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保存年限：

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附件：如文(1060000533_Attach1.pdf、1060000533_Attach2.pdf)

主旨：轉知衛生福利部食品藥物管理署函，有關美國食品藥物管理局就乳房植入物(Breast Implants)公布之安全訊息1份，詳如附件，請 查照。

訂

說明：

一、依106年3月28日衛生福利部食品藥物管理署FDA器字第1061602384號函辦理。

二、本訊息刊登本會網站。

正本：各縣市醫師公會
副本：電子公文交換章 2017-04-11 10:39:49

理事長 邱 泰 源

線

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密等及解密條件或保密期限：
附件：Breast Implants: Update - Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL)(附件請至本機關附件下載區以發文字號及發文日期下載。網址http://ODDW.FDA.GOV.TW/DL/DL1/DLi100.aspx) 識別碼：YOIIZIKV。(A21020000I106160238400-1.pdf)

主旨：檢送美國食品藥物管理局就乳房植入物(Breast Implants)公布之安全訊息1份，詳如附件，請查照。

說明：

一、美國食品藥物管理局公布訊息指出，該局認同世界衛生組織（WHO）之觀點，認為「乳房植入物相關之間變性大細胞淋巴瘤(BIA-ALCL)」是一種罕見的T細胞淋巴瘤，可能因乳房植入物而引發。同時美國食品藥物管理局最新調查資料顯示略述如下:

(一)植入具有紋理(textured)表面之乳房植入物比起光滑表面（不具有紋理）之乳房植入物，更容易造成間變性大細胞淋巴瘤(ALCL)之發生。

(二)間變性大細胞淋巴瘤(ALCL)發生時，常出現於因遲發性(late onset)、持久性義乳週邊血清腫(Persistent seroma)而進行乳房植入物修補手術之患者。。

二、為確保病患使用醫療器材之安全，本署除將於本署網站公

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布旨揭產品之安全警訊外，並籲請醫師在進行旨揭產品之醫療行為時，除應審慎評估該產品之使用風險與效益外，及完整告知患者該類產品之使用風險疑慮，並持續觀察患者術後情形及是否有不良反應發生。

三、另依嚴重藥物不良反應通報辦法第3條規定略以，因藥物所引起之嚴重藥物不良反應發生時，醫療機構、藥局、藥商應依本辦法填具通報書，連同相關資料，向全國藥物不良反應通報中心通報(通報網頁入口:本署網站首頁 > 業務專區 > 通報及安全監視專區 > 通報入口(我要通報) > 醫療器材不良事件通報)。違者，可依藥事法第92條處辦。

正本：台灣美容外科醫學會、台灣整形外科醫學會、台灣臨床腫瘤醫學會、中華民國癌症醫學會、中華民國公立醫院協會、中華民國血液病學會、中華民國美容醫學醫學會、厚都企業有限公司、壯生醫療器材股份有限公司、台灣愛力根藥品股份有限公司、台灣醫院協會、中華民國醫師公會全國聯合會

副本：財團法人藥害救濟基金會全國藥物不良反應通報中心 電子公文交換章 2017-03-28 15:55:31

Breast Implants: Update - Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL)

[Posted 03/21/2017]

AUDIENCE: Plastic Surgery, Oncology, Patient

ISSUE: FDA has updated its understanding of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) to reflect the agency's concurrence with the World Health Organization designation of BIA-ALCL as a rare T-cell lymphoma that can develop following breast implants. At this time, most data suggest that BIA-ALCL occurs more frequently following implantation of breast implants with textured surfaces rather than those with smooth surfaces. BIA-ALCL is a rare condition; when it occurs, it has been identified most frequently in patients undergoing implant revision operations for late onset, persistent seroma. The exact number of cases remains difficult to determine due to significant limitations in world-wide reporting and lack of global implant sales data.

See the **FDA Update (/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm239995.htm)** for additional information, including a summary of Medical Device Reports and medical literature, and recommendations for patient care.

BACKGROUND: In 2011, the FDA identified a possible association between breast implants and the development of anaplastic large cell lymphoma (ALCL), a rare type of non-Hodgkin's lymphoma. FDA continues to collect and evaluate information about ALCL in women with breast implants.

RECOMMENDATIONS: Healthcare providers: If you have patients with breast implants, you should continue to provide them routine care and support. Because it has generally only been identified in patients with late onset of symptoms such as pain, lumps, swelling, or asymmetry, prophylactic breast implant removal in patients without symptoms or other abnormality is not recommended. Be aware that most confirmed cases of BIA-ALCL have occurred in women with textured breast implants. Provide the manufacturers' labeling as well as any other educational materials to your patients before surgery and discuss with them the benefits and risks of the different types of implants.

Patients: Before getting breast implants, make sure to talk to your health care provider about the benefits and risks of textured-surface vs. smooth-surfaced implants. If you already have breast implants, there is no need to change your routine medical care and follow-up.

Healthcare professionals and patients are encouraged to report all confirmed cases of ALCL in women with breast implants to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: **www.fda.gov/MedWatch/report (http://www.fda.gov/MedWatch/report)**
- **Download form (/Safety/MedWatch/HowToReport/DownloadForms/default.htm)** or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

[03/21/2017 - **Update: Anaplastic Large Cell Lymphoma (ALCL) (/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm239995.htm)** - FDA]

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2016 Safety Alerts for Human Medical Products
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2014 Safety Alerts for Human Medical Products
(/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm380008.htm)

2013 Safety Alerts for Human Medical Products
(/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm333878.htm)