RÉPUBLICQUE LIBANAISE
MINISTÈRE DE LA SANTÉ PUBLIQUE
Le Directeur Général

الموضوع: إشعار بمتاحة جهاز طبي Canes, Adjustable-Length, Offset-Handle, Offset and Standard Crook Canes

FDA

بناء على التقرير الصادر عن وكالة ال

الذي يحذر فيه من استعمال الصنف المذكور أعلاه بسبب وجود خلل في عمله مما يعرض المريض

إلى الخطر، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطًا:

- التقرير الصادر عن وكالة ال

البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

مدير عام الصحة
د. وليد عمار
Medicare & Radiation Emitting Device Recalls

U.S. Food & Drug Administration

510(K) Registration & Listing | Adverse Events | Recalls | PMA | Classification | Standards

CFR Title 21 (Radiation Emitting Products) | XRay Assemby | Medical Reports | ICLX | TPLC

New Search

Class 2 Recall Cane

Date Posted
December 18, 2012

Recall Number
Z-0556-2013

Product
Invacare Height Adjustable (walking) Canes, Model Numbers: 8916, 8917, and 40918-6. The device is packaged six (6) canes per shipping carton. The cane is used as an aid in walking or ambulation.

Code Information
The Lot Codes subject to recall are: PW111201, PW120201, PW120101, PW120301, and PW120401

Recalling Firm/Manufacturer
Invacare Corporation
1200 Taylor St
Elyria, Ohio 44035-6248

For Additional Information Contact
Sean Kharche
440-329-6595

Reason for Recall
Following their receipt of several customer complaints, Invacare recalled their height adjustable walking canes. The device was recalled from distribution based on reports indicating that there is a possibility that the button which holds the cane at the desired height, may suddenly and unexpectedly compress, causing the cane to collapse and cause possible injury to the user.

Action
The firm, Invacare, sent an "URGENT MEDICAL DEVICE RECALL (Removal)" letter dated November 6, 2012 to its customers. The letter describes the product, problem and actions to be taken. The customers were instructed to examine their existing stock using the enclosed detailed "Product Tracking Sheet" and quarantine any affected canes; Acknowledge receipt and understanding of the urgent recall notice and indicate the number of canes remaining in inventory on the enclosed, "Provider Response Card". Fax the completed Provider Response Card to Invacare Regulatory Affairs at: 1-844-326-3544; disassemble each cane and discard both pieces in the trash; (Disassembly instructions are also provided); and lastly, contact Invacare Customer Service at 1-800-668-2337, Monday - Friday, 8 a.m. - 8 p.m. EST, to order replacement merchandise at no charge. If you have any questions concerning these instructions, contact Invacare Customer Service at 1-800-668-2337, Monday - Friday, 8 a.m. - 6 p.m. ET.

Quantity in Commerce
38,280 canes

Distribution
Worldwide distribution: USA (nationwide) including states of: AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN KS, KY, LA, MA, MD ME, MI, MN, MO, MS, MT, NC, ND, NE, NJ, NM, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, and WY; and countries of: Australia, Puerto Rico, and Taiwan Province of China.

Links on this page:
4. http://www.fda.gov/MedicalDevices/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
7. ../cPMA/pmn.cfm
8. ../dRI/rl.cfm
9. ../dMAUDE/TextSearch.cfm
10. ../dRES/res.cfm
11. ../cPMA/pma.cfm
12. ../cPCD/classification.cfm

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=114753
1/15/2013