APPROVALS

Vice-President, QA/RA Date

President, NDC Date

Vice-President Sales and Marketing Date

Vice-President, Costa Rica Operations Date

Vice-President Guidewire Development Date

CONTENTS

1. INTRODUCTION AND DESCRIPTION OF AFFECTED PRODUCT

NDC is the legal manufacturer of the HydroFinity Guidewire. The distribution partner, Covidien has responsibility for all customer contact and has all previous distribution information. Therefore, the majority of the actions in this plan reflect the actions to be taken in coordination with Covidien and to be monitored/verified by NDC.

This contains the plan for distribution of a customer communication and execution of a voluntary removal of all models of the Covidien HydroFinity hydrophilic guidewire. This voluntary action is being taken because Covidien has identified through customer complaints the potential for the jacket to become separated from the core wire.

Background:

As of May 19th, 2014, a total of 12 complaints have been received indicating different occurrences of "Jacket Tearing/Damage".

Of the 12 complaints, 10 showed evidence of the jacket adhesion to the core wire was damaged or may have failed. In two cases, (VA201403-0151 and VA201404-0899) the Jacket Tearing/Damage resulted in an embolization when the guidewire and/or jacket material detached. For the other 8 complaints, the damaged jacket did not embolize off the device.

Indication for Use:

The HydroFinity (HF) hydrophilic guidewire facilitates the introduction and placement of catheters and interventional devices to the desired anatomical location during diagnostic or interventional procedures.

Affected products are:

The following Model Numbers are affected (all manufactured lots):

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

2. COMPLAINT SUMMARY

A total of 12 separate complaints have been received indicating different occurrences of "Jacket Tearing/Damage". Product complaint numbers are as follows:

Covidien Complaint	NDC Complaint
VA201401-1351*	CC-01702
VA201403-0053	CC-01721
VA201403-1065*	CC-01735
VA201403-0891	CC-01724
VA201403-0151	CC-01718
VA201401-0368	CC-01686
VA201403-1319	CC-01733
VA201404-0377	CC-01743
VA201404-0468	CC-01745
VA201404-0890	CC-01752
VA201404-0899	CC-01753
VA201405-0407	CC-01759

* Excluded from HHE Scope due to metal accessories used

3. IDENTIFICATION OF PROBLEM

The problem was identified via customer complaint trend analysis and the subsequent internal investigation.

Distribution History (provided by Covidien):

	Total Boxes (5 pk)	Total # Guidewires
Total Quantity (5Pk) Received from NDC	10,399	51,955
Amount Scrapped/Returned	348*	1740*
Quantity Shipped to US Customers	1366	6830
Quantity Shipped to US Trunk Stock	1216	6080
Quantity Shipped to Canada Customers	6	30
Quantity Shipped to Canada Trunk Stock	49	245
Quantity Remaining in Inventory USDC	5513	27565
Quantity Shipped to EMEA Customers and Trunk Stock	480**	2400**
Quantity Shipped to EMEA Consignment Locations	216**	1080**
Quantity Remaining in EMEA DC	1205**	6025**

*Includes 14 shipped to Panama as Not-for-Human Use
**The quantities in the table above are estimates only, information is currently being reconciled.

Number of US Customers	142
Number of Canadian Customers	2
Number of EMEA Customers	*TBD
Countries Affected: United States, Canada, UK, Switzerland, Sweden, Spain, Poland, Norway, Netherlands, Italy, Germany, Austria, Belgium, Denmark, and France	15

*A determination of the number of EMEA Customers impacted is in process.

4. HEALTH HAZARD EVALUATION

A Health Hazard Evaluation has been completed on this event with the following expected impact:
"The assessment of the potential impact is a "Temporary reversible impairment" as a result of the possible caging off of collateral arteries or vessel dissection/damage. The jacket material is very visible under Fluoroscopy and is very likely that embolized material would be identified and removed."

5. REGULATORY STATUS SUMMARY

The HydroFinity Guidewire is commercially available in the United States under 510(k) clearance (K121398). The device is CE Marked (0086) through BSI for European Union distribution and has local approval for other countries affected. NDC owns and is responsible for the US and European Union regulatory submissions and approvals. Covidien is responsible for the Canadian regulatory submission and license approval.

6. NEED FOR FURTHER REGULATORY CLEARANCE/APPROVALS

A design change to improve the jacket adhesion is being evaluated. Based on the scope of this design change, an evaluation for re-registration/approvals for each country will be performed by NDC with input from Covidien. Any US or EU regulatory submission for design or process changes will be the responsibility of NDC. Product re-registration/submissions will be performed as required.

