Rev 1: September 2018

FSN Ref: MC333 FSN FSCA Ref: MC333 FSCA

Date: 27.01.2022

Urgent Field Safety Notice
Oracol+ S14 Saliva Collection Device

For Attention of*:

[redacted]

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

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Urgent Field Safety Notice (FSN)
Device Commercial Name
Risk addressed by FSN

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	The device affected by this FSN is the S14 Oracol+ saliva collection device. Photo is shown below to clearly show which device is affected. S14 Oracol+ 
1.	2. Commercial name(s)
	Oracol+ Saliva Collection Device
1.	3. Primary clinical purpose of device(s)*
	Intended for use in the collection of saliva samples for use in in vitro diagnostic tests
1.	4. Device Model/Catalogue/part number(s)*
	S14
1.	5. Affected serial or lot number range
	13183/1, 13315/1, 14068/1, 14479/1, 14728/1, 15069/1, 15793/1, 15794/1, 16014/1, 16081/1, 16047/1, 16073/1, 16094/1, 16099/1, 16097/1, 16119/1, 16153/1, 16145/1, 16156/1, 16163/1, 16192/1, 16193/1, 16196/1, 16368/1, 16203/1, 16723/1, 16753/1, 16749/1, 16818/1

2 Reason for Field Safety Corrective Action (FSCA)*

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2.	1. Description of the product problem*
	The S14 device has been demonstrated by in house and customer testing to leak sample during the centrifugation process that extracts sample from the swab. The leak is occurring at the join between the microtube and the main body where the sample is escaping through the screw fit connection. The devices are only leaking a small amount of saliva sample approx. 50µl when the average sample collected in the microtube is between 250 - 800µl.
2.	2. Hazard giving rise to the FSCA*
	The leakage of the saliva sample from the device could potentially lead to the infection of laboratory staff responsible for the processing of the device.
2.	3. Probability of problem arising
	The leakage is present in approximately 16% of the devices.
2.	4. Predicted risk to patient/users
	The likelihood of injury would be low due to the personal protective equipment in use when processing the samples. The laboratory staff would be taking precautions against laboratory acquired infections which would involve good personal hygiene where regular hand washing would be required and wouldn't be touching their face, mouth, eyes, or ears. Good laboratory practice would be in use where work surfaces and equipment would be regularly cleaned and cleaned immediately if coming into contact with biohazardous materials. Laboratory staff would be wearing personal protective equipment (PPE) like laboratory coats, gloves, and eye protection. All these protective factors would block the biohazardous pathogens from coming into contact with the laboratory staff.
2.	5. Further information to help characterise the problem
	None
2.	6. Background on Issue
	A user reported that the Oracol + device is leaking saliva sample during the centrifugation process. The leaking of the saliva could potentially lead to the infection of the users by pathogenic microbes. Such an infection may result in the need for medical treatment. However, no incidence of infection was recorded. The investigation found that the device is leaking sample through the screw fit between the main body and the 2ml microcentrifuge tube therefore establishing the device is responsible for the leakage rather that the user. The investigation consisted of centrifuging Oracol+ devices where the swab contained varying volumes of water to replicate the leak. The outcome of the investigation was that 2 out 12 samples leaked this test was repeated on three different batches with the same result.
2.	7. Other information relevant to FSCA
	None

3. Type of Action to mitigate the risk*

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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 **Please destroy any remaining stock of S14 Oracol+ devices that you have.**	
3.	2. By when should the action be completed?	25/02/2022
3.	3. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	No
3.	**4. Action Being Taken by the Manufacturer** ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None **The S14 device will be removed from sale. Until the design of the device is altered to prevent sample leakage from the device.**	
3	5. By when should the action be completed?	04/02/2022

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4. General Information*		
4.	1. FSN Type*	New
4.	2. Further advice or information already expected in follow-up FSN? *	No
4.	3. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	**Malvern Medical Developments**
	b. Address	**Unit 10, Northbrook Close, Worcester, WR3 8BP**
	c. Website address	**www.malmed.co.uk**
4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * Yes	
4.	5. List of attachments/appendices:	**A health hazard evaluation form.**
4.	6. Name/Signature	**William Gray** **Quality Assurance Manager** [redacted]

	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.