檔　　號：
保存年限：

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發文日期：中華民國112年5月18日
發文字號：牙全彥字第01272號
速別：
密等及解密條件或保密期限：
附件：詳說明段。

主旨：函轉衛生福利部食品藥物管理署函美國食品藥物管理局發布「某些成人用牙科器材之安全問題評估」之安全訊息，詳如說明段，請查照並轉知會員。

說明：依據衛生福利部食品藥物管理署112年5月3日FDA器字第1121604103號函辦理，隨函檢附影本乙份。

正本：各縣市地方公會　牙醫全聯會 投對章(223)

請加入牙醫全聯會LINE@

理事長 陳彥廷

本案依照分層負責規定 授權 醫事審議委員會 主委決行

正本

檔　　號：
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發文日期：中華民國112年5月3日
發文字號：FDA器字第1121604103號
速別：普通件
密等及解密條件或保密期限：
附件：美國FDA安全訊息

主旨：美國食品藥物管理局 (下稱 FDA)發布「某些成人用牙科器材之安全問題評估」之安全訊息，請惠予轉知所屬會員知悉，請查照。

說明：

一、美國FDA於112年3月30日發布「某些成人用牙科器材之安全問題評估」之安全訊息（網址：https://www.fda.gov/medical-devices/safety-communications/evaluation-safety-concerns-certain-dental-devices-used-adults-fda-safety-communication)，如附件。

二、美國FDA正在評估成人使用固定式腭擴張器 (palatal expander) 之安全問題，使用這些牙科器材治療成人阻塞型睡眠呼吸中止 (OSA) 或顳顎關節障礙 (TMD) 之安全性和有

社團法人中華民國牙醫師公會全國聯合會 發文附件專用章

效性尚未經確定，且將可能導致嚴重併發症，如：牙齒外翻、牙根裸露...等。

三、請轉知所屬會員，醫事機構倘發現病人因使用旨揭產品引起嚴重不良反應時，應依醫療器材管理法第48條及醫療器材嚴重不良事件通報辦法規定，向全國藥物不良反應通報中心（網址：http://qms.fda.gov.tw）進行通報，違者將依醫療器材管理法第70條規定辦理。

正本：社團法人中華民國牙醫師公會全國聯合會、中華民國齒顎矯正學會、台灣口腔矯正醫學會、中華民國醫院牙科協會、中華牙醫學會
副本：財團法人藥害救濟基金會

署長吳秀梅

Evaluation of Safety Concerns with Certain Dental Devices Used on Adults
FDA Safety Communication

Español (/medical-devices/safety-communications/evaluacion-de-los-problemas-de-seguridad-de-determinados-dispositivos-dentales-utilizados-en-adultos)

Date Issued: March 30, 2023

The U.S. Food and Drug Administration (FDA) is evaluating safety concerns with the use of certain dental devices that are **fixed** (non-removable) palatal expanders used on adults to remodel the jaw or to treat conditions.

The devices of concern include:

- Anterior Growth Guidance Appliance (AGGA) and Fixed Anterior Growth Guidance Appliance (FAGGA),
- Anterior Remodeling Appliance (ARA) and Fixed Anterior Remodeling Appliance (FARA),
- Osseo-Restoration Appliance (ORA) and Fixed Osseo-Restoration Appliance (FORA), and
- Any other similar device types.

The FDA is aware of these devices being used to treat conditions such as obstructive sleep apnea (OSA) and temporomandibular joint disorder (TMD) of the jaw, and to remodel the jaw in adults. However, the safety and effectiveness of these devices intended for these uses have not been established, and these devices are not cleared or approved by the FDA.

The FDA is also aware of reports of serious complications with use of these devices. The FDA is asking patients, caregivers, and health care providers to report any complications with these devices to the FDA. Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices. The FDA is working to evaluate information from all available sources to provide additional information on this issue.

Recommendations for Patients, Caregivers and Health Care Providers

- Be aware the FDA is evaluating safety concerns with the use of certain dental devices, such as the AGGA, FAGGA, ARA, FARA, ORA, and FORA.
- Be aware the safety and effectiveness of these devices to treat conditions such as OSA and TMD, or to remodel the jaw in adults have not been established. These devices intended for these uses have not been cleared or approved by the FDA.
- Consult with a dental professional for problems or concerns with a dental device. Use of the AGGA, FAGGA, ARA, FARA, ORA, or FORA dental devices on adults may result in serious complications which may require intervention, such as:
  - Chronic pain
  - Tooth dislocation
  - Flared teeth
  - Uneven bite
  - Difficulty eating
  - Damaged gums
  - Exposed roots
  - Bone erosion
  - Tooth loss
- Report any problems with these devices to the FDA.

Device Description

Palatal expanders are dental devices typically used to widen the roof of the mouth (palate) to make room for crowded teeth. Palatal expanders are generally used during orthodontic treatment for children and adolescents whose upper jaw bones are not yet fused. At this time, the FDA is not aware of safety concerns related to orthodontic use of palatal expanders in children and adolescents (https://www2.aaoinfo.org/wp-content/uploads/2020/04/AAO_trifold-Palatal-Expansion-NB.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer).

In contrast, an adult's upper jaw bones are fused, and when a fixed palatal expansion device applies force, the palate is resistant to expansion. If forces are applied incorrectly to the teeth, serious complications can occur including chronic pain, tooth dislocation, flared teeth, uneven bite, difficulty eating, damaged gums, exposed roots, bone erosion, and tooth loss. These complications typically require intervention by a health care professional.

The safety and effectiveness of fixed (non-removable) palatal expanders being used to treat conditions such as OSA and TMD, or to remodel the jaw in adults have not been established and these devices have not been cleared or approved by the FDA.

FDA Actions

The FDA is informing patients, caregivers, and health care providers about safety concerns with the use of certain dental devices on adults, such as the AGGA, FAGGA, ARA, FARA, ORA, FORA, and any similar device types. The FDA is identifying and contacting responsible entities to communicate our concerns. The FDA plans to investigate potential violations and take action if appropriate. The FDA is working to further evaluate all available information about the issue. We will continue to monitor complaints and reports of adverse events associated with this issue.

The FDA will keep patients, caregivers, and health care providers informed as significant information becomes available.

Reporting Problems with A Device

If you experience any issues with any medical device, the FDA encourages you to file a voluntary report through MedWatch (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program) or call 1-800-332-1088 for more information on how to mail or fax the form.

Health care personnel employed by facilities that are subject to the FDA's user facility reporting requirements (/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities) should follow the reporting procedures established by their facilities.

Please include the following information in your reports:

- Device information, including name, brand, origin, or any other identification provided (if known)
- Details of adverse event and medical and/or surgical interventions (if applicable)

If you believe a medical device is being marketed in a manner that violates the law, you can file a report through FDA's Allegations of Regulatory Misconduct (/medical-devices/medical-device-safety/reporting-allegations-regulatory-misconduct) process. You can also contact your local FDA Consumer Complaint Coordinator (/safety/report-problem-fda/consumer-complaint-coordinators) to report concerns.

Questions?

- If you have questions, email the Division of Industry and Consumer Education (DICE) at DICE@fda.hhs.gov (mailto:DICE@fda.hhs.gov) or call 800-638-2041 or 301-796-7100.