This English version is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail. The PMDA shall not be responsible for any consequence resulting from use of this English version.

July 25, 2016

Administrative Notice

To: Members (of the Associations/Committees listed in Appendix 1)

Medical Device Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau,
Ministry of Health, Labour and Welfare

Safety Division, Pharmaceutical Safety and Environmental Health Bureau,
Ministry of Health, Labour and Welfare

Precautions in the Package Insert of Power Morcellators

The U.S. Food and Drug Administration (FDA) has reported that “when used for hysterectomy or myomectomy in women with uterine fibroids, power morcellators pose a risk of spreading unsuspected cancerous tissue notably uterine sarcomas, beyond the uterus” in regards to the use of power morcellators (active cutting instruments used by laparoscopically inserting into the body cavity to remove tissues).

Given the above, please note that the “Precautions” in the package insert of power morcellators newly approved or certified in the future will be handled as follows in order to ensure proper use after marketing.

Furthermore, we inform you that similar administrative notices have been sent to Association of Registered Certification Bodies under PMDAct (ARCB) and to Pharmaceuticals and Medical Devices Agency.

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1. In the “Contraindications” section of the package insert for power morcellators, the following text should be added:

   The product should not be used if the patient has or is suspected to have malignant tumors. [There is a risk of cancer cells metastasizing due to dispersion of tissue fragments.]

2. In the “Important Precautions” section of the Precautions in the package insert for power morcellators, the following text should be added:

   Uterine tissue may contain unsuspected cancer. The use of the product may spread the cancer, and decrease the long-term survival of patients. This information should be shared with patients, and informed consent should be obtained before the use of the product.

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(Appendix 1)

The Japan Federation of Medical Devices Associations
American Medical Devices and Diagnostics Manufacturers' Association
Medical Equipment Committee of the European Business Council in Japan