Indiana State Department of Health
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Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

DATE: May 28, 2015

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

FROM: Laurie Kidwell, RRT Supervisor
Food Protection Program

SUBJECT: CareFusion – RECALL [Medical Devices]

AFFECTED PRODUCT: **AVEA ventilator**

SUMMARY: **Class I Recall; The recall is in response to a potential malfunction of an AVEA ventilator specific 5 psi pressure transducer.**

The global recall involves AVEA ventilators manufactured, serviced and distributed from July 1, 2011 to March 15, 2015. A list of affected model and serial numbers is available at the CareFusion website. Refer to Figure 1 for the location of model and serial numbers.

SUGGESTED ACTION: **For consumer inquiry only. Customer inquiries related to this action should be addressed to the CareFusion Recall Support Center at 1.888.562.6018 or email SupportCenter@carefusion.com between the hours of 6:30 a.m. to 5:00 p.m. PDT.**

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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.

Carefusion Provides Update on Voluntary Global Recall of Avea® Ventilator

Contact:
Consumer:
888-562-6018

Technical Support:
888-231-2466

Media:
Troy Kirkpatrick
(858) 617-2361
Email: troy.kirkpatrick@carefusion.com

FOR IMMEDIATE RELEASE — May 27, 2015 — San Diego, CA — CareFusion, a BD company (NYSE:BDX), provided an update on a global voluntary recall that was initiated on April 21, 2015 to address an issue with certain units of AVEA® ventilators.

The recall has been designated as a Class I recall by the U.S. Food and Drug Administration (FDA), which means the Agency believes that there is a reasonable probability that use of the recalled product will cause serious adverse health consequences or death. To date, no report of patient injury has been received related to this issue.

The AVEA ventilator is only used in hospitals and other health care facilities and is intended for continuous breathing support for neonatal through adult patients. The recall is in response to a potential malfunction of an AVEA ventilator specific 5 psi pressure transducer. The affected AVEA ventilators may develop a failure mode over a period of time, where, by design, the ventilator activates false Extended High Ppeak or Circuit Occlusion audio and visual alarms, opens the safety valve and stops ventilating. If this occurs, alternate ventilation support will be required to reduce the potential of hypoxemia or hypercapnia.

The global recall involves AVEA ventilators manufactured, serviced and distributed from July 1, 2011 to March 15, 2015. CareFusion learned of this issue through customer reports identifying Extended High Ppeak or Circuit Occlusion alarms. A list of affected model and serial numbers is available at the CareFusion website. Refer to Figure 1 for the location of model and serial numbers.

CareFusion puts patient safety first and will continue to work diligently with customers and global regulatory authorities to resolve this issue in a timely manner. The company has notified customers of the recall with an urgent recall letter. The CareFusion Recall Support Center is contacting global customers via telephone to coordinate on-site AVEA ventilator correction in a timely, effective manner.

The FDA and other regulatory authorities have been notified.

Instructions to Customers

CareFusion does not require the return of affected AVEA ventilators.

In the interim, if an AVEA ventilator exhibits a sustained Extended High Ppeak or Circuit Occlusion alarm followed by the opening of the safety valve that cannot be cleared by powering the ventilator off and back on again, immediately remove the ventilator from service, provide alternate ventilation and contact CareFusion Technical Support at the contact information listed below to report the issue.

Customer inquiries related to this action should be addressed to the CareFusion Recall Support Center at 1.888.562.6018 or email SupportCenter@carefusion.com between the hours of 6:30 a.m. to 5:00 p.m. PDT.

For technical support or to report a problem, please contact CareFusion Technical Support at 1.800.231.2466 or email Support.Vent.US@carefusion.com.

Adverse reactions or quality problems experienced with the use of this product should 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.

Countries with AVEA ventilators affected by the global recall:

ISO Code	Country
AL	Albania
AS	American Samoa
AR	Argentina
AU	Australia

ISO Code	Country
AT	Austria
BH	Bahrain
BD	Bangladesh
BB	Barbados
BE	Belgium
BZ	Belize
BM	Bermuda
BO	Bolivia
BA	Bosnia and Heherzegowina
BR	Brazil
CA	Canada
CL	Chile
CN	China (People's Rep)
CO	Colombia
CR	Costa Rica
HR	Croatia
CY	Cyprus
CZ	Czech (Rep)
DO	Dominican Republic
EC	Ecuador
EG	Egypt
SV	El Salvador
SV	El Salvador
EE	Estonia
FR	France
GE	Georgia
DE	Germany
GB	Great Britain
GR	Greece
GT	Guatemala
HN	Honduras (Rep)
HK	Hong Kong, China
HU	Hungary (Rep)
IN	India
ID	Indonesia
IE	Ireland
IL	Israel
IT	Italy
JP	Japan
JO	Jordan
KR	Korea (Rep)
KW	Kuwait
LV	Latvia
LB	Lebanon
LY	Libyan Jamahiriya
LT	Lithuania
MY	Malaysia
MX	Mexico
MD	Moldova (republic of)
KR	Korea (Rep)
KW	Kuwait
MA	Morocco
NP	Nepal
NL	Netherlands

ISO Code	Country
NI	Nicaragua
NO	Norway
OM	Oman
PK	Pakistan
PS	Palestine
PA	Panama (Rep)
PY	Paraguay
PE	Peru
PH	Philippines
PL	Poland
PT	Portugal
PR	Puerto Rico
QA	Qatar
RO	Romania
RU	Russian Federation
RW	Rwanda
SA	Saudi Arabia
SG	Singapore
SK	Slovakia
SI	Slovenia
ZA	South Africa
ES	Spain
TW	Taiwan
TH	Thailand
TN	Tunisia
TR	Turkey
AE	United Arab Emirates
UK	United Kingdom
UY	Uruguay
US	United States
VE	Venezuela
VN	Vietnam
YE	Yemen

About CareFusion

CareFusion, a BD company, serves the health care industry with products and services that help hospitals measurably improve the safety and quality of care. The company develops industry-leading technologies including Alaris® infusion pumps and IV sets, MaxPlus® and MaxZero™ IV connectors and sets, Pyxis® automated dispensing and patient identification systems, AVEA®, LTV® series and Air*Life*® ventilation and respiratory products, ChloraPrep® products, MedMined® services for data mining surveillance, V. Mueller® surgical instruments, and an extensive line of products that support interventional medicine. For more information please visit www.carefusion.com.

About BD

BD is a leading medical technology company that partners with customers and stakeholders to address many of the world's most pressing and evolving health needs. Our innovative solutions are focused on improving medication management and patient safety; supporting infection prevention practices; equipping surgical and interventional procedures; improving drug delivery; aiding anesthesiology and respiratory care; advancing cellular research and applications; enhancing the diagnosis of infectious diseases and cancers; and supporting the management of diabetes. We are more than 45,000 associates in 50 countries who strive to fulfill our purpose of "*Helping all people live healthy lives*" by advancing the quality, accessibility, safety and affordability of healthcare around the world. In 2015, BD welcomed CareFusion and its products into the BD family of solutions. For more information on BD, please visit www.bd.com.

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