PRODIMED

PRODIMED SAS
6 rue Louis Armand
95130 Le Plessis Bouchard - France

at Plessis-Bouchard,
May 25th, 2020

URGENT: FIELD SAFETY NOTICE EN Batch recall –PRODIMED RA#20_001
Letter sent by PRODIMED only to concerned Export Distributors

To the attention of concerned Distributor:

Recipients: Quality Manager & Director

Identification PRODIMED FSN Batch recalls RA# 20_001
French National Competent Authority ANSM registry number: R2005997
Legal manufacturer: PRODIMED
Description of the product: - Commercial references - Batch number: The complete list of products, references and batch numbers concerned is available on the ANSM website: Safety information - Withdrawal of batches and products.
Inventory of products delivered within your organization: See in appendix # 1.

Dear Sir or Madam,

We inform you that PRODIMED has initiated a voluntary recall on manufacturing batches in its range. As far as you are concerned, the details can be found in Appendix 1 attached to this letter.

1) Description of Product

The description of the medical devices concerned and the complete list of concerned products by product code, lot number, are available on the ANSM website: Safety information -Withdrawal of batches and products.

2) Reason of the voluntary recall of products

During the ethylene oxide sterilization cycle, an undetermined portion of the batch of the devices involved may not have been in contact with ethylene oxide. The sterile state of the products may not be guaranteed.

No incident reports related to this risk have been reported to PRODIMED to date.

As a precautionary principle of patient's safety, PRODIMED decided to recall the batches concerned, in agreement with the National Agency for Safety of Medicines and Health Products.

3) Potential risk for patients

In addition to the normal risk of infection associated with any interventional procedure, there is an additional potential risk: if a potentially affected product is used in interventional procedure.

In case of infection, medical treatment may be required.

4) Origin of the problem

As part of the annual review of the sterilization cycles, PRODIMED has identified a non-compliance in the preparation of the products before sterilization that could question the effectiveness of the sterilization process.

5) Corrective and preventive actions

As a precautionary principle for patient safety, PRODIMED decided to recall the affected batches on the market.

In parallel with this decision, PRODIMED has started a corrective and preventive action plan to guarantee the sterile condition of future manufacturing batches.

PRODIMED

6) **Action to be taken by the Distributors**

Our records indicate that you have received at least one of the above mentioned devices. Therefore, you are concerned by this action.

Please read this notice carefully and take the steps outlined below:
Kindly:

1. Immediately check your inventory and quarantine any device affected by the product recall according to Customer listing attached in appendix #1.
2. Disseminate this notice to all relevant individuals within your organization
3. Remain internally vigilant against this notice until all required actions are taken within your organization.
4. Recall the products in the territories under your responsibility according to the same instructions, and according to the terms of the QTA established with PRODIMED (if applicable). A translation of this letter into your local language will be provided by Prodimed to enable you to communicate with your customers.
5. Complete the Field Safety Notice RA20_001 response form and attach it to the completed, dated and signed inventory, regardless of the level of your stock (even zero). Indeed, your confirmation will allow PRODIMED to carry out a complete traceability of this recall and avoid any unnecessary reminder.
6. Send back the response form and the completed, dated and signed inventory by email to: customer-service@prodimed.com, or by fax: +33 23746388.
7. After agreement of the Export Customer Service, proceed to the destruction of the products quarantined in front of judicial officer with statement of destruction. If at the local level, you do not have the possibility to appeal to a judicial officer, please inform PRODIMED before any steps in order to define, on a case-by-case basis, the procedure to be followed.
8. Send back the statement of destruction certified by the judicial officer as well as the inventory completed and signed by email to: customer-service@prodimed.com, or by fax: +33 237463887.

We would be much obliged if you could reply to this notice within the 15 days from the receipt date about product in your inventory. Relating products recovered from your customers, you could reply later.

Upon receipt of the certified statement of destruction, PRODIMED's Export Customer Service Department may refund the destroyed product with a credit note.

To assist you in recall management, your PRODIMED's Sales Manager in charge of your account will revert to you. Support provided by PRODIMED will be studied, on a case-by-case basis, with said Sales Manager. The effective management process will be done after prior agreement and upon presentation of supporting documents.

