75 North Fairway Drive
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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

Correction Removal #: 1423507-FEBRUARY1702017-0001R
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

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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
- 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

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]

Helen V. Cox, RN
Clinical Risk Coordinator, Customer Advocacy
Medical and Procedural Solutions
847-362-9362
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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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)

Name	
Telephone Number	
Email	

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

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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 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
- **FDA Web**: MedWatch website at 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

- 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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URGENT: Medical Device Recall
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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.

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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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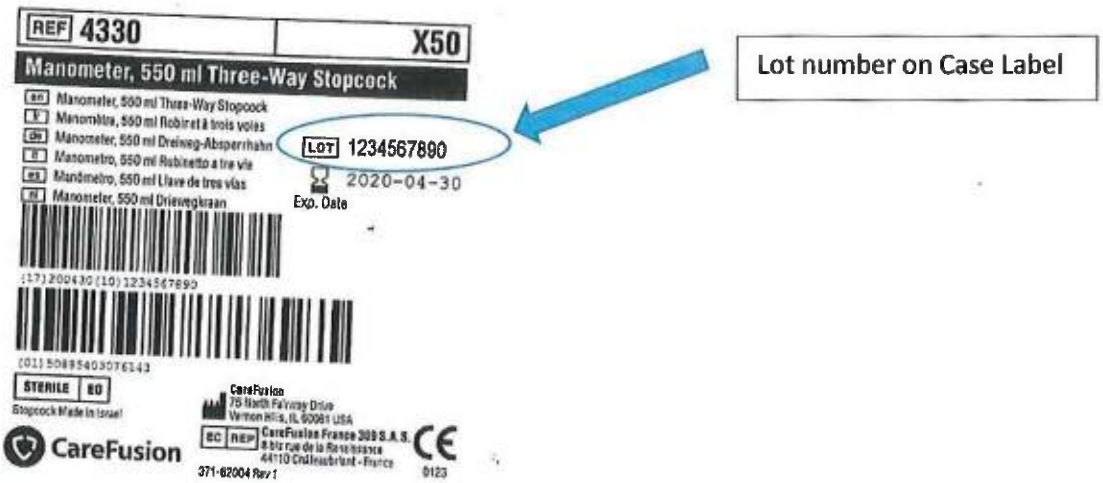
Graphics on where to locate the Product Code / Lot Code
ATTACHMENT "B"

