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قطاع الأجهزة والمستلزمات الطبية
المركز الوطني لبلاغات الأجهزة والمستلزمات الطبية

Medical Devices Sector
National Center for Medical Devices Reporting

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

رسالة سلامة

Safety Communication

To: Healthcare Provider	**إلى: مقدمي الرعاية الصحية**

Title	Recommendations for healthcare providers regarding the reprocessing procedures of duodenoscopes	**العنوان**
Medical Device Description	Reusable Duodenoscopes	**اسم ووصف الجهاز/المستلزم الطبي**
Manufacturer	All	**اسم المصنع**
Authorized Representative	All	**الممثل المعتمد**
Medical Devices Marketing Authorization (MDMA)	All	**إذن التسويق**
Potential /Associated risks	Based on the SFDA's post-market clinical evaluation study to analyze and evaluate the safety of reusable duodenoscope devices, the study findings indicated a potential risk of increasing contamination rate associated with reprocessed duodenoscopes.	**المخاطر المحتملة/ المرتبطة بالجهاز أو المستلزم الطبي**
Recommendations	Recommendations for healthcare providers: -Follow the manufacturer's instructions for reprocessing procedures of duodenoscopes. -Use appropriate cleaning equipment for duodenoscopes in compliance with the manufacturer's instructions for use. -Healthcare providers should be trained in reprocessing procedures of duodenoscopes. -Apply a robust microbiological surveillance system, reprocessing environments' cleanliness, and distal end of the duodenoscope design. -Develop schedules for routine inspection and periodic maintenance in accordance with the manufacturer's instructions. -Have a quality control program that includes sampling, microbiological culturing, and other monitoring methods for duodenoscopes. -Report all adverse events or complaints cases of using duodenoscopes to the SFDA.	**التوصيات**
For Reporting	SFDA 19999 مركز الاتصال الموحد · NCMDR · تيقظ Saudi Vigilance	**للإبلاغ**