

Voluntary Field Corrective Action

3M™ Prevena™ Plus 125 Therapy Unit and System Kits

February 25

Dear Valued Customer,

At Solventum, we are dedicated to the care of our patients, and your satisfaction and confidence in our products are of upmost importance to us. This letter is to inform you that we are initiating a voluntary field corrective action on 3M™ Prevena™ Plus 125 Therapy Unit and System Kits distributed between 11 March and 18 December 2024.

Solventum has identified that devices distributed between this period were released with a leak alarm threshold lower than the design specification. This results in the therapy unit prematurely alarming although there is no leak within the system and potentially continuing to alarm during therapy although there is no visible leak.

This voluntary field corrective action is to inform customers who purchased the affected products of this issue to cease use and quarantine the impacted devices and to provide instructions on how to return devices for replacement.

Solventum has received 342 complaints for this issue, but zero (0) reports of injury have been reported. There are no risks to patients. The devices continue to provide negative pressure wound therapy, but due to the lower leak alarm threshold, nuisance alarms may be triggered and continue during therapy although there are no visible leaks.

Our records indicate that you have purchased one or more products affected by this voluntary field corrective action.

Actions required by your facility:

1. **Communicate Field Action:** This voluntary field corrective action notice must be distributed to all individuals who need to be aware within your organisation and to any organisation where the potentially affected devices have been transferred or sold.
2. **Check Your Inventory:** Screen your facility or other storage locations for the impacted products and lot numbers listed in Attachment 1.
3. **Discontinue Use:** Immediately cease use and quarantine any impacted product.
4. **Complete Response Form:** Complete the Field Notice Receipt and Customer Response Form in Attachment 2, acknowledging you have received a copy of this notice and select one of two options:
 - a. Acknowledge you do not have any product impacted by the field action.
 - b. Acknowledge you have product impacted by the field action and complete the product code, lot numbers and quantities you have identified and quarantined.
5. **Contact Us:** Return the form via email to FSCA-EMEA@solventum.com

Solventum's Commitment to You

1. **Support Return of Impacted Product:** Solventum will reach out to your facility to help coordinate the return shipment of any impacted product
2. **Replace Impacted Product Free of Charge:** Once impacted product has been received by Solventum, we will authorise a replacement free of charge.

- a. You will be informed of timelines for shipping replacement product once your free of charge order is processed.
 - b. Solventum plans to ship product as it becomes available to help reduce wait times.
3. **Quality Assurance:** Product which is returned to Solventum will be assessed and reprogrammed to comply with correct quality specifications.
 - a. You may receive returned product which has undergone reprogramming, which will have a visual identifier confirming the assessment and reprogramming.

We deeply regret any inconvenience this issue may have caused you or your patients. Rest assured, we have taken all necessary steps to address this issue and to prevent any recurrence. If you have any questions or concerns, please do not hesitate to contact your local customer service team, who are ready to assist you and ensure a smooth resolution.

Solventum Customer Service Contact Information

| Country | Phone Number | Email |
|-----------------------------|-------------------------|------------------------------------|
| Austria | + 43 186 330 | vac-kundenservice@solventum.com |
| France | 0800 47 8347 - Option 1 | kcifrserviceclient@solventum.com |
| Germany | 0800 7833 524 | vac-kundenservice@solventum.com |
| Ireland | 1800 33 33 77 | ircs@solventum.com |
| Portugal | +351 210200444 | contacto.pt@solventum.com |
| Spain | +34 919030895 | contacto.es@solventom.com |
| Switzerland | 0848 848 900 | postmasterch@solventum.com |
| United Kingdom | 0800 980 8880 | ukcustserv@solventum.com |
| Other International Markets | +44 1344921178 | internationalcc-hcbg@solventum.com |

We greatly appreciate your understanding and cooperation as we undertake this voluntary field corrective action.

Sincerely,

Andrew Jackson

Regulatory Affairs Manager

Mail: FSCA-EMEA@solventum.com

Attachment 1. List of Products and Lots Impacted

3M™ Prevena™ Plus Peel and Place System Kits

| Product Code | Item Description | Lot Number | Plug Type |
|--------------|---|------------|-----------|
| PRE3201V008 | PREVENA PLUS System with PEEL & PLACE Dressing 35cm | C17273V008 | UK Plug |
| PRE3201V008 | PREVENA PLUS System with PEEL & PLACE Dressing 35cm | C17882V008 | UK Plug |
| PRE3201V008 | PREVENA PLUS System with PEEL & PLACE Dressing 35cm | C18391V008 | UK Plug |
| PRE3201V008 | PREVENA PLUS System with PEEL & PLACE Dressing 35cm | C19240V008 | UK Plug |
| PRE3201V009 | PREVENA PLUS System with PEEL & PLACE Dressing 35cm | C16796V009 | EU Plug |
| PRE3201V009 | PREVENA PLUS System with PEEL & PLACE Dressing 35cm | C17755V009 | EU Plug |
| PRE3201V009 | PREVENA PLUS System with PEEL & PLACE Dressing 35cm | C17955V009 | EU Plug |

