



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

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**URGENT: Medical Device Recall**  
**PACKAGING INTEGRITY – OPEN SEAL**  
**MANOMETER TRAY**  
**JAMSHIDI NEEDLE BIOPSY**  
**ILLINOIS (TJ) NEEDLE ASPIRATION**  
**JAMSHIDI (TJ) NEEDLE BONE MARROW**  
**THORACENTESIS/PARACENTESIS KIT**

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**Correction Removal #: 1423507-FEBRUARY1702017-0001 R**  
**FSCA-RE: ISRC-2017-0001**

February 17, 2017

Dear Business Partner, Chairman Medical Board & Relevant Heads of Departments:

**Product Name:**

CareFusion a subsidiary of BD has identified a potential risk associated with the packaging integrity- open seal of the attached product – lot codes (attachment “A”). 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.

**Problem Statement/Affected Product:**

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

Affected Product – 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



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**POTENTIAL RISK:**

If this failure were to occur while in use in 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.

How to recognize that the device may fail: When the device is inspected prior to use the heat seal on the packaging should form a closed system with no openings to maintain sterility. This can be seen on the packaging with visual inspection prior to use.

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

A credit will be applied to your account for the affected product upon receipt of the affected unit(s) or receipt of certification of destruction documented on the Customer Response Form.

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

- Return the affected unit(s) to:  
CareFusion *a subsidiary of* BD,  
400 Foster Road  
Mannford, OK 74044  
Attention: ISRC-2017-0001 Recall Coordinator  
Include a copy of the response form with the returned unit.

Or

Complete the Customer Response Form certifying that all affected product in your inventory has been **destroyed** and mail/email a copy of the response form to:

CareFusion *a subsidiary of* BD  
75 North Fairway Drive  
Vernon Hills, IL 60061  
Attention: Recall Coordinator  
Email: [GMB-GLB-ISFieldActions@bd.com](mailto:GMB-GLB-ISFieldActions@bd.com)



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

The United States Food and Drug Administration has been notified of this action. Any adverse reactions experienced with the use of this product, and/or quality problems should also be reported to the FDA's MedWatch Program by:

- Web: MedWatch website at [www.fda.gov/medwatch](http://www.fda.gov/medwatch)
- Phone: 1 800-FDA-1088 (1 800-332-1088)
- Mail: MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787

For questions and support 1-800-323-9088 Prompt 3  
Or email: [GMB-GLB-ISFieldActions@bd.com](mailto:GMB-GLB-ISFieldActions@bd.com)

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

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

Sincerely,

[Redacted Signature]  
Helen V. Cox, RN  
Clinical Risk Coordinator, Customer Advocacy  
Medical and Procedural Solutions  
847-362-9362  
[Helen.cox@bd.com](mailto:Helen.cox@bd.com)

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



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## URGENT: Medical Device Recall

### PACKAGING INTEGRITY – OPEN SEAL

#### 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

CareFusion, a subsidiary of BD Identifier: **ISRC-2017-0001**  
Correction Removal #: **1423507-February172017-0001R**

Name of Hospital / Facility	
Hospital / Facility Address	
Name	
Telephone number	
Email address	
Signature	
Date	

☐

I have read and understand the contents of this Medical Device Recall and confirm that our medical equipment inventory has been checked, and we no longer have the affected product in our inventory



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- ☐ I have read and understood the contents of this Medical Device Recall and confirm that our medical equipment inventory has been checked, and we have the following affected product in our inventory

Equipment Inventory Table:

Model Number	Lot Number	QTY

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

- ☐ I have read and understood the contents of this Medical Device Recall and certify that I have destroyed all affected product indicated above as available inventory at the time of receipt of this notification.
- ☐ I have read and understood the contents of this Medical Device Recall and have returned all affected product indicated above as available inventory for credit.



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- ☐ **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 product with a copy of the Customer Response Form to:

CareFusion a subsidiary of BD,  
400 Foster Road  
Mannford, OK 74044  
Attention: ISRC-2017-0001 Recall Coordinator  
Correction Removal #: 1423507-February172017-0001R

Or

Complete the Customer Response Form certifying that all affected product in your inventory has been destroyed and mail/email a copy of the Customer Response Form to:

CareFusion a subsidiary of BD  
75 North Fairway Drive  
Vernon Hills, IL 60061  
Attention: Recall Coordinator  
Email: [GMB-GLB-ISFieldActions@bd.com](mailto:GMB-GLB-ISFieldActions@bd.com)





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## Medical Device Recall Frequently Asked Questions

CareFusion *a subsidiary of* BD is committed to ensuring patient safety and maintaining the highest level of regulatory compliance with the FDA and other Agency's around the globe.

