

### FDA Wants to Hear From You Regarding TMJ Splint Related Issues

Following the [CBS News and Kaiser Health News investigation of temporomandibular \(TMD\) devices](#), the FDA has released the following safety alert below. Although this area is not currently regulated by the FDA, these devices can change the craniofacial structure as well as provoke increased pain. We frequently hear from patients, including adolescents, who have been harmed by such devices (including those which are removable and made in dental laboratories from patient impressions in a dental office).



The TMJ Association encourages patients and the public to report an adverse experience with *any* TMJ device (including those not on the FDA's list below). It is important that the FDA be made aware of all TMJ splint issues.

Splints are known by a wide variety of names such as: intraoral appliance, stabilization appliance, occlusal appliance, interocclusal appliance, repositioning splint, bruxism splint, night guard, mouth guard, and others, with names denoting commercial vendors promoting particular designs.

File a FDA MedWatch Report at: <https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program>

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

<https://www.fda.gov/medical-devices/safety-communications/evaluation-safety-concerns-certain-dental-devices-used-adults-fda-safety-communication>

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 remodeling 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](#).

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](#) 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](#) 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](#) process. You can also contact your local [FDA Consumer Complaint Coordinator](#) 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.

## About The TMJ Association...*Changing the Face of TMJ*

The TMJ Association, Ltd. is a nonprofit, patient advocacy organization whose mission is to improve the quality of health care and lives of everyone affected by Temporomandibular Disorders (TMJ). For over 30 years, we have shared reliable information on TMJ with people like you. We invite you to visit our

website, [www.tmj.org](http://www.tmj.org).



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