**Ministry of Health, Labour and Welfare**

Safety Division, Pharmaceutical and Food Safety Bureau

Translated by **Pharmaceuticals and Medical Devices Agency**

Office of Safety I



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# Notification

PFSB/ELD/OMDE Notification No. 0729-2
PFSB/SD Notification No. 0729-1

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

## Partial Modifications to Instructions on Revisions of the Precautions Associated with Amendments to the Notes on Compilation for Medical Device Package Inserts

Amendments to the “Notes on Compilation” in the package insert for medical devices have been made according to the PFSB Notification of the Pharmaceutical and Food Safety Bureau, MHLW, dated October 2, 2014, “Regarding Amendments to the Notes on Compilation of Package Inserts for Medical Device” (PFSB/SD Notification No. 1002-8), and the Notification of the Safety Division, Pharmaceutical and Food Safety Bureau, MHLW, dated October 2, 2014, “Regarding the Notes on Compilation of Package Inserts for Medical Device (Bylaws)” (PFSB/SD Notification No. 1002-1) and “Regarding the Notes on Compilation of Precautions in Package Inserts for Medical Device Package Inserts” (PFSB/SD Notification No. 1002-5).

The details of the instructions on revisions to the package insert provided for the following notifications due to these amendments are outlined in the appendix. This notification asks for your cooperation in making these widely known to affiliated vendors.

- “Regarding Self-checks for Electrosurgical Devices, etc.” (PFSB/ELD Notification No. 1201001 and PFSB/SD Notification No. 1201001 dated December 1, 2003)
- “Regarding Revisions of Precautions in the Package Insert for Intraocular Lens (IOL)” (PFSB/ELD/OMDE Notification No. 0720-4 and PFSB/SD Notification No. 0720-5 dated July 20, 2011)

(Appendix)

The following modifications on revision of the Precautions should be made respectively when making subsequent revisions to the package insert. Refer to Table 1 for electrosurgical devices, etc., and refer to Table 2 for IOL.

Table 1. Electrosurgical devices, etc.

| Conventional description<br>(Description to be deleted is lined through.) | Revised description<br>(Description to be added is underlined.) |
|---|---|
| ~~"RELATIVE CONTRAINDICATIONS (As a general rule, this device is contraindicated in the following patients. If the use of this device is considered essential, it should be used carefully.)"~~<br>~~Patients who have a history of undergoing surgery related to the biliary tract.~~<br>~~[There are risks of severe complications such as liver abscess or sepsis associated with bacteria proliferation due to retrogradation of intestinal bacteria in necrotic sites of the liver after undergoing ablation of liver parenchyma cells, etc.]~~ | (Deleted)<br><br>"PRECAUTIONS (The device should be used carefully in the following patients.)"<br>Patients who have a history of undergoing surgery related to the biliary tract.<br>[There are risks of severe complications such as liver abscess or sepsis associated with bacteria proliferation due to retrogradation of intestinal bacteria in necrotic sites of the liver after undergoing ablation of liver parenchyma cells, etc.] (See "Important Precautions.")<br><br>"Important Precautions"<br>If the patient has a history of undergoing biliary tract reconstruction associated with pancreaticoduodenectomy, the patient may suffer from decreased or complete loss of sphincter function in the duodenal papilla. As a result, there may be risk |

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| | of severe complications such as liver abscess or sepsis associated with bacteria proliferation due to retrogradation of intestinal bacteria in necrotic sites of the liver after undergoing ablation of liver parenchyma cells, etc. Therefore, the product should be used carefully after reviewing the sphincter function of the duodenal papilla and ablation site, etc. |

Table 2. Intraocular lens (IOL)

| Conventional description<br>(Description to be deleted is lined through.) | Revised description<br>(Description to be added is underlined.) |
|---|---|
| ~~"RELATIVE CONTRAINDICATIONS (As a general rule, IOL is contraindicated in the following patients. If the use of IOL is considered essential, it should be used carefully.)"~~<br>~~Children under 2 years of age (See "Important Precautions.")~~<br><br>"Precautions (IOL should be used carefully in the following patients.)"<br>~~Children aged 2 or older~~<br><br>"Important Precautions"<br>IOL implantation should be performed in children under the supervision of ophthalmologists with adequate knowledge and experience of characteristics of children. Especially, IOL implantation and manipulation could be difficult in the small eyes of children under 2 years of age, and it has been reported that additional surgery may be required due to axial length growth. The child's guardian should be thoroughly informed of these possible risks in advance. | (Deleted)<br><br>"Precautions (IOL should be used carefully in the following patients.)"<br>Pediatrics (See "Important Precautions.")<br><br>"Important Precautions"<br>IOL implantation should be performed in children under the supervision of ophthalmologists with adequate knowledge and experience of characteristics of children. Especially, IOL implantation and manipulation could be difficult in the small eyes of children under 2 years of age, and it has been reported that additional surgery may be required due to axial length growth. The child's guardian should be thoroughly informed of these possible risks in advance, and IOL should be used carefully after considering the risks and benefits. |