



Medline Assembly France SAS – 5 Rue Charles Lindbergh, 44110 Chateaubriant France

Chateaubriant 15th October 2021

URGENT: FIELD SAFETY NOTICE Medical Device Safety Advisory Notice

ATTENTION: Pharmacist/Risk Manager responsible for medical device vigilance and the Biomedical Engineering Department

SECURITY INFORMATION of Medline Surgical Gowns

Medline reference: FSN 21-13
MoH reference:
Product description: Medline Surgical Gowns
Action type: Safety advisory notice only
Product codes:

Surgical Gown Reference	batch
9506CEA	21BAJG001
9507CEA	21BAJG001
E3506CEA	21BAJG001
E3516CEA	21BAJG001
E3545CEA	21BAJG001
S3516CEC	21BAJG001
9508CEA	21BAJG001
9512CEA	21BAJG001
9508CEA	21CAJG001
9509CEA	21CAJG001
9516CEA	21CAJG001
E3545CEA	21CAJG001
S3545CEC	21CAJG001

Dear Customer,

This letter is to advise you that Medline issued a field safety notice related to Medline's Surgical Gowns.

Although no serious injuries have occurred, Medline received some user reports relating to two quality related defects affecting eleven references of Medline Surgical Gowns produced under lot numbers 21BAJG001 and 21CAJG001.

Figures 1 and 2 below show pictures of the two defects. Figure 1 shows an example of a sewing defect of the cuff and seam, and Figure 2 shows a potential pouch sealing defect. Therefore, in order to assure continued supply, please visually inspect the packaging for open seals and inspect the sewing of the sleeves and cuffs

Medline Assembly France SAS Regulatory Affairs

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Commercial registry number: 799.255.393 RCS Nantes • VAT #: FR08 799 255 393





before use. The defects will be visible to the unaided eye. In the event that a defect is observed, discard the product before use and contact your account representative.



Figure 1: Sewing defect on cuff and seam



Figure 2: Open seal defect

We appreciate your support and we apologize for the inconvenience. Medline is working as quickly as possible to correct the issues.

The relevant competent authorities have been informed of this safety notice. Please proceed to the following page to acknowledge receipt of this notice.

Please contact us at the email provided below if you have any questions.

Yours sincerely,
xxx

This urgent safety information is only addressed to facilities that have received the products concerned.





**Please fax or email the acknowledgement receipt to: +49 2821 7510 7822 or
gmb-eu-ra-kleve@medline.com**

Reference: FSN-21/13

Please complete the acknowledgement form and send it back by either fax or email as soon as possible, but no later than 30th November 2021.

Table 1: Medline Surgical Gowns concerned by this notification are listed in the below table.

Surgical Gown Reference	batch
9506CEA	21BAJG001
9507CEA	21BAJG001
E3506CEA	21BAJG001
E3516CEA	21BAJG001
E3545CEA	21BAJG001
S3516CEC	21BAJG001
9508CEA	21BAJG001
9512CEA	21BAJG001
9508CEA	21CAJG001
9509CEA	21CAJG001
9516CEA	21CAJG001
E3545CEA	21CAJG001
S3545CEC	21CAJG001

I have read and I understand the instructions provided. I acknowledge receipt of the FSN-21/13 by signing this document and returning it to Medline.

I also agree to further distribute and communicate this important information within my facility as required. If you distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them.

If you are a dealer, wholesaler, distributor/reseller, that distributed any affected products to other facilities: per Medical Device Regulation 2017/745, Article 14, part 4, please distribute this notification to your customers and provide confirmation to Medline that your customers have been notified by completing the information below and returning it to Medline at the address listed above:

Date: _____
Account Number: _____
Name: _____
Position: _____
Facility or Business Entity: _____
Address: _____
City: _____
Telephone: _____
Email address: _____
Signature: _____

