Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: May 19, 2014

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

FROM: Laurie Kidwell, RRT Supervisor
Food Protection Program

SUBJECT: Ventlab LLC – RECALL [Medical Device]

AFFECTED PRODUCT: Ventlab™ Resuscitator Bags

SUMMARY: **Unclassified Recall; The recall is due to a sticking duckbill valve that resulted in the resuscitation bags delivering no air through the patient valve, to the patient.**

The table below provides the resuscitation bag series, features, respective lot numbers and manufacture dates of the recalled models:

RESUSCITATION BAG SERIES	FEATURES	LOT NUMBERS	MANUFACTURE DATES
AF1000, AF2000, AF5000, BT4000, VN2000, VN5000, VT1000	W/ MANOMETER	105147 - 107609	01/10/2013 - 05/21/2013
AF1000, AF2000, AF3000, AF4000, AF5000, BT2000, BT3000, BT4000, PRO-1900, SC7000, SC8120, SS3200, VN2000, VN3000, VN4000, VN5000	W/ MANOMETER AND W/ POP-OFF VALVE	106245 - 107291	03/04/2013 - 05/06/2013
VN2102	W/ MANOMETER AND W/ POP-OFF VALVE	200349	6/20/2013
AF1000, AF2000, AF3000, AF4000, AF5000, BT2000, BT3000, BT4000, BT5000, BVM700, CPRM2000, CPRM3000, PRO-1000, PRO-2000, SC7000, SC8020, VN2000, VN3000, VN4000	W/ MANOMETER AND W/ POP-OFF VALVE	107029 - 107634	04/11/2013 - 05/23/2013

VN2002	W/ MANOMETER AND W/ POP-OFF VALVE	200492	7/1/2013
SC8000, SC9000	W/O MANOMETER AND W/O POP-OFF VALVE	101441 - 107461	05/17/2012 - 05/09/2013
CPRM1000	W/O MANOMETER AND W/O POP-OFF VALVE	99523 - 107315	02/14/2012 - 05/02/2013

The products can be identified by the part number, description and lot number on the case labels, as well as a small white label on the individual packaging bag.

The recalled products were distributed nationwide.

SUGGESTED ACTION: **For consumer inquiry only. End Users with questions may contact Ventlab LLC. via telephone at 1-844-635-5326 between the hours of 8:30 AM to 5:00 PM (EST) Monday through Friday. Consumers may also contact the company via e-mail at PFA@ventlab.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.

Ventlab, LLC. Issues a Nationwide Recall of Ventlab Resuscitator Bags Due to Possible Health Risk

Contact:
Consumer:
(844) 635-5326
Email: PFA@ventlab.com

FOR IMMEDIATE RELEASE - May 14, 2014 - Ventlab LLC. of Grand Rapids, Michigan has initiated a voluntary medical device removal of a limited number of Ventlab™ Resuscitator Bags after becoming aware of complaints regarding a sticking duckbill valve that resulted in the resuscitation bags delivering no air through the patient valve, to the patient. The valves may stick due to incomplete curing during the manufacturing process. Resuscitation bags affected may not

function properly and may result in a delay of treatment and life threatening health consequences that include hypoxia and hypoventilation.

End users who have resuscitation bags within the lot numbers listed below should stop using them and immediately contact Ventlab, LLC. for further instructions on the return of these products.

The table below provides the resuscitation bag series, features, respective lot numbers and manufacture dates of the recalled models:

RESUSCITATION BAG SERIES	FEATURES	LOT NUMBERS	MANUFACTURE DATES
AF1000, AF2000, AF5000, BT4000, VN2000, VN5000, VT1000	W/ MANOMETER	105147 - 107609	01/10/2013 - 05/21/2013
AF1000, AF2000, AF3000, AF4000, AF5000, BT2000, BT3000, BT4000, PRO-1900, SC7000, SC8120, SS3200, VN2000, VN3000, VN4000, VN5000	W/ MANOMETER AND W/ POP-OFF VALVE	106245 - 107291	03/04/2013 - 05/06/2013
VN2102	W/ MANOMETER AND W/ POP-OFF VALVE	200349	6/20/2013
AF1000, AF2000, AF3000, AF4000, AF5000, BT2000, BT3000, BT4000, BT5000, BVM700, CPRM2000, CPRM3000, PRO-1000, PRO-2000, SC7000, SC8020, VN2000, VN3000, VN4000	W/ MANOMETER AND W/ POP-OFF VALVE	107029 - 107634	04/11/2013 - 05/23/2013
VN2002	W/ MANOMETER AND W/ POP-OFF VALVE	200492	7/1/2013
SC8000, SC9000	W/O MANOMETER AND W/O POP-OFF VALVE	101441 - 107461	05/17/2012 - 05/09/2013

CPRM1000	W/O MANOMETER AND W/O POP-OFF VALVE	99523 - 107315	02/14/2012 - 05/02/2013

The recalled products were distributed nationwide and can be identified by the part number, description and lot number on the case labels, as well as a small white label on the individual packaging bag.

There has been one report of injury requiring medical intervention due to the lack of a functional resuscitation bag and 31 reports of a delay in oxygenation due to the requirement to utilize a 2nd or 3rd device. The FDA has been notified of this voluntary action by Ventlab, LLC.

Ventlab, LLC. will notify its distributors and customers by a direct mailing and arrange for the return and replacement of all of the recalled resuscitation bags listed above.

End Users with questions may contact Ventlab LLC. via telephone at 1-844-635-5326 between the hours of 8:30 AM to 5:00 PM (EST) Monday through Friday. Consumers may also contact the company via e-mail at PFA@ventlab.com.

Adverse reactions or quality problems experienced with the use of these products 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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