Attachment 1: Customer Letter Template

COVIDIEN

Urgent Product Recall

PLEASE USE THIS LETTER AS YOUR REPLY FORM

XXXX, 2014

«Name»
«Address1»
«Address2»
«City», «State» «Post»

Device Recall: HydroFinity™ Guidewire

Dear Doctor _____:

The purpose of this letter is to advise you that Covidien is conducting a recall of all HydroFinity™ Guidewires due to reports of the outer polymer jacket to the core wire being damaged during use. Damage to the jacket can result in embolization of polymer, potentially leading to vessel occlusion or damage. Vessel occlusion may necessitate surgical intervention to resolve.

The HydroFinity™ Guidewires is designed and manufactured by Nitinol Devices and Components (NDC). Covidien is the sole distributor of this guidewire.

All HydroFinity™ Guidewire lots are affected. The product model numbers are printed on the primary and secondary package labeling.

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

The product model numbers being removed are:

HPRA35150	**HPSA35150**
HPRA35180	**HPSA35180**
HPRA35260	**HPSA35260**
HPRS35150	**HPSS35150**
HPRS35180	**HPSS35180**
HPRS35260	**HPSS35260**

Our records indicate that your facility has been shipped HydroFinity Guidewires. The table (reply form) at the end of this letter identifies the affected devices that have been shipped to you from Covidien. We are requesting that these devices be returned to Covidien. Your account will be credited the applicable amount for returned devices.

Next Steps
Please review the information in the table below and provide the appropriate product disposition, signature and date. Specifically:

1) **Stop using product listed in this letter immediately**
2) **Segregate this product from other inventory**
3) **Fill out the reply (verification) form at the end of this letter**
    - **If you do not have any product identified in this letter, please fax or email the completed form to Covidien at <Add Fax Number> or <Add email Address>.**
    - **If you do have product, your sales representative will assist you in completing the verification form and arranging for return of the product.**
    - **Please fax the completed form to Covidien (XXX-XXX-XXXX) or email to <Add email Address>.**
4) Your sales representative will be available to answer any questions regarding this recall and assist you in completing the verification form, returning product and addressing any account credits.

This action is being conducted with the knowledge of the United States FDA and other regulatory authorities. Adverse events experienced with the use of these products should be reported to Covidien as well as the FDA's MedWatch Adverse Event Reporting program either online, by phone or fax.

- Online: www.fda.gov/medwatch/report.htm
- Phone: 1-800-FDA-1088
- Fax: 1-800-FDA-0178
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We apologize for this inconvenience. If you have any questions regarding this request, please contact me at (202)310-[redacted].

Sincerely,

[redacted]
Chief Medical Officer
Covidien Vascular Therapies

«Name»-«Address1»-«Address2»-«City»-«State»-«Post» - «BillToVendor» - «ShipTo»

Please Complete Reply Form - Sign and Fax to (XXX) XXX-XXXX or email to <Add email Address>.

Please review the inventory described below.

Catalog Number	Lot Number	Total Number of Boxes Shipped to Your Facility (Note there are 5 guidewires in each box)	Number of Boxes used	Number of Boxes Returned Directly to Covidien	Returned Goods Authorization No. (RGA)
«item_1»	«lot_1»	«qty_1»			
«item_2»	«lot_2»	«qty_2»			

I have reviewed the inventory described in the table, above.

Print Name & Title : _____

Signature: _____ Date:_____