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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 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 study conducted by SFDA to identify the common factors associated with Surgical Staplers and staples hazards within KSA practice, the study shows that (Lack of Training on Surgical Staplers) is a main factor that could lead to several problems and complications.	المخاطر المحتملة/ المرتبطة بالجهاز أو المستلزم الطبي
Recommendations	<p>General Recommendations for Healthcare Providers and Users</p> <ul style="list-style-type: none"> Surgeons and users of surgical staplers must have an appropriate Training by qualified trainers. Healthcare providers and users must be aware that they are obligated to read, understand and follow the instructions for use, technical characteristics, performance parameters, and any necessary information the manufacturer provides in which the device operates safely and effectively. Healthcare providers and users must ensure that the components of the device and staples used with the stapler are all original and compatible. Healthcare providers and users are highly advised to report any related incident /Adverse Event to SFDA. 	التوصيات
For Reporting	  	للإبلاغ