



رقم المحفوظات: ٣٨/٢٥
رقم الصادر: ١٣/١/٢٤٤٦٩
بيروت، في: ٢٢ نيسان ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي مغروس

Mesh, Polymeric, Various Mesh and Suture Products

الجهاز المعني بالمتابعة:

- Mesh, Polymeric, Various Mesh and Suture Products
- Trade Mark: Ethicon Inc A Johnson & Johnson Co
- Local Representative:

بناءً على التوصية الصادرة عن الشركة المصنعة، والتي تشير الى وجود خلل في عملية تعقيم الصنف الوارد أعلاه، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطا:

- التوصية الصادرة عن الشركة المصنعة

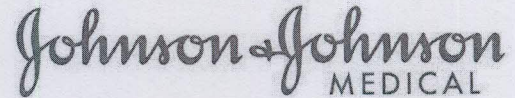
يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

مدير عام الصحة

وليد عمار





To: Affiliate Company Representative
see e-mail distribution list

April 10, 2013

URGENT VOLUNTARY PRODUCT RECALL

**Specific Lots of:
LAPRA-TY™ II, PDS™ II,
Vicryl™, Vicryl™ Plus, Vicryl* Mesh,
Ultrapro™, Ultrapro™ Plug
See Attachment 1**

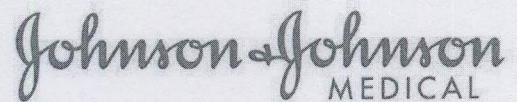
Johnson & Johnson MEDICAL GmbH is voluntarily recalling specific lots of LAPRA-TY™ II, PDS™ II, Vicryl™, Vicryl™ Plus, Vicryl* Mesh, Ultrapro™, and Ultrapro™ Plug (see Attachment 1 for listing of product codes and lot numbers). The company has identified the potential that a defect could compromise the integrity of the foil pouch which could impair the sterile barrier of the product and allow possible degradation of the absorbable implant. We have not received any reports of adverse events related to this issue. This issue was identified internally during a routine quality control inspection.

This letter is an update to letters originally sent on January 31, 2013. One additional lot of UltraPro Plug (Product Code UPPM1, Lot # EM8BQHA0) has been identified as distributed to customers.

This recall only impacts the product codes and lots listed in Attachment 1. Please only return product codes/lots listed in this attachment.

Effective immediately, please:

- Identify and quarantine any of the recalled products from your inventory (physical quarantine – cage or other suitable restricted access area).
- Check with your customers if they still have any of the listed products in their stock. If yes, have the products sent back to you immediately.
- Fill out the attached “Recall Confirmation Form” and send the completed form to the contact provided on the form by **May 15, 2013**.
- Disposition the returned product by either:
 - Destroying all devices that the customers return to you and sending a “Certificate of Destruction” to Anke Winter (undersigned) once the returned products have been destroyed; or
 - Returning all devices that the customers return to you to:
FTAO of [REDACTED]
J&J European Distribution Centre
Rue De Luxembourg 5
Courcelles B-6180
Belgium



Please disseminate this notice to those within your organization who need to be aware of this action, or to any organization where the potentially affected devices have been transferred.

In Attachment 2, you will find photos to help your customers identify affected products.

If you have any questions regarding this voluntary product recall, please contact:

Anke Winter
awinter@its.jnj.com
Telephone: +49 40 5297 5078

The undersigned confirms that the appropriate European Regulatory Agency has been notified.

Thank you for your cooperation and immediate assistance.

Sincerely,
Johnson & Johnson MEDICAL GmbH

i.A. Anke Winter

Enclosures (2):

- Attachment 1: List of Impacted Product Codes and Lot Numbers
- Attachment 2: Photos for How to Identify Recalled Products

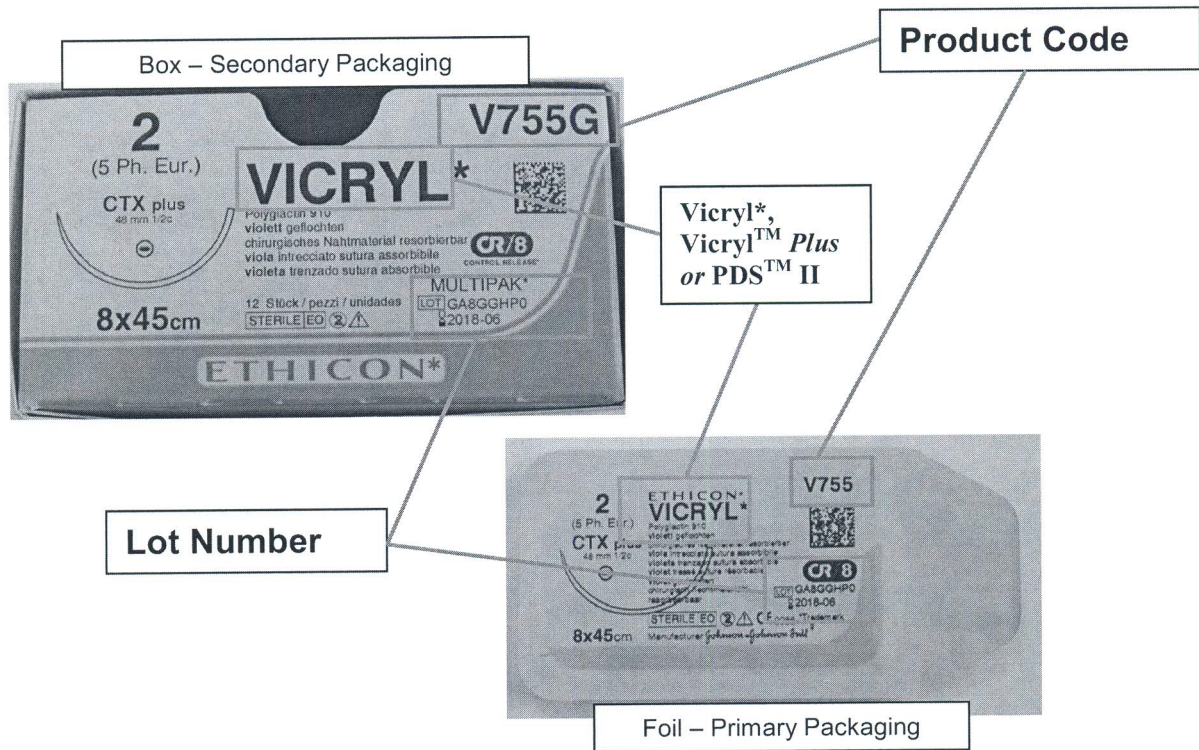
Attachment 1: List of Impacted Product Codes and Lot Numbers

