URGENT FIELD SAFETY NOTICE

Device Recall: Pipeline™ Embolization Device

April XX, 2014

Dear Doctor _____:

Through internal testing, Covidien has identified one component lot of delivery wires used in the Pipeline Embolization Devices that has a potential for the PTFE (polytetrafluoroethylene) coating to delaminate and detach from the delivery wire. PTFE is a lubricious coating that is applied to the delivery wire to reduce friction and facilitate deployment of the Pipeline Embolization Device. PTFE particulate resulting from delaminated coating may lead to embolic occlusion of the cerebral vasculature.

Covidien has not received reports of patient injuries resulting from this issue.

For affected product that has been used, no action is necessary and patients should continue to be managed in accordance with standard of care.

Our records indicate that your facility has been shipped affected lots of Pipeline Embolization Devices. The table below identifies the affected devices that have been shipped to you from Covidien. We are requesting that these devices be returned to Covidien.

Product Name	Product Code	Lot number	Quantity Shipped

Next Steps

1) **Stop using product listed in this Field Safety Notice immediately.**
2) **Segregate this product from other inventory.**
3) **Please complete the attached Verification Form in its entirety. Fax or email the completed Form using the contact details stated on the form. If you do not have any units in your inventory, simply return the Verification Form indicating you have zero (0) units.**
4) **Upon receiving your form, Customer Service will contact you to organize the return of your products. You will receive credit for returned products.**
5) **Please forward this letter to all colleagues within your organisation who need to be made aware of it or to any organisation/persons where the potentially affected devices have been transferred.**

Your response is vital to our monitoring of the effectiveness of this Field Safety Corrective Action (FSCA). Please complete the attached Verification Form and return to Covidien via the instructions provided above.

This action is being conducted with the knowledge of the [add local Competent Authority]. To ensure timely removal of the affected product, it is important that we receive the Return Verification form as soon as possible. Please return the completed verification form within 10 days of this notification.

We appreciate your attention to this matter and apologize for this inconvenience and assure you that Covidien has implemented appropriate measures to protect against recurrence of this problem. If you have any questions regarding this request, please contact your local Covidien Representative XXXX XXXXXX at xxx-xxx-xxxx.

Sincerely,

Add Local Signature
RA or Sales/Marketing