

Template for a Field Safety Notice Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	FSN Ref: CAPA23-051 Rev01
FSN Date*	August 16th 2023
Product/ Device name*	POLYFILM®
Product Code(s) / Vygon code	PF121401 / VPEPF121401
Batch/Serial Number (s)	<input type="checkbox"/> A200006 <input type="checkbox"/> A210007 <input type="checkbox"/> A210008 <input type="checkbox"/> A220009 <input type="checkbox"/> A220010

2. Customer Details	
Account Number	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

<input type="checkbox"/>	I confirm receipt of the Field Safety Notice and that I read and understood its content.
<input type="checkbox"/>	I performed all actions requested by the FSN.
<input type="checkbox"/>	I have received products from these batches and I confirm that I have used them <input type="checkbox"/> A200006 Quantity : <input type="checkbox"/> A210007 Quantity : <input type="checkbox"/> A210008 Quantity : <input type="checkbox"/> A220009 Quantity : <input type="checkbox"/> A220010 Quantity :
<input type="checkbox"/>	I have affected devices in stock and I confirm their destruction to VYGON. (complete quantity and date of destruction) <input type="checkbox"/> A200006 Quantity : Destruction date : <input type="checkbox"/> A210007 Quantity : Destruction date : <input type="checkbox"/> A210008 Quantity : Destruction date : <input type="checkbox"/> A220009 Quantity : Destruction date : <input type="checkbox"/> A220010 Quantity : Destruction date :
<input type="checkbox"/>	For each batch, send a photo of some devices before destruction
<input type="checkbox"/>	I do not have any affected devices.

Name*
Signature*
Date*

4. Return acknowledgement to sender	
Email	VGLFSN@vygon.com
Customer Helpline	(+33) 01.39.92.63.81
Postal Address	VYGON 5 rue Adeline 95440 ECOUEN FRANCE
Web Portal	N/A
Fax	(+33) 01 39 92 64 82
Deadline for returning the customer reply form*	August 31st 2023

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