

Safety Communication

رسالة سلامة

A potential hardware issue has been identified

Device/ Product Description:	Xstrahl X150 / Gulmay Medical 150	
Affected product:	Serial numbers GM0055 (2002) to GM0533 (2020)	
Manufacturer:	Xstrahl Ltd	
Problem:	The treatment applicators consist of a main body and a base plate component where the base plate consists of a stainless-steel disk and lead disk. There is the risk that the main body and base plate can become detached, which may lead to an increase in radiation leakage dose outside the intended field size.	
Recommendation /Actions:	<p>Contact local agent for return of the 150 Gulmay Medical / Xstrahl treatment applicators to implement modification.</p> <p>For more information, please click here</p> <p>If you think you had a problem with your device or a device your patient uses, please report the problem to SFDA through: NCMDR Vigilance system (19999) unified call center</p>	
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