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قطاع الأجهزة والمستلزمات الطبية  
المركز الوطني لبلاغات الأجهزة والمستلزمات الطبية

Medical Devices Sector  
National Center for Medical Devices Reporting

رسالة سلامة  
Safety Communication

To: Healthcare Provider		إلى: مقدمي الرعاية الصحية
<b>Title</b>	Recommendations for the safe and effective use of Acellular Dermal Matrix in Breast Reconstruction	العنوان
<b>Medical Device Description</b>	Acellular Dermal Matrix	اسم ووصف الجهاز/المستلزم الطبي
<b>Manufacturer</b>	All	اسم المصنع
<b>Authorized Representative</b>	All	الممثل المعتمد
<b>Medical Devices Marketing Authorization (MDMA)</b>	All	إذن التسويق
<b>Potential /Associated risks</b>	<p>As per the SFDA post-market clinical evaluation study, that analyze and evaluate the safe and effective use of Acellular Dermal Matrix (ADM) in Breast Reconstruction and how the ADM is being implanted after mastectomy. The study findings explicitly show that the use of ADM in breast reconstruction is associated with numerous complaints worldwide that shall be monitored, such as Seroma, Necrosis, Redbreast syndrome, and Wound healing issues.</p> <p>In addition, there is a potential risks due to an off-label use of certain ADM products that is not approved for breast reconstruction.</p>	المخاطر المحتملة/ المرتبطة بالجهاز أو المستلزم الطبي
<b>Recommendations</b>	<p>In order to reduce or eliminate the ADM associated complaints, here are some recommendations for healthcare providers:</p> <ol style="list-style-type: none"> <li>1. Use ADM that have Medical Devices Marketing Authorization (MDMA) certificate from the SFDA.</li> <li>2. Implant ADM that is authorized and labeled specifically for breast usage.</li> <li>3. Do not use in breast reconstruction any ADM that is not approved for breast reconstruction since it is considered off-label use of medical devices.</li> <li>4. Discuss with the patient all the potential benefits and risks of using ADM in breast reconstruction.</li> <li>5. Follow manufacture recommendation for proper use of ADM.</li> <li>6. Ensure to report any complaints/adverse events related to ADM to the SFDA through reporting channels.</li> </ol>	التوصيات
<b>For Reporting</b>	  	للإبلاغ