The Q&A below may help answer some of your questions. Should you have any other questions, contact CareFusion *a subsidiary of* BD Customer Support at 800.323.9088 (8:00 am CST – 5:00 pm CST).

### Q&A

**Q: Why is CareFusion *a subsidiary of* BD recalling/removing this product from the marketplace?**

**A:** As part of CareFusion *a subsidiary of* BD's commitment to patient safety, a voluntary Medical Device Recall is being initiated due to a potential patient safety risk.

**Q: How are we communicating this product recall/removal to our customers?**

**A:** CareFusion *a subsidiary of* BD is providing this recall communication to our distributors and healthcare facilities that purchased and/or received any of the recalled products.

**Q: How do I receive credit for any recalled product(s)/lot(s) in my possession?**

**A:** If you are a Healthcare Facility that did **NOT purchase product directly** through CareFusion *a subsidiary of* BD please contact **your distributor** to initiate the credit process, if required.

If you are a Healthcare Facility **OR** Distributor that **purchased product direct** through CareFusion *a subsidiary of* BD please perform the following actions:

- Complete and return the **Customer Response Form**. The quantity indicated on the **Customer Response Form** of the affected product will be credited to your account.

**Q: What if I have clinical questions regarding this recall?**

**A:** Customers may contact CareFusion *a subsidiary of* BD's Clinical Risk Coordinator, Helen Cox, RN via email at [helen.cox@bd.com](mailto:helen.cox@bd.com) for assistance with any clinical questions.



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**Q: Has CareFusion a subsidiary of BD received any adverse event reports associated with any of the recalled products?**

**A: NO.** CareFusion a subsidiary of BD has received Six (6) complaints with zero (0) associated reports of any adverse events.

**Q: Is there a patient/user safety issue associated with this product recall?**

**A:** Yes, there is a patient safety risk involving the potential packaging integrity – open seal which maintains the sterility of the device. Although the packing integrity- open seal issue is visually obvious, if used on a patient it has the potential to result in an inflammatory/Infectious response locally and/or systemically.

**Q: Can customers (i.e. distributors, healthcare facilities, etc.) ignore this recall?**

**A:** No. It is important that our distributors and healthcare facilities take prompt action and return the affected unit(s) of all recalled products with a copy of the **Customer Response Form**. Attention to this recall is mandated by FDA regulations (specifically, 21 CFR Part 7).

**Q: Is there product customers can order to replace the affected lots?**

**A:** Yes. CareFusion a subsidiary of BD has replacement product available.

**Q: What should customers do if an adverse event occurs following use of any of the recalled products?**

**A:** In accordance with standard industry practice, customers must report any adverse event, associated with any products, to CareFusion a subsidiary of BD Customer Support and/or the FDA's MedWatch Program via any of the following communication methods:

- **CareFusion a subsidiary of BD:** 800.323.9088 (option #3 (Monday-Friday 8:00 am CST – 5:00 pm CST) Or email: [GMB-US-Complaint-Intake@carefusion.com](mailto:GMB-US-Complaint-Intake@carefusion.com)
- **FDA Web:** MedWatch website at [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)
- **FDA Fax:** 1-800-FDA-0178
- **FDA Mail:** MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD, 20852-9787 (refer to <http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm272194.htm> for the actual document)





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**Q: What steps do customers need to take in support of this recall?**

**A:** CareFusion *a subsidiary of BD* requires customers to take the following steps in a prompt manner:

- Step #1: Inspect current inventory on-hand
- Step #2: Complete the **Customer Response Form** by checking all appropriate boxes and providing all accurate information as necessary.
- Step #3: Return affected unit(s) of all recalled products on hand including the Customer Response Form to:  
CareFusion a subsidiary of BD,  
400 Foster Road  
Mannford, OK 74044  
Attention: ISRC-2017-0001 Recall Coordinator  
Correction Removal #: 1423507-FEBRUARY172017-0001R

Or

Complete the Customer Response Form certifying that all affected product in your inventory has been destroyed and mail/email a copy of the response form to:

CareFusion *a subsidiary of BD*  
75 North Fairway Drive  
Vernon Hills, IL 60061  
Attention: Recall Coordinator  
Email: [GMB-GLB-ISFieldActions@bd.com](mailto:GMB-GLB-ISFieldActions@bd.com)

- Include a copy of the Customer Response Form with the returned unit.
- Please ***promptly return*** the enclosed Customer Response Form to expedite the correction process and acknowledge receipt of this notification.



