REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH
The Director General

الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ٢٧/٥٠
رقم الصادر: ١٢/١/٢٢٩٦
بيروت، في: ٣ تشرين الأول ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي مغروس

Perfusion systems, Custom Perfusion System with Trillium BioSurface
(a polymer containing non-leaching heparin)

الجهاز المعني بالمتابعة:

- Perfusion systems, Custom Perfusion System with Trillium BioSurface (a polymer containing non-leaching heparin)
- Trade Mark: Medtronic Inc Cardiac Rhythm Disease Management Div
- Local Representative: Intermedic/ Prime Medical/ Tamer Frères

نرجو الاطلاع على التقارير الصادرة عن وكالة ال FDA بخصوص بعض الاجهزة العائدة لشركة Medtronic والتي في بعض محتوياتها هناك أجزاء تم سحبها من السوق من قبل شركة Edwards LifeSciences.

مرفق ربطاً:

- التقارير الصادرة عن وكالة ال FDA

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

مدير عام الصحة
وليد عمار

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Class 2 Recall
Medtronic Custom Perfusion System with Trillium BioSurface

See Related Information[21]

Date Posted	August 27, 2013
Recall Number	Z-2106-2013
Product	Medtronic Custom Perfusion System with Trillium BioSurface (a polymer containing non-leaching heparin). Model Numbers: TL4X17R8, TL5D01R, TL5D02R, TL5D02R3, TL5D02R5, and TL6A65R7. Sterilized by Ethylene Oxide. Do no Reuse. Product Usage: Usage: This product is indicated for use in the extracorporeal circuit during cardiopulmonary surgery.
Code Information	Lot: 11646955, 11669565, 11672312, 11713195, 11724203, 11749965, 11750036, 11787651, 11799982, 11822299, 11822308, 11878727, 11892549, 11908754, 11977672, 11982378, 11990416, 12019895, 12033691, 12075354, 12089790, 12096228, 12105079, 12111165, 12139696, 12155284, 12172596, 12178118, 12182890, 12191658, 12204951, 12204958, 12221793, 12227544, 12233759, 12236465, 12292171, 12323842, 12385431, 12399363, 12403798, 206110970, 206141990, 206142625, 206388507, 206476850, 206618547, 206649829, 206720637, 206758173, 206758215, 206851679, 206919848, 207003064, and 207030516.
Recalling Firm/ Manufacturer	Medtronic Inc. Cardiac Rhythm Disease Management 8200 Coral Sea St NE Saint Paul, Minnesota 55112-4391
Consumer Instructions	Contact the recalling firm for information
Reason for Recall	Medtronic was notified that Edwards Lifesciences has initiated a product recall for the Rigid Suction Wand, model S099B. The Wands are included within certain Perfusion Tubing Packs that are manufactured and distributed by Medtronic.
Action	Metronic sent an "Urgent Field Safety Notice" letter dated July, 2013 to all affected customers. The letter described the affected product, problem and actions to be taken by User. Customerss were advised to remove and destroy all affected products. At the same time customers were informed that replacement products can be ordered by contacting their Medtronic representative. Customers were requested to complete the Customer Confirmation Certificate and fax it to Medtronic at 651-367-0612. For any questions they can contact Medtronic Lifeline Technical Services at 877-526-7890 or their Medtronic representative.
Quantity in Commerce	758
Distribution	Worldwide Distribution - USA Nationwide CA, IL, LA, MI and the country of CANADA

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Class 2 Recall
Medtronic Custom Perfusion System

See Related Information[21]

Date Posted	August 27, 2013
Recall Number	Z-2105-2013
Product	Medtronic Custom Perfusion System with Carmeda BioActive Surface. Model Numbers: CB1D82R12 and CB5N73R7. Sterilized by Ethylene Oxide, Do no Reuse. Product Usage: Usage: This product is indicated for use in the extracorporeal circuit during cardiopulmonary surgery.
Code Information	Lot: 12096267, 12105099, 12139669, 12166396, 12198322, 12309957, 12416020, 206119223, 206120062, 206180336, 206233199, 206384131, 206496179, 206649807, 206699258, 206758209, 206851971, 206864385, 206919887, 207003072, and 207071455.
Recalling Firm/ Manufacturer	Medtronic Inc. Cardiac Rhythm Disease Management 8200 Coral Sea St NE Saint Paul, Minnesota 55112-4391
Consumer Instructions	Contact the recalling firm for information
Reason for Recall	Medtronic was notified that Edwards Lifesciences has initiated a product recall for the Rigid Suction Wand, model S099B. The Wands are included within certain Perfusion Tubing Packs that are manufactured and distributed by Medtronic.
Action	Metronic sent an "Urgent Field Safety Notice" letter dated July, 2013 to all affected customers. The letter described the affected product, problem and actions to be taken by User. Customerss were advised to remove and destroy all affected products. At the same time customers were informed that replacement products can be ordered by contacting their Medtronic representative. Customers were requested to complete the Customer Confirmation Certificate and fax it to Medtronic at 651-367-0612. For any questions they can contact Medtronic Lifeline Technical Services at 877-526-7890 or their Medtronic representative.
Quantity in Commerce	217
Distribution	Worldwide Distribution - USA Nationwide CA, IL, LA, MI and the country of CANADA

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Class 2 Recall
Medtronic Custom Perfusion System

See Related Information[21]

Date Posted	August 27, 2013
Recall Number	Z-2104-2013
Product	Medtronic Custom Perfusion System. Model Numbers: 1D80R8, 1E34R1, 1F75R1, 1G49R2, 1G75R1, 1P07R8, 1P91R4, 5B15R11, and 5P51R9. Sterilized by Ethylene Oxide, Do no Reuse. Product Usage: This product is indicated for use in the extracorporeal circuit during cardiopulmonary surgery.
Code Information	Lot: 11110924, 11178379, 11281864, 11341336, 11346822, 11357000, 11386060, 11387461, 11412023, 11448066, 11501190, 11506220, 11506223, 11528161, 11552139, 11577959, 11600953, 11623004, 11664710, 11672387, 11718344, 11719034, 11736936, 11816427, 11839402, 11843611, 11869817, 11896503, 11930457, 11995799, 11995883, 12000022, 12024743, 12024776, 12075385, 12093515, 12096289, 12166420, 12249817, 12264661, 12309956, 12374421, 12411720, 206168235, 206219230, 206325047, 206388493, 206476804, 206581948, 206597875, 206689812, 206709358, 206720707, 206851972, 206852054, 206864691, 206904419, 206991490, 207003054, 207100337, and 207121513.
Recalling Firm/ Manufacturer	Medtronic Inc. Cardiac Rhythm Disease Management 8200 Coral Sea St NE Saint Paul, Minnesota 55112-4391
Consumer Instructions	Contact the recalling firm for information
Reason for Recall	Medtronic was notified that Edwards Lifesciences has initiated a product recall for the Rigid Suction Wand, model S099B. The Wands are included within certain Perfusion Tubing Packs that are manufactured and distributed by Medtronic.
Action	Metronic sent an "Urgent Field Safety Notice" letter dated July, 2013 to all affected customers. The letter described the affected product, problem and actions to be taken by User. Customerss were advised to remove and destroy all affected products. At the same time customers were informed that replacement products can be ordered by contacting their Medtronic representative. Customers were requested to complete the Customer Confirmation Certificate and fax it to Medtronic at 651-367-0612. For any questions they can contact Medtronic Lifeline Technical Services at 877-526-7890 or their Medtronic representative.
Quantity in Commerce	13223
Distribution	Worldwide Distribution - USA Nationwide CA, IL, LA, MI and the country of CANADA

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