

The Metz Appliance ©



- **The Metz Appliance Overview**
- **The Metz Appliance Prescription Form**
- **Instructions for Use Manual for Prescribing Dentist**
- **Photo Images of The Metz Appliance**
- **Instructions for Use Manual for Patient**

The Metz Dental Laboratory, Inc.
1271 East Broad Street
Columbus, Ohio 43205
Telephone: (614) 252-4444

The Metz Appliance

Product Overview

The Metz Appliance is a mandibular repositioning oral appliance used to treat snoring and mild to moderate obstructive sleep apnea. It is composed of an upper and a lower tray made to fit the occlusal surface of the teeth. These full arch trays are connected to each other by stainless steel arms that are set to conform to the predetermined occlusal relationship of the upper and lower arches. These arms have an adjusted length that can be adjusted as needed to exert a forward force on the lower jaw and advance the mandible relative to the maxilla. The advancement of the lower jaw increases the patient's pharyngeal space which facilitates improved air exchange. Fenestrations in the upper and lower trays allow the wearer greater comfort and tongue movement. The primary advantage in treating snoring or sleep apnea with The Metz Appliance is its "ADJUSTABILITY". The post and sleeve mechanism advances the jaw into a forward position. If the desired relief is not immediately achieved, The Metz Appliance allows for additional forward movement.

With standard hardware, the mandible is advanced in 1 mm increments by adding advancement shims to secure them so the patient will not lose the shims or advancement position.

The telescopic version of the The Metz Appliance allows the prescribing dentist to advance the mandible more precisely. One turn of the advancement collar, until the next hole appears, advances the mandible in $\frac{1}{4}$ mm increments. **Please be aware that the arrows indicate the directions of advancement, ie: right side-up, left side-down.**



Rx

The Metz Dental Laboratory, Inc.



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The Appliance Changes as the Knowledge Changes

Dr. _____
 Street _____
 City _____ State _____ Zip _____
 Phone Number _____ Fax Number _____
 Date _____
 Due Date _____
 Patient _____

THE METZ APPLIANCE

- Please include upper and lower casts or impressions.
- Please include protruded bite record (George Gauge preferred)
- Please include centric bite record

METZ Appliance Fee \$410.00 ____

SPECIAL INSTRUCTIONS:

ANTERIOR APPLIANCE



Normal Cut Shown - Please note any changes

Lingual Addition

- ___ None
- ___ 2mm
- ___ 4mm
- ___ Other

Specific angle of anterior guidance _____ °

Retention

- ___ Minimal Blockout (very tight - requires internal adjustment of appliance)
- ___ Average amount of Blockout
- ___ Loose fit (may require chairside relines)

PIVOTAL APPLIANCE

Pivotal Appliance Fee \$125.00

Anterior Appliance Fee \$125.00
 Rush Fee (- 3 Lab Days) \$20.00
 Mounting \$20.00

Signature of Doctor _____

License Number _____

rev. 4/13

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Instructions for Use Manual for Prescribing Dentist



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1. Important Notice

Warnings

Carefully read all instructions before use. Observe all cautions and warnings throughout these instructions. Failure to do so may result in complications.

Use of the device may cause:

- Tooth movement or changes in dental occlusion
- Gingival or dental soreness
- Pain or soreness to the temporomandibular joint
- Obstruction of oral breathing
- Excessive salivation

Caution

U.S. Federal and State laws restrict the sale of this product to a physician or on a physician's order.

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.

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

Adverse Reactions

There are no known adverse reactions

2. Manufacturer

The product is manufactured by The Metz Dental Laboratory, Inc.

3. Indications for Use

The Metz Appliance is intended for use in patients 18 years of age or older for the reduction of snoring and mild to moderate obstructive sleep apnea.

4. Product Description

The Metz Appliance is a mandibular repositioning oral appliance used to treat snoring and mild to moderate obstructive sleep apnea. It is composed of an upper and a lower tray made to fit the occlusal surface of the teeth. These full arch trays are connected to each other by stainless steel arms that are set to conform to the predetermined occlusal relationship of the upper and lower arches. These arms have an adjusted length that can be adjusted as needed to exert a forward force on the lower jaw and advance the mandible relative to the maxilla. The advancement of the lower jaw increases the patient's pharyngeal space which facilitates improved air exchange. Fenestrations in the upper and lower trays allow the wearer greater comfort and tongue movement.