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**AFFECTED PRODUCT / LOT CODES**

**ATTACHMENT "A"**

Product Description	Lot Code	Intended Use
MANOMETER TRAY STERILE 10/BX	0000837810	Single piece, 550 mm manometer kit for various pressure monitoring procedures
MANOMETER TRAY STERILE 10/BX	0000840335	Single piece, 550 mm manometer kit for various pressure monitoring procedures
MANOMETER TRAY STERILE 10/BX	0000842213	Single piece, 550 mm manometer kit for various pressure monitoring procedures
MANOMETER TRAY STERILE 10/BX	0000848531	Single piece, 550 mm manometer kit for various pressure monitoring procedures
MANOMETER TRAY STERILE 10/BX	0000851181	Single piece, 550 mm manometer kit for various pressure monitoring procedures
MANOMETER TRAY STERILE 10/BX	0000853962	Single piece, 550 mm manometer kit for various pressure monitoring procedures
JAMSHIDI NEEDLE BIOPSY 15G X 100MM DISP	0000840334	Intended use for soft tissue biopsies such as liver, kidney, prostate, thyroid, lymph node, lung, and breast.
JAMSHIDI NEEDLE BIOPSY 16G X 100MM DISP	0000848028	Intended use for soft tissue biopsies such as liver, kidney, prostate, thyroid, lymph node, lung, and breast.
JAMSHIDI NEEDLE BIOPSY 17G X 100MM DISP	0000848018	Intended use for soft tissue biopsies such as liver, kidney, prostate, thyroid, lymph node, lung, and breast.
JAMSHIDI NEEDLE BIOPSY 16G X 70MM DISP	0000848017	Intended use for soft tissue biopsies such as liver, kidney, prostate, thyroid, lymph node, lung, and breast.



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ILLINOIS (TJ) NEEDLE ASPIRATION 15GA	0000836578	The Disposable Intraosseous Infusion Needle provides for a safe and simple technique to gain vascular access to deliver fluids and drugs to critically ill or injured children.
ILLINOIS (TJ) NEEDLE ASPIRATION 15GA	0000838953	The Disposable Intraosseous Infusion Needle provides for a safe and simple technique to gain vascular access to deliver fluids and drugs to critically ill or injured children.
ILLINOIS (TJ) NEEDLE ASPIRATION 15GA	0000841213	The Disposable Intraosseous Infusion Needle provides for a safe and simple technique to gain vascular access to deliver fluids and drugs to critically ill or injured children.
ILLINOIS (TJ) NEEDLE ASPIRATION 15GA	0000841215	The Disposable Intraosseous Infusion Needle provides for a safe and simple technique to gain vascular access to deliver fluids and drugs to critically ill or injured children.
ILLINOIS (TJ) NEEDLE ASPIRATION 15GA	0000842719	The Disposable Intraosseous Infusion Needle provides for a safe and simple technique to gain vascular access to deliver fluids and drugs to critically ill or injured children.
ILLINOIS (TJ) NEEDLE ASPIRATION 15GA	0000842721	The Disposable Intraosseous Infusion Needle provides for a safe and simple technique to gain vascular access to deliver fluids and drugs to critically ill or injured children.
ILLINOIS (TJ) NEEDLE ASPIRATION 15GA	0000845423	The Disposable Intraosseous Infusion Needle provides for a safe and simple technique to gain vascular access to deliver fluids and drugs to critically ill or injured children.
ILLINOIS (TJ) NEEDLE ASPIRATION 15GA	0000848061	The Disposable Intraosseous Infusion Needle provides for a safe and simple technique to gain vascular access to deliver fluids and drugs to critically ill or injured children.
ILLINOIS (TJ) NEEDLE ASPIRATION 15GA	0000849715	The Disposable Intraosseous Infusion Needle provides for a safe and simple technique to gain vascular access to deliver fluids and drugs to critically ill or injured children.
ILLINOIS (TJ) NEEDLE ASPIRATION 15GA	0000850938	The Disposable Intraosseous Infusion Needle provides for a safe and simple technique to gain vascular access to deliver fluids and drugs to critically ill or injured children.
ILLINOIS (TJ) NEEDLE ASPIRATION 15GA	0000852076	The Disposable Intraosseous Infusion Needle provides for a safe and simple technique to gain vascular access to deliver fluids and drugs to critically ill or injured children.
ILLINOIS (TJ) NEEDLE ASPIRATION 15GA	0000854859	The Disposable Intraosseous Infusion Needle provides for a safe and simple technique to gain vascular access to deliver fluids and drugs to critically ill or injured children.
ILLINOIS (TJ) NEEDLE ASPIRATION 18GA	0000836574	The Disposable Intraosseous Infusion Needle provides for a safe and simple technique to gain vascular access to deliver fluids and drugs to critically ill or injured children.
ILLINOIS (TJ) NEEDLE ASPIRATION 18GA	0000841212	The Disposable Intraosseous Infusion Needle provides for a safe and simple technique to gain vascular access to deliver fluids and drugs to critically ill or injured children.
ILLINOIS (TJ) NEEDLE ASPIRATION 18GA	0000852078	The Disposable Intraosseous Infusion Needle provides for a safe and simple technique to gain vascular access to deliver fluids and drugs to critically ill or injured children.