7. METHOD OF NOTIFICATION TO CONSIGNEES AND PRODUCT REPLACEMENT

United States:
Covidien will be responsible for customer notification and product removal in the United States. Customers will be notified by direct mail of this recall. The customer direct mail notification will be followed by a Covidien Territory Manager visit to affected sites. The Territory Manager will retrieve any unused product or provide documentation that no affected devices remain at the site, and provide written documentation (refer to the attached sample reconciliation form) to Post

Market Vigilance (PMV). Account credit for any purchased but not used products will be provided. Any affected devices will be returned under a Customer Service assigned RGA.

Covidien will provide a summary report on a monthly basis, to NDC, reflecting the progress on these activities and the data below:

HydroFinity Field Action				
Date of Update	5/13/2014			
Initiate Date	4/9/2014			
Est. Close out Date	6/30/2014			
Days In Response Tracking				
Customer Response Required			Units to be recovered	
Customer Response Received			Units Recovered	
% Response Received			**% Product Returned**	

OUS:

Covidien will be responsible for customer notification and product removal in countries outside the United States. All Covidien Regional Business Unit Regulatory Affairs (RBU-RA) will be notified of the issue. Impacted Regions (Europe and Canada) will be provided the following documents to support regulatory body notification and customer communications: the approved customer communication and verification form; sales reps FAQ and instructions; and the approved Field Action Plan. The RBUs, where applicable, will execute the actions for their respective regions (per regional and local policies, procedures, and regulations) and provide regular updates as well as evidence of effectiveness and reconciliation to the Field Action Coordinator. Evidence will include a copy of the completed verification form from each affected customer site.

8. DISPOSITION OF INVENTORY

Affected devices contained in Covidien inventory locations will be dispositioned per assigned NCMR 14-385 and Hold H201405-09.

Covidien will determine how they wish the inventory dispositioned.

9. DISPOSITION OF RETURNED PRODUCT

All product is to be returned to the Covidien US DC. The returned product will be placed in quarantine upon product return and dispositioned per the assigned NCMR 14-385 and Hold H201405-09. If affected product cannot be returned from locations out of the United States, certificates of destruction of this product must be provided to the Field Action Coordinator.

10. FIELD ACTION NOTIFICATION TO REGULATORY AUTHORITIES

United States:

A written report required by 21 CFR Part 806 will be submitted by NDC to the San Jose, CA FDA District Office within 5 working days of approval of the field action. Covidien will provide a courtesy notification to the Minneapolis, MN District Office concerning the recall.

OUS:

The Covidien Regional Business Unit Regulatory Affairs groups (RBU-RA) will be made aware of the situation and provided supporting information.

Affected regions (EMEA and Canada) will be provided necessary documentation to facilitate customer and regulatory notification, and product return and/or reconciliation.

For affected countries in the EU, NDC will have the responsibility to notify the Notified Body (BSI), Authorized Representative (QNET) and the Competent Authorities.

The following Covidien RBU contacts will be notified of this action:

- Asia- Rachel Leong and QI Li
- ANZ- Geoff Braid, Naeema Mohamed, and Martin Devitt
- Canada- Dawn Boyce and Joe DiMarzo
- EMEA- Tom Breslin, Derek Kelly (RA), Dominik Reterski, and Inge Vandenbussche
- Japan- Akio Oki, Haruhisa Yamada (QA), Isao Yasui, and Yuko Toriumi
- LatAm- Mauro Castro, Miriam Santos, and Claudia Navarro

11. EFFECTIVENESS LEVEL CHECKS

The effectiveness level check will be executed by Covidien. NDC will receive the evidence of the effectiveness level check upon completion. The field action will be conducted to the consignee/user level. For this action the effectiveness level checks is defined as: 100% of worldwide consignees will be notified with 100% required response for closure of US customers, and a minimum 80% response for OUS customers.

12. CORRECTIVE ACTION

NDC has initiated 2 CAPAs for this issue. One CAPA (CA-01228) is to address the design changes necessary to resolve the performance issue and the second CAPA (CA-01246) will be used to track and close the recall activities. To monitor and assure corrective action is taken, Covidien has assigned a Supplier Corrective Action Request (SCAR) as follows: CAPA2014-007237.

13. PRESS RELEASE

As directed by the FDA, if a press release is required for this field action, NDC will be responsible for its creation and distribution. Covidien will review and approve NDC's Press Release prior to distribution. Covidien may choose to create and distribute a Covidien Press Release. Covidien will provide such document to NDC for review prior to distribution.

14. FIELD ACTION SCHEDULE

Note: The following provides a summary of activities to be completed and expected timing. It reflects the proposed actions of Covidien and the corresponding actions of NDC.

