

Date: April 9th, 2021

Control Number: 5866

URGENT FIELD SAFETY NOTICE

Dear Valued Customer,

Henry Schein has become aware of a quality issue from our Private-Label manufacturing partner, F.M S.p.A., related to their professional contract sterilization service provider, Steril Milano S.r.l.. Steril Milano S.r.l. conducted an internal investigation which revealed that the sterility of certain products they processed may have been compromised. As a result, Henry Schein has placed a hold on the impacted specific products lots listed on **Page 2-4** and is working with the appropriate regulatory authorities to address this issue. We request you take the immediate actions listed below.

Clinical impact:

The usage of non-sterile medical devices in a clinical environment may lead to an increased risk of infection which may cause severe damages. F.M. S.p.A. has not identified any notice of adverse event or serious damage to patients which might be linked to this field safety corrective action. If the product has already been used, no patient follow-up activity is needed.

Actions Required:

1. **CHECK** all locations to confirm if you have any units of the affected products/lot numbers in your possession by utilizing **Table A– Affected Product** on **Page 2 - 4** of this notification.
2. **SEGREGATE and QUARANTINE** all products/lots listed in **Table A– Affected Product** on **Page 2 - 4** of this notification.
3. **NOTIFY** any one whom you may have distributed or forwarded product affected by this notification.
4. **RETURN** Only the specified items/lot numbers listed on **Page 2 - 4** purchased from Henry Schein, Inc.
5. **COMPLETE** the enclosed acknowledgment form and return either by Fax: (833) -559-8609 or email HSResponseForm@henryschein.com. Please respond even if you are not affected by this notification.

If you have further questions, please contact recalls@henryschein.com. We recognize the criticality of this issue and we appreciate your understanding and patience.

Sincerely,

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TABLE A – Affected Product		
HSI Product Code	Product Description	Lot Number
900-8450	Maxima Vented I.V. Infusion Set with injection bulb	16E158
		16H084
		16I091
		16J119
		16K077
		16L080
		17B175
		17H117
		18C070
		18D069
900-8451	Maxima Vented I.V. Infusion Set without injection bulb, Luer Lock	16H081
		16H093
		16J123
		16K101
		17H118
		18B040
900-8452	Heidelberg extension line 75cm	18C066
		16E155
		16J075
		16K102
		17H114
		17K019
		17L038
		18A057
900-8453	Withdrawal cannula, luer lock (Taky-Spike-Plus)	18D072
		16J121
		16K078
		17B171
		17C073
		17D029
		17D119
		17E134
		17K017
		18C059
		18E019
		18L063
		18L082
19C111		
19D109		
19F070		

TABLE A – Affected Product

HSI Product Code	Product Description	Lot Number
900-8454	3-way stop cock, red	16E154
		16J117
		17B172
		17K018
900-8455	Bottle transfer cannula	16E153
		16H086
		17B169
		17F058
		17G056
		17K039
		18A056
		18L062
900-8456	Bottle transfer cannula	19E076
		16F069
		16G136
		16I055
900-8918	Heidelberg extension line 30cm	17C114
		16E020
		16E151
		16K100
		17H116
		17K021
		17L039
900-8919	Heidelberg extension line 100cm	18B039
		18C072
		17H113
		18B038
900-8920	Heidelberg extension line 140cm	18C071
		18D071
		16E156
		16E157
		16F067
		16F068
		16G133
		16J074
		16J102
17D147		
17H115		
17K020		

TABLE A – Affected Product		
HSI Product Code	Product Description	Lot Number
900-8920	Heidelberg extension line 140cm	18C009
		18C068
		18D070

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URGENT FIELD SAFETY NOTICE Henry Schein Response Form

Please read each question below and check the answer you have chosen		Yes	No
1.	Did you read and understand the information that has been provided and will follow the necessary instructions to ensure the proper actions will be taken?		
2.	Did you receive shipments of the impacted product? <i>(If no, please sign and return the form)</i>		
3.	Do you currently have any of the impacted product on hand?		
4.	If yes to question 3, the total number of products quarantined?		
5.	Did you further distribute or forward the impacted product?		
6.	If yes to question 5, the total number of impacted customers?		
7.	Did you notify the impacted customers of this URGENT Field Safety Notice <i>(If yes, please provide a copy of the notification)</i>		
8.	Did you notify your Authorized Representative? <i>If no, please explain why below.</i>	Date Notified:	

FORWARD RESPONSES ONLY TO:

Email: HSResponseForm@henryschein.com

- Or -

Fax: (833) -559-8609

Person/function responsible for the receipt and management of URGENT Field Safety Notices at your facility

Company Name and Country:	
Print Name and Title:	
Signature:	
Date:	