



Baxter issued an *Urgent Medical Device Correction* bulletin to dialysis providers and Peritoneal Dialysis (PD) patients on January 7, 2022. The bulletin states that products containing bleach, along with other disinfectants and solvents, should not be used on Baxter MiniCap Extended Life PD Transfer Sets to avoid catheter component damage.

Angelini Pharma manufactures Alcavis 50 High-Level Disinfectant. This product is an FDA 510-k (K871583)-cleared disinfectant specifically for use on both Central Venous and PD catheter components. Alcavis 50 is a sodium-hypochlorite solution that is manufactured through electrolysis that yields a milder composition in terms of ionic strength and pH than common household bleach. It has undergone third-party catheter component compatibility studies for the FDA clearance process showing compatibility with 18 different catheter materials (study available on request). We will repeat compatibility studies in the immediate future, specifically with the Baxter MiniCap Extend Life Transfer set and make the results of those studies available on our website [www.angelinipharma-us.com](http://www.angelinipharma-us.com)

Although Baxter considers routine Alcavis 50 use on Transfer Sets to be off label, most Home Dialysis programs apply Alcavis 50 to the PD catheter Transfer Sets as Alcavis 50 has been proven to decrease the incidence of peritonitis (Funes, I. Daily Dialysis Conference; Abstract of the Year 2009). Angelini Pharma has not received any notification of issues from our customers and distributors related to the use Alcavis 50 on Baxter Transfer Sets.

Baxter told Angelini that only three catheter damage events occurred in parts of the world that use Alcavis 50. Please contact Baxter's Quality Department for more details on the issue.

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<b>Proprietary Name:</b>	ALCAVIS 50	
<b>Classification Name:</b>	SET, ADMINISTRATION, FOR PERITONEAL DIALYSIS, DISPOSABLE	
<b>Product Code:</b>	<a href="#">KDJ</a>	
<b>Device Class:</b>	2	
<b>Regulation Number:</b>	<a href="#">876.5630</a>	
<b>Medical Specialty:</b>	Gastroenterology	
<b>Registered Establishment Name:</b>	<a href="#">AZIENDE CHIMICHE RIUNITE ANGELINI FRANCESCO SPA</a>	
<b>Registered Establishment Number:</b>	3005516853	
<b>Premarket Submission Number:</b>	<a href="#">K871583</a>	
<b>Owner/Operator:</b>	<a href="#">AZIENDE CHIMICHE RIUNITE ANGELINI FRANCESCO SPA</a>	
<b>Owner/Operator Number:</b>	9080699	
<b>Establishment Operations:</b>	Contract Manufacturer	