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## **Urgent Field Safety Notice**

**Commercial name of the affected product, Absorbent Pad**

**FSCA-identifier 2 November 2015**

**Type of action Device Exchange**

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Date: 6 November 2015

Attention: Endoscope reprocessing department

**Details on affected devices:**

All absorbent pads part number 100605

**Description of the problem:**

Routine testing of a small number of absorbent pads has identified a very low level of bacterial contamination by Bacillus species ( $\leq 20$ cfu/100ml). 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 absorbent pads. GS Medical are currently assessing the potential health hazards associated with this issue.

**Advice on action to be taken by the user:**

All unused pads, part number 100605 will be removed from your facility and replaced with an alternative product. Disposal will be arranged by the manufacturer.  
No further action is required.

**Transmission of this Field Safety Notice: (if appropriate)**

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

**Contact reference person:**

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

Signature