Hospital Name
Address
Address

FIELD SAFETY NOTICE

SeriScaffold® surgical scaffold

11th January 2013

Dear Dr ,

The purpose of this letter is to advise you that Allergan is voluntarily recalling distributed devices from 2 lots of SeriScaffold® surgical scaffold devices (currently referred to as SERI™ Surgical Scaffold) manufactured in 2011. The following table lists the device part number and affected lot numbers.

DEVICE NAME	PART #	LOT #
SeriScaffold® surgical scaffold	SCF10X25AEGEN	P2011080101B
		P2011090901A

All surgeons and surgical centers having received these lots are being notified. Our records indicate that you received device(s) from one of the lots listed in the table above.

Reason for the Voluntary Recall:

Allergan has determined that certain devices labeled with the part and lot numbers described above may have been packaged in improperly sealed pouches. The SeriScaffold® surgical scaffold is dual packaged in an inner and outer pouch and sterilized. During inspection it was found that the outer pouch seal was compromised on certain devices; however the inner pouch which contains the product, was found to have an intact seal. Potentially, if the inside of the outer pouch is contaminated, it can lead to the contamination of the exterior of the inner pouch which in turn can cause the product to be contaminated when it is being removed from the inner pouch. Additionally, if the contaminated inner pouch is dropped in the sterile field, it can potentially lead to contamination of the sterile field.

No customer complaints related to this condition have been received to date.

Allergan would like to assure its customers that it is taking steps to correct the process and implement additional controls in order to ensure the integrity of the outer seal.

Clinical implications:

Use of a device with a defective outer seal could compromise device sterility. Should this occur on a device being utilized, its use may result in an infection to the patient and/or the deposition of non-infectious particulate contaminants from the environment of use. At-risk populations include patients who are immunocompromised, patients who are chemo- and/or radiation-treated, and the elderly.

Customer Action Requested:

Customers are requested to take the following steps in order to ensure that the devices listed above are not utilized and are returned to Allergan:

- Quarantine any unused devices in inventory and do not utilize them if they bear the lot numbers identified in this notice.

- Please complete the attached acknowledgement form urgently and return to Allergan. The completed form can be emailed to [redacted]@Allergan.com or mailed to the attention of:

[redacted]
Allergan
Marlow International,
Parkway,
Marlow,
SL7 1YL
UK

An Allergan representative will be in touch with you to provide product return instructions and also arrange to replace your inventory.

We apologize for any inconvenience this incident may have caused you and appreciate your assistance in returning the device(s) to us. If you have questions regarding this recall, please contact [redacted] at +44 1628 494 450, Mon – Fri, 9 a.m. to 5 p.m. (UK).

Yours sincerely,

[redacted]
Associate Director Product Surveillance, EAME

MEDICAL DEVICE FIELD SAFETY NOTICE ACKNOWLEDGEMENT FORM

SeriScaffold® surgical scaffold

Customer Information:

Customer/Hospital Name	
Street Address	
Town/State/Zip	

- I have read and understand the recall instructions provided in the recall letter dated January 7th, 2013.

  _____ Yes _____ No

- Are there any of the listed device lots in inventory at your facility?

  _____ Yes _____ No

  If Yes, fill out the table below.

PART #	LOT #	QUANTITY
SCF10X25AEGEN	P2011080101B	
	P2011090901A	

Customer/Hospital Representative Information:

Name/Title	
Signature/Date	
Telephone	
Email Address	

Email or Mail Completed Form To:
E-mail: [redacted]@Allergan.com
Mail:
Allergan
Marlow International,
Parkway,
Marlow,
SL7 1YL
UK