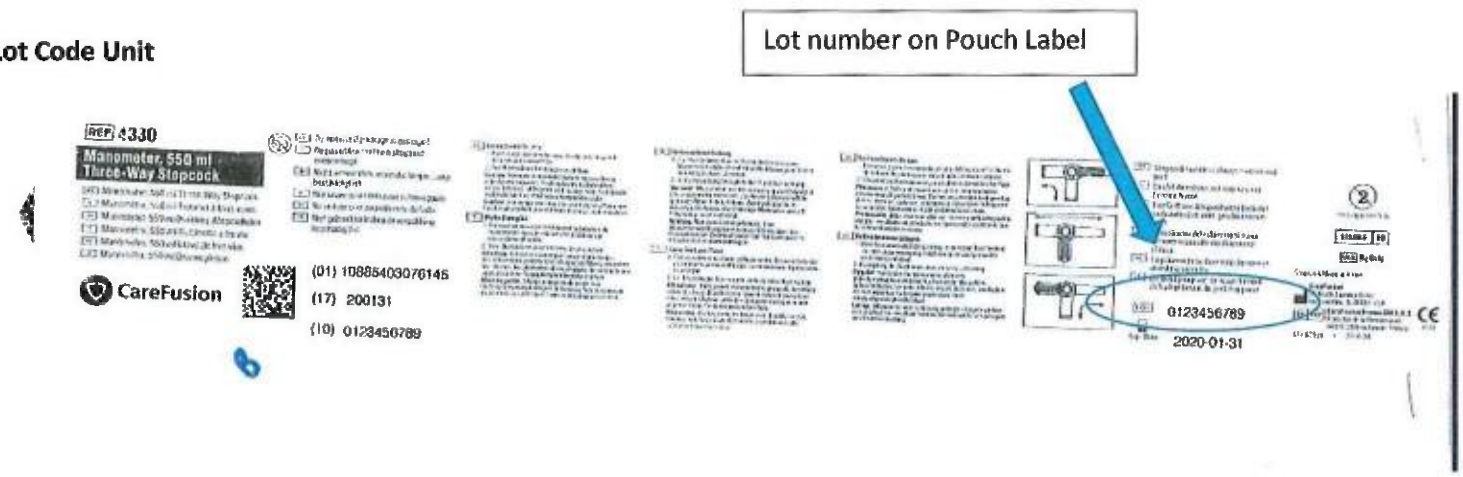
Product code: 4330

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

Lot Code Case



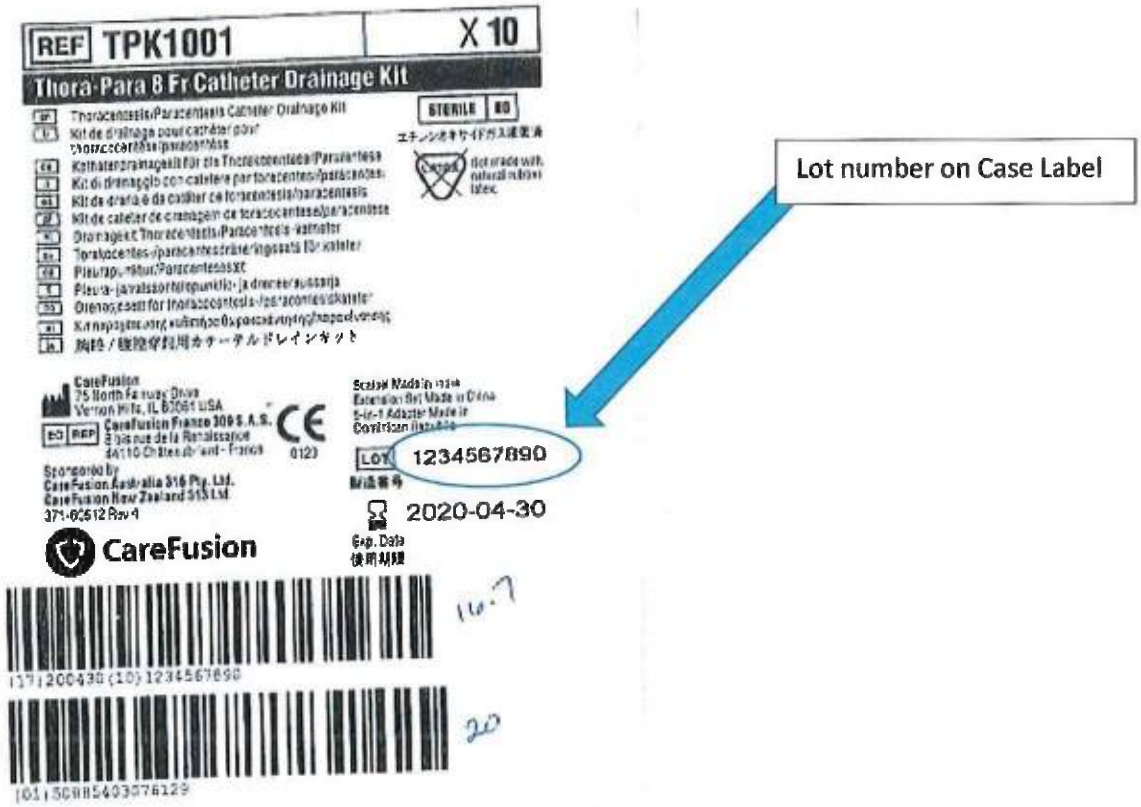
Lot Code Unit



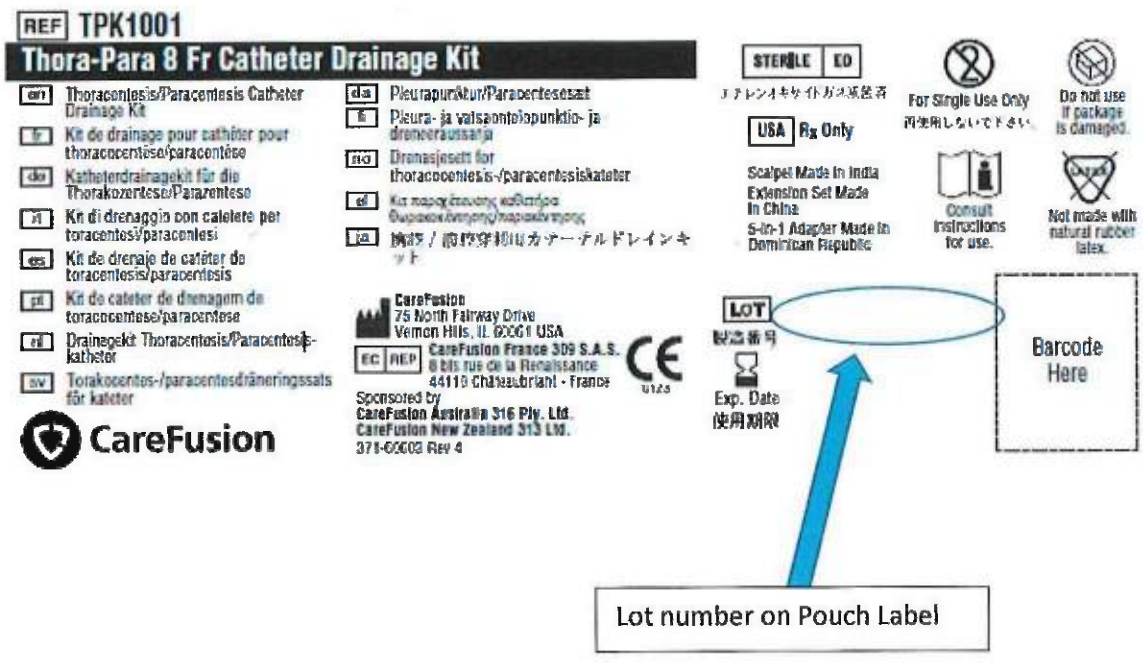