The primary advantage in treating snoring or sleep apnea with the The Metz Appliance is its "ADJUSTABILITY". The post and sleeve mechanism advances the jaw into a forward position. If the desired relief is not immediately achieved, The Metz Appliance allows for additional forward movement.

With standard hardware, the mandible is advanced in 1 mm increments by adding advancement shims to secure them so the patient will not lose the shims or advancement position.

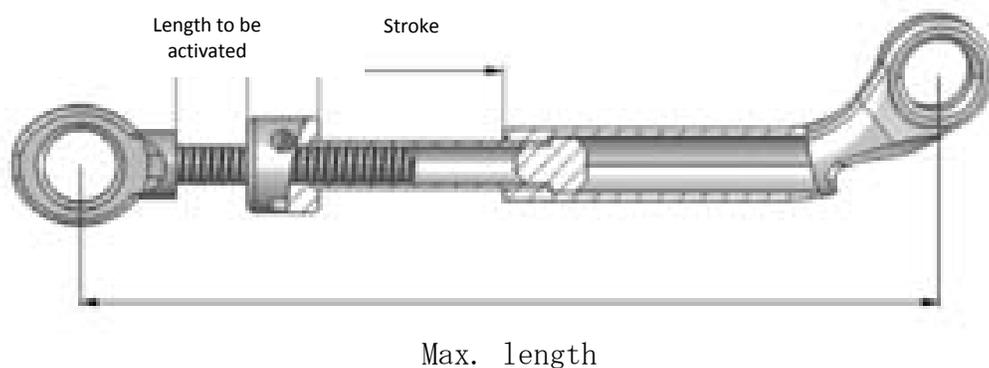
The telescopic version of The Metz Appliance allows the prescribing dentist to advance the mandible more precisely. One turn of the advancement collar, until the next hole appears, advances the mandible in ¼ mm increments. **Please be aware that the arrows indicate the directions of advancement, ie: right side-up, left side-down.**

The Metz Appliance Material Options:

The Metz Appliance is fabricated from two material options, which include Durasoft 1.8mm material, as well as 2mm Clear Splint Biocryl. Opposing ball hooks located in the upper and lower canine areas are joined by elastics to maintain the vertical dimension. The standard elastic samples provided are #64, 5/6"-8oz. The elastics will need to be replaced periodically. Any size elastic can be substituted as long as the mandible is maintained in the forward closed bite position.

Telescopic Hardware

The telescopic hardware for The Metz Appliance allows the clinician to advance the mechanism without the use of shims. The unique threaded system will not separate and provides for advancement in more precise $\frac{1}{4}$ mm increments. The adjustment collar on the lower portion of the arm near the bicuspid will gradually allow up to 7 mm of movement.



5. Patient Evaluation

Apnea is typically characterized by excessive daytime sleepiness, frequent morning headaches and hypertension. A patient whose bed partner reports that the patient stops breathing and gasps for air during sleep should be evaluated for Obstructive Sleep Apnea. If you are treating snoring, it is important to screen for possible sleep apnea as well. All Obstructive Sleep Apnea patients can be considered snorers, but not all snorers have Obstructive Sleep Apnea.

Do not treat a patient with The Metz Appliance without a referral from a medical professional who is trained in the field of sleep disorders. Only such a physician can diagnose Obstructive Sleep Apnea.

In addition to your routine dental examination, you should ask the patient or his or her bed partner to complete the Epworth Sleepiness Scale. The Metz Appliance is reliable and effective but there are many factors that determine the success of the appliance. The patient's weight is an important concern. The appliance will be more effective if the patient's weight is less than 125% of their ideal body weight. If the body weight is 150% over their ideal body weight, the patient may not have a favorable response to the The Metz Appliance.

6. Construction Records

A construction bite is required. It should be open to 4-5 mm incisally and reflect the desired start position of the mandible. A mandibular advancement of 60-65% of the distance from centric occlusion to full protrusion is recommended.

A set of upper and lower work models poured in dental stone is recommended. If hard acrylic material is selected, two sets of models are suggested. If only one set of models is provided, The Metz Dental Lab, Inc. will duplicate your models (additional charge) so that your technician can make the majority of your chair-side adjustments.