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JAMSHIDI (TJ) NEEDLE BONE MARROW 13GX3.5	0000848831	Intended use for the posterior iliac crest biopsy technique.
JAMSHIDI (TJ) NEEDLE BONE MARROW 13GX3.5	0000851431	Intended use for the posterior iliac crest biopsy technique.
JAMSHIDI (TJ) NEEDLE BONE MARROW 13GX3.5	0000854856	Intended use for the posterior iliac crest biopsy technique.
JAMSHIDI (TJ) NEEDLE BONE MARROW 8G X4	0000841227	Intended use for the posterior iliac crest biopsy technique.
JAMSHIDI (TJ) NEEDLE BONE MARROW 8G X4	0000846706	Intended use for the posterior iliac crest biopsy technique.
JAMSHIDI (TJ) NEEDLE BONE MARROW 8G X4	0000848560	Intended use for the posterior iliac crest biopsy technique.
JAMSHIDI (TJ) NEEDLE BONE MARROW 8G X4	0000849684	Intended use for the posterior iliac crest biopsy technique.
JAMSHIDI (TJ) NEEDLE BONE MARROW 8G X4	0000853455	Intended use for the posterior iliac crest biopsy technique.
JAMSHIDI (TJ) NEEDLE BONE MARROW 11G X4	0000840667	Intended use for the posterior iliac crest biopsy technique.
JAMSHIDI (TJ) NEEDLE BONE MARROW 11G X4	0000841228	Intended use for the posterior iliac crest biopsy technique.
JAMSHIDI (TJ) NEEDLE BONE MARROW 11G X4	0000845874	Intended use for the posterior iliac crest biopsy technique.
JAMSHIDI (TJ) NEEDLE BONE MARROW 11G X4	0000849717	Intended use for the posterior iliac crest biopsy technique.
JAMSHIDI (TJ) NEEDLE BONE MARROW 11G X4	0000850937	Intended use for the posterior iliac crest biopsy technique.
JAMSHIDI (TJ) NEEDLE BONE MARROW 11G X4	0000852121	Intended use for the posterior iliac crest biopsy technique.
JAMSHIDI (TJ) NEEDLE BONE MARROW 8G X6	0000841216	Intended use for the posterior iliac crest biopsy technique.





