



**URGENT: Recall**  
**pH Indicator Strips 0-6**

FSN REF: CAR 26

15 March 2021

Dear Valued Customer:

Johnson Test Papers Ltd. is issuing a recall for one LOT of pH Indicator Strips 0-6 after receiving a notification that the wrong product may be in the pH Indicator Strips 0-6 packaging. Avanos Medical is the exclusive distributor in the UK for the product and is working closely with Johnson Test Papers Ltd. to support this recall. This field safety notice is being issued because there is a possibility of erroneous pH value when the wrong pH paper is compared with the reference chart on the pack. An erroneous pH value could lead to an incorrect reading at the pH 5.5 and 6 values.

**What is the reason for this Field Safety Notice?**

During production of one batch of pH Indicator Strips 0-6 the production line was cleared and set up for the pH indicator strips 2-9. Inadvertently some of the 2-9 pH indicator strips were packaged in the packs intended for the pH Indicator Strips 0-6.

Johnson Test Papers was made aware of this issue when a customer who noticed the test pad was a different color. The middle pad for the pH Indicator Strips 0-6 is blue whereas the middle pad for the pH Indicator Strips 2-9 is green.

The hazard of using the pH 2-9 indicator strip with the pH 0-6 printed scale is that the value read will not be accurate. Misinterpretation of pH may lead to a wrong clinical decision of nasogastric tube position in the stomach leading to additional clinical procedures or initiation of feeding while the feeding tube is not in the stomach.

Due to the nature of the production error, it is expected that only a few packs of the total lot contain the wrong pH indicator strips.

**Which products are impacted?**

This FSN pertains to the Johnson Test Papers **pH Indicator Strips 0-6** with **product code 103.3CE** and **LOT code 103CE29** identified in Table 1:

*Table 1: Impacted Product Codes*

| Product Code | Product Commercial Name    | Lot Number |
|--------------|----------------------------|------------|
| 103.3CE      | pH Indicator Strips pH 0-6 | 103CE29    |



### **What should I do in response to this Field Safety Notice?**

Our distribution records indicate that your facility has received one or more packs of the affected products. Consequently, Avanos requires you to immediately take the following actions:

- **DISCONTINUE** using the specific product / lot code combinations provided in Table 1, including opened packs of this product with LOT code 103CE29.
- **CHECK** all storage and usage locations to determine if any impacted product is in your possession.

### **Unused Inventory**

For affected products that are not used and in your inventory:

- **SEGREGATE and QUARANTINE** the devices according to your facility's procedures, including the opened packs that are being used in your facility.
- **IMMEDIATELY COMPLETE and RETURN** the attached Field safety notice Acknowledgement Form included in (Attachment 1) of this FSN to Avanos by email to [EMEAFieldAction@avanos.com](mailto:EMEAFieldAction@avanos.com).

You will receive further instructions from us how to return the affected products. Avanos will replace the returned products that are left in your inventory free of charge.

### **Inventory Already Used**

If you have already used the affected products, please follow these steps:

- If there are any concerns about potential erroneous results with pH Indicator Strips, **IMMEDIATELY** take a gastric aspirate sample and verify correct placement of the feeding tube by use of the correct pH Indicator Strips
- **IMMEDIATELY COMPLETE** the attached Field safety notice Acknowledgement Form (Attachment 1) checking the box indicating that you have no inventory.
  - Note that if you can check multiple boxes if you also have unused inventory.
- **RETURN** the form to Avanos by email to [EMEAFieldAction@avanos.com](mailto:EMEAFieldAction@avanos.com).

***Please respond within five (5) business days of receipt of this letter.***

If you require further assistance, please contact your sales representative or Avanos customer service ([customerservice.uk.ie@avanos.com](mailto:customerservice.uk.ie@avanos.com)).

The MHRA has been informed about this Field Safety Notice.

Please maintain a copy of this letter for your records.



Johnson Test Papers Ltd. has taken the necessary steps to prevent shipment of the affected products and is completing an investigation to prevent recurrence of this issue. A review of the production risk assessment has been taken. Additional steps will be introduced to ensure complete line clearance and production segregation is maintained including the introduction of additional signage and additional barriers between production areas. A review of the training will also take place and additional training will be provided to key member of staff using this event as a case study to prevent future reoccurrences.

Please share this communication within your organization, with other departments where affected devices have been transferred, and any other associated organisations that may be impacted by this action.

We thank you for your assistance and appreciate your prompt attention in this matter.

We apologize for any disruptions to patient care this issue may cause your clinical facility.

Sincerely,

Adam Bhui  
Director  
Johnson Test Papers Ltd.

A handwritten signature in blue ink, appearing to be "A. Bhui", written in a cursive style.

Klien van Dam  
Sr Manager QA/RA EMEA  
Avanos Medical

A handwritten signature in blue ink, appearing to be "K. van Dam", written in a cursive style.



**ATTACHMENT 1: Recall Acknowledgement Form**

Please complete this form to acknowledge that you have received and understand this Field Safety Notice.

**Please check this box if you have no inventory of impacted products.**

**Please check this box if you have unused inventory of impacted products, and complete the table below**

Please complete the chart below indicating the Quantity of packs for return.

| <b>Impacted Product Code</b> | <b>Product Description</b> | <b>Lot Number</b> | <b>Quantity for Return (packs)</b> |
|------------------------------|----------------------------|-------------------|------------------------------------|
| 103.3CE                      | pH Indicator Strips pH 0-6 | 103CE29           |                                    |

**Please check this box if you have forwarded this FSN to other affected parties (only for distributors)**

Please complete the information below so we can contact you in case of any further query. We also need your contact details to organize the return and replacement of any affected products that are in your inventory.

|  |                      |
|--|----------------------|
| Account No. (if known)                                 | Facility Name        |
|  |                      |
| Contact Name (to organize return of affected products) | Contact Phone Number |
|  |                      |
| Contact E-mail   |                      |
|  |                      |
| Signature  | Date                 |
|  |                      |

Please return a copy of this Recall Acknowledgement Form by email to Avanos:

- [EMEAFieldAction@avanos.com](mailto:EMEAFieldAction@avanos.com)

**Please Return within 5 business days of receipt of this notice.**