Indiana State Department of Health
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Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

DATE: April 16, 2015

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

FROM: Laurie Kidwell, RRT Supervisor
Food Protection Program

SUBJECT: OriGen Biomedical – RECALL [Medical Device]

AFFECTED PRODUCT: **VV13F Reinforced Dual Lumen ECMO Catheters**

SUMMARY: **Unclassified Recall; The recall has been initiated because the products have been found to have the potential for a separation of the clear extension tube from the hub that it is inserted in, which potentially could result in required intervention to prevent permanent impairment/damage.**

OriGen VV13F Reinforced Dual Lumen ECMO Catheters manufactured on September 22, 2014 and distributed from February 16 to March 26, 2015 have been recalled:

OriGen Reinforced Dual Lumen ECMO Catheters
VV13F
Lot N18549, 238 Units
Manufactured 09/2014
Expiration 09/2018

The recalled product was distributed to ECMO sites in the following states: Indiana, Michigan, Ohio, and Kentucky.

SUGGESTED ACTION: **For consumer inquiry only. If you have any questions regarding this recall, you can contact the company at: OriGen Biomedical Attn: Bernie R Silvers 7000 Burleson Rd, Bldg. D Austin, TX 78744. CST Monday – Friday 8:00-5:00 +1 512 474 7278.**

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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.

OriGen Biomedical Issues Nationwide Recall of OriGen VV13F Reinforced Dual Lumen ECMO Catheters

Contact:
Consumer:

+1-512-474-7278
www.origen.com

FOR IMMEDIATE RELEASE – April 15, 2015 – Austin, TX – On March 30, 2015, OriGen Biomedical initiated a nationwide recall for one lot of 51 VV13F Reinforced Dual Lumen ECMO Catheters. These VV13F Reinforced Dual Lumen ECMO Catheters have been found to have the potential for a separation of the clear extension tube from the hub that it is inserted in, which potentially could result in required intervention to prevent permanent impairment/damage.

Customers who have this lot of VV13F Reinforced Dual Lumen ECMO Catheters should return any product that they currently have to OriGen Biomedical.

OriGen VV13F Reinforced Dual Lumen ECMO Catheters manufactured on September 22, 2014 and distributed from February 16 to March 26, 2015 have been recalled:

OriGen Reinforced Dual Lumen ECMO Catheters
VV13F
Lot N18549, 238 Units
Manufactured 09/2014
Expiration 09/2018

The OriGen VV13F Reinforced Dual Lumen ECMO Catheters is indicated for use as a single cannula for both venous drainage and re-infusion of blood in the internal jugular vein during extracorporeal life support procedures of six hours or less in Neonatal Intensive Care and Pediatric Intensive Care ECMO centers.

OriGen Biomedical voluntarily recalled OriGen VV13F Reinforced Dual Lumen ECMO Catheters Lot N18549 after becoming aware of a reported adverse event. Origen Biomedical has notified the FDA of this action.

OriGen Biomedical is aware of one product failure and has received a complaint associated with the problem. This serious adverse event resulted in a serious patient injury.

The recalled product was distributed to ECMO sites in the following states:

California
Texas
Pennsylvania
Michigan
Indiana
Hawaii
Ohio
New York
Kentucky
Oregon
Florida

If you have any questions regarding this recall, you can contact the company at:

OriGen Biomedical
Attn: Bernie R Silvers
7000 Burleson Rd, Bldg. D
Austin, TX 78744

CST Monday – Friday 8:00-5:00
+1 512 474 7278

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

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