



---

*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.*

PSEHB/PSD Notification No. 0218-1

February 18, 2022

To: Commissioners of Prefectural/Cities with Established Health  
Centers/Special District Health Department (Bureau)

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

Occurrence of Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) in Patients Implanted with a Gel-filled Breast Implant or Tissue Expander, and Information Provision to the Patients (Request for Information Dissemination)

We would like to express our sincere appreciation for your continued efforts on implementing safety measures for medical devices.

Regarding the information provision for patients implanted with a gel-filled breast implant or tissue expander and other relevant persons (hereinafter referred to as “patients, etc.”), we have asked for your cooperation in widely disseminating the contents of the information provision materials (hereinafter referred to as “information provision documents”) prepared for patients, etc. and published by the Japan Oncoplastic Breast Surgery Society, the Japan Society of Plastic and Reconstructive Surgery, the Japanese Breast Cancer Society, and the Japan Society of Aesthetic Plastic Surgery (JSAPS) (hereinafter referred to as “4 academic societies”), by issuing the “Information Provision on Incidence of Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) in Patients, etc. with Gel-filled Breast Implants and Tissue Expanders (Request for circulation)” (PSEHB/PSD Notification No.0730-4 issued by the Director of Pharmaceutical Safety Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare dated July 30, 2021).



---

*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.*

As shown in the Annex 1\*, the 4 academic societies have recently announced the occurrences of BIA-ALCL, which are counted as the 3rd and 4th cases in Japan (both patients have undergone implantation of an unapproved gel-filled breast implant), and as shown in the Annex 2\*, the information provision documents were revised. In the updated information provision documents etc., the information related to the period between implantation and the onset of BIA-ALCL, the safety information on available products in Japan, etc. have been updated as well as attention on the importance of regular medical examination and self-examination for disease detection being raised again.

Since it is extremely important to provide accurate information widely to those who have an intention of undergoing breast reconstruction with gel-filled breast implant and who had undergone reconstruction with gel-filled breast implant, we would like to ask for your further cooperation in widely disseminating the contents of the information provision documents again by various means such as publication in public relations magazines of each local government and provision of information using social media.

The latest information provision documents are available on the website of the Japan Oncoplastic Breast Surgery Society.

URL: <http://jopbs.umin.jp/general/> (only in Japanese)

---

\* Please refer to the Japanese version of the Notification for the Annexes.  
<https://www.pmda.go.jp/files/000245090.pdf>