Urgent Medical Device Recall

February 1, 2023

Dear Dialysis Provider:

Problem Description

Baxter Healthcare Corporation is issuing an Urgent Medical Device Recall for the MiniCap product listed below. These devices are packaged in foil pouches, which may have been incorrectly sealed, i.e., the pouches may have open or weak seals. This could lead to exposure to air, resulting in insufficient iodine/dry sponge inside the MiniCap, which could lead to the potential for inadequate disinfectant. The affected product was distributed from 18 October 2022 to 26 January 2023 in the United States.

Affected Product

Product Code	Product Description	Lot Numbers	Expiry Date	UDI Number
5C4466P	MiniCap Disconnect Cap with Povidone-Iodine	GD912051	31-Mar-2024	0085412007694
		GD912068	30-Apr-2024	
		GD912099	30-Apr-2024	
		GD912112	30-Apr-2024	
		GD912143	30-Apr-2024	
		GD912204	31-May-2024	

Hazard Involved

Open or weak seals on the MiniCap pouch could lead to insufficient iodine or a dry sponge due to exposure to air. This may result in inadequate disinfectant properties, potentially increasing the risk of peritonitis. Baxter has not received any reports of peritonitis related to this issue.

Actions to be taken by Customers

1. Please assess each patient's individual next steps based on your clinical evaluation. Baxter is urgently prioritizing delivery of new product to all your impacted patients. Please note that patients may receive equivalent supplies from Baxter manufacturing sites that produce this product for Europe.

2. Home patients are being sent an Urgent Medical Device Recall notification with the following instructions:

    a) Check your stock and set aside all product with the affected lot numbers. The product code and lot number can be found on the individual product packaging and shipping carton. Refer to Figures 1 and 2 below.

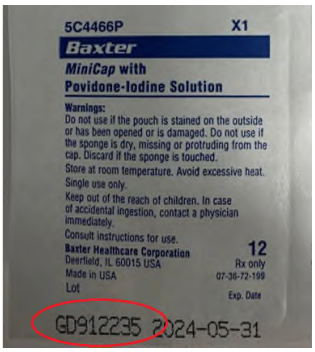


Figure 1. Lot Location (product)

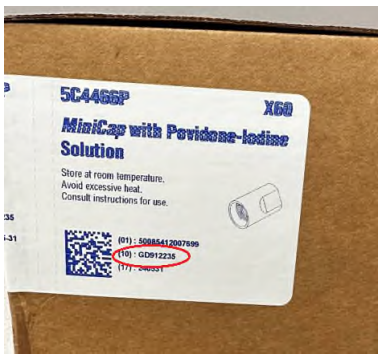


Figure 2. Lot Location (carton)

b) Contact Baxter HomeCare Services to arrange for return of impacted product and for ordering replacement product. Baxter HomeCare Services can be reached at 800-284-4060 between the hours of 7:00 am and 6:00 pm Central Time, Monday through Friday. Please have the following ready when calling:

- Baxter 8-digit ship-to account number
- Product code
- Lot number
- Quantity of product to be returned

c) If all of your product is impacted by this recall and you are unable to get unaffected lot numbers, resulting in a significant delay in therapy, please follow the below steps:

i. Contact your clinic for clinical guidance.

ii. Check each pouch and do not use the MiniCap contained inside of any pouches that look like those seen in Figures 3 and 4 below.

Figure 3. Open Seal

Figure 4. Weak or incomplete seal that runs to the outer edge of the packaging

iii. If you have affected product that **does not** look like Figures 3 and 4 above, Baxter recommends the continued use of the MiniCaps within the pouches only until you receive replacement product that is not affected. Please also consult with your clinic before taking this step.

d) Baxter is prioritizing getting you the replacement product as quickly as possible. The label for the replacement product may look different than the product you have. Refer to Figures 5 and 6 below. When you receive the new supply, the text on the pouch may look different as well. Please be aware that the MiniCap itself is exactly the same and should be used in the exact same manner.

