

Date: 28 November 2024

 $Reference\ Number:\ SG\text{-}2411\text{-}425\text{-}H$

قطاع الأجهزة والمستلزمات الطبية المركز الوطني لبلاغات الأجهزة والمستلزمات الطبية

Medical Devices Sector National Center for Medical Devices Reporting الميئة الحامة للخذاء والحوا Saudi Food & Drug Authority

رسالة سلامة Safety Communication

الى: مقدمي الرعاية الصحية إلى: مقدمي الرعاية الصحية

Title	Spread of Cancerous Cells After Hysterectomy and Myomectomy Procedures	العنوان
Medical Device Description	Laparoscopic Power Morcellators (LPM)	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	The process of morcellation could shred some cancerous cells causing them to disperse faster, resulting in an upstage of the hidden uterine cancer from stage one up to stage four.	المخاطر المحتملة/ المرتبطة بالجهاز أو المستلزم الطبي
Recommendations	 Healthcare providers should be encouraged to use tissue containment systems during LPM procedures. Healthcare providers should focus on continuous training to ensure that healthcare professionals consistently guarantee compatibility between tissue containment systems and LPMs, following manufacturers' recommendations. Healthcare providers should report the spread of malignant cancerous tissue after using Laparoscopic Power Morcellators for hysterectomy or myomectomy in patients diagnosed with uterine fibroids to the SFDA as an adverse event. 	التوصيات
For Reporting	SFDA 19999 OCMDR OCMDR Saudi Vigilance	للإبلاغ

Code: MDS-F-310-020-V4