

---

## **URGENT FIELD SAFETY NOTICE**

### **Affected product:**

**MANOMETER TRAY**

**JAMSHIDI NEEDLE BIOPSY**

**ILLINOIS (TJ) NEEDLE ASPIRATION**

**JAMSHIDI (TJ) NEEDLE BONE MARROW**

**THORACENTESIS/PARACENTESIS KIT**

**FSCA reference number:** ISRC-2017-0001

**Type of Action:** Product Removal

---

March 9, 2017

Dear Business Partner:

CareFusion a subsidiary of BD is voluntarily performing a Medical Device Recall to remove affected devices subject to the below described potential risk.

### **DETAILS ON THE AFFECTED DEVICES:**

Manometer Tray, Jamshidi Needle Biopsy, Illinois (TJ) Needle Aspiration, Jamshidi (TJ) Needle Bone Marrow, Thoracentesis/Paracentesis Kit

This recall applies to the following:

Attachment "A" - Affected Product – Lot Code List

Attachment "B" - Graphics on where to locate the Product Code; Lot Code

### **DESCRIPTION OF THE PROBLEM:**

CareFusion a subsidiary of BD has identified a potential risk associated with the packaging integrity - open seal of the affected products. If this failure is not recognized prior to a procedure it has the potential to result in an inflammatory / infectious response locally and/or systemically.

**Six (6)** customer complaints have been received to date in the time frame of 01-NOV-2014 to 31-DEC-2016 with the issue of sterile packaging integrity. In all 6 reports the failure was recognized on visual inspection prior to patient use. No cases have been reported of patient(s) experiencing a serious injury or illness.

**ACTION TO BE TAKEN BY THE CUSTOMER / USER:**

- Check your inventory for the affected devices and place them in quarantine
- Complete the Customer Response Form certifying that all affected product in your inventory has been placed in quarantine and mail/email a copy of the response form to:

CareFusion France 309 S.A.S  
8 bis rue de la Renaissance  
44110 Châteaubriant  
France  
[Beatrice.Lambert@bd.com](mailto:Beatrice.Lambert@bd.com)  
+33 2 28 50 40 70

- Please ***promptly return*** the enclosed Customer Response Form to expedite the correction process and acknowledge receipt of this notification.
- **Transmission of this Field Safety Notice**

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please transfer this notice to other organisations on which this action has an impact.

**ACTIONS TO BE TAKEN BY CareFusion a subsidiary of BD:**

At receipt of your customer response form, Carefusion will inform you about further action to be taken of your quarantined products and a credit will be applied to your account for the affected product after certification and documentation of the required actions.

We appreciate your ***prompt return*** of the enclosed Customer Response Form to expedite the correction process and acknowledge receipt of this Notification.

This Field Safety Notice has been notified to the appropriate Regulatory Agency.



75 North Fairway Drive  
Vernon Hills, Illinois 60061  
**BD.com**

We recognize the inconvenience this issue may cause your facility and thank you for your support in this important matter.

Sincerely,

Yves Després  
Senior Regulatory Director Western Europe / EMA  
Medical and Procedural Solutions  
+33 2 28 50 40 70  
Yves.despres@bd.com

Enclosure(s):        Customer Response Form  
                          Affected Product Code List (Attachment "A")  
                          Graphics on where to locate the Product Code; Lot Code  
                          (Attachment "B")

**URGENT FIELD SAFETY NOTICE**

---

**CUSTOMER RESPONSE FORM****Acknowledgment and Verification Form**

---

Product Reference: 4330; SN1015X; SN1016X; SN1017X; SN7016X; TIN3015;  
TIN3018; TJC3513; TJC4008; TJC4011; TJC6008; TJC6011; TJM3513;  
TJM4008; TJM4011; TJM6008; TJM6011; TPK1001

