



**URGENT MEDICAL DEVICE PRODUCT RECALL**

**BD Jamshidi™ Crown Bone Marrow Biopsy/Aspiration Needle with MAC**

August 1, 2019

Product name	Catalog No.	Lot No.	UDI
8 G x 10 CM Jamshidi™ Crown Bone Marrow Biopsy/Aspiration Needle with MAC	TJM4008	0001159474	(01)10885403044564 + (10)0001159474(17)220831

**For the Attention of:** Medical Director, Risk Manager, Medical Device Safety Officer, Nurse Manager

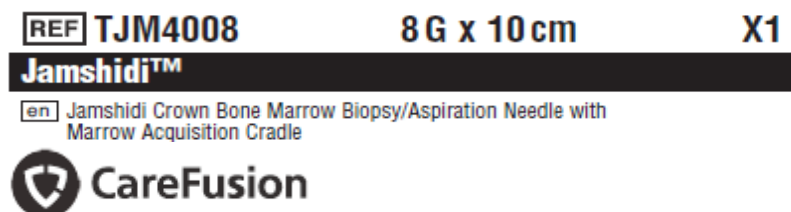
**Description of the problem and health hazard(s):**

BD is conducting a voluntary recall for one lot of 8ga x 10cm Jamshidi™ Crown Bone Marrow Biopsy/Aspiration Needle with MAC (lot referenced in table above). The recall is being conducted as some pouches from the affected lot may not be sealed properly. If a device from an unsealed pouch is used it could cause contamination or infection.

Our records indicate your facility received affected product.

**Please Take the Following Action(s):**

1. Immediately review your inventory for the specific Catalog and Lot number listed above (see reference labeling below). Destroy all product subject to the recall following your institution's process for destruction.



2. Share this recall notification with all users of the product within your facility to ensure that they are also aware of this recall.

3. Complete the attached Customer Response Form and return to the BD contact noted on the form whether or not you have any of the impacted material so that BD may acknowledge your receipt of this notification and process your product replacement.
4. Report any adverse health consequences experienced with the use of this product to BD. Events may also be reported to the FDA's MedWatch Adverse Event Reporting program.  
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 Fisher's Lane, Rockville, MD 20852-9787

**Actions Taken by BD:**

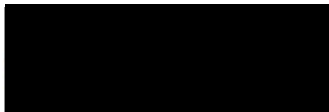
1. BD has identified the root cause of this situation and has implemented corrective actions.
2. BD will process product replacement for any discarded inventory.

**Contact Information:** If you require further assistance, please contact:

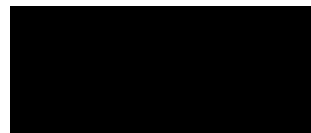
BD Contact	Contact Information	Areas of Support
BD Customer/Technical Support	800-638-8663 Monday – Friday between 7:00am and 7:00pm (EST) in the United States.	For customers outside the US, contact your local BD representative or distributor.

BD is committed to advancing the world of health. Our primary objectives are patient and user safety and providing you with quality products. We apologize for any inconvenience this issue may have caused you and thank you in advance for helping us to resolve this matter as quickly and effectively as possible.

Sincerely,



Gail Griffiths  
Sr. Director, Corporate Regulatory Compliance



VP Quality Assurance

**CUSTOMER RESPONSE FORM**  
**BD Jamshidi™ Crown Bone Marrow Biopsy/Aspiration Needle with MAC**

**Please assist BD by promptly returning this form to:**

**BD Regulatory Compliance**

**Email: [BDRC8@bd.com](mailto:BDRC8@bd.com)**

**Fax No.: 312-949-0231**

**Facility:** \_\_\_\_\_

Please use full, current facility name. Do not use initials.

**Ship to Street Address:** \_\_\_\_\_

**City:** \_\_\_\_\_ **State:** \_\_\_\_\_ **Zip:** \_\_\_\_\_

**Contact Person:** \_\_\_\_\_

**Telephone No.:** \_\_\_\_\_ **Fax No.:** \_\_\_\_\_

**Email Address:** \_\_\_\_\_

☐ I have read and understood the attached notice.

Name:	
Title:	
Signature/Date:	

☐ We do not have any of the affected product(s) on hand.

☐ We have the following units on hand and request replacement.

Catalog No.	Lot No.	Units (Qty.)
TJM4008	0001159474	

☐ I confirm that I have destroyed all affected product indicated above as available inventory at the time of receipt of this notification.