Product code: TPK1001

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

Lot Code Case



Lot Code Unit

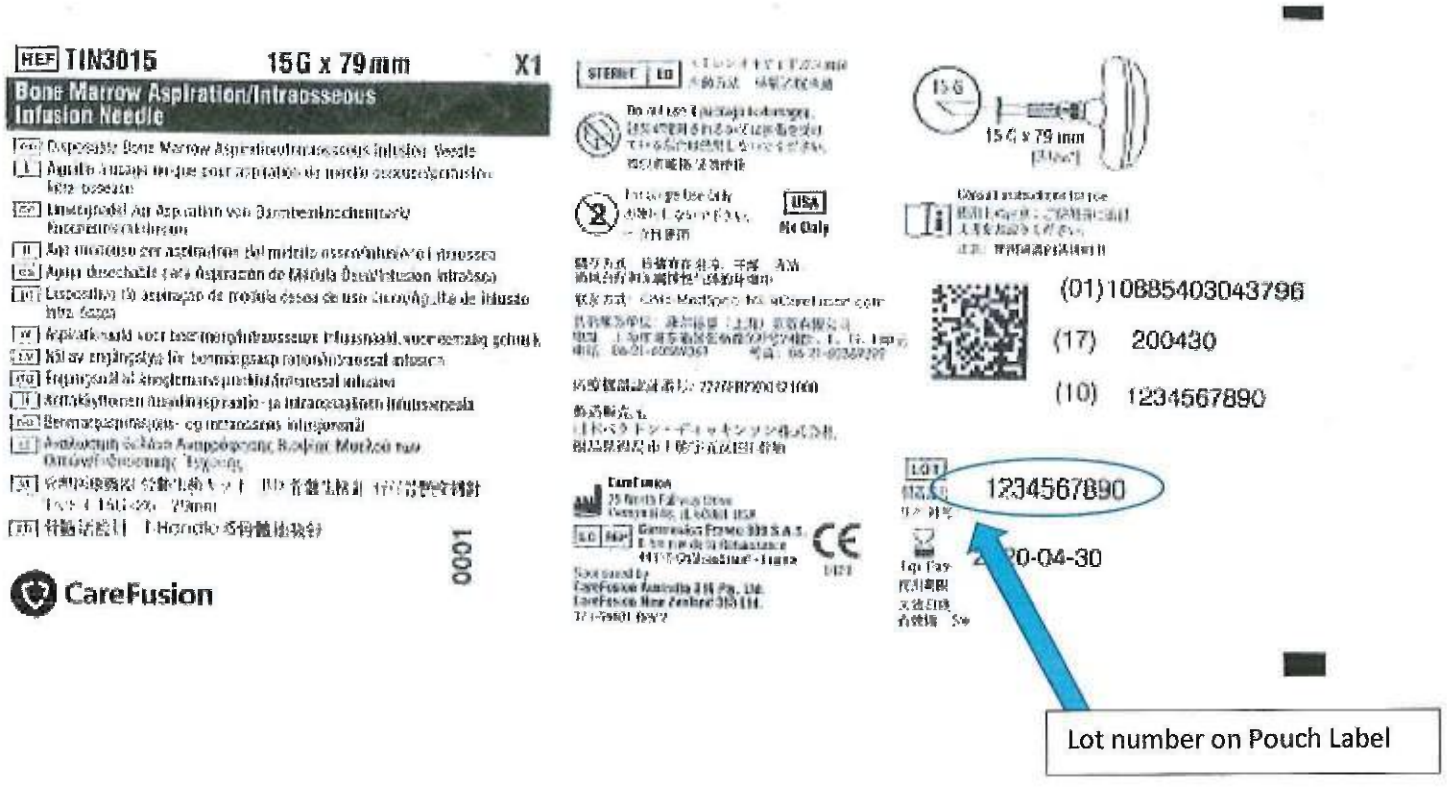


Product code: TJ or TIN

