



Urgent Field Safety Notice

Commercial Name of the affected product: Surgapad

FSCA-Identifier 20th November 2015

Type of action: Device Change

Date: 03rd December 2015

Attention:

Details of affected devices

All Sterile Surgapad – Code number P52513 / P52514 / P52515

Description of the problem.

It was discovered after testing that a number of Sterile Surgapad contained a very low level of contamination, ≤ 3 cfu per 100ml of test fluid. No reports of harm to patients user or environment have been received to date but as a preventive measure, users are advised to quarantine the Surgapad. GS Medical are currently assessing the potential health hazards associated with this issue.

Advice on action to be taken by user:

All unused Suragpad, Part number P52513 / P52514 and P52515 will be removed from your facility and replaced with an alternative product. Disposal will be arranged by manufacturer. No further action is required.

Transmission of this Field Safety Notice:

Please transfer this notice to any other areas within your organisation where the potentially affected devices may have been transferred

Contact Reference person:

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The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

Signed:


