

Safety Communication

رسالة سلامة

Device may power off without notification to the user resulting in a stoppage of negative pressure wound therapy

Device/ Product Description:	Negative-pressure wound therapy Unit
Brand:	ACTIV.A.C.
Affected product:	All models and serial numbers
Manufacturer:	KCI USA Inc.
Problem:	<p>The manufacturer clarify that the Therapy Units may power off without notification to the user (i.e., no alarm or warning) resulting in a stoppage of negative pressure wound therapy.</p> <p>Inactive therapy may lead to injuries such as reversible maceration, localized infection or wound deterioration.</p>
Recommendation /Actions:	<p>Recommendations for Health Care Providers and Facility Staff:</p> <ul style="list-style-type: none">• Make sure that this document, with accompanying FSNs, are reached to the end-users.• Replace V.A.C.® dressing with alternate dressing if therapy is interrupted or if the unit is powered off for more than two hours. .• Communicate with the authorized representative to perform the required corrective action.• <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 do not hesitate to report the problem to SFDA through:</p> <p>NCMDR Vigilance system 19999 unified call center</p>

**Devices/Products
photo:**



**Authorized
Representative
Details**

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