



رقم المحفوظات: ٧/٢٥
رقم الصادر: ١٣/١/٢١٨٨
بيروت، في: ١٥ شباط ٢٠١٣

جانب نقيب المستشفيات الخاصة في لبنان

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

الجهاز المعنى بالمتابعة:

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

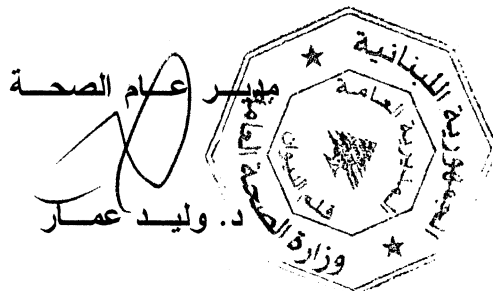
بناء على التقرير الصادر عن وكالة ال FDA الذي يحذر فيه من استعمال الصنف المذكور أعلاه بسبب وجود خطأ في التصنيع، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطاً:

- التقرير الصادر عن وكالة ال FDA

يبلغ:

- دائرة البرامج والمشاريع ✓
- المستشفيات الحكومية
- المحفوظات



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510(k)⁷ | Registration & Listing⁸ | Adverse Events⁹ | Recalls¹⁰ | PMA¹¹ | Classification¹² | Standards¹³ | CFR Title 21¹⁴ | Radiation-Emitting Products¹⁵ | X-Ray Assembler¹⁶ | Medsun Reports¹⁷ | CLIA¹⁸ | TPLC¹⁹

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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***Sterilized by T10^6 (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;amp;amp;quot; TissueNet's Porcine DBM product line is used as a bone void filler
Code Information	Product Code: RT53001 Tissue ID: TN29041-11-0072 Through TN29041-11-0081; and TN29041-11-0083 through TN29041-11-0119
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 Putty-Porcine (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	25 units
Distribution	Worldwide Distribution including Turkey, Greece, & Mexico.

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**Class 2 Recall
UltraFill DBM**



Date Posted	January 07, 2013
Recall Number	Z-0652-2013
Product	UltraFill DBM labeled in part: &amp;amp;amp;amp;amp;amp;amp;amp;amp;quot;***TISSUENET***Sterilized by T10^6 (r)***Description: UltraFill DBM***Size: 5cc***Product Code: RT53005***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.
Code Information	Product Code: RT53005 Tissue ID: TN48005-11-0021 through TN48055-11-0059; TN48055-11- 0070 through TN48055-11-0075; TN58063-11-0101 through TN58063-11-0142; TN61039-11-0031 through TN61039-11-0097; TN70037-11-0017 through TN70037-11-0018; TN70037-11-0020 through TN70037-11-0037; TN74060-11-0021 through TN74060-11-0047; TN74060-11-0050 through TN74060-11-0056
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 Putty-Porcine (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	208 units
Distribution	Worldwide Distribution including Turkey, Greece, & Mexico.

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**Class 2 Recall
UltraFill DBM**



Date Posted	January 07, 2013
Recall Number	Z-0653-2013
Product	UltraFill DBM labeled in part: &amp;amp;amp;amp;amp;amp;amp;amp;amp;quot;***TISSUENET***Sterilized by T10^6 (r)***Description: UltraFill DBM***Size: 10cc***Product Code: RT53010***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.
Code Information	Product Code: RT53010 Tissue ID: 07-175-330 through 07-175-359; TN61032-11-0017 through TN61032-11-0041; TN62034-11-0001 through TN62034-11-0024; TN62053-11-0155 through TN62053-11-0209; TN67049-11-0291 through TN67049-11-0316; TN70037-11-0020 through TN70037-11-0037; TN74060-11-0021 through TN74060-11-0047; TN74060-11-0050 through TN74060-11-0056
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 Putty-Porcine (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.

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