FSN Ref: NC2023/61

Date: 2023/09/26

Field Safety Notice
SteriFeed Colostrum Collector

This document contains important information for the continued safe and proper use of your product.
Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

Please retain this letter for your records.

For Attention of*:Chief Medical Officer, Heads of Children and Young person's services, Head of Procurement Services, MDSOs, Patient Safety Specialists, Heads of Midwifery and Neonatal Units, Clinical Lead Neonatal Units, Chief Midwife

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

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Field Safety Notice (FSN)
SteriFeed Colostrum Collector
Choking hazard if the collector cap is not removed before use

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	SteriFeed 11201 1ml Colostrum Collector 
1.	2. Commercial name(s)*
	1ml Colostrum Collector (Syringes for Single Use)
1.	3. Unique Device Identifier(s) (UDI-DI)
	15060287770661
1.	4. Primary clinical purpose of device(s)*
	For the collection of colostrum from Mothers
1.	5. Device Model/Catalogue/part number(s)*
	11201
1.	6. Software version
	NA
1.	7. Affected serial or lot number range
	Product Code 11201
1.	8. Associated devices
	NA

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	When the colostrum collector is used to feed babies the cap must be removed. If it is not removed it can be fired into the babies mouth. This can cause the baby to choke.
2.	2. Hazard giving rise to the FSCA*
	If the cap is not removed when used as a feeding device the baby could choke and die as a consequence.
2.	3. Probability of problem arising
	If the product is used as instructed on the SteriFeed IFU then the probability is nil, as the device should only be used to collect and store colostrum. Users should seek healthcare professional guidance on how to feed the harvested colostrum to the baby. However if the Colostrum Collector is used as feeding device then the risk of harm due to choking increases. We are aware of a total of 6 incidences where the cap was inadvertently left on and entered the babies mouth.
2.	4. Predicted risk to patient/users
	The risk to the patient is severe if used as a feeding device with the cap left on inadvertently.
2.	5. Further information to help characterise the problem
	There is only risk when the Colostrum Collector is used incorrectly as a Feeding device. The event only happens if the cap is not removed.
2.	6. Background on Issue
	Following the first reported incident in October 2020, we updated the Sterifeed IFU and the packaging with the instruction to remove the cap before use and to replace onto the collector when finished. In September 2023, we were made aware of a total of 6 incidents. One of these, had to have surgery for the cap to be removed. Whilst this type of event is rare, it can be of serious nature. We are now looking into changing the design of this device to make it inherently safer.
2.	7. Other information relevant to FSCA
	Users should seek healthcare professional guidance on how to feed the harvested colostrum to the baby

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 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?	User should always use the Sterifeed IFU
3.	3. Particular considerations for: Choose an item. Is follow-up of patients or review of patients' previous results recommended? No 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 FSNreceipt confirmation to be returned within 7 days of receiving form
3.	5. Action Being Taken by the Manufacturer* ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☒ IFU or labelling change ☒ Other ☐ None We are looking at a design change to improve the inherent safety of the product.	
3.	6. By when should the action be completed?	IFU to be updated by 3/10/23, Product change 6 months
3.	7. Is the FSN required to be communicated to the patient /lay user?	Yes
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?	
	Yes Not appended to this FSN	

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	Medicare Colgate Ltd
	b. Address	Unit 1/2 Post Cross Business Park, Cullompton, Devon EX15 2BB
	c. Website address	www.sterifeed.com
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	Etienne Colgate Managing Director
		

	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.