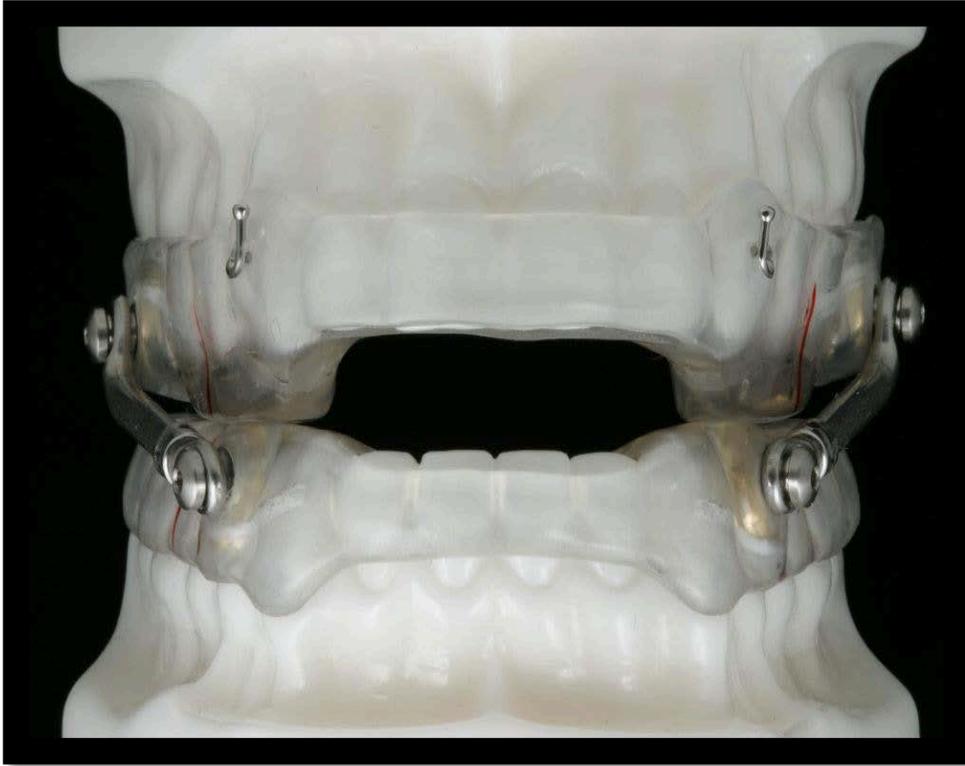
7. Delivery of Appliance

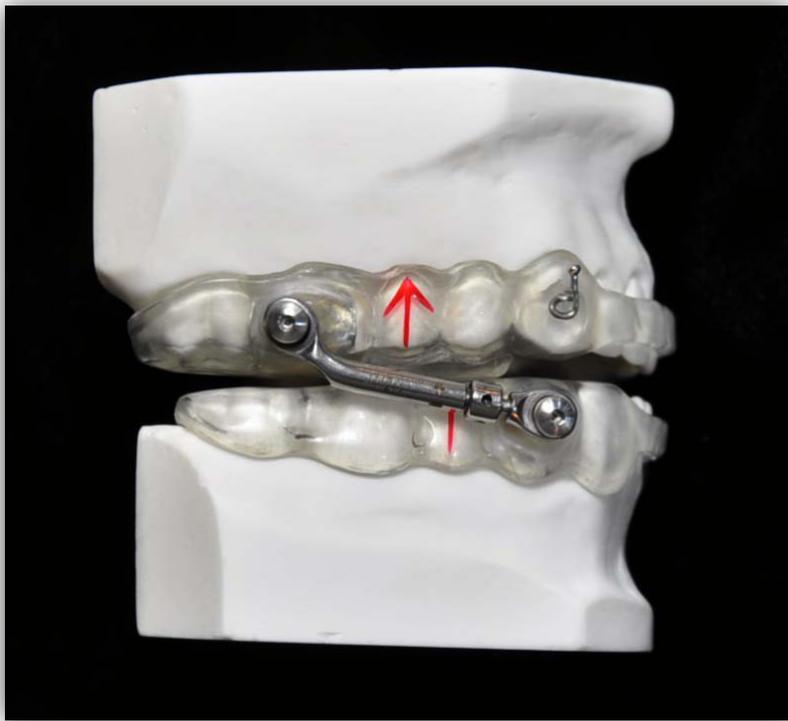
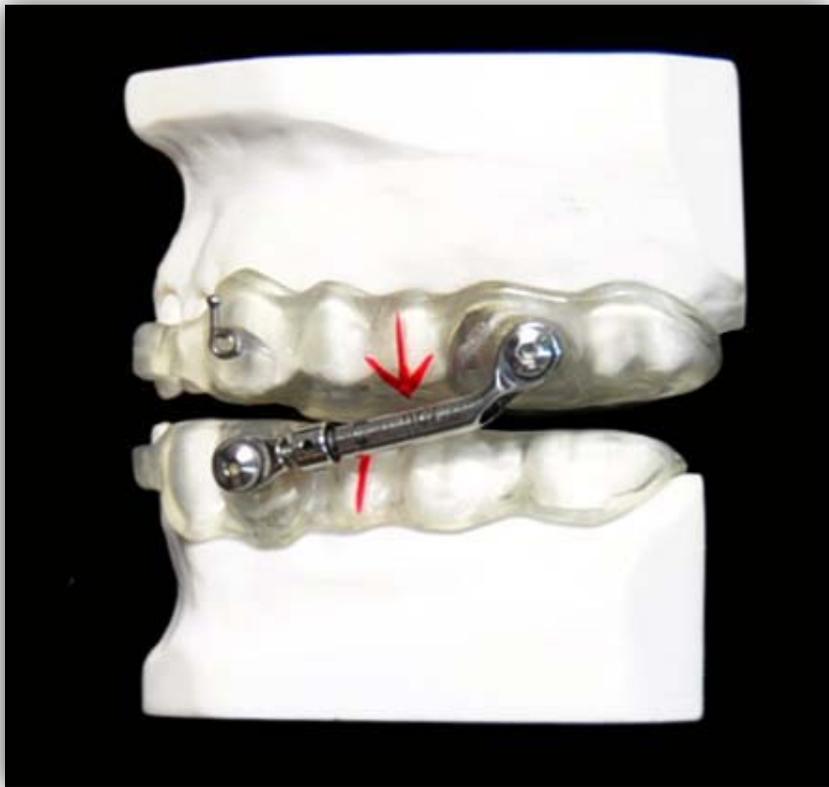
The Metz Appliance simply needs to be evaluated for retention and areas of discomfort. After one week, check for any areas of irritation and ask the patient to assess the comfort and effectiveness of the appliance. The patient's report will determine if advancement adjustments are necessary. You may use the Minolta 300i Pulse Oximetry Test or Epworth to determine the progress.

8. Adjustment

1. Have the patient place the device in their mouth.
2. Adjust the side arms to the patient's maximum mechanical protrusion. The patient will feel a slight stretch in their temporomandibular joints at this point. If the patient doesn't reach this maximum passive protrusion with this initial setting, adjust the side arms.
3. The advancement should be to the maximum protrusion that the patient is comfortable. Note it may take several nights of wearing and adjustments for the patient to become comfortable.

9. Photo Images of The Metz Appliance





The Metz Appliance

Instructions for Use Manual for Patient



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1. Important Notice

Warnings

Carefully read all instructions before use. Observe all cautions and warnings throughout these instructions. Failure to do so may result in complications.

If symptoms of breathing difficulties or other respiratory disorders persist, with or without the device, you should contact your prescriber (dentist) immediately. You may experience soreness or discomfort in your jaw or teeth. If discomfort persists, you should contact your prescriber (dentist). In the morning, you may feel your bite has changed. This sensation should disappear within one hour. If it continues for more than four hours, you should contact your prescriber (dentist). You should return to your prescriber (dentist) at least once yearly or as often as necessary, for re-evaluation. If the appliance becomes loose, damaged, or does not fit properly, contact your prescriber (dentist).

Use of the device may cause:

- Tooth movement or changes in dental occlusion
- Gingival or dental soreness
- Pain or soreness to the temporomandibular joint
- Obstruction of oral breathing
- Excessive salivation
- Temporary actual or perceived bite change. This subsides about 30 minutes after you remove the appliance and use the Exercise Bite Tabs
- Unconsciously taking the appliance out of your mouth at night
- Permanent bite change
- Dislodgement of dental work
- Gagging

These are possible side effects associated with using the Healthy Sleep Appliance. These side effects are not common, but if you experience any of these side effects, contact your prescriber (dentist) immediately.

