

MIRADRY SYSTEM UPDATE

23 December 2015

Dear Miradry User,

I, Servicom Medical (Singapore) Pte Ltd, the Registrant of the medical device(s) Miramar MiraDry System, *on behalf of Miramar Labs Inc*, the Product Owner of the medical device, would like to inform you of some new important safety information about your MiraDry System.

Recently, we became aware that some clinics were using non-recommended substances to provide lubrication on the skin prior to placing the miraDry Handpiece; specifically they were using IPL Laser coupling gel. In some cases, the gel was thick enough that it prevented the cooling plate in the miraDry Handpiece from correctly contacting and cooling the skin. Some minor blisters occurred. It is possible that more severe burns could occur.

Please remember that the only recommended substances to use are K-Y® jelly or K-Y liquid.

To clarify this point, Miramar Labs Inc. have added a new warning in the labelling:

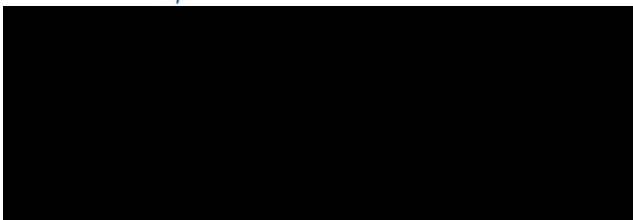
- **DO NOT use lubricants other than the recommended lubricants (KY Jelly or KY liquid). Use of other substances such as ultrasound gel or IPL laser coupling gel can reduce the effectiveness of the surface cooling, leading to blisters or burns.**

Also remember that only a very thin sheen of K-Y jelly or K-Y liquid is required.

We have included an updated copy of the MD4000-MC User Manual (LB0193.D) with the new warning included (see page 14). Please destroy the older copy of the manual.

We thank you for your continued business. For further enquiries on this notice, please contact us at (+65) 62248701 or email inquiry@servicom.com.sg.

Best regards



Asst. Manager, Admin & Marketing Support

Servicom Medical (Singapore) Pte Ltd

CC: Mai-Iy Wilcox, Regulatory Project Manager

Miramar Labs Inc