OLYMPUS®

July 27, 2016

IMPORTANT DEVICE SAFETY INFORMATION:
UPDATED LABELING FOR THE OLYMPUS
PKS PLASMASORD

Attention: Surgical Risk Management Department

Products: GYRUS ACMI PKS PlasmaSORD
Manufactured prior to January 2015 (Expiration date prior to January 2018)
Ref 962000PK

Dear Health Care Professional:

Olympus America Inc. ("OAI") is writing to bring to your attention that the labeling of the GYRUS ACMI PKS PlasmaSORD was updated in January 2015 to add **Contraindications and a Boxed Warning**. This safety information was made available to customers through communications by the OAI sales force and the OlympusConnect Customer Portal website in January 2015. OAI is writing to reinforce this updated safety information through this customer notification letter at the request of the U.S. Food and Drug Administration ("FDA").

Products Affected:
PKS PlasmaSORD products that were manufactured prior to January 2015 (which have an expiration date prior to January 2018) were shipped with the prior labeling. Enclosed with this letter is the updated labeling containing the Contraindications and Warning that were added in 2015. Please make this labeling available in connection with the affected products bearing an expiration date prior to January 2018. Products shipped since January 2015 have been distributed with the updated labeling.

Updated Labeling:
On November 25, 2014, FDA issued an immediately effective guidance document with recommended labeling statements for laparoscopic power morcellators. In response to FDA's labeling recommendations, Olympus made revisions to the Instructions for Use (IFU) that accompany the PKS PlasmaSORD (catalog number 962000PK). These revisions incorporate the two contraindications and the Boxed Warning recommended by FDA.

The following two contraindications were added to the Contraindications section of the IFU:

Laparoscopic power morcellators are contraindicated in gynecological 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.

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The following Boxed Warning was added to the Warnings section of the IFU:

***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.**

Actions Requested:
Our distribution records indicate that you may have received a PKS PlasmaSORD morcellator manufactured prior to January 2015. Although all PKS PlasmaSORD production after January 2015 incorporated the revised IFU, to ensure all consignees of PKS PlasmaSORD devices were made aware of these revisions, a copy of the revised IFU accompanies this letter.

1. Please check your inventory for any PKS PlasmaSORD devices manufactured prior to January 2015, which will bear an expiration date before January 2018.

2. Please assure that the revised labeling accompanies any PKS PlasmaSORD devices manufactured prior to January 2015, and that relevant personnel are made aware of the two Contraindications and Boxed Warning.

3. Upon receipt of this letter and the revised IFU, Olympus requires that the enclosed Reply Form be completed and returned to Olympus at FAX (484) 896-7128.

Olympus regrets any inconvenience from this action and fully appreciates your prompt cooperation. Please do not hesitate to contact me directly at 484-896-5688 or at laura.storms@olympus.com for any questions concerning this matter.

Sincerely,

Laura Storms

Laura Storms
V.P., Regulatory Affairs & Quality Assurance