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

Lot Code Case

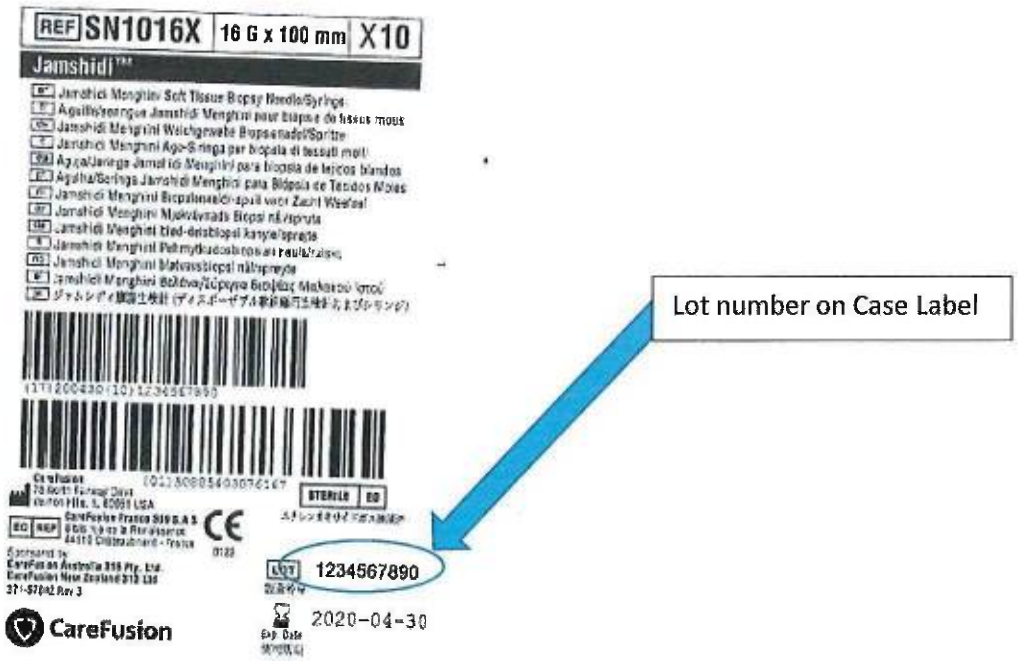
Lot Code Unit



Product code: SN_____X

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

Lot Code Case



Lot Code Unit