

SPINE SAFETY CAUTIONARY NOTICE:

Information for Healthcare Professionals: ShoulderFlex Massager: Warning-Risk of Strangulation

SOURCE: FDA MedWatch

AUDIENCE: Consumers

ISSUE: FDA is warning consumers again not to use the ShoulderFlex Massager, imported by King International and sold by various companies, due to serious potential health risks. Hair, clothing or jewelry can become entangled in the ShoulderFlex Massager and cause serious injury or even death from strangulation. There have been reports of one death and one near death, due to strangulation, associated with the use of this device.

BACKGROUND: The ShoulderFlex Massager is a personal massage device sold in retail stores, catalogs and over the Internet. It is intended to provide users with a deep tissue massage to the neck, shoulders and back area while lying down.

King International recalled the ShoulderFlex Massager on Aug. 31, 2011; however, during a recent compliance audit, the FDA found that the company has gone out of business. King International has not followed through with recall procedures; the 800 number established by the firm for this recall is no longer in service; and many of the companies that sell this device are not aware of the recall or did not properly notify customers who purchased the massager.

RECOMMENDATIONS: The ShoulderFlex Massager poses serious risks. Consumers should stop using this device, health care providers should not recommend it to their patients and businesses should stop distributing and selling the device," said Steve Silverman, director of the Office of Compliance in the FDA's Center for Devices and Radiological Health.

The FDA recommends that customers and consignees safely dispose of the ShoulderFlex Massagers so that the device cannot be used. The massage fingers should be removed and disposed of separately from the device; the power supply should be disposed of separately, as well.

Read the MedWatch safety alert, including links to the FDA Safety Communication and News Release, at:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm284510.htm>

The North American Spine Society is committed to quality patient care through promotion of patient safety and prevention of medical errors. NASS monitors a variety of

government and other resources for patient safety-related notices that may be useful to our members. Information from these notices is also archived on the NASS website at <http://www.spine.org/Pages/PracticePolicy/ClinicalCare/SpineSafetyAlerts/Default.aspx>. This information is provided as a service for information and education only.