VOLCANO
PRECISION GUIDED THERAPY

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

Re: **Volcano Pioneer Plus Intravascular Ultrasound Guided Re-Entry Catheter**

July 31, 2015

Dear Volcano Customer:

Volcano Corporation is initiating a voluntary Field Safety And Corrective Action of all currently distributed **Pioneer Plus Intravascular Ultrasound Guided Re-Entry Catheters** due to a manufacturing defect that could result in a small wire extended through the catheter shaft.

During recent manufacturing testing it was noted that some Pioneer Plus catheters were found to have defective interior metal braids with strands that extended through the catheter shaft. Should this occur, there is a potential of injury to a patient's blood vessel wall through which the catheter is passed. Additionally, the exposed braid wire could engage a stent strut or edge and result in stent movement from its desired location if the stent was recently implanted. Furthermore, advancement or withdrawal of the Pioneer Plus catheter through the sheath or guide catheter could be impeded resulting in a loss of the therapeutic benefit of the device, extended case time due to extra catheter manipulations and/or a secondary intervention if the catheter and sheath need to be withdrawn together.

In reviewing Volcano's internal complaints, there were no failures identified that could be attributed to this defect at this time. As a result, we believe the likelihood for this defect to cause an injury is low.

Volcano is recalling all currently distributed Pioneer Plus catheters because we have not been able to isolate the defect to any specific lots. Visual inspection of the catheter prior to use will not identify a defective catheter.

Therefore, Volcano asks that you immediately quarantine and return all Volcano Pioneer Plus catheters in your inventory. If you have affected product, please complete the attached form and fax (see list of numbers on the reply form) or e-mail to verecall@volcanocorp.com. Volcano will email the RMA number and a shipping label for the return. A credit nota will be issued for any returned product. If you have questions you can call 00 32 2 679 10 76.

If you have no affected product, please complete, sign, and return the attached form to confirm that you have no Volcano Pioneer Plus catheters in your 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. Please ensure that a copy of this Field Safety Notice is provided to all personnel within your organization who handle this product. 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 continued support.

Sincerely,

Peter Dekempeneer
RA/QA Manager Volcano International

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