

ShoulderFlex Massager by King International: Safety Communication - Risk of Strangulation

AUDIENCE: Physical Medicine, Orthopedics, Consumer

ISSUE: FDA notified health professionals and consumers of serious health risks posed by the ShoulderFlex Massager. FDA is aware of reports to the Consumer Product Safety Commission of one death and one near-strangulation associated with the ShoulderFlex Massager. These incidents occurred when a necklace and clothing became caught in a piece of the device that rotates during use. Two other reports involved clothing and hair became caught in the device.

BACKGROUND: The ShoulderFlex Massager, distributed by King International, 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. 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.

RECOMMENDATION: Do not use or recommend use of the ShoulderFlex Massager. Dispose of the device components separately so that the massager cannot be reassembled and used. The FDA is evaluating King International's plan for recall of the ShoulderFlex Massager, which may lead to additional action or communication by the FDA or King International.

Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with this product. Healthcare professionals and patients are encouraged to report adverse events or side effects to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm [1]
- [Download form](#) [2] or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

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<http://www.mdtmag.com/news/2011/08/shoulderflex-massager-king-international-safety-communication-risk-strangulation>

Links:

[1] <http://www.fda.gov/MedWatch/report.htm>

[2] <http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm>

[3] <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm269721.htm>

[4] <http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm269765.htm>

[5] <http://www.ecnmag.com/News/Feeds/2011/08/applications-medical-electronics-shoulderflex-massager-by-king-international-safety/>