

Date: 26-10-2022

Reference Number: SG-2210-399-H

قطاع الأجهزة والمستلزمات الطبية
المركز الوطني لبيانات الأجهزة والمستلزمات الطبية

Medical Devices Sector
National Center for Medical Devices Reporting

رسالة سلامة
Safety Communication

To: Healthcare Providers	إلى: مقدمي الرعاية الصحية
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Title	Recommendations for Healthcare Providers regarding the safe use of the Injectable Dermal Filler	العنوان
Medical Device Description	Injectable Dermal Filler	اسم ووصف الجهاز/المستلزم الطبي
Medical Device Products Identifier	All	الأرقام للجهاز/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 the current local practices of injectable dermal filler. The study revealed the below issues associated with using injectable dermal filler: The most common complications of injectable dermal filler are swelling, bruising, tenderness, pain, redness, rash, itching, and difficulty performing activities. In addition, there are less common complications, including infection, bumps under the skin, necrosis, draining wounds, and allergic reactions. The following rare complications also could happen, such as blindness, severe allergic reaction, and migration which means movement of injectable dermal fillers from the injection site.	المخاطر المحتملة/ المرتبطة بالجهاز أو المستلزم الطبي
Recommendations	Recommendations for healthcare providers: <ul style="list-style-type: none"> - Follow the injectable dermal filler's intended uses according to the manufacturer's recommendations to avoid or decrease any complications. - Use the injectable dermal fillers that have marketing authorization certificate from Saudi FDA. - Healthcare providers must be specialized, trained, and qualified to use injectable dermal fillers. - Healthcare providers must have a policy and procedure for allergic tests for patients before receiving injectable dermal fillers. - Inform the patient of all possible complications of injectable dermal fillers and the specific product they intend to use. 	التوصيات

For Reporting	  	للإبلاغ:
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