Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: June 19, 2014

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: Laurie Kidwell, RRT Supervisor
Food Protection Program

SUBJECT: Nitinol Devices & Components, Inc. – RECALL [Medical Device]

AFFECTED PRODUCT: **HydroFinity™ Hydrophilic Guidewires**

SUMMARY: **Unclassified Recall; The recall is due to two reports of the outer polymer jacket to the core wire being damaged when the guidewire was withdrawn rapidly through certain delivery catheters and ten cases where the product was less severely damaged during use. Damage to the jacket can result in embolization of polymer, potentially leading to vessel occlusion or damage.**

HydroFinity™ Hydrophilic Guidewires. The HydroFinity Guidewire is a product developed and manufactured by NDC and distributed by Covidien. It is a nitinol-core, polymer-jacketed guidewire with a hydrophilic coating intended for use in catheter placement and other procedures to treat vascular diseases.

The recalled products were distributed nationwide.

SUGGESTED ACTION: **For consumer inquiry only. For information or to report a problem, please contact NDC Customer Service at 1-510-683-2000 Monday - Friday between the hours of 8:00 am and 5:00 pm PST or email quality@nitinol.com.**

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Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

NDC Implements Voluntary Recall of the Hydrofinity™ Hydrophilic Guidewire

Contact:
Consumer:
(510) 683-2000
Email: quality@nitinol.com

FOR IMMEDIATE RELEASE - FREMONT, CA – June 18, 2014 – Nitinol Devices & Components, Inc. (NDC) announced today a voluntary recall of its HydroFinity™ Hydrophilic Guidewires. The HydroFinity Guidewire is a product developed and manufactured by NDC and distributed by Covidien. It is a nitinol-core, polymer-jacketed guidewire with a hydrophilic coating intended for use in catheter placement and other procedures to treat vascular diseases.

NDC is conducting this recall due to two reports of the outer polymer jacket to the core wire being damaged when the guidewire was withdrawn rapidly through certain delivery catheters and ten cases where the product was less severely damaged during use.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. Two cases were reported where the polymer jacket separated from the device and embolized. One case required surgical intervention.

NDC and Covidien have taken the necessary steps to prevent future shipments of the recalled products. Covidien alerted customers by letter on June 3, 2014 and is recalling all product. Unused product should be returned to Covidien. Additionally, NDC has notified regulatory agencies in the countries where the HydroFinity Guidewire is distributed: U.S., Belgium, Denmark, France, Germany, Italy, Norway, Sweden, UK and Canada.

NDC has apprised the U.S. Food and Drug Administration (FDA) of this action. Any adverse events experienced with the use of this product and/or quality problems should be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax:

- **Online:** www.fda.gov/medwatch/report.htm (form available to fax or mail), or
- **Regular Mail or Fax:** Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

For information or to report a problem, please contact NDC Customer Service at 1-510-683-2000 Monday - Friday between the hours of 8:00 am and 5:00 pm PST or email quality@nitinol.com.

ABOUT NDC

NDC is a technically-driven contract manufacturer of Nitinol-based medical devices headquartered in Fremont, Calif. NDC has a proven, 20-year track record of partnering with the medical device community and delivering high-quality Nitinol devices and components.

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