

URGENT FIELD SAFETY CORRECTIVE ACTION PRODUCT RECALL – ACTION REQUIRED

Gas/Water Feeding Valve Model: OF-B194

<Date>

To: <Customer address>

Attention: Risk Manager

Ref. FCA-PMJ-13-02: **Field Safety Notice for OF-B194 Gas/Water Feeding Valves**

PENTAX Medical has become aware of a product issue associated with the OF-B194 Gas/Water Feeding Valve that may impact patient safety. The valves are provided for PENTAX GI Video Endoscopes (90i/90k series and i10/k10 series).

Please ensure that all potential users in your facility are made aware of this safety notification.

**Possible
Safety
Issue**

We have been informed about a product issue involving the OF-B194 Gas/Water Feeding Valve. The reported defect may cause improper stoppage of the supply of CO₂ gas during an endoscopic procedure with the potential for serious hazard to the patient and/or user. PENTAX Medical is investigating the product issue and has discovered a manufacturing assembly failure, which cannot be corrected at your facility.

**Affected
Product
Details**

Model Number: OF-B194
Device Description: Gas/Water Feeding Valves
Affected lots: All

**Safety
Instructions**

Stop the use of the OF-B194 Gas/Water Feeding Valve that you ordered between April, 2009 and present.
PENTAX Medical cannot guarantee the safe and effective function of the valve.

**Product
Correction**

PENTAX Medical is working to resolve this issue as quickly as possible and is recalling all distributed OF-B194 Gas/Water Feeding Valves.
We currently expect shipment of the new valves to resume September 17, 2013.

**Contact
Information**

<Describe how the customer - consignee can contact PENTAX Medical with any question. Contact name with phone number, fax number or email address.>

In addition, enclosed with this letter is the Field Safety Corrective Action Response Form. Please forward this letter and the Field Safety Corrective Action Response Form to the User Department(s) in your facility so they can review the information provided and complete the response form.

We sincerely regret any inconvenience caused by this action and appreciate your immediate attention to this matter.

Please be assured that maintaining the highest levels of safety and quality is our foremost priority. If you have any questions, please contact us immediately.

Sincerely,



{RQH name}

{Title and Company name}

{Department name}