



MHRA Device Safety Information

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

This is a copy of web content published by the Medicines & Healthcare products Regulatory Agency on 10 October 2023. The original webpage can be accessed <u>here</u>.

Summary

The SteriFeed colostrum collection device is intended to be used only to collect and store colostrum. It should not be used as an infant feeding device as the cap, if not removed, can easily get dislodged and become stuck in the baby's throat.

Action for healthcare professionals

- Remove the cap before using the device.
- When instructing parents on using the device, remind them to always remove the cap from the tip of the syringe prior to use.
- Advise parents on how to feed the collected colostrum to the baby.
- Report adverse incidents to your local incident management system (often referred to as Ullyses or Datix) and to the Incident Reporting & Investigation Centre (IRIC): <u>https://www.nss.nhs.scot/health-facilities/incidents-and-alerts/report-an-incident/</u>

Equipment details

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

Background

Colostrum can be expressed from about week 37 of pregnancy. It has become common practice in the NHS for women to be offered antenatal colostrum harvesting. Some local trusts supply kits for colostrum collection. The kits are also available to buy online.

The SteriFeed colostrum collection device is intended to be used only to collect and store colostrum. The device is not designed for feeding. However, we understand that it has also been used for feeding colostrum to babies.

We are aware of 6 incidents in which the push cap became lodged in the back of the baby's mouth when it was not removed from the top end of the syringe before being inserted into the baby's mouth for feeding. There were no fatalities, however one infant required emergency surgery.

Background (Continued)

The intended use of the device is not for directly feeding the colostrum to babies. The cap must always be removed before use. Healthcare professional advice should be sought for guidance on feeding the collected colostrum to the baby.

The manufacturer is undertaking a design change to minimise the choking hazard associated with the cap. Work is underway on this change and it will take approximately 6 months

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

Enquiries

Enquiries and adverse incident reports should be addressed to:

Incident Reporting & Investigation Centre (IRIC)

NHS National Services Scotland Tel: 0131 275 7575 Email: <u>nss.iric@nhs.scot</u>

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 <u>CEL 43 (2009)</u>, 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 <u>https://www.nss.nhs.scot/</u>