
Urgent Field Safety Notice

Affected Devices: Olympus KV-5 Suction Pump – Patient Connecting Tube MAJ-103
FSCA Identifier : 15 February 2016
Type of Action: Correction - Update to the Instructions for Use regarding the use of the Olympus KV-5 Suction Pump Patient Connecting Tube MAJ-103

Date: 15 February 2016

Attention: Health Care Facility Practitioners

Details on affected devices:
The Olympus KV-5 suction pump is intended for aspiration use during flexible endoscopy and general medical or surgical suction. It is intended for use within a healthcare facility under the direction of a trained physician. The MAJ-103 Patient Connecting Tube connects the endoscope to the suction jar via the jar lid connection ports. The suction jar is connected to the KV-5 suction pump via a microbial filter, Filter Connecting Tube and suction jar lid connection ports.

Description of the problem:
This FSN has been issued to inform end users of an update to the KV-5 Instructions for Use regarding the use of disposable item MAJ-103 Patient connecting tube. The text in the Instructions for Use has changed from: 'Single patient list unless local or National Hospital Policy dictates otherwise' to 'single patient use'. There have been no adverse events reported prior to the update to the Instructions for Use relating to the MAJ-103. The update to the KV-5 Instructions for Use consolidates the text in line with current National Hospital Policy which requires patient connecting tubing to be single patient use.

Advise on action to be taken by the user:

- *identify and quarantine the Instructions for Use for KV-5 Suction devices,*
- *return confirmation form (Attachment 1) to the manufacturer identifying the number of KV-5 Instructions for Use required*
- *On receipt of updated Instructions for Use, destroy quarantined Instructions for use*
- *This action should be initiated immediately.*

Transmission of this Field Safety Notice:
This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Contact reference person:
Alison Prior
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Stock Road
Southend on Sea
Essex
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United Kingdom

Email:alison.prior@olympus.co.uk

The undersign confirms that this notice has been notified the appropriate Regulatory Agency
Signature Alison Prior.

Enclosures: Attachment 1 – FSN Confirmation Form