Henry Schein

Rev 1: September 2018
FSN Ref: **#6361** FSCA Ref: #6361

Date: September 28th 2022

Urgent Field Safety Notice (FSN)
Self Aspirating Syringe, Dual Action

For Attention of*: Dentists, customers of Henry Schein, who purchased the product

The small risk that has been identified is the possibility that a patient swallows the metal ring that could have come off from the cartridge holder from the self aspirating syringe

Contact details of local representative (name, e-mail, telephone, address etc.)*
Henry Schein Dental BV, Joop Houpst, QA/RA, Veluwezoom 16, 1327 AG Almere. Tel. 036 5358600. Joop.houpst@henryschein.nl

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Urgent Field Safety Notice (FSN)
Self-Aspirating Syringe, Dual Action

1. **Information on Affected Devices***	
1.	1. Device Type(s)*
	Self-aspirating injection syringe for 1.8 ml cartridges
1.	2. Commercial name(s)
	Henry Schein self-aspirating syringe dual action
1.	3. Unique Device Identifier(s) (UDI-DI)
	Complete when this becomes available.
1.	4. Primary clinical purpose of device(s)*
	Applying anesthetics to patients by dentists
1.	5. Device Model/Catalogue/part number(s)*
	900-6404
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	LOT 20210904
1.	8. Associated devices
	N/A

2 **Reason for Field Safety Corrective Action (FSCA)***	
2.	1. Description of the product problem*
	The metal ring that is attached to the cartridge holder of the syringe may be loose, allowing it to move freely, which is not intended. In exceptional cases, the ring could end up in the patient's mouth when injecting anaesthetic fluid.
2.	2. Hazard giving rise to the FSCA*
	The greatest hazard to the patient might be swallowing the metal ring. Up to today we received no notifications from dentists that this has occurred. There is no danger to the dentist using the syringe. We recall the instruments concerned to mitigate the risk to zero.
2.	3. Probability of problem arising
	Very low risk. No adverse events were reported
2.	4. Predicted risk to patient/users
	The bracket on the syringe is large enough that it would be both easily visible to the dentist that it was sliding off, and would be readily apparent to a patient that a large piece of metal was in their mouth, thus making it unlikely that this issue would lead to a hazardous event.
2.	5. Further information to help characterise the problem
	N/A
2.	6. Background on Issue
	Henry Schein has become aware of a quality issue from our Private-Label manufacturing partner. Investigation determined that this defect was caused by a manufacturing difference between the previous and current approved vendor. Our current vendor uses only an adhesive to attach the bracket to the barrel of the syringe, where-as the previous vendor used both adhesive and a mechanical stop. The mechanical stop for the bracket is not visible on the finished good therefor the precaution was not detected in the pre-

	production samples provided. Without the mechanical stop in place, the bracket may become dislodged from the barrel.
2.	7. Other information relevant to FSCA
	N/A

	3. Type of Action to mitigate the risk*	
3.	**1. Action To Be Taken by the User*** ☒ Identify Device ☒ Quarantine Device ☒ Return Device ☐ Destroy Device ☐ On-site device modification/inspection ☐ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☐ Other ☐ None Customer has been notified of a Field Safety Corrective Action for Control #6361	
3.	2. By when should the action be completed?	Specify where critical to patient/end user safety October 25th 2022
3.	3. Particular considerations for: N/A Is follow-up of patients or review of patients' previous results recommended? No There is patient follow up required when the metal ring has been swallowed. This has not occurred up to today	
3.	4. Is customer Reply Required * Deadline for return is	Yes October 25th 2022
3.	**5. Action Being Taken by the Manufacturer** ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☒ Other ☐ None Our current vendor will mirror the previous vendor's manufacturing process (i.e., adhesive, and mechanical stop) for this product code, which will subsequently be evaluated prior to acceptance of the modification.	
3	6. By when should the action be completed?	1/1/2023
3.	7. Is the FSN required to be communicated to the patient /lay user?	No
3	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet? Choose an item. N/A	

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	N/A
4.	**3.** For Updated FSN, key new information as follows:	
	N/A	
4.	4. Further advice or information already expected in follow-up FSN? *	No
4	5. If follow-up FSN expected, what is the further advice expected to relate to: N/A	
	N/A	
4	6. Anticipated timescale for follow-up FSN	N/A
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Henry Schein Inc.
	b. Address	135 Duryea road, Melville NY 11747
	c. Website address	www.henryschein.com
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * Yes	
4.	9. List of attachments/appendices:	FSN NL HSI #control 6361 Dutch, Risk Analysis, FSCA Report Form, IGJ Questionnaire
4.	10. Name/Signature	..
		..

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback..*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.