Rev 1: September 2018

FSN Ref: NC 661 FSCA Ref: NC 661

Date: 10-MAR-2023

Urgent Field Safety Notice
Collagen

For Attention of*: Identify either by name or role who needs to be aware of the hazard and/or take action. If this is multiple recipients then include full list.

Contact details of local representative (name, e-mail, telephone, address etc.)*

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Urgent Field Safety Notice (FSN)
Collagen
Risk addressed by FSN

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Collagen is used in platelet aggregation studies as part of a panel of agonists to assess platelet function in platelet rich citrated plasma samples. The equine Type I tendon collagen is provided in a 2 x 1mL liquid format at a concentration of 100ug/mL. The reagent is a uniform clear suspension after gentle mixing.
1.	2. Commercial name(s)
	Collagen
1.	3. Unique Device Identifier(s) (UDI-DI)
	Complete when this becomes available.
1.	4. Primary clinical purpose of device(s)*
	Collagen is used in platelet aggregation studies to assess platelet function in platelet rich citrated plasma samples. Platelet aggregation studies produce qualitative and quantitative results that aid in the diagnosis of platelet function disorders. The assays are intended for use in a general adult patient population with suspected platelet function disorders. These platelet agonists have been designed for use on semi-automated platelet aggregometers by a trained laboratory professional in a clinical laboratory. Each laboratory should establish a quality control program. Normal and abnormal controls should be tested prior to each batch of patient samples to ensure satisfactory instrument and operator performance. If controls do not perform as expected, patient results should be considered invalid.
1.	5. Device Model/Catalogue/part number(s)*
	5368
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	21797618
1.	8. Associated devices
	Collagen is designed for use on semi-automated light-transmission platelet aggregometers by a trained laboratory professional in a clinical laboratory. It is recommended for use as one of a panel of agonists used at doses that are able to discriminate between normal and abnormal platelet function. The agonists that should be included in clinical panels for LTA are adenine diphosphate (ADP), epinephrine, collagen (type I, tendon), arachidonic acid and ristocetin. Appropriate dilutions may also be made with 0.9% Saline.

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	This lot of Collagen has demonstrated poor aggregation response at very low doses of 1.25ug/mL
2.	2. Hazard giving rise to the FSCA*
	The risk to patient is a delay on patient result reporting as normal and abnormal controls will not meet the reference range criteria and therefore, an alternative lot should be used to mitigate the issue.
2.	3. Probability of problem arising
	Current investigations are such that the issue is limited to this lot however, please enact the above advice to ensure the quality of result on any lot as standard practice.
2.	4. Predicted risk to patient/users
	This issue is easily identifiable using control measures therefore, there should be no risk to the patient. Please ensure that adequate control measures are implemented.
	5. Further information to help characterise the problem

2.	N/A
2.	6. Background on Issue
	Two customer complaints were raised on the same day reporting poor aggregation responses.
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	
	Provide further details of the action(s) identified.	
3.	2. By when should the action be completed?	Identification, quarantine and destruction of device must be completed by 31 March 2023
3.	3. Particular considerations for: IVD Is follow-up of patients or review of patients' previous results recommended? No. When controls out of range, patient results should not be reported. Provide further details of patient-level follow-up if required or a justification why none is required	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	**5. Action Being Taken by the Manufacturer** ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None Provide further details of the action(s) identified.	
3	6. By when should the action be completed?	31 March 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. Choose an item.	

	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:	
	Eg patient management, device modifications etc	
4	6. Anticipated timescale for follow-up FSN	For provision of updated advice.
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Only necessary if not evident on letter-head.
	b. Address	Only necessary if not evident on letter-head.
	c. Website address	Only necessary if not evident on letter-head.
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	If extensive consider providing web-link instead.
4.	10. Name/Signature	Insert Name and Title here and signature below

	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.