الجِمَهُورِيَّةَ الْلبنانيَّة
وزارة الصحَّة العاَمَّة
المديَّة العامَّة

rack المحفوظات:  
رقم الصادر:  
بيروت، في 6 مارس 2012

Mediline جانب شركة

الموضوع: إشعار ب万余 جهاز طبي مغروس.

الجهاز المعني بالمذكَّرة:
- Vascular cannula and catheters, catheter embolectomy, Bard thrombectomy catheters and Bard biliary and cholangiography catheters.
  Trade Mark: Applied Medical Resources
  Local Representative: Mediline

بناءً على التقارير الصادرة عن الوكالة البريطانية
Medicine and Health Care Products Regulatory Agency (UK) MHRA
والتوصية الصادرة عن الشركة المصنعة والتي تفيد بوجود خلل أثناء استعمال الصفن
المذكور أعلاه والذي يؤدي إلى مضاعفات على المريض، نرجو منكم متابعة هذا الموضوع مع
الاطباء الاجتماعيين والعمل بموجب التوصيات الصادرة عن الشركة المصنعة.

مرفق ربط:
- التوصية الصادرة عن الشركة المصنعة.

بِنَاءَةً
- دارَةَ البرامج والمشاريع
- الموقع الإلكتروني لوزارة الصحة
- المستندات الحكومية
- الملفات

مدير عام الصحَّة

القيمة متبعة للأصدٍر

د. وليد سالم

وفقًا للمؤتمر

عناية عصَّم
Bard Limited  
Forest House, Tilgate Forest Business Park  
Brighton Road, Crawley  
West Sussex, RH11 9BP  
England, UK.

REFERENCE: FA2012-12

URGENT MEDICAL DEVICE FIELD SAFETY NOTICE  
VOLUNTARY RECALL

Catalogue Numbers: CB052308, CB054008, CB062313, CE0260ST,  
CE0280ST, CE0340, CE0340ST, CE0380, CE0380ST, CE0440,  
CE0440ST, CE0480, CE0480ST, CE0580, CE0580ST, CE0680,  
CE0680ST, CE0780, CE0780ST

Dear [Contact Name]

Applied Medical, the manufacturer of the Bard® Thrombectomy Catheters and  
Bard® Biliary and Cholangiography Catheters has issued a Medical Device Recall  
as they have become aware that in some instances there is potential for loose plastic  
particulate shavings to reside on the catheters.

Catalogue numbers CB052308, CB054008, CB062313, CE0260ST,  
CE0280ST, CE0340, CE0340ST, CE0380, CE0380ST, CE0440, CE0440ST, CE0480, CE0480ST,  
CE0580, CE0580ST, CE0680, CE0680ST, CE0780, CE0780ST and specified lots  
listed in Table 1 are affected.

All other lots in your inventory that are not listed in Table 1 are acceptable to  
use. If you have already used the devices, no further action is required. No  
other Bard® device sizes, catalogue numbers or lots are affected by this Field  
Safety Notice.

Bard® Thrombectomy Catheters and Bard® Biliary and Cholangiography  
Catheters with active shelf life are subject of this recall action. According to our  
records, you have received the Bard® Thrombectomy Catheters and Bard® Biliary  
and Cholangiography Catheters.

As Bard® is a distributor of these devices, please ensure that all potential users  
are made aware of this recall.
Bard Limited  
Forest House, Tilgate Forest Business Park  
Brighton Road, Crawley  
West Sussex, RH11 9BP  
England, UK.

Reason for Recall:

Bard® Thrombectomy Catheters and Bard® Biliary and Cholangiography Catheters are being recalled, through instruction by the legal manufacturer (Applied Medical), in relation to a recently discovered non-conformance where loose, plastic particulate shavings were found on the vascular catheters. A customer experience report was also recently received where there was a similar observation of particulate matter being present on the catheter balloon (without using the device).

Therefore, Applied Medical has decided to initiate a voluntary recall of the affected vascular catheter lots.

Please refer to the attached correspondence from Applied Medical for further details of this recall.

Do not use or further distribute any affected product.

Table 1 provides a complete list of all product catalogue and lot numbers affected by this Field Safety Corrective Action. We ask that you check all inventory locations for the product above.