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JAMSHIDI (TJ) NEEDLE BONE MARROW 8G X6	0000848569	Intended use for the posterior iliac crest biopsy technique.
JAMSHIDI (TJ) NEEDLE BONE MARROW 8G X6	0000851432	Intended use for the posterior iliac crest biopsy technique.
JAMSHIDI (TJ) NEEDLE BONE MARROW 8G X6	0000852122	Intended use for the posterior iliac crest biopsy technique.
JAMSHIDI (TJ) NEEDLE BONE MARROW 8G X6	0000853458	Intended use for the posterior iliac crest biopsy technique.
JAMSHIDI (TJ) NEEDLE BONE MARROW 11G X6	0000841124	Intended use for the posterior iliac crest biopsy technique.
JAMSHIDI (TJ) NEEDLE BONE MARROW 11G X6	0000848571	Intended use for the posterior iliac crest biopsy technique.
JAMSHIDI (TJ) NEEDLE BONE MARROW 11G X6	0000853975	Intended use for the posterior iliac crest biopsy technique.
JAMSHIDI (TJ) NEEDLE BM 13G X3.5 ASP MAC	0000836582	Intended use for the posterior iliac crest biopsy technique.
JAMSHIDI (TJ) NEEDLE BM 13G X3.5 ASP MAC	0000838949	Intended use for the posterior iliac crest biopsy technique.
JAMSHIDI (TJ) NEEDLE BM 13G X3.5 ASP MAC	0000843968	Intended use for the posterior iliac crest biopsy technique.
JAMSHIDI (TJ) NEEDLE BM 13G X3.5 ASP MAC	0000849685	Intended use for the posterior iliac crest biopsy technique.
JAMSHIDI (TJ) NEEDLE BM 13G X3.5 ASP MAC	0000852933	Intended use for the posterior iliac crest biopsy technique.
JAMSHIDI (TJ) NEEDLE BM 8G X 4 ASP MAC	0000841349	Intended use for the posterior iliac crest biopsy technique.
JAMSHIDI (TJ) NEEDLE BM 8G X 4 ASP MAC	0000841348	Intended use for the posterior iliac crest biopsy technique.
JAMSHIDI (TJ) NEEDLE BM 8G X 4 ASP MAC	0000843961	Intended use for the posterior iliac crest biopsy technique.



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JAMSHIDI (TJ) NEEDLE BM 8G X 4 ASP MAC	0000849132	Intended use for the posterior iliac crest biopsy technique.
JAMSHIDI (TJ) NEEDLE BM 8G X 4 ASP MAC	0000852123	Intended use for the posterior iliac crest biopsy technique.
JAMSHIDI (TJ) NEEDLE BM 8G X 4 ASP MAC	0000853877	Intended use for the posterior iliac crest biopsy technique.
JAMSHIDI (TJ) NEEDLE BM 11G X3.5 ASP MAC	0000836575	Intended use for the posterior iliac crest biopsy technique.
JAMSHIDI (TJ) NEEDLE BM 11G X3.5 ASP MAC	0000838950	Intended use for the posterior iliac crest biopsy technique.
JAMSHIDI (TJ) NEEDLE BM 11G X3.5 ASP MAC	0000840195	Intended use for the posterior iliac crest biopsy technique.
JAMSHIDI (TJ) NEEDLE BM 11G X3.5 ASP MAC	0000843075	Intended use for the posterior iliac crest biopsy technique.
JAMSHIDI (TJ) NEEDLE BM 11G X3.5 ASP MAC	0000843076	Intended use for the posterior iliac crest biopsy technique.
JAMSHIDI (TJ) NEEDLE BM 11G X3.5 ASP MAC	0000846708	Intended use for the posterior iliac crest biopsy technique.
JAMSHIDI (TJ) NEEDLE BM 11G X3.5 ASP MAC	0000852932	Intended use for the posterior iliac crest biopsy technique.
JAMSHIDI (TJ) NEEDLE BM 11G X3.5 ASP MAC	0000853878	Intended use for the posterior iliac crest biopsy technique.
JAMSHIDI (TJ) NEEDLE BM 11G X3.5 ASP MAC	0000854861	Intended use for the posterior iliac crest biopsy technique.
JAMSHIDI (TJ) NEEDLE BM 11G X3.5 ASP MAC	854983	Intended use for the posterior iliac crest biopsy technique.
JAMSHIDI (TJ) NEEDLE BM 8G X 6 ASP MAC	0000842725	Intended use for the posterior iliac crest biopsy technique.
JAMSHIDI (TJ) NEEDLE BM 8G X 6 ASP MAC	0000853971	Intended use for the posterior iliac crest biopsy technique.