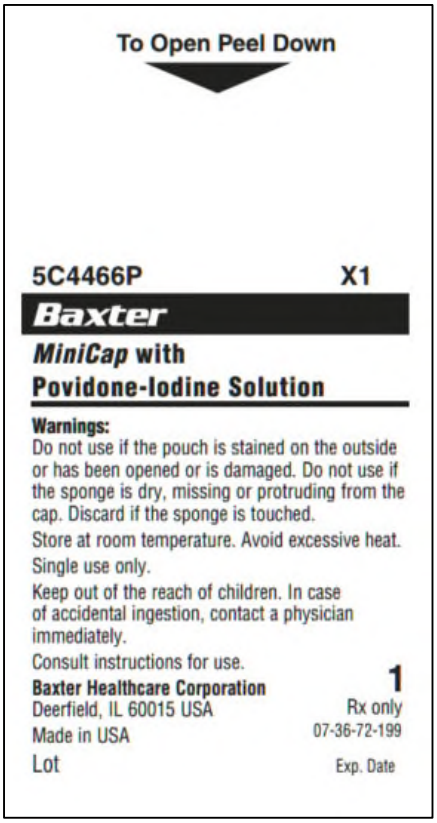


Figure 5. Product Code 5C4466P Label

Figure 6. Product Code SPC4466 Label

3. Immediately locate, isolate, and cease all use of the affected lot numbers of the product. The product code and lot number can be found on the individual product packaging and shipping carton.

4. Contact Baxter Healthcare Center for Service to arrange for return and credit. Baxter Healthcare Center for Service can be reached at 888-229-0001 between the hours of 7:00 am and 6:00 pm Central Time, Monday through Friday. Please have your Baxter 8-digit ship-to account number, product code, lot number, and quantity of product to be returned ready when calling.

5. **If you received this communication directly from Baxter, please acknowledge receipt by responding on our customer portal at https://BaxterFieldActionCustomerPortal.onprocess.com/.** Log in to the portal using the account number listed on the enclosed reply form instruction sheet. Acknowledging receipt of this notification will prevent you from receiving repeat notices. If you do not complete the acknowledgement, you will receive a phone call from OnProcess Technology on behalf of Baxter to confirm your receipt of this notification.
6. If you purchased this product from a distributor, please note that responding via the Baxter customer portal is not applicable. If a response is requested by your distributor or wholesaler, please respond to the supplier according to their instructions.
7. If you distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them.
8. 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 Urgent Medical Device Recall in accordance with your customary procedures and **check the associated box on the customer portal**.

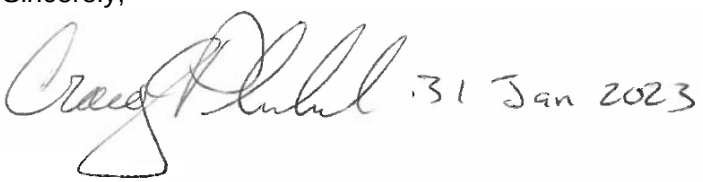
Further information and support For general questions regarding this communication, contact Baxter Corporate Product Surveillance at 800-437-5176, between the hours of 8:00 am and 5:00 pm Central Time, Monday through Friday.

The United States Food and Drug Administration (FDA) will be notified of this action. Any adverse events or quality problems experienced with the use of these products may be reported using one of the following options:

- Calling Baxter Product Surveillance at 800-437-5176 between the hours of 8:00 am and 5:00 pm Central Time, Monday through Friday.
- Emailing to Baxter at: corporate_product_complaints_round_lake@baxter.com.
- Reporting to the FDA MedWatch Serious Injury Reporting Program:
  - **Online:** By completing and submitting the report online at: https://www.accessdata.fda.gov/scripts/medwatch/
  - **Regular mail or Fax:** Download the form from www.fda.gov/MedWatch/getforms.htm or call 800-332-1088 to request a reporting form, then complete and mail it to the address on the pre-addressed form or submit by fax to 800-332-0178.

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

Sincerely,



Craig Plunkard
Senior Director, Quality
Baxter Healthcare Corporation

Enclosure: Reply Form Instruction Sheet
Peritoneal Dialysis Patient Letter

Urgent Medical Device Recall

February 6, 2023

Dear Peritoneal Dialysis Patient:

Problem Description

Baxter Healthcare Corporation is issuing an Urgent Medical Device Recall for the MiniCap product listed below. These devices are packaged in foil pouches, which may have been incorrectly sealed, i.e., the pouches may have open or weak seals. This could lead to exposure to air, resulting in insufficient iodine/dry sponge inside the MiniCap, which could lead to the potential for inadequate disinfectant. The affected product was distributed from 18 October 2022 to 26 January 2023 in the United States.

Affected Product

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		GD912099	30-Apr-2024	
		GD912112	30-Apr-2024	
		GD912143	30-Apr-2024	
		GD912204	31-May-2024	

Hazard Involved

Open or weak seals on the MiniCap pouch could lead to insufficient iodine or a dry sponge due to exposure to air. This may result in inadequate disinfectant properties, potentially increasing the risk of peritonitis. Baxter has not received any reports of peritonitis related to this issue.

