



رقم المحفوظات: ٢٠١٣
رقم الصادر: ١٤/١/٢٥٥٠
بيروت، في: ٠ - آب - ٢٠١٣

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي مغروس

Collagen dental regeneration membrane; Dressing, wound, collagen, Various BioMend, CollaCote, CollaPlug, and CollaTape Collagen

الجهاز المعني بالمتابعة:

- Collagen dental regeneration membrane; Dressing, wound, collagen, Various BioMend, CollaCote, CollaPlug, and CollaTape Collagen
- Trade Mark: Integra LifeSciences Corporation
- Local Representative: Asmar Medical

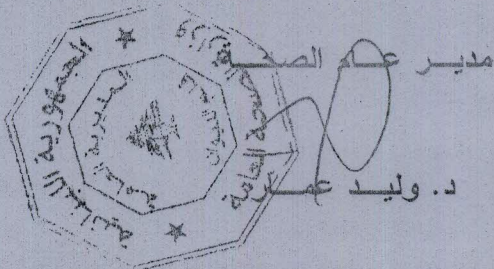
بناء على التوصية الصادرة عن الشركة المصنعة والتي تشير الى وجود خلل في تصنيع الصنف المذكور أعلاه مما قد يؤثر على سلامة المريض، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطا:

- التوصية الصادرة عن الشركة المصنعة

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات



April 9, 2013

URGENT: MEDICAL DEVICE RECALL

BioMend[®] Absorbable Collagen Membrane
BioMend[®] Extend[™] Absorbable Collagen Membrane
CollaCote[®] Absorbable Collagen Wound Dressing for Dental Surgery
CollaPlug[®] Absorbable Collagen Wound Dressing for Dental Surgery
CollaTape[®] Absorbable Collagen Wound Dressing for Dental Surgery

Dear Valued Customer,

Integra LifeSciences has identified through an internal Quality Assurance review of processes that we may have deviated from a production process during the manufacture of specific lots of product. Accordingly, we are recalling those specific lots according to the instructions below. Our records indicate you have purchased at least one of those lots.

Our goal at Integra LifeSciences is to provide you with the best quality products and services to ensure the highest level of patient safety. We are therefore asking you do the following:

1. Verify if you have any lots of the product on the next page and if so, **STOP** using that product.
2. Remove that product from service.
3. Complete the Return Acknowledgment Form on the next page. Send it to Integra as directed on the form.
4. Our Customer Service department will contact you to return and replace the product.

The product lots in question passed all product finished goods testing, are sterile, and were tested and accepted for endotoxin levels. However, due to the process deviation they may have been released with higher levels of endotoxins than permitted by the specifications for the products. Higher endotoxin levels may result in a fever in the immediate postoperative period. We are not aware of any reports of patient injuries or other adverse events in connection with these product lots. **However, if you have already implanted or used collagen sponge products affected by this recall, we recommend you monitor the patient for a fever in the immediate postoperative period according to the standard hospital or clinician protocol.** Please report any adverse event of this nature to us at the telephone number below or you may also make such reports to the FDA MedWatch Adverse Event Reporting program

Providing the completed Return Acknowledgement Form additionally ensures that Integra has achieved a level of effectiveness required by the Food and Drug Administration (FDA) in providing this information to you. Please maintain a copy of this notice and a signed copy of the acknowledgement form for your records. Regulatory agencies may perform audits of field actions to verify that customers have been notified and understand the nature of the field action being taken.

For assistance or any other questions that you may have, please contact Customer Service at 1-855-532-1723

We appreciate your compliance and cooperation and sincerely apologize for any inconvenience this action may cause you.

Sincerely,

Sherry Siegel, MD
Director, Medical Affairs, Neurosurgery
Integra LifeSciences

PMAP#: 0032498

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PRODUCT RECALL RETURN ACKNOWLEDGMENT FORM

BioMend® Absorbable Collagen Membrane
BioMend® Extend™ Absorbable Collagen Membrane
CollaCote® Absorbable Collagen Wound Dressing for Dental Surgery
CollaPlug® Absorbable Collagen Wound Dressing for Dental Surgery
CollaTape® Absorbable Collagen Wound Dressing for Dental Surgery

Please Complete and Return Promptly

Please fill out this form and return to one of the following:

- FCA@integralife.com (Email)
- 1-609-275-9445 (FAX)

I have received, read, and understand the information provided in the Integra Medical Device Recall Notification and will distribute to all applicable team members.

- I do not have any product with a Lot Number on the list below.
- I do have product with a Lot Number on the list below.

Please circle the Lot Number(s) of your product and record the total quantity of those Lot Number(s). The Lot Number is located on the top flap of the box and on the label of the individual product package.

