

Date: May 11<sup>th</sup>, 2021

Control Number: 5920

## URGENT FIELD SAFETY NOTICE

Dear Valued Customer,

Henry Schein has become aware of a quality issue from our Private-Label manufacturing partner Delta Med SpA, 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** and is working with the appropriate regulatory authorities to address this issue. We request you take the immediate actions listed below.

### Clinical impact:

The use of non-sterile medical devices may lead to an increased risk of patient infection. However, we would like to also underline that up to now Delta Med was never notified of adverse events or damages to patients potentially attributable to the problem covered by this problem.

### 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 3** of this notification.
2. **SEGREGATE and QUARANTINE** all products/lots listed in **Table A– Affected Product** on **Page 3** 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 3** purchased from Henry Schein can be returned; non-affected items will not be accepted.

**United States Customers** should return the product to: HSI's Returns Facility:  
41 Weaver Rd, Denver, PA 17517.

**EU Customers** should return the product to: Henry Schein Services GmbH  
Am Heisterbusch 9 D-19258 Gallin Germany

5. **COMPLETE** the enclosed acknowledgment form and return either by Fax: (833) -559-8609 or email [HSResponseForm@henryschein.com](mailto:HSResponseForm@henryschein.com). Please respond even if you are not affected by this notification.

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

Sincerely,

Thanushree Balakrishna  
Quality Assurance  
Henry Schein Inc.

**TABLE A – Affected Product**

HSI Product Code	Product Description	Lot Number
9009426	Winged needle infusion set - gray - 27G - 0,4mm - 20mm	All Lots
9009427	Winged needle infusion set - orange - 25G - 0,5mm -20mm	
9009428	Winged needle infusion set - blue - 23G - 0,6mm -20mm	
9009429	Winged needle infusion set - black - 22G - 0,7mm - 20mm	
9009430	Winged needle infusion set - green -21G - 0,8mm - 20mm	
9009431	Winged needle infusion set - beige - 19G - 1,1mm -20mm	
9009432	Winged needle infusion set - rose - 18G - 1,2mm - 20mm	
9009433	I.V. catheter with port and wings - G14 - orange - 2,0mm - 45mm	
9009434	I.V. catheter with port and wings - G16 - gray - 1,75mm - 45mm	
9009435	I.V. catheter with port and wings - G17 - 45mm - Ø1,5mm - white	
9009436	I.V. catheter with port and wings - G18 - 45mm - Ø1,3mm - green	
9009437	I.V. catheter with port and wings - G20 - 32mm - Ø1,0mm - rose	
9009438	I.V. catheter with port and wings - G22 - 25mm - Ø0,9mm - blue	
9009439	I.V. catheter with port and wings - G24 - 19 mm - Ø0,74mm - yellow	
9009915	I.V. catheter with port and wings - G26 - violet - 0.64mm - 19mm	
9009440	I.V catheter straight No Port without wings- G14 - 45mm - orange	
9009441	I.V catheter straight No Port without wings - G16 - 45mm - gray	
9009442	I.V catheter straight No Port without wings - G18 - 32mm - green	
9009443	I.V catheter straight No Port without wings - G18 - 45mm - green	
9009444	I.V catheter straight No Port without wings - G20 - 32 mm - rose	
9009445	I.V catheter straight No Port without wings - G22 - 25mm - blue	
9009446	I.V catheter straight No Port without wings - G24 - 19mm - yellow	
9009447	I.V catheter straight No Port with wings - G14 - 45 mm -orange	
9009448	I.V catheter straight No Port with wings - G16 - 45 mm - gray	
9009449	I.V catheter straight No Port with wings - G18 - 32mm - green	
9009450	I.V catheter straight No Port with wings - G18 - 45mm - green	
9009451	I.V catheter straight No Port with wings - G20 - 32 mm - rose	
9009452	I.V catheter straight No Port with wings - G22 - 25 mm - blue	
9009453	I.V catheter straight No Port with wings - G24 - 19 mm - yellow	
9009454	IV Catheter VET G14 x70mm	
9009455	Obturator G24 for dual entry catheter	
9009456	Obturator G22 for dual entry catheter	
9009457	Obturator G20 for dual entry catheter	
9009458	Obturator G18x45mm for dual entry catheter	
9009459	Obturator G17 for dual entry catheter	
9009460	Obturator G16 for dual entry catheter	
9009461	Obturator G14 for dual entry catheter	
9009462	Obturator G24 for single entry catheter	
9009463	Obturator G22 for single entry catheter	
9009464	Obturator G20 for single entry catheter	
9009468	Obturator G18x45mm for single entry catheter	
9009465	Obturator G18x32mm for single entry catheter	
9009466	Obturator G16 for single entry catheter	
9009467	Obturator G14 for single entry catheter	

## 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 <b>URGENT Field Safety Notice</b> <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](mailto: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:	