Item	Action and Responsibility	Schedule	Person Responsible
Covidien Actions			
1	Prepare announcement/FAQ to the sales force and applicable employees (Covidien Marketing)	Within 2 working days from approval of this Field Action Plan	Michelle McDonald
2	Develop a final listing of product distribution to include customer name, location, contact information and product quantity received. (Covidien Logistics)	Within 2 working days from approval of this Field Action Plan	Mike Edel/Mary Kay Jensen
3	Provide communication of Field Action, including approved HHE, Field Action Plan, Customer Letter and FAQs to Covidien RBU contacts (Covidien Marketing, Covidien GBU Field Action Coordinator)	Within 2 working days from approval of this Field Action Plan	Mike Geary / Michelle McDonald
4	Notify San Jose, CA FDA District Office of Field Action (NDC)	Within 5 working days from approval of this Field Action Plan	NDC Rep
5	Provide courtesy notification to the Minneapolis, MN FDA District Office of Field Action (PMV)	Within 5 working days from approval of this Field Action Plan	Mike Geary
6	Inform applicable Notified Body. Provide verification of notification to Covidien. (NDC)	Within 5 working days from approval of this Field Action Plan*	NDC Rep
7	Notify and consult Canadian Authorities regarding the Field Action (Covidien RBU Regulatory)	Within 5 working days from approval of this Field Action Plan*	Joe DiMarzo
8	Translate Customer letter and other materials per section 7 of this FAP, provide translation of Field Safety Notice to the applicable Competent Authorities as required. Align with NDC on this action. (Covidien RBU RA)	Within 5 working days from approval of this Field Action Plan*	Tom Breslin, (Country Manager Support as needed) / NDC Rep
9	Notify US Sales Reps. of Field Action (Covidien Sales/Marketing).	Within 3 working days from approval of this Field Action Plan	Michelle McDonald
10	Provide customer letter to affected US sites via UPS with confirmation (Covidien PMV)	Within 3 working days from approval of this Field Action Plan	Mike Geary/Mary Kay Jensen (Stericycle)
11	Provide customer letter to affected EMEA sites with delivery confirmation (Covidien RBU RA)	Within 3 working days from translation of notification letter and Competent Authority Acceptance	Tom Breslin (Country Mgr Support as needed)
12	Provide customer letter to affected Canada sites with delivery confirmation (Covidien RBU RA)	Within 3 working days from approval of this Field Action Plan	Joe DiMarzo
13	Notify Covidien warehouse management of the Field Action to ensure proper handling and control of returned units. (Covidien GBU Field Action Coordinator)	Within 2 working days from approval of this Field Action Plan	Mike Geary
14	Receive and properly secure returned product (USDC, Covidien RBU DC's)	31-Jul-14	Mike Riley, RBU DC's

Item	Action and Responsibility	Schedule	Person Responsible
15	Complete product inventory reconciliation (Covidien GBU Field Action Coordinator)	15-Aug-14	Mary Kay Jensen
16	Effectiveness checks and follow-up as needed (Covidien GBU Field Action Coordinator, Applicable Covidien RBU's).	31-Aug-14	Stericycle/Mary Kay Jensen
17	Disposition Product NCMR (Covidien CM Quality)	Per assigned NCR / Hold (NCMR 14-385 and H201405-09)	Mike Basel
18	Determine root cause and plan corrective action via CAPA (NDC). Issue Covidien SCAR (Covidien Supplier Quality)	Per CAPA Plan (Reference Covidien SCAR CAPA2014-007237)	NDC Rep/Jon Mayotte
19	Prepare interim and final reports for applicable CA's, regulatory agencies. Submit reports as required (NDC and Covidien RBU Regulatory as required)	As required	NDC Rep
20	Prepare interim and final reports for FDA. Submit reports as required (NDC)	As required	NDC Rep
21	Provide follow-up information as may be requested from FDA District Office (NDC)	As required	NDC Rep
22	Close Covidien's responsible portion of the field action (Covidien GBU Field Action Coordinator)	15-Sep-14	Mary Kay Jensen
Nitinol Devices and Component, Inc. Actions			
23	Complete HHE (NDC)	23-May-14	C. Faris
24	Complete Recall Strategy/Plan (This document)	23-May-14	C. Faris
25	Notify Regulatory Agencies (FDA, QNET, BSI)	27-May-14	C. Faris
26	Monitor progress of Recall	Monthly beginning 27-Jun-14	C. Faris
27	Complete Effectiveness Check of Recall using Covidien Data	15-Sep-14	C. Faris
28	Complete/Close Recall with Regulatory Agencies	30-Sep-14	C. Faris

* May be impacted by regional/country regulatory requirements.

15. CONTENT OF NOTIFICATION TO CONSIGNEES (Covidien Responsibility)

The customers will be notified as described in section 7. The customer notification letter is included as Attachment 1. The customer letter may be modified for OUS sites to comply with specific regulatory requirements within the region and to provide proper device return and contact information.

Attachment 1: Customer Letter Template

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
-

We apologize for this inconvenience. If you have any questions regarding this request, please contact me at (202)310-5120.

Sincerely,

Mark A. Turco, MD
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:_____