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Advisory Notice

For Medline International Sterile Absorbent Cotton O.R Towels that are included in ArcRoyal procedure packs
FSN19H002

Urgent Field Safety Notice

28 August 2019

Dear Valued Customer,

ArcRoyal has been informed of an urgent safety notification concerning Medline sterile absorbent OR Towels. Its objective is to draw users' attention on the recommendations of use. ArcRoyal place the towels into CPT's (custom procedure trays) that may be in your inventory.

Details:

Recently, Medline has observed an increase of linting of these towels and if used incorrectly the can release cotton particles in the incision site. Medline is working closely with its supplier to reduce linting of the cotton towels. There is no standard applicable to particulate release for woven absorbent towels. ArcRoyal have received zero Customer Complaints on the Medline International OR Towel nor have we have had any internal issues reported by our QA or Production Departments.

Recommendations for Use:

Medline sterile cotton O.R towels are Class I Rule 4 non-invasive towels used to absorb fluids, including blood and body fluids at the surgical incision site or for drying hands. For fluids absorption inside the abdomen, a laparotomy sponge is an appropriate medical device as classified: IIa Rule 7 Surgically invasive short-term use.

Details of affected devices

ArcRoyal supply customers with the following affected OR Towel (see table below);

Medline Code	ArcRoyal Code	Description
28700002CEA	10-007081	Towel OR 43x66cm Cotton 2/PK

Advice

If you are using Medline OR towels as an invasive absorbent pad, then it is recommended to use a more appropriate device such as a Lap Sponge. If the products are used according to the recommendations for use no further action is required.

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Transmission of this Advisory

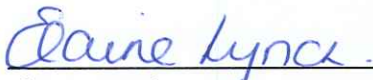
We are committed to patient safety and would appreciate your immediate attention and cooperation to this matter. Please immediately forward this information to all departments within your organisation.

We sincerely apologize for any inconvenience that this may cause and thank you for your business and continued support. If you have any questions or concerns, please do not hesitate to contact your ArcRoyal representative.

Yours Sincerely,



Fiona Lynch
Quality Manager, ArcRoyal



Elaine Lynch
Quality Compliance Specialist, ArcRoyal