

**\*\*\*\* URGENT MEDICAL DEVICE RECALL \*\*\*\***

Re: **Volcano PV .035 Catheter, REF number 88901, S/N 50002518 xxx**  
**Volcano Prestige Plus 185cm J-Tip, REF number 9185J, SN 50004551 xxx**

June 4, 2015

Dear Volcano Customer:

Volcano Corporation is initiating a voluntary recall of **one lot of PV .035 Catheter** and **one lot of Prestige Plus 185 cm J-Tip** because an incorrect expiration date may be printed on the outside of the package. The lot and serial numbers of devices subject to this recall are provided below.

REF Number	Device	Lot Number	SN
88901	PV. 035 Catheter	50002518	All
9185J	Prestige Plus 185cm J-Tip	50004551	005 - 060

The lot number and serial number may be found on the package label as indicated in the illustration below.

Product	Label Illustration	Comments
PV .035 Catheter		SN will read as follows:  SN 0232 50002518 xxx
Prestige Plus 185cm J-Tip		SN will read as follows:  SN 0111 50004551 xxx Where xxx = 005-060

We are initiating this recall as a precaution due to the potential that the product may be labeled beyond its expiration date. A small number of units were impacted by a relabeling procedure at the manufacturing facility and may have been labeled with an expiration date that is later than the actual expiration date. These products could reach their expiration date as early as September, 2015, so prompt attention to this recall is required.

Although the risk of malfunction is low, performance of this product cannot be assured if it is used beyond the expiration date. Therefore, Volcano asks that you immediately examine your product inventory for product affected by this recall. Should you identify any affected product, quarantine the affected product, complete the attached form, and then contact Volcano Customer Service at (800) 228-4728, option 4 to arrange for the return of any product in your inventory. A credit will be issued for any returned product.



PRECISION GUIDED THERAPY

If you have no inventory of the affected product, please complete, sign, and return the attached form indicating that you no longer have inventory.

We recognize the inconvenience this may cause you, your staff, and your patients. However, this action reflects Volcano Corporation's commitment to patient safety and high quality standards. No other lots of product are impacted.

Please ensure that a copy of this Product Recall Notification is provided to all personnel within your organization who handle these products. Thank you for your prompt attention to this important matter. On behalf of Volcano, we appreciate your partnership and your continued support.

Sincerely,



Lisa M. Quaglia  
AVP, Regulatory Affairs and Quality Compliance

**Volcano Customer Service**

✉ 2870 Kilgore Road, Rancho Cordova, CA 95670

☎ 800-228-4728, select Option 4

📧 [customerservice@volcanocorp.com](mailto:customerservice@volcanocorp.com)

### CUSTOMER RETURN FORM

**Volcano PV .035 Catheter/Volcano Prestige Plus 185cm J-Tip**

**Hospital Name:** \_\_\_\_\_

**Hospital Address:** \_\_\_\_\_

**Contact Email:** \_\_\_\_\_

**Contact Phone:** \_\_\_\_\_

**Instructions:**

1. Complete the information below.
2. Fax completed form to Volcano Customer Service at (916) 638-8812.
3. Volcano will email the RMA number and a shipping label for the return.
4. Remove any affected inventory and return it to Volcano Corporation per instructions.

\_\_\_\_\_ NO, I don't have any affected product in inventory

\_\_\_\_\_ YES, I have inventory and am returning the following products:

Device	# Units Returning	RMA Number
PV. 035 Catheter		
Prestige Plus 185cm J-Tip		

Completed By:	Name	Signature	Date

**Upon completion, please return form to Volcano Customer Service by Fax (916) 638-8812. Questions? Please call (800) 228-4728, option 4.**