



رقم المحفوظات: ٥٧٤٥
رقم الصادر: ١٣/١/٢٧٤٧
بيروت، في: ٢٢ كانون الثاني ٢٠١٢

جانب نقيب المستشفيات، الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي

Canes, Adjustable-Length, Offset-Handle, Offset and Standard Crook Canes

الجهاز المعني بالمتابعة:

- Canes, Adjustable-Length, Offset-Handle, Offset and Standard Crook Canes
- Trade Mark: Invacare Corporation
- Local Representative:

بناء على التقرير الصادر عن وكالة ال FDA

الذي يحذر فيه من استعمال الصنف المذكور أعلاه بسبب وجود خلل في عمله مما يعرض المريض الى الخطر، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطاً:

- التقرير الصادر عن وكالة ال FDA

يبلغ:

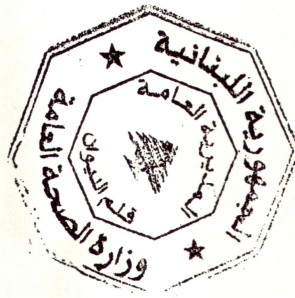
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- المستشفيات الحكومية

- المحفوظات

مدير عام الصحة

د. وليد عمار



وثيقة مطابقة للأصل
تحتوي على ٢٢ كانون الثاني ٢٠١٢
رئيس قسم البروتين والتطعيمات
العلاقات الصحية والادوية
تسليم



U.S. Food & Drug Administration

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⁶ 510(k)⁷Registration & Listing⁸Adverse Events⁹Recalls¹⁰PMA¹¹Classification¹²Standards¹³ CFR Title 21¹⁴Radiation-Emitting Products¹⁵X-Ray Assembler¹⁶Medsun Reports¹⁷CLIA¹⁸ITPLC¹⁹

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**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
Consumer Instructions	Contact the recalling firm for information
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- 440-326-3544; 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, PR, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, and WY; and countries of: Australia, Puerto Rico, and Taiwan Province of China.

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