Refer to attachment "A" for Product - Lot Code list

FSCA #: **ISRC-2017-0001**

---

<b>Name of Hospital / Facility</b>	
<b>Distributor</b>	
<b>Hospital / Facility</b>	
<b>Distributor</b>	
<b>Address</b>	
<b>Name</b>	
<b>Telephone number</b>	
<b>Email address</b>	
<b>Signature</b>	
<b>Date</b>	

- I have read and understand the contents of this Field Safety Notice and confirm that our inventory has been checked, and we no longer have the affected product in our inventory
- I have read and understood the contents of this Field Safety Notice and confirm that our medical equipment inventory has been checked, and we have the following affected product in our inventory

Model Number	Lot Number	QTY

Note: If more space is needed for the above table please attach a separate document.

- Wholesaler/Distributor only:** I have identified and notified all customers that purchased any affected product. Check below which method of notification was used (**Include date and method**):

**Date of Notification:** \_\_\_\_\_

**Mail**\_\_ ; **E-mail**\_\_ ; **Fax**\_\_ ; **Phone**\_\_

The following person shall be contacted to coordinate the action (please complete if different than above)

<b>Name</b>	
<b>Telephone Number</b>	
<b>Email</b>	

Please return a copy of the Customer Response Form to:

CareFusion France 309 S.A.S  
8 bis rue de la Renaissance  
44110 Châteaubriant  
France  
[Beatrice.Lambert@bd.com](mailto:Beatrice.Lambert@bd.com)  
+33 2 28 50 40 70

Once the form has been returned to CFN we will be contacting you regarding the disposition on any affected products.

**URGENT Field Safety Notice  
 AFFECTED PRODUCT / LOT CODES**

**ATTACHMENT "A"**

<b>Product Code</b>	<b>Lot Code</b>	<b>Product Description</b>
4330	0000837810	MANOMETER TRAY STERILE 10/BX
4330	0000840335	MANOMETER TRAY STERILE 10/BX
4330	0000842213	MANOMETER TRAY STERILE 10/BX
4330	0000848531	MANOMETER TRAY STERILE 10/BX
4330	0000851181	MANOMETER TRAY STERILE 10/BX
4330	0000853962	MANOMETER TRAY STERILE 10/BX
SN1015X	0000840334	JAMSHIDI NEEDLE BIOPSY 15G X 100MM DISP
SN1016X	0000848028	JAMSHIDI NEEDLE BIOPSY 16G X 100MM DISP
SN1017X	0000848018	JAMSHIDI NEEDLE BIOPSY 17G X 100MM DISP
SN7016X	0000848017	JAMSHIDI NEEDLE BIOPSY 16G X 70MM DISP
TIN3015	0000836578	ILLINOIS (TJ) NEEDLE ASPIRATION 15GA

<b>Product Code</b>	<b>Lot Code</b>	<b>Product Description</b>
TIN3015	0000838953	ILLINOIS (TJ) NEEDLE ASPIRATION 15GA
TIN3015	0000841213	ILLINOIS (TJ) NEEDLE ASPIRATION 15GA
TIN3015	0000841215	ILLINOIS (TJ) NEEDLE ASPIRATION 15GA
TIN3015	0000842719	ILLINOIS (TJ) NEEDLE ASPIRATION 15GA
TIN3015	0000842721	ILLINOIS (TJ) NEEDLE ASPIRATION 15GA
TIN3015	0000845423	ILLINOIS (TJ) NEEDLE ASPIRATION 15GA
TIN3015	0000848061	ILLINOIS (TJ) NEEDLE ASPIRATION 15GA
TIN3015	0000849715	ILLINOIS (TJ) NEEDLE ASPIRATION 15GA
TIN3015	0000850938	ILLINOIS (TJ) NEEDLE ASPIRATION 15GA
TIN3015	0000852076	ILLINOIS (TJ) NEEDLE ASPIRATION 15GA
TIN3015	0000854859	ILLINOIS (TJ) NEEDLE ASPIRATION 15GA
TIN3018	0000836574	ILLINOIS (TJ) NEEDLE ASPIRATION 18GA
TIN3018	0000841212	ILLINOIS (TJ) NEEDLE ASPIRATION 18GA
TIN3018	0000852078	ILLINOIS (TJ) NEEDLE ASPIRATION 18GA

