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الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Medical Devices Sector

National Center for Medical Devices Reporting

Safety Communication

رسالة سلامة

To: Healthcare Providers and Practitioners	إلى: مقدمي الرعاية الصحية والممارسين الصحيين
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Title	Recommendations for Healthcare Providers and Practitioners Regarding Surgical Staplers	العنوان
Medical Device Description	Surgical Staplers and Staples	اسم ووصف الجهاز/المستلزم الطبي
Manufacturer	All	اسم المصنع
Authorized Representative	All	الممثل المعتمد

Medical Devices Marketing Authorization (MDMA)	All Authorized Surgical Staplers	إذن التسويق
Potential /Associated risks	Based on a risk assessment study conducted by Saudi Food and Drug Authority (SFDA) regarding surgical staplers and staples, two primary hazards were identified: <i>staple firing failures</i> and <i>fracture-like sounds during operation</i> . Analysis revealed that a lack of adequate training and qualification represents the most factor contributing to the aforementioned risks, leading to non-compliance among some healthcare practitioners with the manufacturers' Instructions for Use (IFU).	المخاطر المحتملة/ المرتبطة بالجهاز أو المستلزم الطبي
Recommendations	SFDA strongly urges healthcare providers and practitioners to review and strictly comply with the outcomes and subsequent recommendations as the following: Restriction of Use: Enforce strict protocols to ensure that surgical staplers are operated exclusively by specialized and authorized healthcare practitioners. Mandatory Qualification: Enable and require healthcare practitioners to receive adequate, continuous clinical training to qualify them for using various models of surgical staplers.	التوصيات

	• Enforcement of Internal Audit Mechanisms: Establish internal audit frameworks and checklists within healthcare facilities to verify practitioners' full compliance with the manufacturers' Instructions for Use (IFU), which must include, at a minimum, the following: ○ Tissue and Size Compatibility: Maintain a diverse inventory of staple sizes, ensure the selection of the appropriate cartridge corresponding to tissue thickness and type, and avoid deployment on compromised or diseased tissues. ○ Familiarity with Operational Indicators: Observe varying color-coding schemes used across different manufacturers, visually monitor the firing completeness indicator, and maintain tactile and auditory awareness to differentiate between normal and abnormal device sounds. ○ Management of Malfunctions and Complications: Guarantee that practitioners possess proactive, pre-requisite knowledge of safe and appropriate interventions during intraoperative malfunctions (e.g., managing blood vessels if the device stalls) to ensure rapid response and prevent adverse clinical complications. ○ Product Safety and Reliability: Exercise absolute vigilance against the procurement or clinical use of counterfeit, unverified, or incompatible staples. • Healthcare providers and practitioners are highly advised to report any related incident /Adverse Event to SFDA.	
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For Reporting	 	للإبلاغ
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