Product Description	Product Code	Lot Number
LAPRA-TY™ II	MIC4036	EL8GLTP1
Ultrapro™	UML1	EL8JJQS0
Ultrapro™ Plug	UPPL1	EM8CBBA0
	UPPM1	EM8BQHA0
Vicryl* Mesh	VM210	EL8KJDM0
	VM95	EL8DWPD1
		EL8JRBD0
PDS™ II	EZ11	EM8BQTP0
	X1154G	EL8HGDQ0
		EL8JKWQ0
Vicryl™ Plus	VCP1215E	EG8BZLA5
	VCP2577G	EM8BXQZ0
	VCP636E	EH8JGGA5
	VCP649	EM8BTCZ0
	VCP747G	EC8KWSZ5
		EM8BLMZ0
	VCP754G	EJ8GZBZ5
	VCP9289G	EL8KCHR0

Product Description	Product Code	Lot Number
Vicryl™	4PN2545YG	EK8DDQP5
	6PK2575G	EM8CPWP0
	EB12	EL8DKCM1
		EL8HJXM1
	EB22	EL8JSZM0
	EJ11	EL8GKQP1
		EL8GKQP5
		EL8JJCP5
		EM8BCDP0
		EM8BHTP0
		EM8BSZP0
		EM8CDDP0
	V1209G	EM8CBRR0
	V1217E	EL8JGCP1
	V7361G	EM8CCXP0
	V740G	EM8CKQP0
	V747G	EM8CKRP0
	V754G	EL8KHCP1
	V755G	EM8BGMP0
		EM8BRCP0
	V767G	EA8GSQP5
	V778G	EB8GHWHP5
		EB8GPGP5
		EL8JPQP1
	V786G	EL8KKLP0
	V905E	EM8CPMR0
	V906E	EL8GZQS1

Attachment 2: Photos for How to Identify Recalled Products

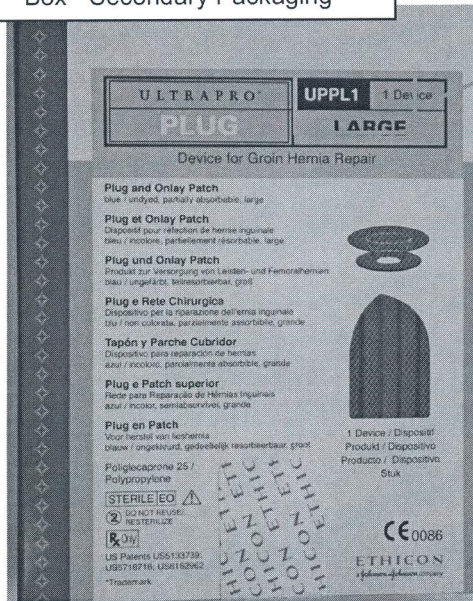
Vicryl*, Vicryl™ Plus, PDS™ II Products



Attachment 2: Photos for How to Identify Recalled Products

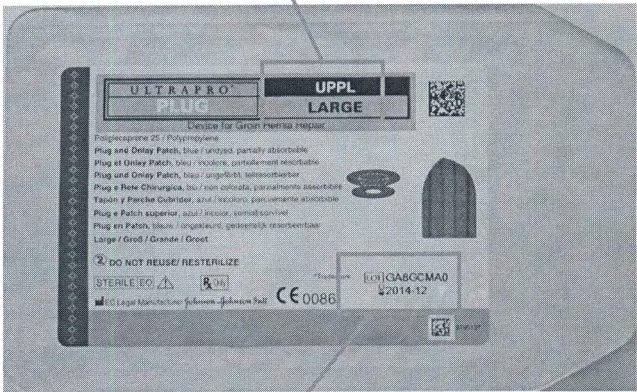
Ultraplug™ Plug

Box - Secondary Packaging



Product Code

Foil - Primary Packaging



Lot Number

Attachment 2: Photos for How to Identify Recalled Products

Lapra-Ty™ Clip Products