<b>Product Code</b>	<b>Lot Code</b>	<b>Product Description</b>
TJC3513	0000848831	JAMSHIDI (TJ) NEEDLE BONE MARROW 13GX3.5
TJC3513	0000851431	JAMSHIDI (TJ) NEEDLE BONE MARROW 13GX3.5
TJC3513	0000854856	JAMSHIDI (TJ) NEEDLE BONE MARROW 13GX3.5
TJC4008	0000841227	JAMSHIDI (TJ) NEEDLE BONE MARROW 8G X4
TJC4008	0000846706	JAMSHIDI (TJ) NEEDLE BONE MARROW 8G X4
TJC4008	0000848560	JAMSHIDI (TJ) NEEDLE BONE MARROW 8G X4
TJC4008	0000849684	JAMSHIDI (TJ) NEEDLE BONE MARROW 8G X4
TJC4008	0000853455	JAMSHIDI (TJ) NEEDLE BONE MARROW 8G X4
TJC4011	0000840667	JAMSHIDI (TJ) NEEDLE BONE MARROW 11G X4
TJC4011	0000841228	JAMSHIDI (TJ) NEEDLE BONE MARROW 11G X4
TJC4011	0000845874	JAMSHIDI (TJ) NEEDLE BONE MARROW 11G X4
TJC4011	0000849717	JAMSHIDI (TJ) NEEDLE BONE MARROW 11G X4
TJC4011	0000850937	JAMSHIDI (TJ) NEEDLE BONE MARROW 11G X4
TJC4011	0000852121	JAMSHIDI (TJ) NEEDLE BONE MARROW 11G X4

<b>Product Code</b>	<b>Lot Code</b>	<b>Product Description</b>
TJC6008	0000841216	JAMSHIDI (TJ) NEEDLE BONE MARROW 8G X6
TJC6008	0000848569	JAMSHIDI (TJ) NEEDLE BONE MARROW 8G X6
TJC6008	0000851432	JAMSHIDI (TJ) NEEDLE BONE MARROW 8G X6
TJC6008	0000852122	JAMSHIDI (TJ) NEEDLE BONE MARROW 8G X6
TJC6008	0000853458	JAMSHIDI (TJ) NEEDLE BONE MARROW 8G X6
TJC6011	0000841124	JAMSHIDI (TJ) NEEDLE BONE MARROW 11G X6
TJC6011	0000848571	JAMSHIDI (TJ) NEEDLE BONE MARROW 11G X6
TJC6011	0000853975	JAMSHIDI (TJ) NEEDLE BONE MARROW 11G X6
TJM3513	0000836582	JAMSHIDI (TJ) NEEDLE BM 13G X3.5 ASP MAC
TJM3513	0000838949	JAMSHIDI (TJ) NEEDLE BM 13G X3.5 ASP MAC
TJM3513	0000843968	JAMSHIDI (TJ) NEEDLE BM 13G X3.5 ASP MAC
TJM3513	0000849685	JAMSHIDI (TJ) NEEDLE BM 13G X3.5 ASP MAC
TJM3513	0000852933	JAMSHIDI (TJ) NEEDLE BM 13G X3.5 ASP MAC
TJM4008	0000841349	JAMSHIDI (TJ) NEEDLE BM 8G X 4 ASP MAC