Lot Number	Catalog Number	Description	Release Date	Quantity Released
1105251	0103	BioMend® Absorbable Collagen Membrane	12/23/2010	2015
1105252	0107	BioMend® Absorbable Collagen Membrane	12/22/2010	436
1105392	0105	BioMend® Absorbable Collagen Membrane	12/28/2010	734
1105393	0105P	BioMend® Absorbable Collagen Membrane	12/28/2010	926
1105394	0107P	BioMend® Absorbable Collagen Membrane	12/28/2010	494
1105391	0103	BioMend® Absorbable Collagen Membrane	2/4/2011	1943
1105463	0107	BioMend® Absorbable Collagen Membrane	2/7/2011	914
1105462	0103	BioMend® Absorbable Collagen Membrane	2/11/2011	1997
1110142	0105	BioMend® Absorbable Collagen Membrane	2/11/2011	956
1110480	0107P	BioMend® Absorbable Collagen Membrane	2/18/2011	257
1110671	0103P	BioMend® Absorbable Collagen Membrane	3/7/2011	1274
1110807	0105P	BioMend® Absorbable Collagen Membrane	3/7/2011	973
1110805	0103	BioMend® Absorbable Collagen Membrane	3/15/2011	2007
1110808	0107	BioMend® Absorbable Collagen Membrane	3/15/2011	453
1110806	0103	BioMend® Absorbable Collagen Membrane	3/18/2011	2007
1110672	0103P	BioMend® Absorbable Collagen Membrane	3/24/2011	990
1111144	0103	BioMend® Absorbable Collagen Membrane	3/31/2011	2006
1111145	0103	BioMend® Absorbable Collagen Membrane	4/13/2011	1920
1111146	0105	BioMend® Absorbable Collagen Membrane	4/13/2011	970
1111147	0107	BioMend® Absorbable Collagen Membrane	4/13/2011	394

Lot Number	Catalog Number	Description	Release Date	Quantity Released
1111358	0103	BioMend [®] Absorbable Collagen Membrane	4/19/2011	2002
1111362	0105	BioMend [®] Absorbable Collagen Membrane	4/19/2011	879
1111865	0107	BioMend [®] Absorbable Collagen Membrane	4/29/2011	684
1111959	0105P	BioMend [®] Absorbable Collagen Membrane	4/29/2011	980
1111958	0103P	BioMend [®] Absorbable Collagen Membrane	5/4/2011	2006
1111640	0105	BioMend [®] Absorbable Collagen Membrane	5/13/2011	1326
1112022	0107P	BioMend [®] Absorbable Collagen Membrane	5/24/2011	903
1104847	0141	BioMend [®] Extend [™] Absorbable Collagen Membrane	12/20/2010	1817
1104846	0140	BioMend [®] Extend [™] Absorbable Collagen Membrane	12/20/2010	2015
1104848	0142	BioMend [®] Extend [™] Absorbable Collagen Membrane	12/20/2010	392
1105175	0140	BioMend [®] Extend [™] Absorbable Collagen Membrane	12/20/2010	1776
1105253	0140	BioMend [®] Extend [™] Absorbable Collagen Membrane	12/22/2010	2017
1105254	0141	BioMend [®] Extend [™] Absorbable Collagen Membrane	1/26/2011	1963
1105176	0141	BioMend [®] Extend [™] Absorbable Collagen Membrane	2/4/2011	627
1110820	0142	BioMend [®] Extend [™] Absorbable Collagen Membrane	3/7/2011	660
1110809	0141	BioMend [®] Extend [™] Absorbable Collagen Membrane	3/28/2011	1233
1110819	0142	BioMend [®] Extend [™] Absorbable Collagen Membrane	3/28/2011	656
1110811	0140	BioMend [®] Extend [™] Absorbable Collagen Membrane	3/28/2011	1286
1110810	0140	BioMend [®] Extend [™] Absorbable Collagen Membrane	3/30/2011	1257
1111148	0142	BioMend [®] Extend [™] Absorbable Collagen Membrane	3/31/2011	576
1111149	0140	BioMend [®] Extend [™] Absorbable Collagen Membrane	4/13/2011	1478
1111860	0141	BioMend [®] Extend [™] Absorbable Collagen Membrane	4/29/2011	831
1111859	0140	BioMend [®] Extend [™] Absorbable Collagen Membrane	5/17/2011	1980
1111861	0142	BioMend [®] Extend [™] Absorbable Collagen Membrane	5/17/2011	468
1104963	0101	CollaCote [®] Absorbable Collagen Wound Dressing	12/29/2010	3170
1110481	0101	CollaCote [®] Absorbable Collagen Wound Dressing	3/7/2011	3220
1110791	0101	CollaCote [®] Absorbable Collagen Wound Dressing	3/15/2011	1990
1110673	0101P	CollaCote [®] Absorbable Collagen Wound Dressing	3/25/2011	1470
1110792	0101	CollaCote [®] Absorbable Collagen Wound Dressing	3/28/2011	1730
1111363	0101	CollaCote [®] Absorbable Collagen Wound Dressing	4/12/2011	4110
1111644	0101	CollaCote [®] Absorbable Collagen Wound Dressing	5/17/2011	3340
1111856	0101P	CollaCote [®] Absorbable Collagen Wound Dressing	5/21/2011	3630
1125684	0101	CollaCote [®] Absorbable Collagen Wound Dressing	12/27/2012	2950
1125689	0101P	CollaCote [®] Absorbable Collagen Wound Dressing	1/14/2013	2060
1125685	0101	CollaCote [®] Absorbable Collagen Wound Dressing	1/25/2013	1970
1126014	0101	CollaCote [®] Absorbable Collagen Wound Dressing	3/12/2013	3550
1104500	0102	CollaPlug [®] Absorbable Collagen Wound Dressing	12/20/2010	6600
1104623	0102	CollaPlug [®] Absorbable Collagen Wound Dressing	12/20/2010	4710
1105300	0102P	CollaPlug [®] Absorbable Collagen Wound Dressing	1/4/2011	8070
1105315	0102	CollaPlug [®] Absorbable Collagen Wound Dressing	2/4/2011	7680
1105316	0102	CollaPlug [®] Absorbable Collagen Wound Dressing	2/4/2011	7830
1110234	0102	CollaPlug [®] Absorbable Collagen Wound Dressing	2/14/2011	6780
1110235	0102	CollaPlug [®] Absorbable Collagen Wound Dressing	2/17/2011	6630
1110236	0102	CollaPlug [®] Absorbable Collagen Wound Dressing	3/7/2011	6300
1110237	0102	CollaPlug [®] Absorbable Collagen Wound Dressing	3/7/2011	6730
1110239	0102	CollaPlug [®] Absorbable Collagen Wound Dressing	3/28/2011	7010
1110240	0102	CollaPlug [®] Absorbable Collagen Wound Dressing	3/28/2011	7410
1110238	0102	CollaPlug [®] Absorbable Collagen Wound Dressing	3/30/2011	7310
1105317	0102	CollaPlug [®] Absorbable Collagen Wound Dressing	3/31/2011	7780
1110784	0102	CollaPlug [®] Absorbable Collagen Wound Dressing	3/31/2011	7050

