April 7, 2011

Encik Zamane Bin Abdul Rahman
Medical Device Bureau
Ministry of Health Malaysia
Level 5, no 26 Boulevard Plot 3C4
Persiaran Perdana, Precint 3
62675 Putrajaya, Malaysia

URGENT FIELD SAFETY CORRECTIVE ACTION

DePuy Spine Confidence® Introducer Needle

Dear Sirs:

This letter is to inform you that DePuy Spine has issued a Field Safety Corrective Action (Recall) on two lots of Confidence needles.

Summary

It was recently discovered that one lot of Confidence Diamond Tip Introducer Needle, 11g x 6-inch which are properly labeled (11g x 6 inch) may contain a 13g x 4-inch side hole needle in the sterile package. As a result we are taking steps to rectify the problem. To date we have inspected a significant portion of the 4-inch side hole lot HLPB4F and have found them all to meet specification. However we have decided to take a conservative approach and are recalling both lots.

The most significant complication would be an inability to get the shorter needle to the desired location. If no 6 inch backup needles were on hand the procedure may be aborted. It is more likely that the problem will result in a short delay to the case and frustration for the user. Please note that the 6-inch needle is sometimes used for Viper 2 cases. If the package contains a 4-inch needle the user would not be able to pass the guide wire.

Affected Product:

Product Code	Lot Code	Description
2839-03-611	HLPB4G	Confidence Diamond Tip Introducer Needle 11G x 6-Inch
2839-04-413	HLPB4F	Confidence Introducer Needle Side Hole 13G x 4-Inch

Johnson & Johnson Sdn. Bhd. (3718-D)
Ground Floor, G.01, Block B, 10, Jalan Bersatu 13/4,
46200 Petaling Jaya, Selangor Darul Ehsan, Malaysia
Tel: (603) 7962 6800 Fax: (603)7955 3290

Actions

We have identified only 1 unit of the affected lot imported into Malaysia. The product is still in our warehouse. We have taken immediate action to quarantine the product and is in the process of returning it to our source company.

Communication of this Field Action

No customers have bene identified to have received the affected product thus no customer notification will be sent out.

DePuy confirms that this notice has been notified to the Medical Devices Vigilance System. A copy of the FSCA form is as attached

If you require additional information regarding this matter, please contact the Johnson & Johnson Regulatory Affairs Manager on +603 7962682.

Kind Regards

Ong Yean Ting
Johnson & Johnson Sdn Bhd, Medical Division
Regulatory Affairs Manager