<b>Product Code</b>	<b>Lot Code</b>	<b>Product Description</b>
TJM4008	0000841348	JAMSHIDI (TJ) NEEDLE BM 8G X 4 ASP MAC
TJM4008	0000843961	JAMSHIDI (TJ) NEEDLE BM 8G X 4 ASP MAC
TJM4008	0000849132	JAMSHIDI (TJ) NEEDLE BM 8G X 4 ASP MAC
TJM4008	0000852123	JAMSHIDI (TJ) NEEDLE BM 8G X 4 ASP MAC
TJM4008	0000853877	JAMSHIDI (TJ) NEEDLE BM 8G X 4 ASP MAC
TJM4011	0000836575	JAMSHIDI (TJ) NEEDLE BM 11G X3.5 ASP MAC
TJM4011	0000838950	JAMSHIDI (TJ) NEEDLE BM 11G X3.5 ASP MAC
TJM4011	0000840195	JAMSHIDI (TJ) NEEDLE BM 11G X3.5 ASP MAC
TJM4011	0000843075	JAMSHIDI (TJ) NEEDLE BM 11G X3.5 ASP MAC
TJM4011	0000843076	JAMSHIDI (TJ) NEEDLE BM 11G X3.5 ASP MAC
TJM4011	0000846708	JAMSHIDI (TJ) NEEDLE BM 11G X3.5 ASP MAC
TJM4011	0000852932	JAMSHIDI (TJ) NEEDLE BM 11G X3.5 ASP MAC
TJM4011	0000853878	JAMSHIDI (TJ) NEEDLE BM 11G X3.5 ASP MAC
TJM4011	0000854861	JAMSHIDI (TJ) NEEDLE BM 11G X3.5 ASP MAC

<b>Product Code</b>	<b>Lot Code</b>	<b>Product Description</b>
TJM4011	0000854983	JAMSHIDI (TJ) NEEDLE BM 11G X3.5 ASP MAC
TJM6008	0000842725	JAMSHIDI (TJ) NEEDLE BM 8G X 6 ASP MAC
TJM6008	0000853971	JAMSHIDI (TJ) NEEDLE BM 8G X 6 ASP MAC
TJM6011	0000843077	JAMSHIDI (TJ) NEEDLE BM 11G X6 ASP MAC
TJM6011	0000849713	JAMSHIDI (TJ) NEEDLE BM 11G X6 ASP MAC
TJM6011	0000854659	JAMSHIDI (TJ) NEEDLE BM 11G X6 ASP MAC
TPK1001	0000837811	THORACENTESIS/PARACENTESIS KIT 10/CS
TPK1001	0000842215	THORACENTESIS/PARACENTESIS KIT 10/CS
TPK1001	0000840336	THORACENTESIS/PARACENTESIS KIT 10/CS
TPK1001	0000851185	THORACENTESIS/PARACENTESIS KIT 10/CS



75 North Fairway Drive  
Vernon Hills, Illinois 60061  
[BD.com](http://BD.com)

**URGENT: Medical Device Recall  
PACKAGING INTEGRITY – OPEN SEAL**

**Graphics on where to locate the Product Code / Lot  
Code**

**ATTACHMENT "B"**

# Product code: 4330

See graphics below on where to locate part number and lot number.

## Lot Code Case

**REF 4330** **X50**  
**Manometer, 550 ml Three-Way Stopcock**

EN Manometer, 550 ml Three-Way Stopcock  
FR Manomètre, 550 ml Robinet à trois voies  
DE Manometer, 550 ml Dreiweg-Absperrhahn  
IT Manometro, 550 ml Rubinetto a tre vie  
ES Manómetro, 550 ml Llave de tres vías  
NL Manometer, 550 ml Driewegkraan

**Lot 1234567890**  
Exp. Date 2020-04-30

(17) 200430 (10) 1234567890

(01) 10885403076143

**STERILE EO**  
Stopcock Made in Israel

CareFusion  
75 North Fairway Drive  
Vernon Hills, IL 60091 USA

CE  
CareFusion France 309 S.A.S.  
4 bis rue de la Renaissance  
48110 Cindres/Lez - France

