Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: September 3, 2014

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

FROM: Laurie Kidwell, RRT Supervisor
Food Protection Program

SUBJECT: Cook Medical – RECALL [Medical Device]

AFFECTED PRODUCT: **CloverSnare™ 4-Loop Vascular Retrieval Snare devices**

SUMMARY: **Unclassified Recall; The device was recalled because of a potential for the loop to separate from the shaft, resulting in loss of device function, potential for embolization of snare fragments and the potential need for intervention to retrieve the separated snare.**

The recall affects products manufactured between August 2012 and August 2013 and distributed between March 8, 2013 and July 1, 2014.

Model: CloverSnare™ 4-Loop Vascular Retrieval Snare

Model Number: VRS-6.0-9.0

Lot Numbers: 3583416; 3583418; 3583422; 3583424; 3583426; 3583428; 3583430; 3583432; 3583434; 3583436; 3583440; 3583442; 3583452; 3583456; 3583458; 3583462; 3583464; 3583466; 3583468; 3583470; 3583472; 3583474; 3583476; 3583478; 3583480; 3583482; 3583484; 3583486; 3583488; 3583490; 3583492; 3583494; 3583496; 3583498; 3583500; 3583502; 3583504; 4293921; 4293923; 4293925; 4293927; 4319573; 4319575; 4319577; 4319579; 4319581; 4319583; 4319585; 4319587; 4319589; 4319591; 4572365; 3583418X; 3583430X; 3583442X; 3583442XX; 3583464XXX; 3583480XX; 3583486X

Quantity: 696

The recall affects customers in the United States.

SUGGESTED ACTION: **For consumer inquiry only. Customers with questions may contact Cook Medical Customer Relations at 800-457-4500 or 812-339-2235 Monday through Friday between 7:30 a.m. and 5:00 p.m. Eastern Daylight Time or by email at CustomerrelationsNA@cookmedical.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.

UPDATED: CloverSnare™ 4-Loop Vascular Retrieval Snare Recall

Contact
Consumer
Cook Medical
750 Daniels Way
Bloomington, IN 47404
www.cookmedical.com
812-339-2235

Media
David McCarty, Director,
Global Public Relations,
Cook Medical
812-339-2235, ext. 2387;
812-322-1805 (cell);
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FOR IMMEDIATE RELEASE - August 26, 2014 - On July 10, 2014, Cook Medical initiated a recall of 696 of its CloverSnare™ 4-Loop Vascular Retrieval Snare devices. The device was recalled because of a potential for the loop to separate from the shaft, resulting in loss of device function, potential for embolization of snare fragments and the potential need for intervention to retrieve the separated snare.

Customers have been advised to return the recalled devices to Cook Medical. The recall affects products manufactured between August 2012 and August 2013 and distributed between March 8, 2013 and July 1, 2014.

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Model Number: VRS-6.0-9.0

Lot Numbers: 3583416; 3583418; 3583422; 3583424; 3583426; 3583428; 3583430; 3583432; 3583434; 3583436; 3583440; 3583442; 3583452; 3583456; 3583458; 3583462; 3583464; 3583466; 3583468; 3583470; 3583472; 3583474; 3583476; 3583478; 3583480; 3583482; 3583484; 3583486; 3583488; 3583490; 3583492; 3583494; 3583496; 3583498; 3583500; 3583502; 3583504; 4293921; 4293923; 4293925; 4293927; 4319573; 4319575; 4319577; 4319579; 4319581; 4319583; 4319585; 4319587; 4319589; 4319591; 4572365; 3583418X; 3583430X; 3583442X; 3583442XX; 3583464XXX; 3583480XX; 3583486X

Quantity: 696

In six cases, customers reported separation of the loop snare from the shaft during use. The separation was caused by the application of lateral force to the snare in an effort to change the shape of the device. In four cases of separation, medical intervention to retrieve the separated snare was required.

Cook Medical has notified all customers of the recall by letter and has arranged for affected devices to be returned. In addition, Cook Medical has notified the FDA of this action. The recall affects customers in the United States, Canada, Austria, Belgium, Denmark, Germany, Great Britain, Ireland, Italy, Spain, Sweden and Switzerland. Cook reports that the problem occurred only in these specific lots. There have been no known problems in the devices manufactured after that time.

Customers with questions may contact Cook Medical Customer Relations at 800-457-4500 or 812-339-2235 Monday through Friday between 7:30 a.m. and 5:00 p.m. Eastern Daylight Time or by email at CustomerrelationsNA@cookmedical.com.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report **Online**: www.fda.gov/medwatch/report.htm
- **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

About Cook Medical

Since 1963 Cook Medical has worked closely with physicians to develop technologies that eliminate the need for open surgery. Today we are combining medical devices, biologic materials and cellular therapies to help the world's healthcare systems deliver better outcomes more efficiently. We have always remained family owned so that we have the freedom to focus on what we care about: patients, our employees and our communities. Find out more at www.cookmedical.com, and for the latest news, follow us on Twitter, Facebook and LinkedIn.

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