Lot Number	Catalog Number	Description	Release Date	Quantity Released
1111151	0102	CollaPlug [®] Absorbable Collagen Wound Dressing	4/7/2011	8300
1111152	0102	CollaPlug [®] Absorbable Collagen Wound Dressing	4/15/2011	7470
1111153	0102	CollaPlug [®] Absorbable Collagen Wound Dressing	4/15/2011	7560
1111155	0102	CollaPlug [®] Absorbable Collagen Wound Dressing	4/29/2011	6900
1111156	0102	CollaPlug [®] Absorbable Collagen Wound Dressing	4/29/2011	6720
1111157	0102	CollaPlug [®] Absorbable Collagen Wound Dressing	5/13/2011	6590
1111646	0102	CollaPlug [®] Absorbable Collagen Wound Dressing	5/21/2011	7180
1104502	0100	CollaTape [®] Absorbable Collagen Wound Dressing	12/20/2010	2400
1104503	0100	CollaTape [®] Absorbable Collagen Wound Dressing	12/20/2010	2260
1105298	0100P	CollaTape [®] Absorbable Collagen Wound Dressing	2/4/2010	2080
1105310	0100	CollaTape [®] Absorbable Collagen Wound Dressing	2/4/2011	2920
1105309	0100	CollaTape [®] Absorbable Collagen Wound Dressing	2/4/2011	2850
1110145	0100P	CollaTape [®] Absorbable Collagen Wound Dressing	2/7/2011	1890
1110249	0100	CollaTape [®] Absorbable Collagen Wound Dressing	2/17/2011	2850
1110674	0100P	CollaTape [®] Absorbable Collagen Wound Dressing	3/18/2011	2470
1111366	0100	CollaTape [®] Absorbable Collagen Wound Dressing	3/30/2011	2640
1111367	0100	CollaTape [®] Absorbable Collagen Wound Dressing	3/31/2011	2910
1111368	0100	CollaTape [®] Absorbable Collagen Wound Dressing	4/7/2011	2630
1111854	0100P	CollaTape [®] Absorbable Collagen Wound Dressing	4/29/2011	2440
1111370	0100	CollaTape [®] Absorbable Collagen Wound Dressing	5/13/2011	3230
1112262	0100	CollaTape [®] Absorbable Collagen Wound Dressing	5/23/2011	2800
1125130	0100	CollaTape [®] Absorbable Collagen Wound Dressing	12/21/2012	3050
1125686	0100	CollaTape [®] Absorbable Collagen Wound Dressing	1/17/2013	2590
1125687	0100	CollaTape [®] Absorbable Collagen Wound Dressing	1/28/2013	2960
1125688	0100	CollaTape [®] Absorbable Collagen Wound Dressing	2/6/2013	2100
1126015	0100	CollaTape [®] Absorbable Collagen Wound Dressing	3/14/2013	2430

Facility Name

Printed Customer Name / Signature

Street Address

City/State/Zip Code

Telephone Number

Date