



Medicines & Healthcare products Regulatory Agency

SteriFeed Colostrum Collection device and risk of choking due to infant airway occlusion, DSI/2023/010

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.

Devices Details

Device Name: SteriFeed Colostrum Collector

Product code: 11201

Manufactured by: Medicare Colgate

Explanation of identified safety issue

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.

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.

Actions

Actions 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.
- There are specific reporting arrangements for healthcare professionals to follow in each of region. Healthcare professionals should report incidents:
 - in England and Wales to the [Yellow Card scheme](#) or via the Yellow Card app
 - in Scotland to [Incident Reporting & Investigation Centre \(IRIC\)](#) and their local incident recording system
 - in Northern Ireland to the [Northern Ireland Adverse Incident Centre](#) and their local incident recording system

Actions for users

- Remove the cap from the top end of the syringe before using the device.
- Seek advice from a healthcare professional for guidance on how to feed the harvested colostrum to your baby.

Actions for manufacturers

- Device design change to minimise the risk of choking.

Stakeholder engagement

NHS England
NHS Scotland
NHS Northern Ireland
NHS Wales
UK drugs in lactation

