KARL STORZ Endoscopy Singapore Sales Pte Ltd

URGENT PRODUCT NOTIFICATION FOR KARL STORZ LAPAROSCOPIC POWER MORCELLATORS

HSA Alert Ref No 2015/0618

11 May 2015

Affected Product:	KARL STORZ Laparoscopic Power Morcellators
Batch/Lot No:	All Serial/Lot Numbers
Recall for Product Correction (Reason):	Updates in KARL STORZ Instruction Manuals

Dear Doctor/Healthcare Professional,

This is to inform you that KARL STORZ has followed the FDA's "Immediately in Effect Guidance Document: Product Labeling for Laparoscopic Power Morcellators" and has implemented a labeling change for our morcellators.

We are providing you with a PDF copy of the newly revised instruction manual(s) for KARL STORZ Laparoscopic Power Morcellators along with this letter. Please discard any old instruction manual(s) you have and start using the new one instead.

Please make sure any users in your facility planning on using laparoscopic power morcellators, are aware of the new contraindication, warning, and black box warning below that have been implemented into the newly revised instruction manual(s).

CONTRAINDICATION: Laparoscopic power morcellators are contraindicated in gynecologic surgery in which the tissue to be morcellated is known or suspected to contain malignancy.

CONTRAINDICATION: Laparoscopic power morcellators are contraindicated for removal of uterine tissue containing suspected fibroids in patients who are:
• peri- or post-menopausal, or
• candidates for en bloc tissue removal, for example, through the vagina or via a mini-laparotomy incision.

WARNING: Uterine tissue may contain unsuspected cancer. The use of laparoscopic power morcellators during fibroid surgery may spread cancer, and decrease the long-term survival of patients. This information should be shared with patients when considering surgery with the use of these devices.

WARNING: The safety and effectiveness of using tissue extraction bags to capture tissue released during laparoscopic power morcellation procedures have not been established.

For more information on the updated Safety Communication about the laparoscopic power morcellator that the FDA issued on November 24, 2014, please refer to the FDA website, http://www.fda.gov/medicaldevices/safety/alertsandnotices/ucm424443.htm. It is important that you share this communication with your colleagues.

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200819602C

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Action:

a) Read this Urgent Product Notification.

b) Distribute the PDF copy of the newly revised KARL STORZ Instruction Manual to users within your facility and disregard previous KARL STORZ Instruction Manual(s) for this product. Product does not require to be returned to the company.

c) Return the completed 'Acknowledgement Slip'.

This Urgent Product Notification has been taken following consultation with the Health Sciences Authority (HSA).

If you need further information, please contact:

Sandip Mahapatra
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DID: (+65) 6922 9170
Mobile: (+65) 9727 3557

Yours Sincerely,

[redacted]

Sandip Mahapatra
RA/QA Manager
KARL STORZ Endoscopy Singapore Sales Pte. Ltd.

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ACKNOWLEDGMENT SLIP FOR KARL STORZ LAPAROSCOPIC POWER MORCELLATORS

Return To:
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Please complete and return this return slip to your KARL STORZ Singapore sales representative or Email/Fax to the address above.

(Place an X in the box below)

☐ I confirm that I have received the Urgent Product Notification letter for the KARL STORZ Laparoscopic Power Morcellators.

☐ I confirm that I have received and distributed the newly revised KARL STORZ Instruction Manual(s) for KARL STORZ Laparoscopic Power Morcellators to users within the facility and disregarded the previous KARL STORZ Instruction Manual(s) for this product.

Your Contact Information

Name:	
Name of Facility:	
Stamp of Facility:	
Signature:	
Date:	