

**Dental Concepts, L.L.C.
Makers of NIGHTGUARD and BRUXGUARD**

**RECOMMENDATIONS FOR CLASSIFICATION
OF DENTAL MOUTHGUARDS**

September 30, 2005

I. INTRODUCTION

On October 11, 2005, the Dental Products Panel will discuss and make recommendations on the classification of a generic type of unclassified device that FDA refers to as: “Dental mouthguards, product code MQC, intended to provide protection against bruxism, teeth clenching, and grinding.”¹ Also, on October 12, 2005, the Panel will discuss and make recommendations regarding the over-the-counter (OTC) use of these types of products.

Dental Concepts is a manufacturer of dental mouthguards that have been in commercial distribution in the United States for many years. The company will be directly affected by the classification of these devices and has prepared these comments for Panel and FDA consideration in advance of the October 11 and 12, 2005 proceedings. Dental Concepts also intends to participate in the Panel meeting.

II. BRUXISM

Many people engage in some degree of habitual behavior, consisting of repetitive and nonfunctional motor behaviors. Teeth grinding, the habitual grinding and clenching of teeth, is a habit similar to nail biting, tongue thrusting and bracing, finger sucking and biting of the inside of the mouth (Attanasio R). Grinding is considered to be a normal occurrence for many people at some time or another (JADA, Vol 136, www.ada.org/goto/jada April 2005). Studies have demonstrated that teeth grinding occurs in up to 90% of the population (Attanasio R).

The habitual grinding and clenching of teeth is known as “bruxism.” Although bruxism is not an uncommon habit, the medical and dental professions recognize that severe cases can lead to injury. The force of clenching causes pressure on the muscles, tissues, and other structures around the jaw. This activity, if performed to excess, can lead to jaw joint disorders, jaw pain and soreness, headaches, earaches, damaged teeth, and other problems. Excessive grinding may wear down the teeth and be noisy enough at night to disturb bed partners. Like clenching, grinding can lead to jaw pain and other problems (Stedmans Medical Dictionary, Merck Manual, Bennett and Plum, Isselbacher).

¹ 70 Fed. Reg. 54559-54560 (Sept. 15, 2005).

III. DENTAL CONCEPTS PRODUCTS

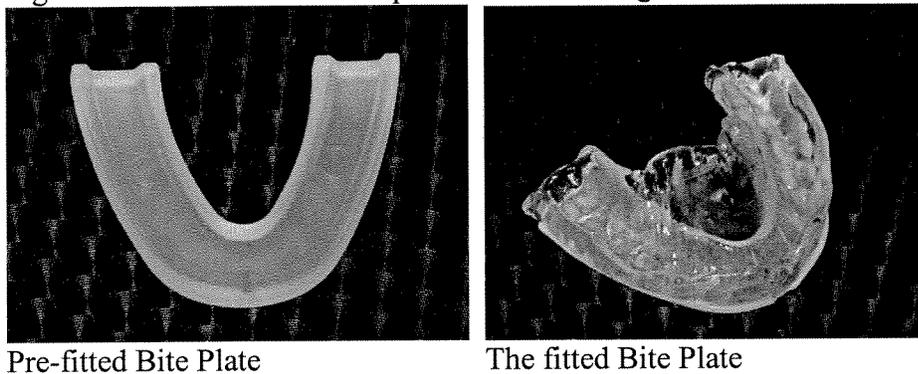
Dental Concepts, L.L.C., is a manufacturer and distributor of protective products intended for consumers experiencing bruxism. Dental Concepts provides two products: the BruxGuard and the NightGuard.

The BruxGuard has 510(k) clearance from FDA and is dispensed by prescription only (K024261). The BruxGuard is “indicated for protection against bruxism (night time teeth grinding), jaw clenching during sleep, short-term pain relief from muscle spasm, and prevention of chronic tension and temporal mandibular joint (TMJ) syndrome.” The BruxGuard is a “boil and bite” product that the dental practitioner heats in boiling water, rinses in cool water, and then inserts into the patient’s mouth, where it molds to the shape of the upper teeth. Because the plastic hardens as it cools, the impression is both exact and permanent. The base material provides a stable platform for the upper material and a positive “firm” stop to properly gauge the depth of the bite created during the molding process. The product incorporates a full-length channel in the upper material for better anterior-posterior fit and a centering notch for better lateral fit. See **Appendix 1** for a copy of the BruxGuard labeling.

Dental Concept’s offers consumers a second product, the NightGuard, which is physically the same as the BruxGuard. The labeling, however, is different. The NightGuard is labeled only as “a custom-fit dental mouthguard to cushion your teeth against night time teeth grinding.” None of the medical claims made by the BruxGuard (*e.g.*, short-term pain relief, prevention of TMJ) are in the labeling for the NightGuard. Because the NightGuard is sold directly to consumers, the instructions in the labeling are written in a manner suitable for lay users. See **Appendix 2** for a copy of the NightGuard labeling.

The NightGuard has been sold directly to consumers for many years. It is a consumer product for prevention of night time teeth grinding with no medical claims. The NightGuard is similar to “boil and bite” athletic mouth guard products used to prevent sport injuries. These products are directly available to the consumer and not regulated by FDA.