371-62004 Rev 1 0123

Lot number on Case Label

## Lot Code Unit

**REF 4330**  
**Manometer, 550 ml Three-Way Stopcock**

EN Manometer, 550 ml Three-Way Stopcock  
FR Manomètre, 550 ml Robinet à trois voies  
DE Manometer, 550 ml Dreiweg-Absperrhahn  
IT Manometro, 550 ml Rubinetto a tre vie  
ES Manómetro, 550 ml Llave de tres vías  
NL Manometer, 550 ml Driewegkraan

**Lot 1234567890**

(01) 10885403076146  
(17) 200131  
(10) 0128450789

**CareFusion**

Lot number on Pouch Label

EN Instructions for Use  
FR Instructions d'usage  
DE Gebrauchsanweisung  
IT Istruzioni per l'uso  
ES Instrucciones de uso  
NL Gebruiksaanwijzing

Lot 1234567890  
Exp. Date 2020-01-31

**CareFusion**

# Product code: TPK1001

See graphics below on where to locate part number and lot number.

## Lot Code Case

**REF TPK1001 X 10**  
**Thora-Para 8 Fr Catheter Drainage Kit**

**REF** Thoracoentesis/Paracentesis Catheter Drainage Kit  
**EN** Kit de drainage pour cathéter pour thoracoentesis/paracentese  
**DE** Katheterdrainagekit für die Thoraxozentesis/Parazentese  
**FI** Kit di drenaggio con catetere per toracoentesi/paracentesi  
**FR** Kit de drainage de cathéter de thoracoentesis/paracentese  
**IT** Drainagec. Thoracoentesi/Paracentesi - catetere  
**JA** Torakoentesis/paracentesisnaeringussata für kateter  
**RU** Плевра- ja vätsäntelapunktio- ja dreneraussatta  
**ES** Drenajeset for thoracoentesis-/paracentesiskateter  
**SV** Kit napajanje srg. kubičnog šupljineg/hapajevnjeg  
**TR** 胸腔 / 胸腔穿刺用カテーテルドレインキット

**STERILE EO**  
 エチレンオキサイドガス滅菌済  
 Not made with natural rubber latex.

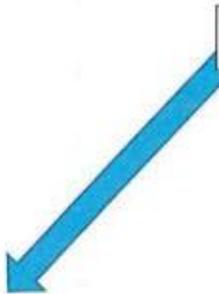
**CareFusion**  
 75 North Fairway Drive  
 Vernon Hills, IL 60061 USA  
**REP** CareFusion France 309 S.A.S.  
 8 bis rue de la Renaissance  
 44110 Châteaubriant - France  
 Sponsored by  
 CareFusion Australia 316 Pty. Ltd.  
 CareFusion New Zealand 313 Ltd.  
 371-6002 Rev 4

**Scalpel Made in India**  
**Extension Set Made in China**  
**S-to-1 Adapter Made in Dominican Republic**

**LOT 1234567890**  
 製造番号  
**2020-04-30**  
 Exp. Date  
 使用期限

1371200430 (10) 1234567890  
 101150085403076129

Lot number on Case Label



## Lot Code Unit

**REF TPK1001**  
**Thora-Para 8 Fr Catheter Drainage Kit**

**en** Thoracoentesis/Paracentesis Catheter Drainage Kit  
**fr** Kit de drainage pour cathéter pour thoracoentesis/paracentese  
**de** Katheterdrainagekit für die Thoraxozentesis/Parazentese  
**fi** Kit di drenaggio con catetere per toracoentesi/paracentesi  
**es** Kit de drenaje de catéter de toracoentesis/paracentesis  
**pt** Kit de cateter de drenagem de toracoentesis/paracentese  
**it** Drainagekit Thoracoentesis/Paracentesis - kateter  
**sv** Torakoentesis-/paracentesisnaeringussata för kateter

