U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Cook CloverSnare 4-Loop Vascular Retrieval Snare - Snare Tip May Break During Use

Recall Class: Class I

Date Recall Initiated: July 17, 2014

Product: CloverSnare 4-Loop Vascular Retrieval Snare

- Model Number VRS-6.0-90
- Manufacturing Dates: August 2012 – August 2013
- Distribution Dates: March 8, 2013 – July 1, 2014
- **Complete Listing of Affected Lot Numbers (https://www.cookmedical.com/web/newsroom/article/-/blogs/cloversnare-153-4-loop-vascular-retrieval-snare-recall)**
- 671 devices have been distributed nationwide

Use: The CloverSnare 4-Loop Vascular Retrieval Snare is used to manipulate and retrieve items in the cardiovascular system, such as temporary implanted devices. This includes inferior vena cava filters or broken devices (e.g., guidewires, coils, balloons, and catheters).

Recalling Firm:
Cook Inc.
750 N Daniels Way
Bloomington, Indiana 47404-9120

Reason for Recall:
There is a potential for the snare loop to separate from the shaft. If this occurs, the snare loop may travel through the vascular system and block blood vessels or become stuck in other organs, such as the heart and lungs. Additional intervention may be necessary to retrieve the separated snare loop from the patient. This failure will also cause the device to stop working. Four injuries have been reported.

The use of the affected product may cause serious adverse health consequences, including death.

Public Contact: Customers with questions may contact Cook Medical Customer Relations at 1-800-457-4500, Monday - Friday, 7:30 a.m. - 5:00 p.m., Eastern Standard Time or email **CustomerrelationsNA@cookmedical.com (mailto:CustomerrelationsNA@cookmedical.com)**

FDA District: Detroit District Office

More Information about this Recall:

On July 17, 2014, Cook Medical sent customers an Urgent Medical Device Recall letter informing them of the product, problem and actions to be taken. The firm requested customers:

- Separate any affected unused products from inventory.
- Collect and return all unused products to Cook Medical as soon as possible for credit.
- Complete and return the Recalled Product Reply Form to Cook Medical, separately or when returning the product.

About Class I Recalls

Class I recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause serious adverse health consequences or death.

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these products to **MedWatch: The FDA Safety Information and Adverse Event Reporting Program (https://www.accessdata.fda.gov/scripts/medwatch/)** either online, by regular mail or by FAX.

Additional Resources

- **Firm Press Release (https://www.cookmedical.com/web/newsroom/article/-/blogs/cloversnare-153-4-loop-vascular-retrieval-snare-recall) (/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)**

Class 1 Recall
CloverSnare 4Loop Vascular Retrieval Snare

See Related Information 22

Date Posted	August 27, 2014
Recall Status[1]	Open
Recall Number	Z-2243-2014
Recall Event ID	68914[23]
Premarket Notification 510(K) Number	K112185[24]
Product Classification	Device, Percutaneous Retrieval[25] - **Product Code** MMX[26]
Product	CloverSnare 4-Loop Vascular Retrieval Snare. Product is packaged in a Tyvek-film sterilizable outer package and is supplied one pouch in a box. The CloverSnare 4-Loop Vascular Retriever is intended for use in the cardiovascular system to manipulate and retrieve foreign objects, including but not limited to, wire guides, coils, balloons, catheters, and filters.
Code Information	Model Number(s): 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, and 3583486X.
Recalling Firm/ Manufacturer	Cook Inc. 750 N Daniels Way Bloomington, Indiana 47404-9120
For Additional Information Contact	Cook Medical Customer Relations Departme 812-339-2235
Manufacturer Reason for Recall	This remedial action is the result of six product complaints associated with separation of the snare from the distal tip of the wire.
FDA Determined Cause [2]	DESIGN: Device Design
Action	Cook Medical sent an Urgent Medical Device Recall letter dated July 17, 2014, to all affected customers. The letter identified the product, the problem, and the action to be taken by the customer. Customers were instructed to review the attached list of affected products and lot numbers shipped to their account, and quarantine any affected product that remains unused. Immediately collect and return all unused affected products to Cook Medical as soon as possible for credit. Complete the attached Recalled Product Reply Form and return to Cook Medical either with the product or separately. Customers were asked to report any Adverse Event to Cook Medical Customer Relations at 800-457-4500 or 1-812-339-2235.
Quantity in Commerce	696 devices total distribution (671 nationwide)
Distribution	Worldwide Distribution - USA including AK, AL, AZ, CA, CT, DC, FL, GA, HI, IA, ID, IL, IN, KY, LA, MD, ME, MI, MN, MO, MS, NC, NE, NH, NJ, NV, NY, OH, OK, PA, SC, TX, UT, VA, WA, WI, WV and Internationally to: Canada, Austria, Belgium, Denmark, Germany, Great

Britain, Ireland, Italy, Spain, Sweden, and Switzerland.

Total Product Life Cycle TPLC Device Report[27]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[28]
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

510(K) Database 510(K)s with Product Code = MMX and Original Applicant = COOK, INC.[29]

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. http://www.fda.gov/default.htm
4. http://www.fda.gov/MedicalDevices/default.htm
5. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
7. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm
8. /scripts/cdrh/cfdocs/cfpmn/denovo.cfm
9. /scripts/cdrh/cfdocs/cfRL/rl.cfm
10. /scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm
11. /scripts/cdrh/cfdocs/cfRES/res.cfm
12. /scripts/cdrh/cfdocs/cfPMA/pma.cfm
13. /scripts/cdrh/cfdocs/cfPCD/classification.cfm
14. /scripts/cdrh/cfdocs/cfStandards/search.cfm
15. /scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm
16. /scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm
17. /scripts/cdrh/cfdocs/cfAssem/assembler.cfm
18. /scripts/cdrh/cfdocs/Medsun/searchReportText.cfm
19. /scripts/cdrh/cfdocs/cfClia/Search.cfm
20. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
21. /scripts/cdrh/cfdocs/cfTPLC/inspect.cfm
22. http://www.fda.gov/safety/recalls/enforcementreports/default.htm
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=68914
24. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K112185
25. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=MMX
26. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=MMX
27. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?id=MMX
28. /scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=7.55
29. ../cfPMN/pmn.cfm?start_search=1&productcode=MMX&applicant=COOK%2C%20INC%2E

Page Last Updated: 09/06/2014

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