Caution

U.S. Federal and State laws restrict the sale of this product to a physician or on a physician's order.

Contraindications

The device is contraindicated for patients who:

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- Have severe respiratory disorders
- Have loose teeth or advanced periodontal disease
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Adverse Reactions

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The Metz Appliance contains NO COLORANTS and is fabricated from dental materials found to be biologically well-accepted, widely used. No components are listed by International Agency for Research on Cancer (IARC), National Toxicology Program (NTP), Occupational Safety and Health Administration (OSHA), and American Conference of Governmental Industrial Hygienists (ACGIH) as carcinogens.

5. Directions for Daily Use

1. Inspect the device prior to each use. Contact your prescriber (dentist) if you see any damage or change.
2. Insert the trays.
3. Gently relax your jaw once the appliance is in your mouth.
4. To remove either the upper or lower trays, gently open your mouth and lift up on the lower tray and/or pull down on the upper tray to loosen the trays and remove.

WARNING: The trays of The Metz Appliance should never be worn separately.

6. Adjusting and Using Exercise Bite Tabs

When the lower jaw is pulled forward during the night, the muscles of the jaw may become sore and your bite may temporarily change. The Exercise Bite Tabs are used to gently guide your jaw back into the normal bite position.

1. Place one Exercise Bite Tab between the teeth on each side of the mouth. See Figure 1.
2. Pull your lower jaw back.
3. When your lower jaw is in the back position, squeeze your back teeth together. See Figure 2.

FIGURE 1-

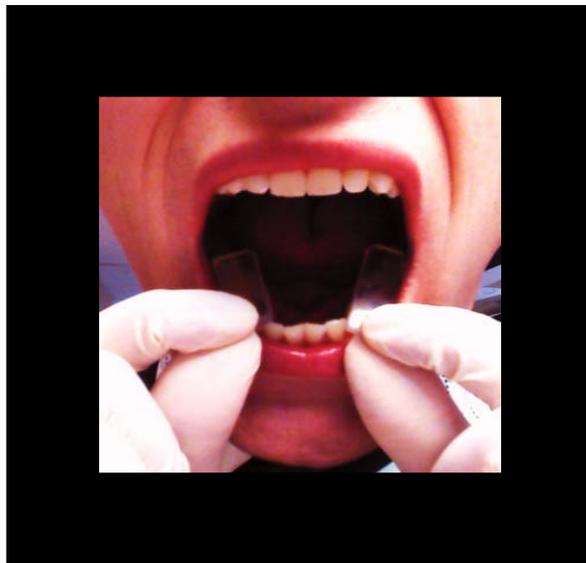
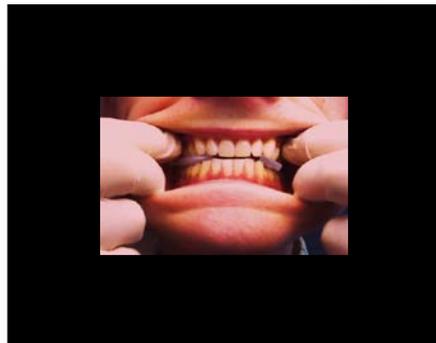


FIGURE 2-



7. Homecare and Storage by Wearer

Each morning after use, thoroughly clean your appliance by using a regular soft toothbrush, cold water, and toothpaste. **DO NOT USE HOT WATER.** The sonic cleaner and retainer brite are available for purchase if patient wants them.

Rinse and thoroughly dry the appliance before placing in the storage case.

If odor develops, appliance can also be cleaned with a non-alcohol mouth rinse. Never use hot water to clean because it could distort the appliance. Do not soak the appliance in any liquid for more than 10 minutes. Do not store or place the appliance in an area of high or direct heat such as near a fireplace, in the car or in a suitcase in the cargo area of an airplane, sunlight, etc. Keep the appliance in its storage case in a cool dry place.

WARRANTY: Upon receipt of The Metz Appliance, the patient is advised that there is a one year manufacturer's warranty.