**CareFusion**  
*has joined BD*



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JAMSHIDI (TJ) NEEDLE BM 11G X6 ASP MAC	0000843077	Intended use for the posterior iliac crest biopsy technique.
JAMSHIDI (TJ) NEEDLE BM 11G X6 ASP MAC	0000849713	Intended use for the posterior iliac crest biopsy technique.
JAMSHIDI (TJ) NEEDLE BM 11G X6 ASP MAC	0000854659	Intended use for the posterior iliac crest biopsy technique.
THORACENTESIS/PARACENTESIS KIT 10/CS	0000837811	To remove fluid and/or air from either the pleural or peritoneal spaces during an acute drainage/aspiration procedure.
THORACENTESIS/PARACENTESIS KIT 10/CS	0000842215	To remove fluid and/or air from either the pleural or peritoneal spaces during an acute drainage/aspiration procedure.
THORACENTESIS/PARACENTESIS KIT 10/CS	0000840336	To remove fluid and/or air from either the pleural or peritoneal spaces during an acute drainage/aspiration procedure.
THORACENTESIS/PARACENTESIS KIT 10/CS	0000851185	To remove fluid and/or air from either the pleural or peritoneal spaces during an acute drainage/aspiration procedure.



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**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

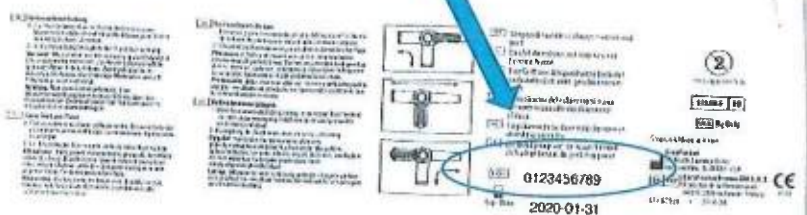


Lot number on Case Label

### Lot Code Unit



Lot number on Pouch Label



## 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**

[en] Thoracocentesis/Paracentesis Catheter Drainage Kit  
 [es] Kit de drenaje para catéter para tórax/centesis/paracentesis  
 [fr] Cathéter drainage kit für die Thoracocentese/Paracentese  
 [it] Kit di drenaggio con catetere per toracentesi/paracentesi  
 [de] Kit de drainage de cathéter de toracocentese/paracentese  
 [pt] Kit de cateter de drenagem de toracocentese/paracentese  
 [ru] Торакцентез/парацентез катетер дренажа  
 [ja] 胸/腹穿刺用カテーテルドレインキット

[en] Sterile EO  
 [es] No  
 [fr] Sterilisé EO  
 [it] Non  
 [de] Sterilisiert EO  
 [pt] Não  
 [ru] Стерильно EO  
 [ja] 滅菌 EO

[en] Not made with natural rubber latex  
 [es] No se hizo con látex natural  
 [fr] Ne contient pas de latex naturel  
 [it] Non contiene lattice naturale  
 [de] Nicht aus Naturkautschuk  
 [pt] Não contém látex natural  
 [ru] Не содержит натурального каучука  
 [ja] 天然ラバーを使用していない

CareFusion  
 75 North Fairway Drive  
 Vernon Hills, IL 60061 USA  
 CareFusion France 309 S.A.S.  
 8 bis rue de la Renaissance  
 44110 Châteaubriant - France  
 CE 0123  
 Sponsored by  
 CareFusion Australia 316 Pty. Ltd.  
 CareFusion New Zealand 313 Ltd.  
 371-60612 Rev 4  
**CareFusion**

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

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

1371200430 (10) 1234567890  
 10130005403076129

Lot number on Case Label

### Lot Code Unit

**REF TPK1001**

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

[en] Thoracocentesis/Paracentesis Catheter Drainage Kit  
 [es] Kit de drenaje para catéter para tórax/centesis/paracentesis  
 [fr] Cathéter drainage kit für die Thoracocentese/Paracentese  
 [it] Kit di drenaggio con catetere per toracentesi/paracentesi  
 [de] Kit de drainage de cathéter de toracocentese/paracentese  
 [pt] Kit de cateter de drenagem de toracocentese/paracentese  
 [ru] Торакцентез/парацентез катетер дренажа  
 [ja] 胸/腹穿刺用カテーテルドレインキット

[en] Sterile EO  
 [es] No  
 [fr] Sterilisé EO  
 [it] Non  
 [de] Sterilisiert EO  
 [pt] Não  
 [ru] Стерильно EO  
 [ja] 滅菌 EO

[en] For Single Use Only  
 [es] Para Uso Único  
 [fr] À Usage Unique  
 [it] Per Singola Utilizzazione  
 [de] Nur für Einmalgebrauch  
 [pt] Para Uso Único  
 [ru] Для однократного использования  
 [ja] 単回使用専用

