
Urgent Field Safety Notice

Cocune wash gloves

FSCA: Vk-20190624_17 (24-06-2019)

FSN: DEV2019-1 (06-06-2019)

Date: 25-06-2019

Details on affected devices:

This FSN concerns the product items CCN 21-1001, CCN 21-1002, CCN 21-1005, CCN 21-1004 of Cocune washing gloves produced in the following lots

00146	00156	02975	02988	03028
03102	03192	03188	03171	03198
03212	03227	03255	00328	00171

Lot numbers 03102, 03188 and 03192 are known to have been sold in Switzerland.

Description of the problem:

Within these specific lots mentioned, the existence of the Burkholderia Cepacia had been discovered. The levels of concentration found vary between all lots, but all exceed the acceptable limits.

Burkholderia Cepacia (BC) is an aerobic gram-negative bacillus found in various aquatic environments. BC is an organism of low virulence and is a frequent colonizer of fluids used in the hospital (eg, irrigation solutions, intravenous fluids). BC rarely causes infection in healthy hosts, but can lead to infection in weak hosts. Furthermore, the stated shelf life on the packages cannot be guaranteed anymore.

The most likely cause of this is the preservative used, which has only been used for the lot numbers mentioned in this FSN. This preservative has proved not to be of sufficient quality in order to limit the growth of BC.

Advise on action to be taken by the user:

We urge you, out of precaution, to stop using the LOT numbers listed in this FSN and exchange them for products from a different production batch. This exchange can be arranged through your regular contact person of Cocune.

Transmission of FSN

We emphasize the importance to inform all of the end users you have sold this product to and to instruct them on the actions they should take as stated in this FSN.

Corrective measures have since been taken to prevent a recurrence. If you have questions or comments about this FSN please contact us.

Yours faithfully,



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