

## URGENT MEDICAL DEVICE RECALL

### 0.5 Micron Hydrophobic Disc Filter UDI Barcode Expiration Date Discrepancy

18 July 2023

Dear Valued Customers:

Smiths Medical is issuing this Urgent Medical Device Recall letter to notify you of an issue on the Portex UDI Barcode for the 0.5 micron Hydrophobic Disc Filter. This notification details the issue, the affected items, and the required steps to perform.

#### Issue:

Smiths Medical identified a labeling error in which the barcode (UDI) was not correctly reflecting the expiration date of the product for part number 002291. Specifically, an additional 3 years was added to the expiration date within the UDI barcode of the label (see Figure 1). An example of the affected product labeling with the manufacturing and expiration date sections is below.

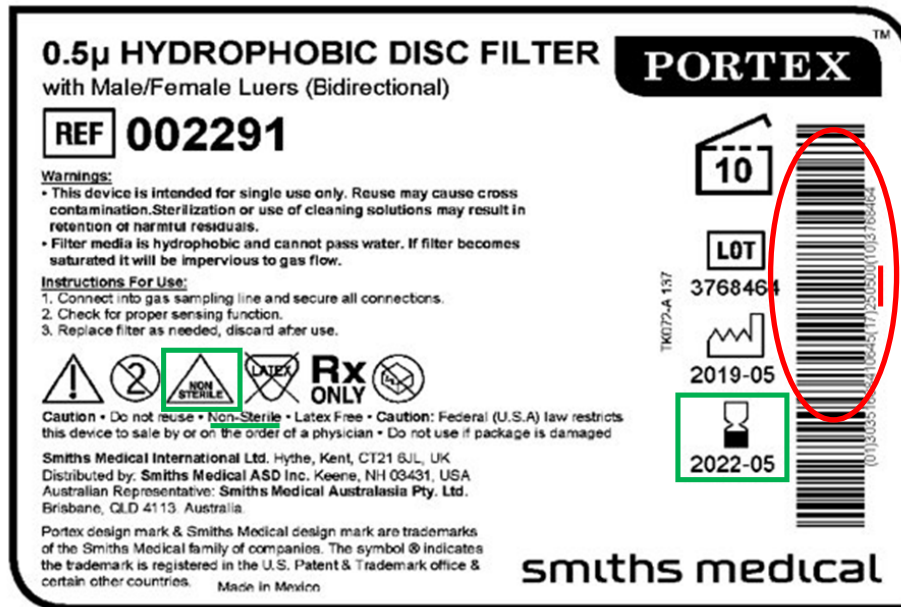


Figure 1

Part Number 002291 with 3 additional years in the UDI barcode expiration date. The correct expiration date is printed at the expiration date symbol. It is important to note this item is distributed non-sterile.

#### Potential Risk:

The identified incorrect expiration date in the UDI barcode could result in the use of impacted devices beyond the actual expiration date of the product. The clinical impact of this mislabeling is delay of therapy due to confusion of the expiration date that is listed in the barcode compared to that written on the label.

Additionally, the potential for the use of a product longer than indicated with the potential for degraded functionality was identified in the circumstance that the user scans the barcode for expiration tracking and/or explicitly confirms the expiration of the product with the UDI barcode.

#### Affected Items:

Our records indicate that the described incorrect expiration date in the UDI barcode affects all lots manufactured between 24-April-2017 to 20-November 2019. Refer to Table 1 for affected product and lot numbers.

Urgent Medical Device Recall: 0.5 Micron Hydrophobic Disc Filter  
UDI Barcode Expiration Date Discrepancy  
Smiths Medical Ref: FA2307-01

**Table 1: Affected Product and Lot Numbers**

Item Number	Product Description	Lot Number
P/N 002291	0.5 MICRON HYDROPHOBIC DISC FILTER	3419998, 3420441, 3429265, 3432722, 3440006, 3467682, 3467683, 3475349, 3489248, 3493797, 3509569, 3521742, 3526245, 3526337, 3529553, 3529672, 3533982, 3542040, 3546408, 3564993, 3570687, 3570840, 3576129, 3576138, 3635067, 3646546, 3658725, 3678314, 3688406, 3695958, 3696009, 3708884, 3727517, 3728938, 3745100, 3754085, 3764388, 3768464, 3784917, 3788804, 3791099, 3798345, 3802616, 3806235, 3843436, 3846795, 3855864, 3855865, 3858487, 3862085, 3864846, 3867640, 3867641, 3874801, 3878332, 3881026, 3884523, 3891892, 3904937, 3917655

**Required Actions for Users:**

- 1) Please discontinue the use and distribution of the affected product **immediately** as listed in Table 1. Check your inventory and quarantine all affected product at your facility.
- 2) Inform all potential users of the product in your organization and anyone that you have further distributed the product to, of this notification.
- 3) Determine the number of affected product in your possession and complete the Response Form (Attachment 1) and return to Sedgwick at [smithsmedical4837@sedgwick.com](mailto:smithsmedical4837@sedgwick.com) or via fax at (877) 907-7035 **within ten days of receipt** to acknowledge understanding of this notification. The form must be returned **even if you do not have the affected product and/or it has already been used**.
- 4) If you have distributed the product further, please indicate the contact information for the new owner of the product on the attached response form.

All affected product **must** be returned for proper processing. Please contact Sedgwick at (888) 943-2402 for further instructions (M-F, 8am-5pm ET). For further inquiries, please contact Smiths Medical using the information provided below.

Smiths Medical Contact	Contact Information	Areas of Support
Global Complaint Management	<a href="mailto:globalcomplaints@icumed.com">globalcomplaints@icumed.com</a>	To report adverse events or product complaints
Customer Service	<a href="mailto:customerservice@icumed.com">customerservice@icumed.com</a>	Additional information or assistance

Smiths Medical is committed to providing quality products and service to our customers. We apologize for any inconvenience this situation may cause.

Sincerely,



Andy Mathein  
Vice President of Quality

**Enclosures:**

- Attachment 1\_Response Form