جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي
Breathing Circuit, Universal Flex 2

المعدة للمتاحة:

- Breathing Circuit, Universal Flex 2
- Trade Mark: King Systems Corp.
- Local Representative:

FDA بناء على التقرير الصادر عن وكالة ال
والذي يشير إلى وجود خطأ في محتوى الملصق للصنف المذكور أعلاه مما قد يؤثر على سلامة
المريض، نرجو منكم تعميم هذا النشرة على جميع المستشفيات المعنية.

مرفق ربطاً:

tقرير الصادر عن وكالة ال

دليل:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

معيدة عام الصحة
وليد عمار

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**Medical & Radiation Emitting Device Recalls**

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**Date Posted**  
September 27, 2013

**Recall Number**  
Z-2272-2013

**Product**  
Universal Flex2 Breathing Circuit Class I 510(k) Exempt An anesthesia breathing circuit is a device that is intended to administer medical gases to a patient during anesthesia. It provides both an inhalation and exhalation route and may include a connector, adaptor, and Y- piece.

**Code Information**  
Part Number DF4110-61 Lot Number I063N

**Recalling Firm/Manufacturer**  
King Systems Corp.  
15011 Herriman Blvd  
Noblesville, Indiana 46060-4253

**Consumer Instructions**  
Contact the recalling firm for information

**Reason for Recall**  
King Systems received a customer complaint indicating that the customer had ordered a breathing circuit with a Latex breathing bag. The product they received contained a Latex breathing bag, but was labeled as non-latex.

**Action**  
Ambu, Inc. sent a letter dated June 24, 2013, informing the customer that they have decided to discontinue the manufacture and sales of the King Systems latex breathing bags and to convert all customers to their King Systems latex-free breathing bags. The customer was advised to adjust their inventories accordingly and transition to the latex free part number as their inventory levels reach their minimums. For questions the customer was advised to call 317-403-8877. For questions regarding this recall call 317-776-1823.

**Quantity in Commerce**  
1 case; 40 units

**Distribution**  
Nationwide Distribution - NE only.

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Links on this page:

4. http://www.fda.gov/MedicalDevices/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
7. /scripts/cdrh/cfdocs/cfPMN/pmnm.cfm
8. /scripts/cdrh/cfdocs/cfrl/r1.cfm
9. /scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm
10. /scripts/cdrh/cfdocs/cfRES/res.cfm
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13. /scripts/cdrh/cfdocs/cfStandards/search.cfm
14. /scripts/cdrh/cfdocs/cfTPLC/inspect.cfm
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16. /scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm
17. /scripts/cdrh/cfdocs/cfAssem/assembler.cfm
18. /scripts/cdrh/cfdocs/Medsun/searchReportText.cfm
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