



2611 Commerce Way
Vista, CA 92081
888-886-5290
www.breg.com



Urgent: Medical Device Recall Notification

Dear Valued Customer:

This is to inform you of a product recall involving:

Power Supply Accessory (model no. AD-0660G) used with Polar Care® Kodiak® cold therapy unit

Power Supply Lot Codes Affected: 3508, 3908, 4308, and 4808 (refer to Photograph 3 for location of lot code)

REASON FOR RECALL

This recall has been initiated due to confirmed reports of failures of the Power Supply accessory. The Power Supply is the accessory device that is plugged into a standard electrical wall socket and provides low voltage power to the Kodiak unit. A small percentage of the Power Supplies in specific manufacturing lots have short circuited at the electrical outlet upon the initial use of the Power Supply, causing the circuit breaker for the specific electrical outlet to trip. Use of the Power Supply has the potential to result in shock, fire or loss of power. There are no reports of injury arising from this issue. There are no issues with the Kodiak® cold therapy unit itself, nor will a defective Power Supply damage the Kodiak.

The recall affects Power Supplies shipped with Kodiak cold therapy units between November, 2008 and June 10, 2009. The suspect Power Supplies are used only with Kodiak cold therapy units, not other Polar Care models (PC300 and PC500).

If a Power Supply from the suspect manufacturing lots has already been used and not caused a short circuit, the Power Supply will continue to operate normally and does not need to be quarantined.

HOW TO IDENTIFY RECALLED PRODUCT

Immediately open all unused Kodiak cold therapy units and inspect the lot code of the Power Supply included with the Kodiak unit (reference Photographs 1 & 2).

Photograph 1



Photograph 2



Power Supply Accessory Box

Open the white Power Supply Accessory Box and locate the Power Supply lot code. The Power Supply lot code can be found on the Power Supply in the lower right hand corner of the label (reference Photograph 3).

Photograph 3



If the lot code on the Power Supply is **3508, 3908, 4308, or 4808**, quarantine the Power Supply and do not use. Please do the following:

- Dispose of all the Power Supplies with a suspect lot code **3508, 3908, 4308, or 4808** by cutting the cord of the unplugged transformer with scissors and discarding in your electrical waste stream. You can call Breg Customer Relations at 1-800-321-0607 to receive replacement Power Supplies.



2611 Commerce Way
Vista, CA 92081
888-886-5290
www.breg.com



Please complete and return the enclosed return response form as soon as possible. Breg expects this action initiated on June 18, 2009 to be completed by July 30, 2009.

FOR SUB ACCOUNTS

If you have further distributed the Kodiak cold therapy unit, please notify Breg of their contact information and the quantity of units you have sent to them. Breg will contact them directly and provide them with copies of this recall notice, the return response form and a stamped envelope for the return of the form.

If you prefer to notify your customers yourself, your notification to your customers must include a copy of this recall notification and the attached return response form. Please notify Breg if this is the case for recordkeeping. Copies of these forms are available from Breg Customer Relations at 1-800-321-0607 or on Breg's website, www.breg.com.

CONTACT INFORMATION

To assure the safety of users, please take immediate action to identify and quarantine the Power Supply as instructed above. We sincerely apologize for the inconvenience that may be caused by complying with this action. If you should have any questions regarding this communication or have any adverse reports related to a defective Power Supply, please contact Breg Customer Relations at 1-800-321-0607. An FAQ document is included with this notification to answer additional questions you may have with the recall process. A copy of this recall notification and FAQ can be found on Breg's website, www.breg.com.

The US Food & Drug Administration has been notified of this communication.

Sincerely,

Kathleen Barber
Vice President, QA/RA
Breg, Inc.
2611 Commerce Way
Vista, CA 92081