Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: November 4, 2013

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

FROM: A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program

SUBJECT: PENTAX Medical Company Recall [Medical Device]

AFFECTED PRODUCT: **PENTAX Medical Company initiated a voluntary nationwide recall of 76 PENTAX Gas/Water Valves, model OF-B194**

SUMMARY: **Voluntary Withdrawal; October 31, 2013 - On September 16, 2013 PENTAX Medical Company initiated a voluntary nationwide recall of 76 PENTAX Gas/ Water Valves, model OF-B194. The valves were offered as a separate purchase for use with PENTAX GI Video Endoscopes (90i/90k series and i10/k10 series). The OF-B194 Valve has been found to have a manufacturing defect which may prevent users from turning off the CO2 gas flow during an endoscopic procedure with the potential for serious hazard to the patient, including: peritonitis, perforations, sepsis, death, and bowel perforations requiring surgical repair. Recalled OF-B194 Gas/ Water Valves were manufactured and distributed from August 2009 through July 2013. A total of 704 valves were distributed worldwide, and 76 valves were distributed in the United States. All units distributed in the United States and Worldwide have been recalled. Products can be identified by the model number (OF-B194) stamped on the valve. Corrected valves have a circle before the model number (O OF-B194).**

SUGGESTED ACTION: **Recommend notification of affected parties via phone, fax, or e-mail.
Customers who have purchased the product may return it to the store for a replacement or a full refund. No injuries have been reported at this time.
If consumers have questions they may contact the store director, Sandi Mathews at 765-939-4409, ext. 611.**

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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.

PENTAX Medical Company Issues Voluntary Nationwide Recall of OF-B194 Gas/ Water Valve

Contact:
Consumer:
(800) 431-5880
Website: www.pentaxmedical.com[1]

FOR IMMEDIATE RELEASE - October 31, 2013 - On September 16, 2013 PENTAX Medical Company initiated a voluntary nationwide recall of 76 PENTAX Gas/ Water Valves, model OF-B194. The valves were offered as a separate purchase for use with PENTAX GI Video Endoscopes (90i/90k series and i10/k10 series). The OF-B194 Valve has been found to have a manufacturing defect which may prevent users from turning off the CO2 gas flow during an endoscopic procedure with the potential for serious hazard to the patient, including: peritonitis, perforations, sepsis, death, and bowel perforations requiring surgical repair.

Customers who have OF-B194 PENTAX Gas/ Water Valves have been advised to immediately examine their inventory and quarantine and stop using the product subject to the recall.

Recalled OF-B194 Gas/ Water Valves were manufactured and distributed from August 2009 through July 2013. A total of 704 valves were distributed worldwide in the following regions: Europe/Middle East/Africa (EMEA) 300 valves, Asia Pacific (APAC) 278 valves, 24 valves in Japan, 26 valves in Canada and 76 valves in the United States. All units distributed in the United States and Worldwide have been recalled.

Products can be identified by the model number (OF-B194) stamped on the valve. Corrected valves have a circle before the model number (O OF-B194).

PENTAX Medical Company voluntarily recalled the OF-B194 Valve after becoming aware of a report to the Australia regulatory authority: A 74-year-old male patient admitted for routine Colonoscopy. Polypectomy performed in sigmoid on advancing to the caecum. Reached right side of colon and noticed Petechiae (discolouration due to minute haemorrhage within tissue). At this stage distended abdomen was noted. Suction reported to not be effective in reducing the distension. An alternative CO2 valve changed in an attempt to halt the flow of CO2 into the bowel. Upon withdrawal of the colonoscope, CO2 was noted to be flowing from the scope despite valve not being depressed, which is irregular. Patient had abdominal x-ray performed in recovery, a number of small perforations detected. Patient returned to operating theatre, right Hemicolectomy performed. Patient transferred to ICU.

Our investigation into the event concluded there is a possibility that some valves may have been incorrectly assembled. No injuries have been reported in the United States to date. PENTAX Medical Company has notified the FDA of this action.

PENTAX Medical Company distributed the product to Medical Facilities and PENTAX Sales Representatives/ Field Support Staff in the United States. All affected Medical Facilities in the United States have been notified of the action, have responded, and replacement OF-B194 Valves have been provided by PENTAX Medical Company.

Customers with questions may contact the company via telephone at 1-800-431-5880 extension 2064 Recall Coordinator Paul Silva, between the hours of 9:00am and 5:00pm EST. Customers may also contact the company via e-mail at PAMC-RA-Group@pentaxmedical.com.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA:

- Online at http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm[2] (form available to fax or mail) or
- Call FDA 1-800-FDA-1088

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