Life-Threatening Injuries Associated with the ShoulderFlex Massager

U.S. Food & Drug Administration

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Audience:

- Consumers who have purchased or use the Shoulder*Flex* Massager
- Businesses that sell the Shoulder*Flex* Massager
- Health care professionals who recommend the Shoulder*Flex* Massager to their patients

Medical Specialties: Physical Therapy, Orthopedics, Physical Medicine

Device:

The Shoulder*Flex* Massager, distributed by King International in Beaverton, OR, is a personal massage device designed for home use to provide deep tissue massage to the neck, shoulder and back while the user lies on a flat surface. It consists of a massage unit that sits beneath the neck, a handheld controller, a memory foam pillow and a machine-washable sleeve. The device contains a rotating bar with removable massage “fingers” that may be adjusted by the user to customize the massage area and depth.

Purpose:

The purpose of this Safety Communication is to urge consumers and health care professionals to stop using the Shoulder*Flex* Massager because of the risk of strangulation or other serious injury.

Summary of Problem and Scope:

The FDA is aware of reports to the Consumer Product Safety Commission of one death and one near-strangulation associated with the Shoulder*Flex* Massager. These incidents occurred when a necklace and clothing became caught in a piece of the device that rotates during use. The FDA is aware of two other reports of incidents

involving clothing and hair becoming caught in the device.

The FDA is concerned that the Shoulder*Flex* Massager presents serious health risks. Hair, clothing, and jewelry can become entangled in the massage device and cause serious injury or death.

King International has distributed 11,934 devices since Oct. 18, 2003. The devices were sold at various stores and online retailers in the United States.

Recommendations for Consumers:

- Do NOT use the Shoulder*Flex* massager.
- Dispose of the device components separately so that the massager cannot be reassembled and used:
    - Dispose of the power supply separately.
    - Remove the massage fingers and dispose of them separately.

Recommendations for Health Care Providers:

- Advise your patients NOT to use the Shoulder*Flex* massager.

FDA Activities:

- The FDA is evaluating King International's plan for recall of the Shoulder*Flex* Massager, which may lead to additional action or communication by the FDA or King International.

Reporting Problems to the FDA:

Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices. If you suspect a problem with the Shoulder*Flex* Massager, we encourage you to file a voluntary report through MedWatch, the FDA Safety Information and Adverse Event Reporting program [1].

Contact Information:

If you have questions about this communication, please contact the Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at DSMICA@FDA.HHS.GOV [2], 800-638-2041 or 301-796-7100.

This document reflects the FDA's current analysis of available information, in keeping with our commitment to inform the public about ongoing safety reviews of medical devices

SOURCE [3]

Source URL (retrieved on *03/07/2014 - 11:07am*):
http://www.mdtmag.com/news/2011/08/life-threatening-injuries-associated-shoulderflex-massager

Links:
[1] http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm
[2] mailto://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/DSMICA@FDA.HHS.GOV
[3] http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm269721.htm