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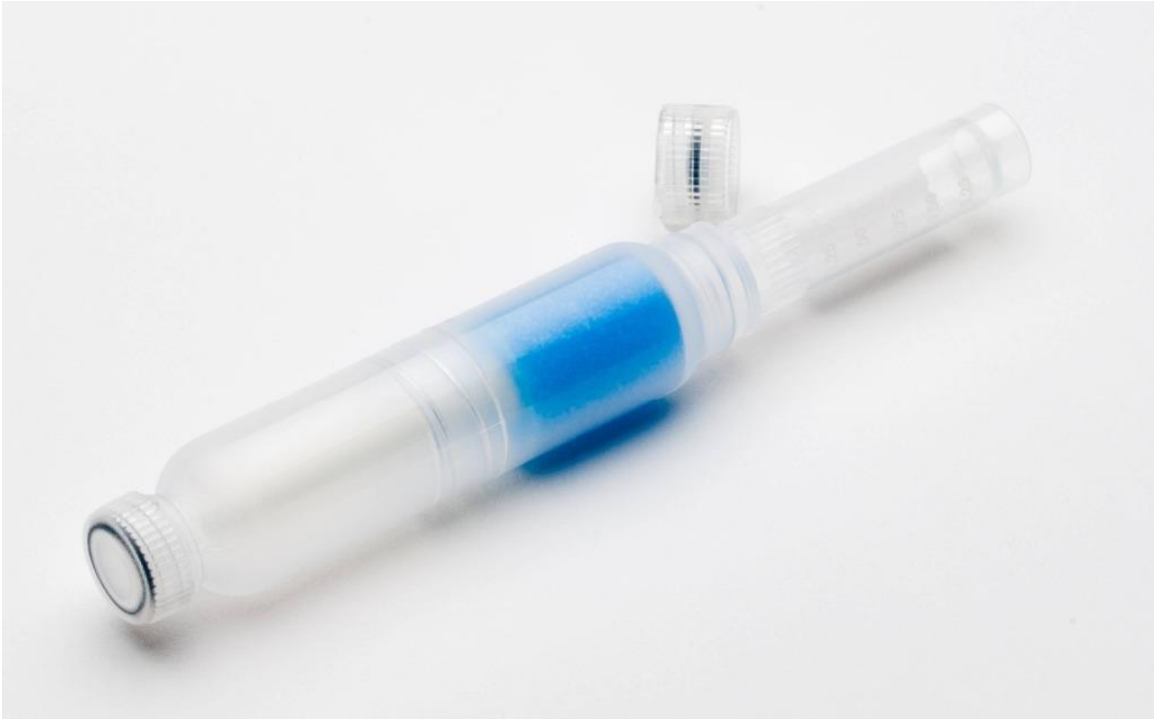
Urgent Field Safety Notice (FSN)
Device Commercial Name
Risk addressed by FSN

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. Unique Device Identifier(s) (UDI-DI)
	N/A
1.	4. Primary clinical purpose of device(s)*
	Intended for use in the collection of saliva samples for use in in vitro diagnostic tests
1.	5. Device Model/Catalogue/part number(s)*
	S14
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	16203/1, 16368/1, 16723/1, 16749/1, 16753/1, 16818/1
1.	8. Associated devices
	N/A

Rev 1: September 2018

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2	**Reason for Field Safety Corrective Action (FSCA)***
2.	1. Description of the product problem*
	The S14 Oracol+ devices are leaking saliva sample through the screw fit between the main body and the 2ml microtube.
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 potential for infection of laboratory staff is low risk for the following factors. The laboratory staff would be wearing PPE which would include gloves thus minimising the potential for contact between the hand and the leaked sample.
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 was performed on 07/01/2022 and 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*
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.

Rev 1: September 2018

FSN Ref: MC333 FSN FSCA Ref: MC333 FSCA

3.	2. By when should the action be completed?	25/02/2022
3.	3. Particular considerations for: Choose an item. Is follow-up of patients or review of patients' previous results recommended? Choose an item. 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)	No
3.	**5. 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.	
3	6. By when should the action be completed?	04/02/2022
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.	

Rev 1: September 2018

FSN Ref: MC333 FSN FSCA Ref: MC333 FSCA

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	Provide reference and date of previous FSN if relevant
4.	**3.** For Updated FSN, key new information as follows:	
	Summarise any key difference in devices affected and/or action to be taken.	
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	**Malvern Medical Developments**
	b. Address	**Unit 10, Northbrook Close, Worcester, WR3 8BP**
	c. Website address	**www.malmed.co.uk**
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * Yes	
4.	9. List of attachments/appendices:	[redacted]
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..*

Rev 1: September 2018

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