Bard® Thrombectomy Catheters and Bard® Biliary and Cholangiography Catheters Table 1 - List of Affected Product Codes and Lot Numbers

<table>
<thead>
<tr>
<th>Model Numbers</th>
<th>Lot Numbers</th>
</tr>
</thead>
<tbody>
<tr>
<td>C0052305, SYNTEL BILIARY 5F-23CM CATH</td>
<td>1164350</td>
</tr>
<tr>
<td>C0054005, SYNTEL BILIARY 5F-40CM CATH</td>
<td>1164305</td>
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<tr>
<td>C0062213, SYNTEL BILIARY 6F-23CM CATH</td>
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<tr>
<td>CE0260505, L2F-60CM PREM SYNTEL CATH</td>
<td>1164307, 1168569</td>
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<tr>
<td>CE0280505, L2F-80CM PREM SYNTEL CATH</td>
<td>1164351</td>
</tr>
<tr>
<td>CE0340505, 3F-40cm (PREM) SYNTEL CATHETER</td>
<td>1164348</td>
</tr>
<tr>
<td>CE0380505, 3F-80CM PREM SYNTEL CATH</td>
<td>1164308, 1164337, 1166033, 1166281, 1166032, 1169029</td>
</tr>
<tr>
<td>CE0400505, 4F-40CM PREM SYNTEL CATH</td>
<td>1164336, 1168610</td>
</tr>
<tr>
<td>CE0480505, 4F-80CM PREM SYNTEL CATH</td>
<td>1164302, 1164303, 1164335, 1164304, 1166283, 1166284, 1166468, 1168605</td>
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<tr>
<td>CE0580505, 5F-80CM PREM SYNTEL CATH</td>
<td>1164345, 1164346, 1168613</td>
</tr>
<tr>
<td>CE0680505, 6F-80cm (PREM) SYNTEL CATHETER</td>
<td>1164330, 1166470</td>
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<tr>
<td>CE0790505, 7F-80cm PREM SYNTEL CATH</td>
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<td>CE0340, 3F-40cm, SYNTEL RT-EMB</td>
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<td>CE0380, 3F-80cm, SYNTEL RT-EMB</td>
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<td>CE0440, 4F-40cm, SYNTEL RT-EMB</td>
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<td>CE0480, 4F-80cm, SYNTEL RT-EMB</td>
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<td>CE0580, 5F-80CM PREM SYNTEL CATH</td>
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<td>CE0680, 6F-80cm, SYNTEL RT-EMB</td>
<td>1164353</td>
</tr>
<tr>
<td>CE0780, 7F-80cm SYNTEL RT-EMB</td>
<td>1169921</td>
</tr>
</tbody>
</table>

INSTRUCTIONS:

Regulatory Agencies and your Competent Authority require detailed reconciliation of all recalled product and Bard® must document your compliance with this voluntary recall.

- Please immediately discontinue use of the Bard® Thrombectomy Catheters and Bard® Biliary and Cholangiography Catheters listed in Table 1

Telephone: +44 1293 527888 • Facsimile: +44 1293 552428

Registered Office as above Registered in England No. 939600
Bard Limited
Forest House, Tilgate Forest Business Park
Brighton Road, Crawley
West Sussex, RH11 9BP
England, UK.

- Segregate and quarantine any units with the affected Lot numbers pending return to Bard®.
- Please pass this Field Safety Notice to all those who need to be aware of it within your organisation and to any organization or Consignee where the potentially affected devices have been transferred. Please provide Bard® with details of any affected devices that have been transferred (if appropriate).
- Please fill out the attached Reply and Effectiveness Check Form even if you no longer have possession of the recalled product. Be sure to state the quantities and lot numbers of each recalled product that you have in your stock. **It is extremely important that we receive this information.**
- Fax or email the Reply and Effectiveness Check Form to the number specified on the form, even if you no longer have possession of the recalled product. If you cannot fax the form please telephone [ENTER BOX NAME] at the number provided on the form, and report the required information verbally.
- **If you have products to return** please package these, mark the outside package as “RECALLED PRODUCT”, and include the RGA number. All products should be returned to the address indicated on the attached Reply and Effectiveness Check Form.

As the Legal Manufacturer, Applied Medical is notifying your Competent Authority of this Field Safety Notice.

Bard® recognizes the impact of this communication on you and your patients. We want to assure you that patient safety remains our primary concern. Should you have any questions or require assistance in this matter, please contact your local sales specialist or [ENTER BOX NAME]

Yours Sincerely,

Enclosures:  
Reply and Effectiveness Check Form  
Correspondence from Applied Medical regarding details of the recall.