The National Society of Dental Practitioners and the Dentist's Advantage Insurance Program for Dentists

RISK MANAGEMENT ALERT

Dentists urged to report issues with certain palatal expanders to FDA

April 11, 2023

The U.S. Food & Drug Administration (FDA) and the American Dental Association (ADA) are asking dental professionals and the public to report concerns with certain fixed palatal expanders to the FDA. 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 recently began evaluating safety concerns of these devices after the Anterior Growth Guidance Appliance was targeted in multiple lawsuits for allegedly causing severe damage to patients' teeth.

These devices are reportedly 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 adult dental patients. Dentists should be aware that, of this writing, there are no peer-reviewed studies to back these claims and the product has not been cleared or approved by the FDA. The FDA warns that 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

Dental professionals and members of the public can file reports through MedWatch, the FDA's medical product safety reporting program. The FDA asks that reports include the following information:

- 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)

Dental professionals employed by facilities that are subject to the FDA's user facility reporting requirements should follow the reporting procedures established by their facilities.