Actions to be taken by Customer

1. Check your stock and set aside all product with the affected lot numbers. The product code and lot number can be found on the individual product packaging and shipping carton. Refer to Figures 1 and 2 below.

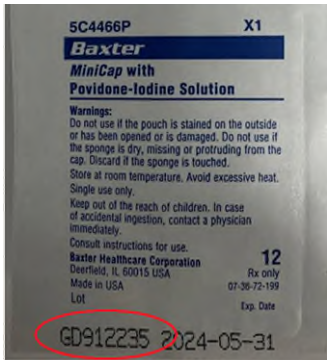

Figure 1. Lot Location (product)

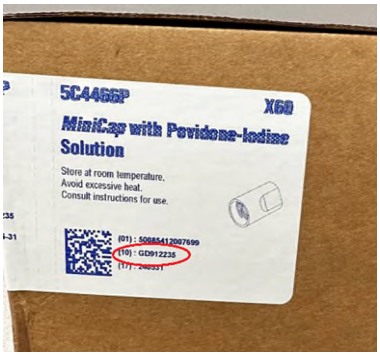

Figure 2. Lot Location (carton)

2. Contact Baxter HomeCare Services to arrange for return of impacted product and for ordering replacement product. Baxter HomeCare Services can be reached at 800-284-4060 between the hours of 7:00 am and 6:00 pm Central Time, Monday through Friday. **Please have the following ready when calling:**
   - **Baxter 8-digit ship-to account number**
   - **Product code**
   - **Lot number**
   - **Quantity of product to be returned**

3. **If all of your product is impacted** by this recall and you are unable to get unaffected lot numbers, resulting in a significant delay in therapy, please follow the below steps:
   a. **Contact your clinic for clinical guidance.**
   b. Check each pouch and do not use the MiniCap contained inside of any pouches that look like those seen in Figures 3 and 4 below.

Figure 3. Open Seal

Figure 4. Weak or incomplete seal that runs to the outer edge of the packaging

c. If you have affected product that **does not** look like Figures 3 and 4 above, Baxter recommends the continued use of the MiniCaps within the pouches *only until you receive replacement product that is not affected.* Please also consult with your clinic before taking this step.

4. Baxter is prioritizing getting you the replacement product as quickly as possible. The label for the replacement product may look different than the label for the product you have. Refer to Figures 5 and 6 below. When you receive the new supply, the text on the pouch may look different as well. Please be aware that the MiniCap itself is exactly the same and should be used in the exact same manner.

Figure 5. Product Code 5C4466P Label

Figure 6. Product Code SPC4466 Label

5. Acknowledge receipt of this letter using one of the two methods detailed on the enclosed Home Patient Reply Form Instruction Sheet. ***This step is required per FDA guidelines.*** Acknowledging receipt promptly will prevent you from receiving repeat notifications. If you do not complete the acknowledgement, you will receive a phone call from OnProcess Technology on behalf of Baxter to confirm your receipt of this notification.

Further information and support

If you have any questions about your PD therapy, please contact your doctor and/or nurse.

For general questions regarding this communication, contact Baxter Corporate Product Surveillance at 800-437-5176, between the hours of 8:00 am and 5:00 pm Central Time, Monday through Friday.

The United States Food and Drug Administration (FDA) will be notified of this action. Any adverse events or quality problems experienced with the use of these products may be reported using one of the following options:

- Calling Baxter Product Surveillance at 800-437-5176 between the hours of 8:00 am and 5:00 pm Central Time, Monday through Friday.
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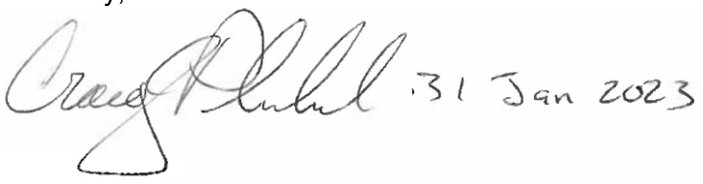
- Reporting to the FDA MedWatch Serious Injury Reporting Program:
  - **Online:** By completing and submitting the report online at: https://www.accessdata.fda.gov/scripts/medwatch/
  - **Regular mail or Fax:** Download the form from www.fda.gov/MedWatch/getforms.htm or call 800-332-1088 to request a reporting form, then complete and mail it to the address on the pre-addressed form or submit by fax to 800-332-0178.

We apologize for any inconvenience this may cause you.

Sincerely,



Craig Plunkard
Senior Director, Quality
Baxter Healthcare Corporation

Enclosure: Home Patient Reply Form Instruction Sheet