Medicare Colgate Ltd
Unit 1/2 Post Cross Business Park, Cullompton, Devon, EX15 2BB
Tel: 01884 266666

URGENT FIELD SAFETY NOTICE

(Field Safety Corrective Action)

FSCA reference number	NC2026/62
Date of this notice	13/8/26
Product name	Vaginal Speculum
Model(s) / catalogue number(s)	KJ-V01-XS, KJ-V01-S, KJ-V01-M, KJ-V01-ML, KJ-V01-L
Affected batch / lot / serial numbers	241025 & 260405
UDI (if applicable)	NA
Type of action	Recall

1. Description of the problem

While cleaning the unused equipment from the previous shift, the Healthcare Professional noted that the product had a foreign object in the sterile sealed package. Medicare Colgate have carried out a further investigation on products with these Lot numbers and we found further products with foreign objects.

2. Risk to health

A foreign object was identified within the sterile sealed packaging of the affected product. The root cause and route of contamination are currently under investigation.

If a product containing a foreign object were used on a patient, potential risks include:

- Introduction of a foreign body into the sterile field or patient tissue

3. Action to be taken by the recipient

- Identify all affected units against the lot numbers above;
- Please Quarantine Product and stop using , & please return goods
- Complete and return the acknowledgement form below within 7 days of receiving the notice;

4. Patient / user follow-up required

Not required

5. Transmission of this notice

Please forward this notice to any organisation to which you have supplied this product, and to any relevant department within your own organisation. Please retain a copy of this notice with your quality records for the retention period set out in the acknowledgement form.

If you have further distributed this product, please confirm to us that you have cascaded this notice, using the acknowledgement form below.

6. Regulatory notification

The Medicines and Healthcare products Regulatory Agency (MHRA) has been informed of this Field Safety Corrective Action.

7. Contact for further information

Name: Sally Roberts

Role: Sales Manager

Tel: 01884 266666

Email: sally@Sterifeed.com

Name: Daniel Hall

Role: QA Manager

Tel: 01884 266666

Email: daniel@sterifeed.com

FSN ACKNOWLEDGEMENT AND RESPONSE FORM

Please complete and return this form to the contact named in Section 7 by [date], even if you hold no affected stock.

FSCA reference number	*[As shown above]*
Your organisation name	
Your account / customer reference	
Completed by (name and role)	
Date completed	
Do you hold, or have you supplied, any affected product? (Y/N)	
If yes, quantity currently held	
If yes, quantity already used/supplied to others before this notice	
Have you completed the action required in Section 3? (Y/N, details)	
Have you cascaded this notice to any organisation you supplied? (Y/N, to whom)	
Any adverse events or health effects to report in connection with this issue?	
Signature	

Please return this form to: daniel@sterifeed.com