3M™ Prevena™ Plus Customizable System Kits

| Product Code | Item Description | Lot Number | Plug Type |
|---------------|-----------------------------|------------|-------------------|
| PRE4001UKV006 | PREVENA PLUS SYSTEM KIT, UK | C17024V006 | UK Plug |
| PRE4001UKV006 | PREVENA PLUS SYSTEM KIT, UK | C17177V006 | UK Plug |
| PRE4001UKV006 | PREVENA PLUS SYSTEM KIT, UK | C17300V006 | UK Plug |
| PRE4001UKV006 | PREVENA PLUS SYSTEM KIT, UK | C17958V006 | UK Plug |
| PRE4001V006 | PREVENA PLUS SYSTEM KIT | C17178V006 | EU Plug |
| PRE4001V006 | PREVENA PLUS SYSTEM KIT | C18062V006 | EU Plug |
| PRE4001V006 | PREVENA PLUS SYSTEM KIT | C18814V006 | EU Plug |
| PRE4001ZAV006 | PREVENA PLUS SYSTEM KIT, ZA | C18060V006 | South Africa Plug |
| PRE4001ZAV006 | PREVENA PLUS SYSTEM KIT, ZA | C18464V006 | South Africa Plug |

3M™ Prevena™ Plus 125 Therapy Unit – Standalone Kit

| Product Code | Item Description | Lot Number | Plug Type |
|--------------|--|------------|-------------------|
| PRE4010V003 | PREVENA PLUS STANDALONE EXTENDED LIFE SYSTEM KIT | C16878V003 | EU Plug |
| PRE4010V004 | PREVENA PLUS STANDALONE EXTENDED LIFE SYSTEM KIT | C16879V004 | UK Plug |
| PRE4010V004 | PREVENA PLUS STANDALONE EXTENDED LIFE SYSTEM KIT | C17684V004 | UK Plug |
| PRE4010V007 | PREVENA PLUS STANDALONE EXTENDED LIFE SYSTEM KIT | C18815V007 | South Africa Plug |
| PRE4010V016 | PREVENA PLUS STANDALONE EXTENDED LIFE SYSTEM KIT | C16880V016 | UK Plug |
| PRE4010V016 | PREVENA PLUS STANDALONE EXTENDED LIFE SYSTEM KIT | C17179V016 | UK Plug |
| PRE4010V016 | PREVENA PLUS STANDALONE EXTENDED LIFE SYSTEM KIT | C17685V016 | UK Plug |
| PRE4010V016 | PREVENA PLUS STANDALONE EXTENDED LIFE SYSTEM KIT | C17960V016 | UK Plug |
| PRE4010V016 | PREVENA PLUS STANDALONE EXTENDED LIFE SYSTEM KIT | C18445V016 | UK Plug |
| PRE4010V016 | PREVENA PLUS STANDALONE EXTENDED LIFE SYSTEM KIT | C18816V016 | UK Plug |
| PRE4010V017 | PREVENA PLUS STANDALONE EXTENDED LIFE SYSTEM KIT | C16881V017 | EU Plug |
| PRE4010V017 | PREVENA PLUS STANDALONE EXTENDED LIFE SYSTEM KIT | C17180V017 | EU Plug |
| PRE4010V017 | PREVENA PLUS STANDALONE EXTENDED LIFE SYSTEM KIT | C17304V017 | EU Plug |
| PRE4010V017 | PREVENA PLUS STANDALONE EXTENDED LIFE SYSTEM KIT | C17686V017 | EU Plug |
| PRE4010V017 | PREVENA PLUS STANDALONE EXTENDED LIFE SYSTEM KIT | C17961V017 | EU Plug |
| PRE4010V017 | PREVENA PLUS STANDALONE EXTENDED LIFE SYSTEM KIT | C18446V017 | EU Plug |
| PRE4010V017 | PREVENA PLUS STANDALONE EXTENDED LIFE SYSTEM KIT | C18817V017 | EU Plug |
| PRE4010V020 | PREVENA PLUS STANDALONE EXTENDED LIFE SYSTEM KIT | C16882V020 | Switzerland Plug |
| PRE4010V020 | PREVENA PLUS STANDALONE EXTENDED LIFE SYSTEM KIT | C17182V020 | Switzerland Plug |
| PRE4010V020 | PREVENA PLUS STANDALONE EXTENDED LIFE SYSTEM KIT | C17307V020 | Switzerland Plug |
| PRE4010V020 | PREVENA PLUS STANDALONE EXTENDED LIFE SYSTEM KIT | C17688V020 | Switzerland Plug |
| PRE4010V020 | PREVENA PLUS STANDALONE EXTENDED LIFE SYSTEM KIT | C18061V020 | Switzerland Plug |
| PRE4010V020 | PREVENA PLUS STANDALONE EXTENDED LIFE SYSTEM KIT | C18448V020 | Switzerland Plug |
| PRE4010V020 | PREVENA PLUS STANDALONE EXTENDED LIFE SYSTEM KIT | C18818V020 | Switzerland Plug |
| PRE4010V021 | PREVENA PLUS STANDALONE EXTENDED LIFE SYSTEM KIT | C17305V021 | South Africa Plug |
| PRE4010V021 | PREVENA PLUS STANDALONE EXTENDED LIFE SYSTEM KIT | C18819V021 | South Africa Plug |

