Safety Action Notice

Reference: SAN2305 **Issued:** 27 October 2023 **Review Date:** 27 October 2024

SteriFeed Colostrum Collection device and risk of choking due to infant airway occlusion: supplementary advice

Summary

This notice supplements the advice issued in MHRA Device Safety Information MDSI2310[1].

Action

1. Remove the cap before using the device.
   - Do not use for feeding of colostrum. The device is intended for collection and storage only.
   - Un-tethered caps should be placed in a suitable container to keep them out of the reach of children. Alternatively, dispose of caps immediately if they are no longer required.
   - Consider use of devices with tethered caps in preference to devices with untethered caps.

2. When instructing parents on using the device, remind them to always remove the cap from the tip of the syringe prior to use.
   - In addition, parents should be:
     - informed not to use the device for feeding,
     - informed of the choking hazard presented by un-tethered caps,
     - advised to place un-tethered caps in a suitable container to keep them out of the reach of children. Alternatively, dispose of caps immediately if they are no longer required.

3. Advise parents on how to feed the collected colostrum to the baby.

   SteriFeed does not provide guidance on suitable methods to transfer colostrum from the collection/storage device to a feeding device or what feeding devices are suitable.

   - The method and additional devices required to feed the harvested colostrum must be determined locally with a risk assessment built into the options appraisal process.
   - Consider the use of devices with tethered caps that can be used for collection, storage and feeding

4. Report adverse incidents to your local incident management system (often referred to as Ullyses or Datix) and to the Incident Reporting & Investigation Centre (IRIC).
   - Parents should be advised to report incidents to the team managing their baby's care.
   - Parents who wish to formally register concerns should be advised to use local feedback and learning mechanisms such as complaints procedures.
   - Parents who wish to raise concerns with a separate body can be advised to complain to the supplier and/or register an incident with MHRA as medical devices regulator using the Yellow Card scheme.
   - Healthcare professionals should report incidents locally and to IRIC, not Yellow Card.

Equipment details

Device Name:	SteriFeed Colostrum Collector
Product code:	11201
Manufactured by:	Medicare Colgate

Background

The SteriFeed colostrum collector is a medical device intended for collection and storage of colostrum only. It is not intended for feeding the harvested colostrum to babies and should therefore not be used for this purpose. Consequently, consideration should be given to a suitable device and safe method for feeding.

MHRA Device Safety Information MDSI2310[1] highlighted that SteriFeed colostrum collectors have been used incorrectly to feed colostrum to babies. In addition, there have been several incidents in which the cap became lodged in the back of the baby's mouth.

Using the device for feeding is considered off-label use and the manufacturer's liabilities for safety and performance of the device may be partly or wholly transferred to the organisation or person using the device off-label if they are involved in an adverse incident[2].

This notice supplements and expands on MDSI2310. The actions provided in MDSI2310 are reproduced in the action section of this notice and additional risk reduction measures are given as bullet points.

Suggested onward distribution

Health & Safety	Neonatal	Special Care Baby Units
Maternity	Risk Management	Supplies/Procurement

References

1. MHRA Medical Device Safety Information, MDSI2310, *SteriFeed Colostrum Collection device and risk of choking due to infant airway occlusion*, adopted and distributed in Scotland by IRIC on 10 Oct 2023
2. Safety Guidance, *Managing Medical Devices, para 3.5, modifying and changing use*, Medicines and Healthcare products Regulatory Agency (MHRA), adopted and distributed in Scotland by IRIC on 26 Feb 2021

Enquiries

Enquiries and adverse incident reports should be addressed to:

Incident Reporting & Investigation Centre (IRIC)
NHS National Services Scotland
Tel: 0131 275 7575 Email: nss.iric@nhs.scot

Accessibility: Please contact us using the above details if you are blind or have a sight impairment and would like to request this alert in a more suitable format.

IRIC remit: general information about adverse incidents, safety alerts and IRIC's role can be found in CEL 43 (2009), *Safety of Health, Social Care, Estates and Facilities Equipment: NHS Board and Local Authority Responsibilities,* issued 30 October 2009.

Report an incident: Information on how to report an adverse incident

NHS National Services Scotland is the common name for the Common Services Agency for the Scottish Health Service https://www.nss.nhs.scot/