

Indications for Use

The ZQuiet[®] Pro-Plus oral appliance is intended to reduce or alleviate nighttime snoring and/or mild to moderate obstructive sleep apnea (OSA) in adult patients 18 years of age or older.

Package Contains:

- ZQuiet[®] Pro-Plus Appliance
- Protective Storage Case
- Adjustment Screw Key
- Patient Instructions for Use & Care

Prescription Device

Caution: Federal law restricts the sale of this device by prescription only.

Product Description

The ZQuiet[®] Pro-Plus consists of separate upper and lower acrylic splints custom made for each individual patient. The two-piece construction provides lateral jaw movement enabling the patient to open and close normally. Sturdy fins on each side maintain the lower jaw in a specific anterior position that optimally opens the airway and provides unobstructed breathing. The fins contact stops on the buccal surface that contain embedded expansion screws that allow the clinician to make micro adjustments at the time of delivery and thereafter on an as-needed basis. A total of 5mm of protrusive adjustment is possible.

Contraindications

The device is contraindicated for patients who

- Have central sleep apnea
- Have severe respiratory disorders
- Have loose teeth or advanced periodontal disease
- Are under 18 years of age
- Are allergic to Acrylic (Methyl Methacrylate)

Material information

The ZQuiet[®] Pro-Plus components are manufactured from methyl methacrylate and stainless steel. These materials are biocompatible, corrosion-resistant and non-toxic under biological conditions.

Precautions

- The prescribing dentist should consider the medical history of the patients, including history of asthma, breathing, or respiratory disorders, or other relevant health problems, and refer the patient to a physician



before prescribing the device.

- This product should only be prescribed by a dentist experienced in the field of sleep disorders.
- All Patients who have been diagnosed with OSA should undergo some type of objective sleep testing (home sleep testing device or an overnight Polysomnogram) to evaluate the efficacy of the ZQuiet[®] Pro-Plus appliance.
- The prescribing dentist should consider performing a temporomandibular joint (TMJ) examination prior to using the ZQuiet[®] Pro-Plus appliance to insure that the patient is not predisposed to TMJ issues which device use could aggravate.
- The patient must be given detailed information on the risks involved with the appliance use, the possible complications (as listed under “Warnings”), and any special behavior that may be necessary for the safe use of the device.
- Special attention should be paid to compliance with the dentist’s instructions and the necessity of regular follow-up examinations.
- The prescribing dentist must provide a copy of the patient “Instructions for Use” to the patient at the time of device fitting and delivery.
- The product must be handled and stored with care. Dropping or impact to the appliance can cause breakage or considerably impair the strength of the product and its resistance to fatigue.
- The patient should be instructed to inform their dentist immediately regarding any unusual wear or damage the appliance. The patient should be monitored in case any changes appear in the regions adjacent to the device. The dentist must then evaluate whether clinical failure of the device has occurred and discuss with the patient any necessary measures that should be taken.



Fitting Instructions

Prior to patient contact, the ZQuiet® Pro-Plus appliance should be properly cleaned and disinfected.

If the ZQuiet® Pro-Plus appliance was ordered with a soft lining instead of ball clasps for retention, be certain to follow the instructions provided and soften the appliance under warm water before inserting.

1. Seat the upper maxillary appliance first, adjust for comfort and remove.



2. Seat the lower mandibular appliance second, adjust for comfort and remove.

Usually the ZQuiet® Pro-Plus inserts immediately, but occasionally slight adjustment is

needed. A colored disclosing indicator such as Pascal Occlude can be used to identify areas of interference. Interferences can be removed with a small egg-shaped bur on a slow speed hand-piece.

3. After necessary adjustments have been made, insert the appliance by seating the maxillary splint first, then have patient advance their lower jaw and place mandibular splint gently into place over the teeth. (Do not have patient bite into place, as this may cause clasping or soft-layer distortion).

4. Verify bilateral occlusal contact. Adjust and modify as needed.

5. Finally, verify that the appliance midline, vertical and protrusive measurements.

It is very important that patients be able to easily and smoothly insert and remove the ZQuiet® Pro-Plus by themselves. They should also be instructed to clean the appliance daily after each use.

Patients should be carefully queried before they leave to make sure the appliance is not irritating their soft tissue and instructed to come in immediately for adjustment if they develop jaw pain, or sore teeth or gums.

Device Adjustment

Adjustments to the ZQuiet® Pro-Plus device should only be made by the clinician or under the clinician's guidance and recommendation. The device has an expansion screw on both sides of the maxillary splint that provide a total of 5.0mm of protrusive adjustment in .10mm increments. It takes 10 turns keyhole to keyhole in the direction of the arrow per 1.0mm of

anterior advancement. Note: each side should be adjusted by the exact number of keyhole turns in relation to the arrow (up or down) to maintain proper jaw alignment.

Patient comfort should be a consideration in further anterior adjustment. Too much protrusion can cause painful TMJ problems that were not initially a patient concern and ultimately delay the treatment.

It is recommended for the patient to have a follow-up visit after 7-10 days of initial use, then again at 30 days, and then every 6 months to ensure fit and effectiveness of the device.

Warning

Some of the following conditions can be associated with use of the device. If lasting pain or other complications occur, the patient should immediately discontinue use of the device.

- Tooth movement or changes in dental occlusion
- Tooth or gingival discomfort
- Pain or soreness to the temporomandibular joint
- Excessive salivation

Warranty

The ZQuiet® Pro-Plus appliance is custom made from high quality materials for each patient. Materials and workmanship is warranted against defect for 3 years.

Product Complaints

Any dissatisfaction with the product quality, labeling or performance should be reported to Gergen's Orthodontic Lab immediately. Furthermore, if the device "malfunctions," (i.e. doesn't meet any of the performance specifications or doesn't perform as intended) and may have caused or contributed to the death or serious injury of the patient, Gergen's Orthodontic Lab should be notified immediately by telephone, fax, or written correspondence. When filing a complaint, the product name and the prescribing dentist name should be provided along with the name and address of the person filing the complaint.

For additional information, please contact the manufacturer.

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