinical Trial of Topical Silicone Gel Sheeting in the Treatment of Hypertrophic Scars and Keloids. *Journal of the American Academy of Dermatology*. 1993. 30(3): 506-507.
- ³⁰ Sawada Y, Sone K. Hydration and Occlusion Treatment for Hypertrophic Scars and Keloids. *British Journal of Plastic Surgery*. 1992. 45:599-603.
- ³¹ Hirshowitz B, Ullmann Y, Vilenski A, and Peled IJ. Silicone occlusive sheeting (SOS) in the management of hypertrophic scarring, including the possible mode of action of silicone, by static electricity. *Eur. J. Plast. Surg.* 16: 5, 1993.
- ³² Gold MH. Topical silicone gel sheeting in the treatment of hypertrophic scars and keloids. A dermatologic experience. *J Dermatol Surg Oncol* 1993 Oct; 19(10):912-6.