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12 February 2015

Chief Executive Officer
<<Customer>>
<<Street Name>>
<<Suburb>> <<State>> <<Post Code>>

Attention: Director of Nursing

Urgent Recall for Product Correction

962000PK – PlasmaSORD

TGA Reference Number: RC-2015-RN-00112-1
ARTG Number: 141561

Dear Health Care Practitioner,

Olympus Australia Pty Ltd (Olympus) following receipt of information from the manufacturer, Olympus Surgical Technologies America (Gyrus ACMI Inc.) and in consultation with the Therapeutic Goods Administration (TGA) is issuing a Recall for Product Correction for the PlasmaSORD item code 962000PK. The nature of this product correction is to replace the Instruction for Use (IFU). Any product you may have is not required to be returned Olympus.

Based on a concern raised in the US relating to the potential risk of transcoelomic spread of undiagnosed cancerous tissue with the use of morcellators in the treatment of uterine fibroids, the manufacturer has issued an updated IFU which has been included in this communication. The following contraindications and warning have been added:

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

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.*

OLYMPUS AUSTRALIA PTY LTD
3 Acacia Place, Notting Hill. VIC 3168
PO Box 985 Mt Waverley. VIC 3149
Phone: 1300 132 992 **Fax**: 03 9543 1350
Web: www.olympusaustralia.com.au
ABN 90 078 493 295

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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.**

A copy of this IFU should also be maintained with any PlasmaSORD devices you may have in inventory.

If any of the PlasmaSORD devices have been transferred from your facility to another, please immediately forward this recall notice accordingly. Additionally, it would be appreciated if you would telephone Olympus so that we can make contact with that facility directly.

Please complete the relevant section(s) of the attached reply form, **Appendix A** and fax to 03 9562 6438 or reply via email to QARA@Olympus.com.au.

Olympus apologises for any inconvenience this may cause and appreciates your prompt co-operation in addressing this situation.

If you have any questions regarding this product correction, please contact myself on (03) 9265 5435 or by email at Danica.Dawidowicz@Olympus.com.au.

Yours Sincerely,

[redacted]

Danica Dawidowicz
Regulatory Affairs Officer
Olympus Australia Pty Ltd

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Appendix A – PlasmaSORD Reply Form

To:	Olympus Australia Pty Ltd
Attention:	QA/RA Department
Email *(prefer method)***:**	QARA@olympus.com.au
Facsimile:	(03) 9562 6438
Postal:	PO Box 985, Mount Waverley, VIC 3169 Australia
Subject:	PlasmaSORD, Recall for Product Correction
TGA Reference Number:	RC-2015-RN-00112-1

From: *(name of institution)*	
Contact Person: *(please print)*	
Telephone:	
Email:	

- We acknowledge receipt of this Recall for Product Correction from Olympus **YES** ☐

  (please tick)

- Recall for Product Correction "Letter" has been sent to all relevant healthcare facility(ies) **YES** ☐

  (please tick)

- We DO NOT have stock which is subject to this recall ☐

  (please tick)

Signature: _____

Date: _____

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