Ministry of Health, Labour and Welfare

Translated by **Pharmaceuticals and Medical Devices Agency**

Safety Division, Pharmaceutical and Food Safety Bureau

Office of Safety I

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.

December 9, 2014

Notification

PFSB/ELD/OMDE Notification No. 1209-3

PFSB/SD Notification No. 1209-4

To: Commissioner of Prefectural Health Department (Bureau)

Counsellor of Minister's Secretariat, Ministry of Health, Labour and Welfare
(Evaluation and Licensing of Medical Device/Cellular and Tissue-based Products)

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

Revision of the Precautions in the Package Insert of the Small Intestinal Capsule Endoscope

For the use of a small intestinal capsule endoscope (hereinafter called as “capsule endoscope”) in pediatric or geriatric patients, the “Precautions” have been given in the package insert on account of no evidence of the safety in these generations. This notification is issued to advise the Marketing Authorization Holders of capsule endoscopes to revise the Precautions as follows on the basis of the findings that no differences have been observed regarding device malfunctions and adverse events such as retention between the age groups among patients who can swallow a capsule endoscope, according to the use status and the device malfunctions and adverse events reported in Japan and overseas.

1. In the “Important Precautions” section in the Precautions in the package insert of the respective capsule endoscope, the following description should be included and the related description(s) should be edited or included:
   Prior to the use of the product, the patients’ ability to swallow it should be checked. The risk of additional treatment for the possible onset of retention, etc. should be thoroughly taken into account in advance, and the product should be used carefully.
2. The revised package insert as advised in the abovementioned item 1 should be uploaded on the Information Services on the website of Pharmaceuticals and Medical Devices Agency (hereinafter referred to as “PMDA”).
3. The respective Marketing Authorization Holder should report to the Medical Device Safety Division, Office of Safety I, PMDA, by January 23, 2015 about the actions taken for the abovementioned items 1 and 2 in addition to the information provided in the revised package insert to the medical institutions, etc.
4. For any capsule endoscope currently under application for approval, the applicant should report to the PMDA that the revision will be made in the respective package insert (draft).

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(Appendix 1)

Olympus Medical Systems Corporation

Covidien Japan Inc.