REPUBLIQUE LIBANAISE
MINISTÈRE DE LA SANTÉ PUBLIQUE
LE DIRECTEUR GÉNÉRAL

الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ١/٢٨
رقم الصادر: ١٢/١/١٦٨٤٧
بيروت، في ١٥ تشرين الأول ٢٠١٢

## جانب شركة Mediline

**الموضوع:** إشعار بمتابعة جهاز طبي مغروس.

**الجهاز المعني بالمتابعة:**

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

بناء 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 الصنف المذكور أعلاه والذي يؤدي الى مضاعفات على المريض ، نرجو منكم متابعة هذا الموضوع مع الاطباء الاختصاصيين والعمل بموجب التوصيات الصادرة عن الشركة المصنعة.

**مرفق ربطاً:**

- التوصية الصادرة عن الشركة المصنعة.

**يبلغ:**

- دائرة البرامج والمشاريع
- الموقع الالكتروني لوزارة الصحة
- المستشفيات الحكومية
- المحفوظات

مدير عام الصحة
د. وليد عمار

الجمهورية اللبنانية
وزارة الصحة العامة
قلم الديوان

وثيقة مصدقة للأصل
بيروت في ١٦ تشرين الأول ٢٠١٢
رئيس قسم امانة السر
عنايات غصن

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

BARD

[Contact Name]
[Department/Title]
[Hospital Name]
[Address Line 1]
[Town/City]
[Postal Code]

[Date]

**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**

| Model Numbers | Lot Numbers |
|---|---|
| CB052308, SYNTEL BILIARY 5F-23CM CATH | 1164350 |
| CB054008, SYNTEL BILIARY 5F-40CM CATH | 1164305 |
| CB062313, SYNTEL BILIARY 6F-23CM CATH | 1164306 |
| CE0260ST, L2F-60CM PREM SYNTEL CATH | 1164307, 1168569 |
| CE0280ST, L2F-80CM PREM SYNTEL CATH | 1164351 |
| CE0340ST, 3F-40cm (PREM) SYNTEL CATHETER | 1164348 |
| CE0380ST, 3F-80CM PREM SYNTEL CATH | 1164308, 1164337, 1166033, 1166281, 1166032, 1169029 |
| CE0440ST, 4F-40CM PREM SYNTEL CATH | 1164336, 1168610 |
| CE0480ST, 4F-80CM PREM SYNTEL CATH | 1164302, 1164303, 1164335, 1164304, 1166283, 1166284, 1166468, 1168605 |
| CE0580ST, 5F-80CM PREM SYNTEL CATH | 1164345, 1164346, 1168613 |
| CE0680ST, 6F-80cm (PREM) SYNTEL CATHETER | 1164330, 1166470 |
| CE0780ST, 7F-80CM PREM SYNTEL CATH | 1164354 |
| CE0340, 3F-40cm, SYNTEL RT-EMB | 1166904 |
| CE0380, 3F-80cm, SYNTEL RT-EMB | 1164344 |
| CE0440, 4F-40cm, SYNTEL RT-EMB | 1164347, 1168609 |
| CE0480, 4F-80cm, SYNTEL RT-EMB | 1164343 |
| CE0580, 5F-80CM PREM SYNTEL CATH | 1164349 |
| CE0680, 6F-80cm, SYNTEL RT-EMB | 1164353 |
| CE0780, 7F-80cm SYNTEL RT-EMB | 1169926 |

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

**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 IBC 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 IBC NAME]

Yours Sincerely,

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