RÉPUBLIQUE LIBANAISE
MINISTÈRE DE LA SANTÉ PUBLIQUE
Le Directeur Général

جمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ٣٧١٢٥
رقم الصادر: ٨٠١٤١/١٣
بيروت، في: ٢٤ نيسان ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي مغروس
Needles, Injection, Subcutaneous Port, Angled Surecan Needles

الجهاز المعني بالمتابعة:

- Needles, Injection, Subcutaneous Port, Angled Surecan Needles
- Trade Mark: B Braun Medical Inc
- Local Representative:

بناء على التقرير الصادر عن الشركة المصنعة
الذي يشير الى خلل في عملية التوضيب مما يؤثر على فعالية التعقيم ، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطاً:

- التقرير الصادر عن الشركة المصنعة

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

الجمهورية اللبنانية
المديرية العامة
قلم السيوان
وزارة الصحة العامة

مدير عام الصحة
د. وليد عمار

Rue de la Musée - Imm. Hussein Mansour - Beyrouth, Liban - Tel.: 961.1.615724 - 615725 - Fax: 961.1.615730 - Email: dirctorgeneral@moph.gov.lb

B|BRAUN

B. Braun Medical SAS
Centre d'Excellence de la Division Aesculap
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BP 10031
F-86361 Chasseneuil Cedex
Tél. : 33 5 49 62 76 00
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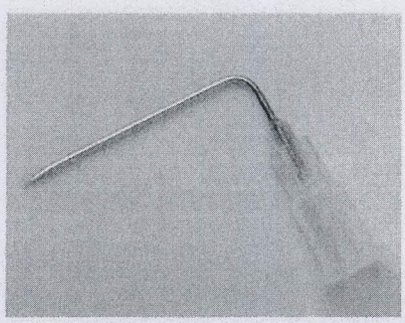
2012-08-17



Field Safety Notice
Voluntary Product Recall

ANGLED SURECAN - needles for access ports
4 batches concerned

Reference	Designation	Batch nr
4439821	ANGLED SURECAN G22X20MM	2F23258663
4439929	ANGLED SURECAN G20X15MM	2F23258668
4439945	ANGLED SURECAN G20X25MM	2F23258660
4439830	ANGLED SURECAN G22X25MM	2F2425A681

NOTE : The recall only impacts these 4 listed batches. No other products are affected.

Dear Sir or Madam,

B.Braun Medical France is voluntarily recalling 4 batches (see the above list) of Angled Surecan needles. This action is being taken as a result of a potential defect in the packaging of the batches produced in June 2012. This packaging defect could compromise the sealing integrity of the single unit packaging and therefore the product sterility. For the patient, the risk is an increased risk of infection. Currently we regard no action to be necessary, for patients that have already received treatment with this system.

Internal investigation has showed sealing temperature deviation on a circled area of the packaging machine. Corrective actions have already been implemented to solve this issue.

If you are in possession of products from the 4 batches above listed, you should remove them from your inventory and return them to the following address with the enclosed recall confirmation form:

Local address

In case of any further questions please contact :

Local contact name and telephone and/or email

We appreciate your immediate attention and apologize for the inconvenience caused. Please be assured that we are making all the necessary efforts to eliminate such issue in the future.

Yours sincerely,

Quality & RA Manager
CoE of Chasseneuil
BBraun Medical France

Please complete this form, even if you do not have any of the concerned products and fax this form back to the following Fax No.XXXXXXXXXXXXX

RECALL CONFIRMATION FORM

Product Recall

Angled Surecan – 4 batches

Reference	Designation	Batch nr
4439821	ANGLED SURECAN G22X20MM	2F23258663
4439929	ANGLED SURECAN G20X15MM	2F23258668
4439945	ANGLED SURECAN G20X25MM	2F23258660
4439830	ANGLED SURECAN G22X25MM	2F2425A681

NOTE : The recall only impacts these 4 listed batches. No other products are affected.

1. We acknowledge receipt of the recall-notification from B.Braun Medical.

2. Please mark accordingly:

☐ We do not have any of the affected products in stock

☐ We will return the following products:

Batch number	Quantity
2F23258663	
2F23258668	
2F23258660	
2F2425A681	

Hospital: _____

Address: _____

_____

_____

Contact Name: _____

Contact Phone Number: _____

Contact e-mail address: _____

SIGNATURE _____ DATE _____