جهوية اللبنانية
وزارة الصحة العامة
المدير العام

جانب نقبي المستشفيات الخاصة في لبنان

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

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

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

مرفق ربطا:
- التقرير الصادر عن الشركة المصنعة

رقم المحفظة: 871
رقم الصادر: 88/1/1/2013
بيروت، في:

مدير عام الصحة

ويق عمار

روان كلا كات

Rue de la Musée - Imr. Hussein Mansour - Beyrouth, Liban - Tel.: 961 1 615724 - 615725 - Fax: 961 1 615730 - Email: directorgeneral@moph.gov.lb
Field Safety Notice
Voluntary Product Recall

ANGLED SURECAN – needles for access ports
4 batches concerned

<table>
<thead>
<tr>
<th>Reference</th>
<th>Designation</th>
<th>Batch nr</th>
</tr>
</thead>
<tbody>
<tr>
<td>4439821</td>
<td>ANGLED SURECAN G22X20MM</td>
<td>2F23258663</td>
</tr>
<tr>
<td>4439929</td>
<td>ANGLED SURECAN G20X15MM</td>
<td>2F23258668</td>
</tr>
<tr>
<td>4439945</td>
<td>ANGLED SURECAN G20X25MM</td>
<td>2F23258660</td>
</tr>
<tr>
<td>4439830</td>
<td>ANGLED SURECAN G22X25MM</td>
<td>2F2425A681</td>
</tr>
</tbody>
</table>

**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**

B.Braun Medical SAS locataire gérant des divisions commerciales AESCULAP® IB5®
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,

[Name]
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. XXXXXXXXXXXXXX

**RECALL CONFIRMATION FORM**

**Product Recall**

**Angled Surecan - 4 batches**

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**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:

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Hospital: ___________________________________________________________
Address: ___________________________________________________________

Contact Name: _______________________________________________________
Contact Phone Number: _______________________________________________
Contact e-mail address: _____________________________________________

SIGNATURE ___________________ DATE ________________________________