[en] Do not use if package is damaged  
 [es] No usar si el paquete está dañado  
 [fr] Ne pas utiliser si l'emballage est endommagé  
 [it] Non usare se il pacchetto è danneggiato  
 [de] Nicht verwenden, wenn die Verpackung beschädigt ist  
 [pt] Não usar se o pacote estiver danificado  
 [ru] Не использовать, если упаковка повреждена  
 [ja] 包装が破損している場合は使用しない

[en] Consult instructions for use  
 [es] Consulte las instrucciones de uso  
 [fr] Consulter les instructions d'usage  
 [it] Consultare le istruzioni d'uso  
 [de] Gebrauchsanweisung lesen  
 [pt] Consultar as instruções de uso  
 [ru] Прочитать инструкцию по применению  
 [ja] 使用説明書を確認

[en] Not made with natural rubber latex  
 [es] No se hizo con látex natural  
 [fr] Ne contient pas de latex naturel  
 [it] Non contiene lattice naturale  
 [de] Nicht aus Naturkautschuk  
 [pt] Não contém látex natural  
 [ru] Не содержит натурального каучука  
 [ja] 天然ラバーを使用していない

CareFusion  
 75 North Fairway Drive  
 Vernon Hills, IL 60061 USA  
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 44110 Châteaubriant - France  
 CE 0123  
 Sponsored by  
 CareFusion Australia 316 Pty. Ltd.  
 CareFusion New Zealand 313 Ltd.  
 371-60612 Rev 4  
**CareFusion**

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

**LOT**  
 製造番号  
 Exp. Date  
 使用期限

Barcode Here

Lot number on Pouch Label

**Product code: TJ or TIN**

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

### Lot Code Case



Lot number on Case Label

**Lot Code Unit**

1000



印刷上の注意：この雑誌に掲載の  
 記事は、必ずしも最新の状況に  
 基づいていない場合があります。  
 印刷：2000年10月10日



(01)10885403043796

(17) 200430

(10) 1234567890



1491 1492  
1493 1494  
1495 1496  
1497 1498  
1499 1500

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 Bopsy Needle/Syringe  
Aguilha/bicornejo Jamshidi Menghini para biópsia de tecidos moles  
Jamshidi Menghini Weichgewebe Biopsienadel/Spritze  
Jamshidi Menghini Ago-Siringa per biópsia de tecuts moles  
Aguja/Siringa Jamshidi Menghini para biópsia de tejidos blandos  
Aguha/Siringa Jamshidi Menghini para Biópsia de Tecidos Moles  
Jamshidi Menghini Biopsienadel-spruit voor Zacht Weefsel  
Jamshidi Menghini Nykelyrads Biopsi nålspruta  
Jamshidi Menghini tied-elastikopel kanyla/spręża  
Jamshidi Menghini Pehmytkudoshlöpssion raukyläruisku  
Jamshidi Menghini Mäkkösteippiel nälspruuta  
Jamshidi Menghini Bolha/Lúpsya Biopsiá Mäkkösteippiel  
ジャムシディ軟組織生検針(ダイスボーザブル軟組織生検針およびシランジ)

1171 200430 (10) 1234567890

0211 80885403076169

STERILE EO

**LOT 1234567890**

2020-04-30

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44110 Chantenay - France  
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371-47562 Rev 3

Lot number on Case Label

### Lot Code Unit

**REF SN1016X 16 G x 100 mm**

**Jamshidi™**

Jamshidi Menghini Soft Tissue Bopsy Needle/Syringe  
Aguilha/bicornejo Jamshidi Menghini para biópsia de tecidos moles  
Jamshidi Menghini Weichgewebe Biopsienadel/Spritze  
Jamshidi Menghini Ago-Siringa per biópsia de tecuts moles  
Aguja/Siringa Jamshidi Menghini para biópsia de tejidos blandos  
Aguha/Siringa Jamshidi Menghini para Biópsia de Tecidos Moles  
Jamshidi Menghini Biopsienadel-spruit voor Zacht Weefsel  
Jamshidi Menghini Nykelyrads Biopsi nålspruta  
Jamshidi Menghini tied-elastikopel kanyla/spręża  
Jamshidi Menghini Pehmytkudoshlöpssion raukyläruisku  
Jamshidi Menghini Mäkkösteippiel nälspruuta  
Jamshidi Menghini Bolha/Lúpsya Biopsiá Mäkkösteippiel  
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