



رقم المحفوظات: ٥٩/٢٥  
رقم الصادر: ١٤٠٧٥/١١/١٤  
بيروت، في:

٢٤ نيسان ٢٠١٣

جانب نقيب الاطباء في لبنان/بيروت

**الموضوع:** إشعار بمتابعة جهاز طبي  
Patient lubricant, OTO EASE

**الجهاز المعنى بالمتابعة:**

- Patient lubricant, OTO EASE
- Trade Mark: Westone Laboratories, Inc
- Local Representative:

بناء على التقرير الصادر عن وكالة ال FDA  
الذي يحذر فيه من استعمال الصنف المذكور أعلاه نظراً لاحتمال اعرض المريض الى مضاعفات  
جراء استعماله هذا الصنف، نرجو منكم متابعة هذا الموضوع مع الاطباء الاختصاصيين والعمل  
بموجب التوصية الصادرة.

**مرفق ربطاً:**

- التقرير الصادر عن وكالة ال FDA

**يبلغ:**

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- مصلحة الصيدله
- المحفوظات



U.S. Food & Drug Administration

Medical & Radiation Emitting Device Recalls

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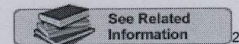


510(k)<sup>7</sup>|Registration & Listing<sup>8</sup>|Adverse Events<sup>9</sup>|Recalls<sup>10</sup>|PMA<sup>11</sup>|Classification<sup>12</sup>|Standards<sup>13</sup>  
 CFR Title 21<sup>14</sup>|Radiation-Emitting Products<sup>15</sup>|X-Ray Assembler<sup>16</sup>|Medsun Reports<sup>17</sup>|CLIA<sup>18</sup>|TPLC<sup>19</sup>

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**Class 2 Recall  
OTO EASE**



<b>Date Posted</b>	July 20, 2012
<b>Recall Number</b>	Z-2058-2012
<b>Product</b>	Oto Ease by Westone, labeled as a bacteria free, greaseless lubricant. Sold in 0.5 oz consumer sized semi transparent flexible plastic bottles. Product Usage: The product is used as a patient lubricant which eases insertion of earmolds and hearing instruments such as hearing aids.
<b>Code Information</b>	Individual products are not identified with lot numbers. There may be lot numbers on the bottom of the bulk packaging of a twelve pack of individual products but the end user may not be aware of a lot number for the specific vial. No expiry is applied to the finished products.
<b>Recalling Firm/Manufacturer</b>	Westone Laboratories, Inc. 2235 Executive Cir Colorado Springs, Colorado 80906-4137
<b>For Additional Information Contact</b>	Ms. Linda Folk 800-357-3240
<b>Reason for Recall</b>	Westone is recalling all Oto Ease ear lubricant in all packaging configurations and sizes due to potential microbial contamination of the product.
<b>Action</b>	Westone Laboratories sent an Urgent Recall letter and Press Release to distributors and customers. The letter identified the affected product, problem and actions to be taken. Customers were instructed to immediately examine their inventory, quarantine product subject to recall and discard or return the product to Westone. In addition, if the affected product have been further distributed please identify your customers and notify them at once of this product recall. Consumers with questions may contact Westone Laboratories at 1-800-357-3240 between the hours of 8:00am and 5:00pm MST or email at otoaeserecall@westone.com.
<b>Quantity in Commerce</b>	Approx 100k sold annually x 15 years.
<b>Distribution</b>	Worldwide Distribution - US (nationwide) and to countries of: Australia, Belgium, Brazil, Canada, France, Germany, Greece, Hong Kong, Ireland, Japan, Korea, Mexico, Panama, Philippines, Russian Federation, and Singapore, Sweden, Switzerland and Thailand and United Kingdom.

Links on this page:

1. <http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdomain>
2. <http://www.addthis.com/bookmark.php>
3. <http://www.fda.gov/default.htm>
4. <http://www.fda.gov/MedicalDevices/default.htm>
5. <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm>
6. </scripts/cdrh/devicesatfda/index.cfm>
7. [../cfPMN/pmn.cfm](..cfPMN/pmn.cfm)
8. [../cfRRL/rl.cfm](..cfRRL/rl.cfm)
9. [../cfMAUDE/TextSearch.cfm](..cfMAUDE/TextSearch.cfm)
10. [../cfRES/res.cfm](..cfRES/res.cfm)
11. [../cfPMA/pma.cfm](..cfPMA/pma.cfm)
12. [../cfPCD/classification.cfm](..cfPCD/classification.cfm)
13. [../cfStandards/search.cfm](..cfStandards/search.cfm)
14. [../cfCFR/CFRSearch.cfm](..cfCFR/CFRSearch.cfm)
15. [../cfPCD\\_RH/classification.cfm](..cfPCD_RH/classification.cfm)
16. [../cfAssem/assembler.cfm](..cfAssem/assembler.cfm)