For further questions, please contact the customer service on the following email: service@prodimed.com, or by phone: + 33 2 37 65 86 20.

In accordance with the recommendations of the Meddev Vigilance Guidance ref. 2.12-1, this safety notice has been communicated to all relevant health authorities and the notified body.

Please inform PRODIMED in case of an undesirable effects observed in relation to the product and the batch concerned. We remind you of the need to report any undesirable effect observed with these devices to PRODIMED and to the health authority in your country.

The safety and well-being of patients and healthcare professionals is the priority of PRODIMED and we want to ensure that only quality products are used by our customers.

We apologize for the inconvenience and thank you in advance for helping us to resolve this issue as quickly and efficiently as possible.

Please accept the expression of my distinguished greetings.

Jean Christophe STERN
Site Director of Plessis Bouchard
Materiovigilance Correspondant

PRODIMED

Meddev Rev 1: July 2018

URGENT: Template for a Field Safety Notice Distributor/Importer

Reply Form FNS RA#20_001

1. Field Safety Notice (FSN) information	
FSN Reference number*	Identification PRODIMED FSN Batch recalls RA# 20_001 French National Competent Authority ANSM registry number: R2006997
FSN Date*	May 25, 2020
Product/ Device name*	Sterile Single Use Prodimed Medical devices – Refer to Customer listing attached in appendix # 1
Product Code(s)	Refer to Customer listing attached in appendix # 1
Batch/Serial Number (s)	Refer to Customer listing attached in appendix # 1

2. Distributor/Importer Details	
Company Name*	
Account Number	
Address*	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Return acknowledgement to Sender	
Email	customer-service@prodimed.com
Distributor/Importer Helpline	Fax # +33 237463887 Phone # + 33 2 37 65 86 20.
Postal Address	PRODIMED 6 rue Louis Armand 95130 Le Plessis Bouchard FRANCE
Web Portal	Pre-filled by manufacturer/sender/requester
Deadline for returning the Distributor/Importer reply form*	For products in Distributor/Importer stock June 8th, 2020 For products recalled from customers by Distributor/Importer : ASAP

4. Distributors/Importers (Tick all that apply)		
☐	*I confirm the receipt, the reading and understanding of the Field Safety Notice.	Distributor/Importer to complete or enter N/A
☐	I have checked my stock and quarantined inventory	Distributor/Importer to enter quantity and date
☐	I have sent back the response form and the completed, dated and signed inventory	Please use Customer listing attached in appendix # 1 for inventory.

PRODIMED

Meddev Rev 1: July 2018

URGENT: Template for a Field Safety Notice Distributor/Importer

Reply Form FNS RA#20_001

4. Distributors/Importers (Tick all that apply)		
☐	I have identified customers that received or may have received this device	
☐	I have attached customer list	
☐	I have informed the identified customers of this FSN	Date of communication:
☐	I have received confirmation of reply from all identified customers	
☐	I have recovered from all identified customers a part of affected devices - enter number of devices recovered and date complete.	Add quantity, Lot/Serial Number/Date Returned (same information as requested by the Customer Reply form) Please use Customer listing attached in appendix # 1.
☐	I have sent back the response form corresponding to products recovered for all identified customers and the completed, dated and signed inventory	Please use Customer listing attached in appendix # 1 for inventory.
☐	I have destroyed affected devices – enter number destroyed and date complete.	Add quantity, Lot/Serial Number/Date Returned (same information as requested by the Customer Reply form Please proceed to the destruction of the products quarantined in front of judicial officer with statement of destruction. This statement must be sent to PRODIMED
☐	Neither I nor any of my customers has any affected devices in inventory	
☐	I have sent back the statement of destruction certified and date complete.	
Print Name*		Distributor/Importer print name here
Signature*		Distributor/Importer sign Here
Date *		

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.

Prodimed Customer Service will check the conformity between quantity announced and quantity delivered by Prodimed.
Prodimed will consider that the balance between quantity delivered by Prodimed and quantity destroyed correspond to quantity used in the territories under your responsibility.
Send back the response form and the completed, dated and signed inventory by email to: customer-service@prodimed.com, or by fax: +33 23746388.

New productions will be available starting from middle of June 2020.
From April 29th, 2020, all products delivered by Prodimed are not concerned by this batch recall.