

FSN Ref: 2023-02(02)
Date: 22 Feb 2023

FSCA Ref: 2023-02(02)

Distributor Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	2023-02(02)
FSN Date*	22 Feb 2023
Product/ Device name*	See Appendix I Product table
Product Code(s)	See Appendix I Product table
Batch/Serial Number (s)	See Appendix I Product table

2. Distributor 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	vigilance@molnlycke.com
Distributor Helpline	+46 20-79 82 64
Postal Address	Mölnlycke Health Care, Box 130 80, SE-402 52 Gothenburg, Sweden
Web Portal	https://www.molnlycke.com/
Deadline for returning the Distributor reply form*	Within 10 business days

4. Distributors (Tick all that apply)										
<input type="checkbox"/>	*I confirm the receipt, the reading and understanding of the Field Safety Notice.									
<input type="checkbox"/>	I have checked my stock and quarantined affected trays									
<input type="checkbox"/>	I have identified customers that received or may have received this device									
<input type="checkbox"/>	I have attached customer list									
<input type="checkbox"/>	I have informed the identified customers of this FSN	Date of communication:								
<input type="checkbox"/>	I have received confirmation of reply from all identified customers									
<input type="checkbox"/>	I have quarantined affected devices ready for return – enter number of quarantined devices ready for return	<table border="1"> <tbody> <tr> <td>Qty:</td> <td>Product name and Lot Number:</td> </tr> <tr> <td>Qty:</td> <td>Product name and Lot Number:</td> </tr> <tr> <td>Qty:</td> <td>Product name and Lot Number:</td> </tr> <tr> <td>Qty:</td> <td>Product name and Lot Number:</td> </tr> </tbody> </table>	Qty:	Product name and Lot Number:	Qty:	Product name and Lot Number:	Qty:	Product name and Lot Number:	Qty:	Product name and Lot Number:
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		Qty:	Product name and Lot Number:
		Qty:	Product name and Lot Number:
		Qty:	Product name and Lot Number:
		N/A	Comments:
<input type="checkbox"/>	Neither I nor any of my customers has any affected devices in inventory		
Print Name*			
Signature*			
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.