

Product Description

The ZQuiet[®] Pro-Plus consists of separate upper and lower components custom made for each individual patient. The appliance incorporates small fins on each side of the appliance that maintains the lower jaw slightly forward and this opens the airway to permit unobstructed breathing. These fins also enable independent movement of the jaw so the patient can open and close their mouth while wearing the appliance. To maximize performance and patient comfort, the device contains embedded screws that allow for micro adjustments at the time of delivery and thereafter on an as-needed basis.

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



Instructions

1. Make sure the device is clean and inspect it prior to each use for damage. Do not use if any parts are cracked, chipped or missing.
2. Clean your teeth properly before inserting your appliance to prevent tooth decay and periodontal problems.
3. If your appliance has the soft lining (absence of metal ball clasps that contact the teeth) hold the appliance under warm water for 30-45 seconds to soften the acrylic lining. This aids in placing the appliance over your teeth.
4. Insert the upper component into the mouth and over the top teeth pressing the device firmly into place using your thumbs to ensure it is seated securely.
5. Slide your lower jaw slightly forward and then place lower component gently by hand onto lower teeth (do not bite into place). Press down on both sides to ensure appliance is seated securely and fits comfortably.
6. In the morning, remove your ZQuiet[®] Pro-Plus device carefully beginning with the lower tray first. Using your fingers gently pry the device up and off of the teeth. Due to the snug custom fit, it may require working each side a little bit at a time. Repeat with the upper tray using caution not to stress or bend the components during removal.
7. Follow the easy cleaning instructions after each use.
8. Adjustments to the ZQuiet[®] Pro-Plus device should only be made by the clinician or under the clinician's guidance and recommendation. It takes 10 turns keyhole to keyhole in the direction of the arrow per 1mm of advancement. Note: each side should be adjusted by the exact number of keyhole turns in relation to the arrow to maintain jaw alignment.



Cleaning Instructions

ZQuiet® Pro-Plus is for single patient use only and should be cleaned after each use to keep it free of harmful germs and bacteria.

To clean the ZQuiet® Pro-Plus appliance, follow these simple instructions:

1. Using a soft toothbrush, scrub all surfaces with warm water and a cleaner designed for dental appliances or alternatively a small amount of mild soap or non-abrasive toothpaste.
2. Rinse thoroughly with clean warm water.
3. After rinsing, shake off all excess water and pat dry with a clean towel.
4. Store ZQuiet® Pro-Plus at room temperature in the supplied case to prevent accidental damage.

DO NOT bleach the appliance or soak in mouthwash containing alcohol.

DO NOT place appliance in boiling water or expose to excessive heat. This may distort appliance and render it unusable.

Comfort Tips & Maintenance

You may experience an adjustment period using ZQuiet® Pro-Plus. Your jaw muscles may experience temporary soreness, like the soreness that may happen to muscles when trying a new exercise. During the initial break-in period it is recommended to wear the device for short periods of time during waking hours. Insert ZQuiet® Pro-Plus for 30-60 minutes while reading or watching TV.

Upon waking in the morning, the lower jaw may continue to feel more forward than usual. This sensation should go away slowly within a period of a couple of hours. Note: If you experience sharp or persistent pain lasting more than several hours after use, you should discontinue use and contact your Dentist.

Your dentist will schedule follow-up visits to ensure proper fit and therapeutic position. Minimally, you should return to the dentist who fit you for the ZQuiet® Pro-Plus appliance every six months for a routine examination

and device inspection. If the appliance becomes loose, damaged or does not fit properly at any time, contact your dentist to have it repaired immediately.

Possible Side Effects

Some of the following possible side effects can be associated with use of The ZQuiet® Pro-Plus. Many of these are normal during the routine adjustment period and should disappear with continued use:

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

Most patients experience little, if any, discomfort after a few weeks of adapting to the ZQuiet® Pro-Plus. If discomfort continues past this point, discontinue use and see your dentist.

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)

Precautions

Dentists 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 the appropriate healthcare provider before prescribing the device. 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.

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.

Manufactured by:

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