Published by
Ministry of Health, Labour and Welfare

Translated by
Pharmaceuticals and Medical Devices Agency

HPB/GAD/MSPO Notification No. 1224-1
PSEHB/MDED Notification No. 1224-13
PSEHB/PSD Notification No. 1224-3
December 24, 2021

To Commissioners of Prefectural Health Departments (Bureaus):

Director, Medical Safety Promotion Office
General Affairs Division, Health Policy Bureau
Ministry of Health, Labour and Welfare (official seal omitted)

Director, Medical Device Evaluation Division,
Pharmaceutical Safety and Environmental Health Bureau,
Ministry of Health, Labour and Welfare (official seal omitted)

Director, Pharmaceutical Safety Division,
Pharmaceutical Safety and Environmental Health Bureau,
Ministry of Health, Labour and Welfare (official seal omitted)

Revision of PRECAUTIONS in the Package Insert of Power Morcellators

In “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, dated July 25, 2016), it was decided to add the following text in the package inserts: “The product should not be used if the patient has or is suspected to have malignant tumors.” “It is possible that unsuspected malignant lesion exists and the use of the product may worsen the prognosis. The information should be shared with patients and informed consent should be obtained before the use of product.”

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Recently, the U.S. Food and Drug Administration (FDA) officially announced the guidance in November 2020 as follows: Power morcellators are contraindicated for use in patients who are 50 years of age or older or postmenopausal, and a tissue collection bag should always be used when using power morcellators in other cases.

After deliberation among the Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare (MHLW), the Pharmaceuticals and Medical Devices Agency (PMDA), and the Japan Society of Gynecologic and Obstetric Endoscopy and Minimally Invasive Therapy, the PRRECAUTIONS section in the electronic package insert was decided to be revised based on the actual status use, etc. in Japan in order to call further attention to the thorough implementation of informed consent including an explanation the handling in the US. ,

Therefore, please be informed that the instructions to revise the PRECAUTIONS section are provided to market authorization holders as shown in attachment 1.

In addition, the Japan Society of Gynecologic and Obstetric Endoscopy and Minimally Invasive Therapy has issued an announcement as shown in attachment 2*, expressing its views on the use of power morcellators and tissue collection bags. Please inform the medical institutions under your jurisdiction of this announcement.

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* Attachment 2 is available only in Japanese and not attached to this English version. Please refer to the following URL for the announcement: http://www.jsgoe.jp/pdf/top/pdf101.pdf (only in Japanese)

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Attachment 1

PSEHB/MDED Notification No. 1224-14
PSEHB/PSD Notification No. 1224-4
December 24, 2021

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

Director, Medical Device Evaluation Division,
Pharmaceutical Safety and Environmental Health Bureau,
Ministry of Health, Labour and Welfare (official seal omitted)

Director, Pharmaceutical Safety Division,
Pharmaceutical Safety and Environmental Health Bureau,
Ministry of Health, Labour and Welfare (official seal omitted)

Revision of Precautions in the Package Insert of Power Morcellators

In “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, dated July 25, 2016), it was decided to add the following text in the package inserts: “The product should not be used if the patient has or is suspected to have malignant tumors.” “It is possible that unsuspected malignant lesion exists and the use of the product may worsen the prognosis. The information should be shared with patients and informed consent should be obtained before the use of product.”

Recently, the U.S. Food and Drug Administration (FDA) officially announced the guidance in November 2020 as follows: Power morcellators are contraindicated for use in patients who are 50 years of age or older or postmenopausal, and a tissue collection bag should always be used when using power morcellators in other cases.

After deliberation among the Pharmaceutical Safety and Environmental

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Health Bureau, Ministry of Health, Labour and Welfare (MHLW), the Pharmaceuticals and Medical Devices Agency (PMDA), and the Japan Society of Gynecologic and Obstetric Endoscopy and Minimally Invasive Therapy, the PRECAUTIONS section in the electronic package insert was decided to be revised based on the actual status of use, etc. in Japan in order to call further attention to the thorough implementation of informed consent including an explanation about the handling in the US.

Therefore, please revise the PRECAUTIONS section as follows and ensure that appropriate information is provided to medical institutions, etc.

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1. In the WARNINGS section of the electronic package insert for power morcellators, the following text should be added:

   It is possible that unsuspected malignant lesion exists and the use of the product may worsen the prognosis. This information and the handling in the U.S. should be shared with patients, and informed consent should be obtained before the use of the product.

2. The electronic package insert revised in accordance with the above 1 should be posted on the package insert information of medical devices on the website of PMDA).

3. The status of provision of information to medical institutions, etc. regarding the measures described in the above 1 and 2 and the contents of revision of the electronic package insert should be reported to the Division of Safety for Medical Devices, Office of Manufacturing Quality and Vigilance for Medical Devices, PMDA by January 31, 2022.

4. Regarding power morcellators under application for approval or certification, the applicant should notify the department in charge of review of the relevant product at PMDA or the registered certification body that a similar correction will be made to the electronic package insert (draft).

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(Appendix 1)

EDAPTECHNOMED Co.,Ltd. representative

KARL STORZ Endoscopy Japan KK representative

Covidien Japan Inc. representative

NAKAMURA Medical Industry Co.,LTD representative

TKB Corporation representative

Adachi Co.,Ltd representative

Lumenis Japan Co.,Ltd. representative