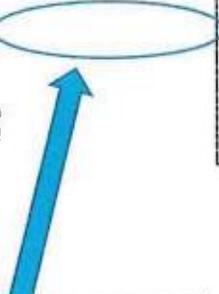
**da** Plevrapunktion/Paracentesesæt  
**E** Plevra- ja vätsäntelapunktio- ja dreneraussatta  
**ru** Drenajeset for thoracoentesis-/paracentesiskateter  
**el** Kit napajanje srg. kubičnog šupljineg/hapajevnjeg  
**ja** 胸腔 / 胸腔穿刺用カテーテルドレインキット

**CareFusion**  
 75 North Fairway Drive  
 Vernon Hills, IL 60061 USA  
**REP** CareFusion France 309 S.A.S.  
 8 bis rue de la Renaissance  
 44110 Châteaubriant - France  
 Sponsored by  
 CareFusion Australia 316 Pty. Ltd.  
 CareFusion New Zealand 313 Ltd.  
 371-6002 Rev 4

**STERILE EO**  
 エチレンオキサイドガス滅菌済  
**USA Rx Only**  
 再使用しないで下さい  
 For Single Use Only  
 Do not use if package is damaged.  
  
 Scalpel Made in India  
 Extension Set Made in China  
 S-to-1 Adapter Made in Dominican Republic  
 Consult instructions for use.  
 Not made with natural rubber latex.

**LOT**  
 製造番号  
**Exp. Date**  
 使用期限

Barcode Here



Lot number on Pouch Label



Product code: SN \_\_\_\_\_ X

See graphics below on where to locate part number and lot number.

### Lot Code Case

**REF SN1016X 16 G x 100 mm X10**

**Jamshidi™**

- Jamshidi Menghini Soft Tissue Biopsy Needle/Syringe
- Agnihāyanaṅga Jamshidi Menghini pour biopsie de tissus mous
- Jamshidi Menghini Weichgewebe Biopsienadel/Spritze
- Jamshidi Menghini Ago-Siringa per biopsia di tessuti molli
- Agnihāyanaṅga Jamshidi Menghini para biopsia de tejidos blandos
- Agnihāyanaṅga Jamshidi Menghini para Biopsia de Tecidos Moles
- Jamshidi Menghini Biopsienadel/Spritze voor Zacht Weefsel
- Jamshidi Menghini Mjékóváradó Biopszi tű/spruta
- Jamshidi Menghini tiel-énebiopel kanyak/sprajce
- Jamshidi Menghini Pehmytkudoshčipson reuklytkivo
- Jamshidi Menghini Matavastšipni nášpurne
- Jamshidi Menghini Bólhwa/Čipyna Biopsij Makkasú krodú
- ジャムシディ軟部組織針 (バイオプサイザル軟部組織生検針)とバイオプサイ

1171200430(10)1234567890

101130805403076169

STERILE EO

LOT 1234567890

2020-04-30

CareFusion

### Lot Code Unit

**REF SN1016X 16 G x 100 mm**

**Jamshidi™**

- Jamshidi Menghini Soft Tissue Biopsy Needle/Syringe
- Agnihāyanaṅga Jamshidi Menghini pour biopsie de tissus mous
- Jamshidi Menghini Weichgewebe Biopsienadel/Spritze
- Jamshidi Menghini Ago-Siringa per biopsia di tessuti molli
- Agnihāyanaṅga Jamshidi Menghini para biopsia de tejidos blandos
- Agnihāyanaṅga Jamshidi Menghini para Biopsia de Tecidos Moles
- Jamshidi Menghini Biopsienadel/Spritze voor Zacht Weefsel
- Jamshidi Menghini Mjékóváradó Biopszi tű/spruta
- Jamshidi Menghini tiel-énebiopel kanyak/sprajce
- Jamshidi Menghini Pehmytkudoshčipson reuklytkivo
- Jamshidi Menghini Matavastšipni nášpurne
- Jamshidi Menghini Bólhwa/Čipyna Biopsij Makkasú krodú
- ジャムシディ軟部組織針 (バイオプサイザル軟部組織生検針)とバイオプサイ

STERILE EO

USA Rx Only

LOT 1234567890

2020-04-30

CareFusion