3M™ Prevena Restor™ ArthroForm™ System Kits

| Product Code | Item Description | Lot Number | Plug Type |
|--------------|---|------------|-----------|
| PRE5001V002 | PREVENA RESTOR ARTHRO-FORM SYSTEM KIT 33X30 CM | C16748V002 | UK Plug |
| PRE5001V002 | PREVENA RESTOR ARTHRO-FORM SYSTEM KIT 33X30 CM | C17760V002 | UK Plug |
| PRE5001V003 | PREVENA RESTOR ARTHRO-FORM SYSTEM KIT 33X30 CM | C16749V003 | EU Plug |
| PRE5001V003 | PREVENA RESTOR ARTHRO-FORM SYSTEM KIT 33X30 CM | C16929V003 | EU Plug |
| PRE5101V002 | PREVENA RESTOR ARTHRO-FORM SYSTEM KIT 46X30 CM | C17763V002 | UK Plug |
| PRE5101V003 | PREVENA RESTOR ARTHRO-FORM SYSTEM KIT 46X30 CM | C17219V003 | EU Plug |

3M™ Prevena Restor™ BellaForm™ System Kits

| Product Code | Item Description | Lot Number | Plug Type |
|--------------|--|------------|-----------|
| PRE5221V002 | PREVENA RESTOR BELLA-FORM SYSTEM KIT 21X19 CM | C16931V002 | UK Plug |
| PRE5221V002 | PREVENA RESTOR BELLA-FORM SYSTEM KIT 21X19 CM | C17220V002 | UK Plug |
| PRE5321V002 | PREVENA RESTOR BELLA-FORM SYSTEM KIT 24X22 CM | C18613V002 | UK Plug |
| PRE5321V002 | PREVENA RESTOR BELLA-FORM SYSTEM KIT 24X22 CM | C18613V002 | UK Plug |
| PRE5321V003 | PREVENA RESTOR BELLA-FORM SYSTEM KIT 24X22 CM | C16751V003 | EU Plug |
| PRE5321V003 | PREVENA RESTOR BELLA-FORM SYSTEM KIT 24X22 CM | C18614V003 | EU Plug |
| PRE5421V002 | PREVENA RESTOR BELLA-FORM SYSTEM KIT 29X27 CM | C16933V002 | UK Plug |
| PRE5421V002 | PREVENA RESTOR BELLA-FORM SYSTEM KIT 29X27 CM | C17223V002 | UK Plug |
| PRE5421V003 | PREVENA RESTOR BELLA-FORM SYSTEM KIT 29X27 CM | C17224V003 | EU Plug |
| PRE5421V003 | PREVENA RESTOR BELLA-FORM SYSTEM KIT 29X27 CM | C17770V003 | EU Plug |
| PRE5421V003 | PREVENA RESTOR BELLA-FORM SYSTEM KIT 29X27 CM | C18074V003 | EU Plug |
| PRE5421V003 | PREVENA RESTOR BELLA-FORM SYSTEM KIT 29X27 CM | C18583V003 | EU Plug |



Attachment 2: Voluntary Field Corrective Action Notice Receipt and Customer Response Form

Please check the box below:

- ☐ We have read the 3M™ Prevena™ Plus 125 Therapy Units and Kits VOLUNTARY FIELD CORRECTIVE ACTION Notice and acknowledge we don't have any products affected by the filed corrective action
- ☐ We have read the 3M™ Prevena™ Plus 125 Therapy Units and Kits VOLUNTARY FIELD CORRECTIVE ACTION Notice and acknowledge we have the following products and lot numbers affected by the filed corrective action, have quarantined the product and understand the product will be returned to Solventum

[illegible]

Attachment 2: Voluntary Field Corrective Action Notice Receipt and Customer Response Form

Please provide your account information

| | | | |
|--|--|-------------|--|
| Facility Name | | | |
| Contact Name / Title | | | |
| Address (no PO boxes, please) | | | |
| City, State/Province, Postal Code | | | |
| Phone Number | | Fax: | |
| E-Mail Address: | | | |

Please provide contact details where any additional information may be sent, if different from above.

| | | | |
|--|--|-------------|--|
| Facility Name | | | |
| Contact Name / Title | | | |
| Address (no PO boxes, please) | | | |
| City, State/Province, Postal Code | | | |
| Phone Number | | Fax: | |
| E-Mail Address: | | | |

Please return your completed form to FSCA-EMEA@solventum.com with “Prevena FCA” and your country and facility name in the subject line. E.g. Prevena FCA – UK – Hospital A.

Person completing this form:

| | |
|------------------|--|
| Name | |
| Signature | |
| Date | |

| | |
|--------------------------------|--|
| Company / Hospital Name | |
| City, Country | |
| Phone | |
| E-mail | |