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Friday, February 20, 2015

Dear Healthcare Professional,

As you may be aware, the FDA has released a public safety communication to inform you of the potential association between duodenoscopes and recent reports of CRE-related incidents at a small number of healthcare facilities in the United States.

PENTAX Medical is actively engaged with the FDA, professional medical societies and other industry partners in analyzing these occurrences and uncovering potential vulnerabilities in duodenoscope design and reprocessing methodologies. We are currently working with the FDA to provide you with information to further mitigate the potential for cross-contamination with these devices. We will issue a formal communication shortly. PENTAX Medical fully supports the recommendations provided to healthcare facilities, staff and patients outlined in the FDA public safety communication that was released yesterday. The FDA safety communication can be accessed online at www.fda.gov or the link below.

http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm434871.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

PENTAX Medical is dedicated to continuously reducing the risk of infection in flexible endoscopy by consistently developing new advancements in flexible endoscope design, reprocessing procedures, customer tools, and training. Over 500,000 ERCP procedures are performed in the United States every year. The emergence of multi-drug resistant bacteria presents a formidable challenge to the entire healthcare community. As is the case for many other types of endoscopic procedures, the rate of infection for ERCP remains extremely low, and the benefits of the procedure far outweigh the risk.

Sincerely,

PENTAX Medical