August 8, 2018

Notification

PSEHB/MDED Notification No. 0808-1
PSEHB/PSD Notification No. 0808-2

To: Commissioners of Prefectural Health Departments (Bureaus)

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

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

Revision of Precautions to the Package Inserts of
Ultrasonic Surgical Aspirator Devices

In our previously issued notice, Precautions in the Package Insert of Power Morcellators (Administrative Notice by the Medical Device Evaluation Division and Safety Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare, dated July 25, 2016), the decision was notified to state, in the package inserts of power morcellators products, that power morcellators should not be used if the patient has or is suspected to have malignant tumors, as use of these devices poses a risk of spreading uterine sarcomas beyond the uterus when used in women with uterine fibroids.

The U.S. Food and Drug Administration (FDA) recently reported that ultrasonic surgical aspirator devices also pose a risk of spreading unsuspected uterine sarcomas beyond the uterus when used in women with uterine fibroids. Based on this report, revision of precautions of the package inserts of ultrasonic surgical aspirator devices and surgical devices equipped with ultrasonic surgical aspirator functionality is believed to be necessary. Commissioners of prefectural health departments (bureaus) are requested to circulate this notification among the Marketing Authorization Holders of these products or other related business entities under their oversight in order to ensure the swiftest possible revision of the precautions as described below and their dissemination of appropriate information to medical institutions.

1. The following language should be added to the Contraindications section of the package inserts for ultrasonic surgical aspirator devices and surgical devices equipped with ultrasonic surgical aspirator functionality:

   This product should not be used to emulsify or fragment uterine fibroids for which the possibility of causing malignant changes cannot be ruled out. [There is a risk of cancer cells metastasizing due to dispersion of tissue fragments.]

2. The package inserts for medical devices as revised according to 1 above shall be uploaded to the website of the Pharmaceuticals and Medical Devices Agency (PMDA) as information concerning package inserts for medical devices.

3. A report on progress with respect to the implementation of the measures required in accordance with 1 and 2 above as well as in the dissemination of information concerning revised package insert content to medical institutions, etc. must be submitted to the Medical Device Safety Division, Office of Safety 1, PMDA by November 1, 2018.