

Date: 19/03/2021
Version V 0

URGENT: SAFETY NOTICE

Diphoterine® and Hexafluorine® Portable Autonomous Showers

For the attention of the Company's Health and Safety correspondent, the Director of the establishment, and those responsible for first aid in the Company.

Subject of the notice:

- Inspection/modification of products by the user
- Specific instructions for use

Prevor ref.: NC 23850

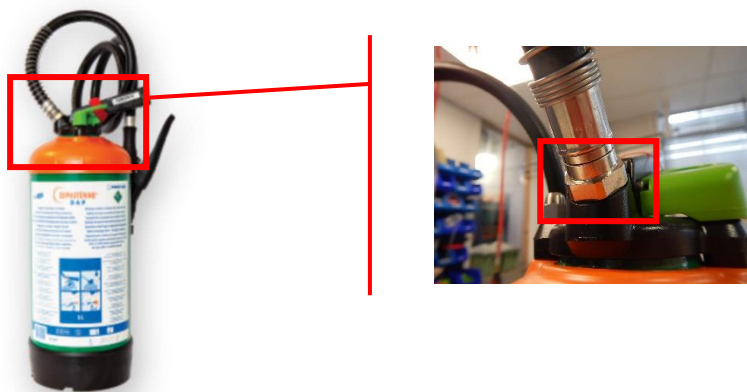
FSCA ref.: R2105990 (ANSM)

Product reference:	<ul style="list-style-type: none">- DAPD- DAPF
Intended use:	<ul style="list-style-type: none">- DAPD: rinsing of chemical splashes on the body- DAPF: rinsing of splashes on the body of hydrofluoric acid and fluorine derivatives in an acidic medium
Manufactured by:	PREVOR Moulin de Verville 95760 VALMONDOIS Tel: +33 1 30 34 76 76 Contact email: affairesreglementaires@prevor.com
Distributed in COUNTRY by:	NAME of distributor Distributor's address Tel Email
Appendices	Appendix 1: List of batch numbers affected Appendix 2: Customer response form

Description of the problem

DAP devices are made up of 4 main elements: the shower body (green cylinder), the shower head (black element to start operating the device), the hose (diffusion pipe) and the internal system containing the solution.

The defect is located at the level of the hose's attachment (following photo) at the head of the DAP.



Two similar incidents were reported to us indicating that **the hose had come off** at the nut holding it in connection with the DAP head.

These two incidents took place under similar circumstances which we were able to reproduce according to the following protocol:

- Activation of the shower (= pressurisation by means of the black handle)
- Diffusion of the solution while applying a stress to the hose (rotation at the nut and/or shaking of the device)

Affected batch: the hoses potentially affected by this defect are numbered **1907**.

Please note that not all devices incorporating this set of hoses are likely to have the defect. However, should this happen, we are aware that this defect coupled with the chemical accident situation can be confusing for the user.

Conduct and potential risk for the user in the event of the hose coming off

The frequency of occurrence of the defect on the hose batch N° 1907 is 0,2%.

If the hose should come off during the dispensing of the solution, it does not create an immediate danger to the user or people nearby.

The DAP remains functional and solution will continue to flow through the DAP port. However, the application of the solution will not be as easy. We recommend lifting the device to keep the solution flowing over the person affected by a chemical splash, as shown in the photo below. The solution stream can be directed using a finger to direct the flow.

Thus, the person can continue the decontamination process thanks to all the effects of the Diphoterine® or Hexafluorine® solutions, which will have the effect of carrying out the essential surface rinsing.



The surprise caused to the user in the event of the hose unhooking can lead to a momentary stop or delay in the application of the solution. In this case, the rinsing may not be optimal or even not complete.

Also, after this DAP has been fully used, we recommend a secondary rinsing by applying a second DAP to the victim.

Finally, as with all cases of chemical splashes on a person, we recommend that you follow your procedure for the care and control of the victim with the appropriate medical service.

