


Safety Communication

رسالة سلامة

Risk of microbial contamination of the sterile fluid path

Device/ Product Description:	MiniCap Extended Life PD Transfer Sets
Affected product:	Product Code: R5C4482 , Lot # All lots within expiry
Manufacturer:	Baxter Healthcare
Problem:	<p>The affected products may cause damage (for example, leaking or cracking), if they come into direct contact with the transfer set:</p> <ul style="list-style-type: none"> • Cleaning products such as hand sanitizer, or those containing, but not limited to, hydrogen peroxide, bleach, alcohol or antiseptic agents • Solvents intended to remove adhesive residue, such as those containing acetone, toluene, xylene, or cyclohexanone
Recommendation /Actions:	<ul style="list-style-type: none"> • If you are using one of the above-mentioned cleaning products or solvents, please discontinue use of this product or solvent immediately. Please ensure all home patients are aware of proper cleaning practices. Clinicians who are not using any of the above-mentioned cleaning products or solvents may continue to use Baxter transfer sets. • If you have patients who have used the cleaning products or solvents listed above and have identified damage to their transfer set, please replace their transfer set and contact Baxter. • Baxter will be updating the Instructions for Use (IFU) for all Luer transfer sets to instruct patients not to allow cleaning products or solvents to come into contact with the transfer set.

	<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>	
Device Picture		
Authorized Representative Details	AR name:	Baxter AG
	Assigned Contact Person:	Ahmed Mohammed Alhamad
	Mobile/Phone:	0554428638
	Email:	ahmed_alhamad@baxter.com