جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي مغروس Ultrafill DBM, Donated Human Tissue Allograft

الجهاز المعني بالتتابع:
- Ultrafill DBM, Donated Human Tissue Allograft
- Trade Mark: Surgical Tissue Network Inc.
- Local Representative:

FDA بناء على التقرير الصادر عن وكالة الالذي يحذر فيه من استخدام الاليف المذكور أعلاه بسبب وجود خطا في التصنيع، نرجو منكم تعميم هذه النشرة على جميع المستشفى المعنية.

مرفق ربط:
- التقرير الصادر عن وكالة الFDA

بلاغ:
- دائرة البرامج والمشاريع المستشفى الحكومية
- المحفظة

مدير عام الصحة

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ليدي عمار
Medical & Radiation Emitting Device Recalls

- New Search

Class 2 Recall
Ultrafill DBM

Date Posted: January 07, 2013
Recall Number: Z-0651-2013
Product: Ultrafill DBM labeled in part: "&amp; amp; amp;amp;amp;amp;amp;amp;amp;amp;amp;quot;TISSUENET"&amp;quot; Sterilized by T106 (r) Description: Ultrafill DBM Size: 1cc Product Code: RT53001 DONATED Human Tissue Allograft SINGLE PATIENT USE ONLY FOR INTERNATIONAL USE ONLY See Package Insert for Additional Information"&amp;amp;amp;amp;amp;amp;amp;amp;amp;quot; TissueNet's Porcine DBM product line is used as a bone void filler

Recalling Firm/Manufacturer: Surgical Tissue Network, Inc.
7022 TPC Dr Ste 400
Orlando, Florida 32822-5140
For Additional Information Contact: Gene S. Elliot
407-380-2424 Ext. 230
Reason for Recall: Surgical Tissue Network Inc., TissueNet Inc. recalled their UltraFill DBM Putty-Porcine (1 cc, 5 cc, 10 cc) because products may contain trace amounts of 316L Stainless Steel particulates.
Action: Surgical Tissue Network sent a Notification of Voluntary Tissue Recall dated March 22, 2012, to all affected customers. The firm issued an additional notification letter on August 30, 2012. The letter identified the product, the problem, and action to be taken by the customer. Consignees were asked to return all listed products that remain in inventory. If the product was further distributed, they were asked to forward the recall information to their customers. Customers were instructed to contact TissueNet's Customer Service Department at 800-465-8800 x283 to coordinate return/replacement of the affected product. Customers with questions were instructed to call 800-465-8800 x230. For questions regarding this recall call 407-380-2424.
Quantity in Commerce: 25 units
Distribution: Worldwide Distribution including Turkey, Greece, & Mexico

Links on this page:
4. http://www.fda.gov/MedicalDevices/default.htm
6. scripts/cdrh/devicesatfda/index.cfm
7. /cFPMN/pmn.cfm
8. /cFRL/ri.cfm
9. /cFMAUNEsTextSearch.cfm
10. /cFRES/res.cfm
11. /cFPMAd/pma.cfm
12. /cFPCD/classification.cfm
13. /cFStandardssearch.cfm
14. /cCFRCFRSearch.cfm
15. /cFPCD_RH/classification.cfm

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfdocs/cfres/res.cfm?id=113067
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Medical & Radiation Emitting Device Recalls

U.S. Food & Drug Administration

Medical & Radiation Emitting Device Recalls

FDA Home > Medical Devices > Databases

New Search

Class 2 Recall
UltraFill DBM

Date Posted
January 07, 2013

Recall Number
Z-0652-2013

Product
UltraFill DBM labeled in part:

Product Code: RT53005
Donated
Human Tissue Allograft
SINGLE PATIENT USE ONLY
FOR INTERNATIONAL USE ONLY
See Package Insert for Additional Information

Product Code: RT53005 Tissue ID: T06055-11-0021 through T07000-11-0070 through T070037-11-0037; T07000-11-0017 through T070037-11-0018; T070037-11-0020 through T070037-11-0037; T470060-11-0021 through T470060-11-0047; T470060-11-0050 through T470060-11-0056

Recalling Firm/
Manufacturer
Surgical Tissue Network, Inc.
7022 TPC Dr Ste 400
Orlando, Florida 32822-5140

For Additional Information Contact
Gene S. Elliott
407-360-2424 Ext. 230

Reason for Recall
Surgical Tissue Network, Inc., DBA TissueNet Inc. recalled their UltraFill DBM Putty-Porcine (1 cc; 5 cc; 10 cc) because products may contain trace amounts of 316L Stainless Steel particulates.

Action
Surgical Tissue Network sent a Notification of Voluntary Tissue Recall dated March 22, 2012, to all affected customers. The firm issued an additional notification letter on August 30, 2012. The letter identified the product, the problem, and action to be taken by the customer. Consignees were asked to return all listed products that remain in inventory. If the product was further distributed, they were asked to forward the recall information to their customers. Customers were instructed to contact TissueNet’s Customer Service Department at 800-465-8800 x283 to coordinate return/replacement of the affected product. Customers with questions were instructed to call 800-465-8800 x230. For questions regarding this recall call 407-360-2424.

Quantity in Commerce
208 units

Distribution
Worldwide Distribution including Turkey, Greece, & Mexico

Links on this page:
4. http://www.fda.gov/MedicalDevices/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
7. ./cDRPM/pcm.cfm
8. ./cDRILst.cfm
9. ./cDRAUDE/TextSearch.cfm
10. ./cDRES/res.cfm
11. ./cDPMA/pma.cfm
12. ./cDCPCD/classification.cfm
13. ./cDStandards/search.cfm

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=113638
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Medical & Radiation Emitting Device Recalls

FDA Home >> Medical Devices >> Databases

New Search

Class 2 Recall
UltraFill DBM

Date Posted
January 07, 2013

Recall Number
Z-0053-2013

Product
UltraFill DBM labeled in part:
TissueNet's Porcine DBM product line is used as a bone void filler.

Code Information
Product Code: RT53010

Recalling Firm/Manufacturer
Surgical Tissue Network, Inc.
7022 TPC Dr Ste 400
Orlando, Florida 32822-5140

For Additional Information Contact
Gene S. Elliot
407-380-2424 Ext. 230

Reason for Recall
Surgical Tissue Network Inc., DBA TissueNet Inc. recalled their UltraFill DBM Puffy-Poricone (1 cc, 5cc, 10cc) because products may contain trace amounts of 316L Stainless Steel particulates.

Action
Surgical Tissue Network sent a Notification of Voluntary Tissue Recall dated March 22, 2012, to all affected customers. The firm issued an additional notification letter on August 30, 2012. The letter identified the product, the problem, and action to be taken by the customer. Consignees were asked to return all listed products that remain in inventory. If the product was further distributed, they were asked to forward the recall information to their customers. Customers were instructed to contact TissueNet's Customer Service Department at 800-465-8800 x283 to coordinate return/replacement of the affected product. Customers with questions were instructed to call 800-465-8800 x230. For questions regarding this recall call 407-380-2424.

Quantity in Commerce
160 units

Distribution
Worldwide Distribution including Turkey, Greece, & Mexico.

Links on this page:
4. http://www.fda.gov/MedicalDevices/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
7. ../CPMN/pmn.cfm
8. ../cRL/cfm
9. ../dMADE/TextSearch.cfm
10. ../dRES/res.cfm
11. ../dPM/tpma.cfm
12. ../dPCD/classification.cfm
13. ../dStandards/search.cfm

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/cfres.cfm?id=113639

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