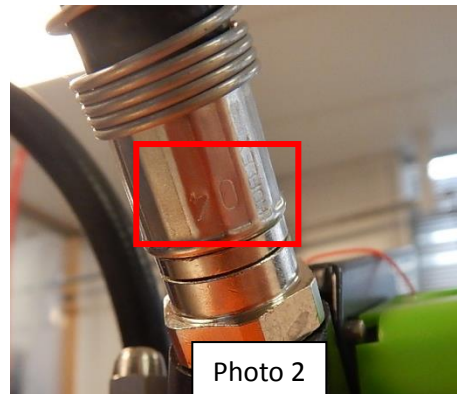
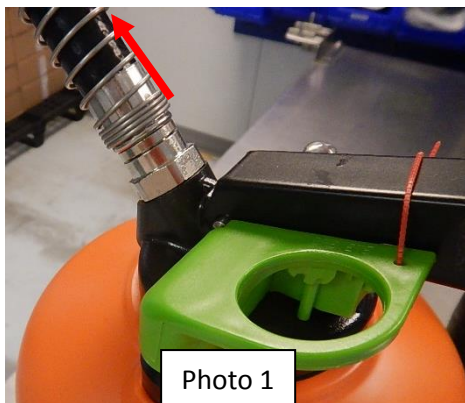
What measures has Prevor taken to resolve this defect?

The defect having been identified, we were able to develop a safety collar that fits over the nut. Thanks to a simple and resistant fixing system, this collar will prevent any risk of the hose coming off.



What is the procedure to follow?

1. Check if the batch number of the hoses connected to your DAP devices is 1907



To read the batch number of the hose: lift the spring (photo 1) and read the 4 digits engraved on the metal part (photo 2).

2. Fill in the form available in appendix 2 and send it back to us by email as soon as possible and at the latest within 10 days following receipt of this letter, whether or not you have identified this hose number.

(XX CENTER EMAIL of subsidiary or distributor XX)

2.a Indicate on the form the batch number of the complete identifiable device as shown below:



2.b Take photos of the hose batch numbers on the devices affected and attach them to the form.

3. If you have identified devices on your site with hose number 1907:

3.a

Inform your employees and potential users of the defect and of the measures to be taken in case of need of use according to the paragraph "Conduct and potential risk".

3.b

We will send you the special securing piece (safety collar) with its assembly plan as soon as you confirm.

Distribution of this Safety Notice

This PREVOR safety notice should be sent to all responsible individuals within your facility - and to the head of any organisation where potentially affected devices have been transferred. Please heed this notice and the resulting measures during the period of use of the device to ensure effective corrective action.

Please note that the competent authorities in your country have been informed of this communication to our customers.

Please report any incidents related to medical devices to the manufacturer, distributor or local representative, and to the relevant national authority if you consider it necessary, as this provides important feedback.

Additional information

We apologise for any inconvenience this may cause, and thank you in advance for your understanding of the measures we have decided to take to ensure the optimal performance of our devices.

If you have any questions, or need assistance in completing your Customer Response Form, please contact your local PREVOR representative.

Contact person:

Joël BLOMET
Chief Executive Officer

PREVOR
Moulin de Verville - 95760 VALMONDOIS - France
Tel: +331 30 34 76 76 email: affairesreglementaires@prevor.com

The signature below confirms that the competent authority for the monitoring of medical devices has been informed of this notice.

Signature:

Appendix 1

LIST OF BATCH NUMBERS AFFECTED

Appendix 2

CUSTOMER RESPONSE FORM

1. Field Safety Notice (FSN)	
FSN reference number* (if applicable)	NC 23850
FSN Date*	19/03/2021
Product/Device Name	DIPHOTERINE® HEXAFLUORINE®
Product Code(s)	DAPD DAPF

2. Customer details	
Company name*	
Account number	
Address	
Delivery address if different from above	
Name of contact person* (if applicable)	
Title or Position	
Phone number* (if applicable)	
Email	

3. Information to be completed

- ☐ I confirm that I have received, read and understood the contents of the safety notice.
(Check the appropriate box)
Yes ☐ No ☐

I have DAPD - Diphoterine® solution devices with hose number 1907*	Yes <input type="checkbox"/> No <input type="checkbox"/> (check the appropriate box)
Number of devices affected	(indicate number)
Batch numbers of the devices affected	(indicate batch numbers)

I have DAPF - Hexafluorine® solution devices with hose number 1907*	Yes <input type="checkbox"/> No <input type="checkbox"/> (check the appropriate box)
Number of devices affected	(indicate number)
Batch numbers of the devices affected	(indicate batch numbers)

☐ I have not identified any DAP devices with hose number 1907 on site.

☐ I am enclosing photos of the affected devices with this response form*

Name	
Signature	
Date:	

Required fields indicated by *

Contact to whom return the form: details + email of the sales department/distributor