



URGENT FIELD SAFETY NOTICE

Revaclear 400 Dialyzer, Revaclear 300 dialyzer

FA-2022-054

Manufacturer: Gambro Renal Products, Inc (SRN: US-MF-000022995)

Safety Alert

November, 2022

Dear Sir/Madam,

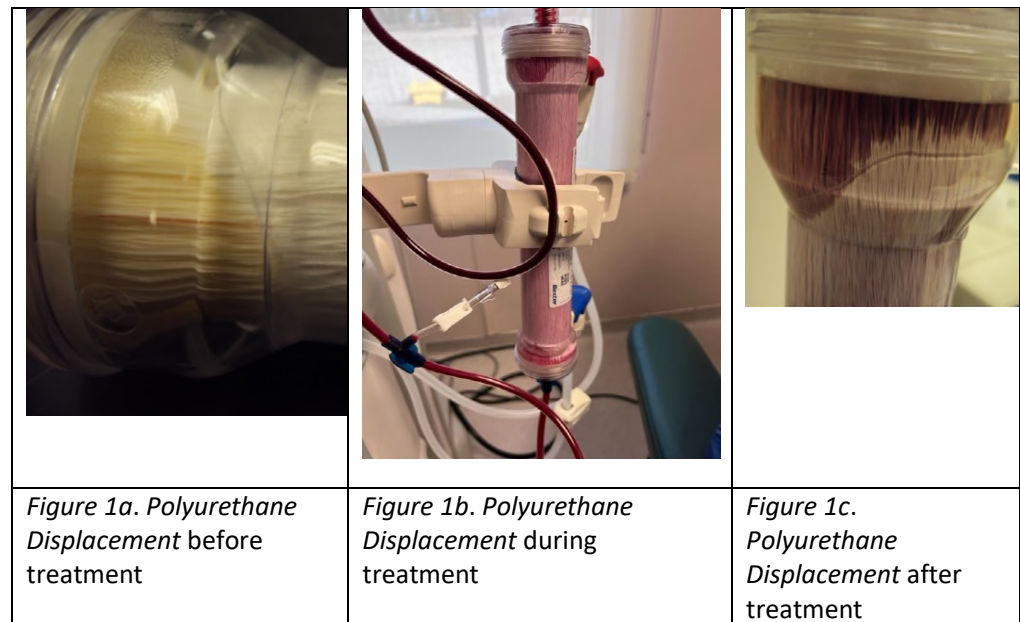
**Problem
Description**

Baxter Healthcare Corporation has identified that certain lots of Revaclear 300 dialyzers and Revaclear 400 dialyzers (listed below) may be impacted by *Polyurethane Displacement* on the fibers at or near the two opposite ends of the dialyzer, i.e., near the header cap and on the opposite side of the dialysate (Hansen) port. This issue causes the fibers in the dialyzer to appear translucent prior to use, which therefore causes the fibers to visually appear more red during treatment even though proper blood flow is occurring through the fibers.

The *Polyurethane Displacement* issue may be mistakenly identified as an *Internal Blood Leak*. *Polyurethane Displacement* does not necessarily mean that an *Internal Blood Leak* is present. Although there are some similarities with the manner in which *Polyurethane Displacement* and an *Internal Blood Leak* may visually appear, these are distinguishable events and only an actual *Internal Blood Leak* will trigger a blood leak alarm.

Typical examples of a dialyzer with *Polyurethane Displacement* are shown below in *Figure 1*. After dialysis therapy has commenced, the *Polyurethane Displacement* will characteristically appear bright red and the affected fibers will be in a concentrated area at either end of the dialyzer, located opposite the dialysate connector.

Figure 1



Affected Product Table

Product Code	Product Description	Lot Number	Expiry Date	UDI Number
114745L	REVACLEAR 300 Dialyzer	C419128801 – C422128401	11/17/2022 – 10/25/2025	07332414123055
114746L	REVACLEAR 400 Dialyzer	C421221401 – C422228501	8/29/2024 – 10/26/2025	07332414124076

Hazard Involved

Displacement of the polyurethane may mistakenly be identified as an internal blood leak. This could prompt the operator to stop therapy and discard the extracorporeal circuit unnecessarily, leading to blood loss equivalent to the extracorporeal circuit volume and delay in therapy. There have been no reports of serious injury related to this issue.

Actions to be taken by Customers

1. Be aware of the difference in appearances between *Polyurethane Displacement* and an *Internal Blood Leak*, and ensure your staff is also aware.
2. If you receive a blood leak alarm, follow your clinical practice to stop the treatment and report the issue to Baxter.
3. If you only observe *Polyurethane Displacement* and there is no blood leak alarm on the machine, you may continue to use the dialyzer.



4. Complete the enclosed customer reply form and return it to Baxter by either faxing it or scanning and e-mailing it or sending it by post, even if you don't have any inventory. Returning the customer reply form promptly will confirm your receipt of this notification and prevent you from receiving repeat notices. **This step is required, per regulatory authorities.**
5. If you purchased this product from a distributor, please note that the Baxter customer reply form is not applicable. If a reply form is provided by your distributor or wholesaler, please return it to the supplier according to their instructions
6. If you distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them.
7. If you are a dealer, wholesaler, distributor/reseller, or original equipment manufacturer (OEM) that distributed any affected product to other facilities, please notify your customers of this notification in accordance with your customary procedures.

**Further
information and
support**

For general questions regarding this communication or any product issue you are experiencing, contact Baxter.

The local Ministry of Health (MOH) has been notified of this action.

We apologize for any inconvenience this may cause you and your staff.

Sincerely,

Baxter Healthcare Corporation