VOLCANO
PRECISION GUIDED THERAPY

****** URGENT FIELD SAFETY NOTICE ******

Re: Volcano Trak Back® II Disposable Pullback Device, part number 91003

August 25, 2014

Dear Volcano Customer:

Volcano Corporation is committed to quality and performance in our products. As a result of this commitment, Volcano Corporation is initiating a voluntary recall of all lots of the Trak Back® II Disposable Pullback Device. The Trak Back II device is designed for use with Volcano's Eagle Eye® family of intravascular imaging catheters. It is intended to move the catheter steadily and precisely, allowing uniform collection of imaging data. There are no concerns related to the ability of the device to perform a "pullback."

We are initiating this recall as a precaution due to a concern related to the integrity of the primary pouch packaging that may impact the product sterility after shipment. Volcano has not received any complaints for this and there have been no reported patient injuries or deaths caused by the use of the product.

Should the integrity of the primary pouch packaging fail to maintain sterility of the device, the use of this device could potentially lead to the introduction of contamination into the sterile field, which could potentially lead to an adverse reaction to the patient. Volcano believes this risk to be low, however this potential breach is difficult to identify.

As a result of this recall we ask that you immediately cease use of the Trak Back II device and return unused devices to our distribution center. The affected product is identified in the table below:

Product Code/Reference Number	Product Description	Lots Affected
91003	Trak Back Pullback Device	All

Please prepare the attached inventory log and then contact Volcano Customer Service by phone at 00 32 679 10 75 or by e-mail to verecall@volcanocorp.com to arrange for the return of any product in your inventory. A credit will be issued for any returned product. The inventory form must be returned even if you have no product in 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. A manual pullback of the Eagle Eye catheter may be performed for your continued use of this device. Alternatively, your Volcano sales representative is available to discuss other alternatives that may meet your physician and staff needs in lieu of using the Trak Back II device.

Please ensure that a copy of this Product Recall Notification is provided to all personnel within your organization who use these products.
The relevant National Competent Authorities have been advised of this Field Safety Corrective Action.

Thank you for your prompt attention to this important matter. On behalf of Volcano, we appreciate your partnership and your continued support.

Sincerely,

Clarisse Halawani
Director Operations

Clarisse Halawani
Operations Director EMEAI
Volcano Europe BVBA/SPRL
Excelsiorlaan 41 - 1930 - Zaventem - Belgium

Volcano Europe Customer Service
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CUSTOMER INVENTORY LOG

Hospital Name: _____

Hospital Address: _____

Contact Email: _____

Contact Phone: _____

Instructions:

1. Complete the information below.
2. Fax completed form to Volcano Customer Service at:
   + 32 2 679 10 79 or e-mail to verecall@volcanocorp.com
   Volcano will email the RMA number and a shipping label for the return.
3. Please remove any unused inventory and return it to Volcano Corporation per emailed instructions.

Trak Back II (91003) Inventory on Site?	__ Yes	__ No
If yes, fill in table below.		

	Trak Back II Serial Number (List one serial number per line. Use additional forms if needed.)
1	
2	
3	
4	
5	
6	
7	

Completed By: Name	Signature	Date

Upon completion, please return form to Volcano Customer Service by Fax 00 32 2 679 10 79
Questions? Please call +32 2 679 10 75 or by e-mail verecall@volcanocorp.com