Figure 1.1. The Dental Concepts BruxGuard / NightGuard



Pre-fitted Bite Plate

The fitted Bite Plate

IV. PROPOSED CLASSIFICATION REGULATION

Under the Federal Food, Drug, and Cosmetic Act (“FDCA”), FDA is required to classify medical devices into one of three classes (i.e., class I, II, or III) on the basis of the controls FDA deems necessary to reasonably assure their safety and effectiveness. The classification system rests on the philosophy that each device should be regulated with the least amount of regulation possible based upon the risk presented. Class I devices are the lowest category of risk and are subject to general controls (e.g., prohibition against adulteration and misbranding, establishment registration and device listing, and adherence to Good Manufacturing Practice requirements). Most class I devices are exempt from premarket notification (or “510(k) clearance”).

Class II devices are the next highest category of risk and are subject to both general and special controls (e.g., FDA guidance, performance standards, or patient registries). Class II devices typically must receive 510(k) clearance, but some may be exempt.

Finally, Class III devices represent the highest category of risk (e.g., life-sustaining, life-supporting and implantable devices, or novel devices not substantially equivalent to lawfully marketed Class I or II devices). Class III devices must receive premarket application, or PMA, approval based upon a demonstration to FDA’s satisfaction that they are safe and effective (almost always based upon a significant clinical trial).

It is important to understand that the very same device may be placed in different regulatory classes based upon alternative labeled uses. For instance, an immunohistochemistry reagent intended for diagnostic use may be in class I, II, or III depending upon the specific labeled use. 21 C.F.R. § 864.1860. Similarly, a device may be placed in class I when sold for one purpose and treated as a consumer product that is not regulated by FDA when sold for another purpose. For instance, FDA’s regulations treat teething rings with medical claims as medical devices, but teething rings without such claims as consumer products. 21 C.F.R. § 872.5550. The agency has stated:

FDA has determined that it will regulate as medical devices only those teething rings (fluid-filled or solid) for which medical claims are made. Teething rings without medical claims are under the

regulatory authority of the Consumer Product Safety Commission (CPSC).

Dental Devices; General Provisions and Classifications of 110 Devices, 52 Fed. Reg. 30,082, 30,089 (Aug. 12, 1987).

Dental protective products that are available for those experiencing bruxism come in two varieties: (1) dental mouthguards available only from healthcare providers and (2) dental mouthguards that are sold directly to consumers through retail establishments. The reason for applying different classifications to these two types of products is that they are aimed at two different user populations. The prescription devices are intended for patients whose bruxism has caused pain and other sequellae requiring medical management under the care of a dental professional. The personal use products, in contrast, are labeled for consumers who simply wish to avoid grinding their teeth; these products are not labeled with medical claims of any kind.

Dental Concepts proposes the following classification regulation for the Panel's consideration:

“872.XXXX Dental mouthguard for bruxism

(a) Dental mouthguard for bruxism intended for personal use –

(1) *Identification.* A dental mouthguard for bruxism is a device intended for personal use and is intended to provide a physical barrier between the upper and lower teeth during night time teeth grinding or clenching.

(2) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in 872.9.

(b) Dental mouthguard for bruxism intended for use in the management of related medical conditions –

(1) *Identification.* A dental mouthguard for bruxism is a device intended for use as a physical barrier between the upper and lower teeth during night time teeth grinding or clenching to aid in the management of bruxism-related medical conditions and sequellae (*e.g.*, short-term pain relief from muscle spasm, prevention of chronic tension, and mitigation of temporal mandibular joint (TMJ) syndrome).

(2) *Classification.* Class II (Special Controls). The special control for these devices is the FDA guidance document entitled “Class II Special Controls Guidance Document: Dental Mouthguard for Bruxism Intended for Use in the Management of Medical Conditions; Guidance for Industry and FDA.” For the availability of this guidance document see 872.1(e).”

V. BASIS FOR THE PROPOSED CLASSIFICATION

Dental Concepts believes that different classifications are justified for the two types of devices that comprise *dental mouthguards for bruxism* based on the distinctly different target patient

populations that will use them. One device type is a prescription device, labeled for patients whose bruxism has caused pain and other sequelae that requires medical management under the care of a dental professional. In contrast, the other type of product is labeled for consumers who simply wish to provide a protective barrier between their upper and lower teeth during periods in which they grind their teeth.

To determine the appropriate regulatory controls necessary to assure the safety and effectiveness of the two types of devices that constitute *dental mouthguards for bruxism*, we approached the classification by considering the merits of applying the highest level of regulatory control, *i.e.*, class III, and progressed through the lower classifications in search of the least burdensome regulatory controls that will afford consumers a reasonable assurance of device safety and effectiveness. This exercise quickly dismisses class III as an appropriate classification. Neither device type meets the statutory criteria for designation as a class III device. Neither device type is for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health. Furthermore, neither device type presents a potential unreasonable risk of illness or injury.

It may be that class II (special controls) are appropriate for *dental mouthguards for bruxism* that are prescribed by dental professionals for the management of medical conditions that are (or may be) related to bruxism. Given the importance of achieving a proper fit that meets the specific needs of a patient, as well developing instructions for use that contribute to the management of specific medical conditions, FDA may be justified in developing special controls to assure this device type's safety and effectiveness.

For *dental mouthguards for bruxism* intended for personal use, however, Dental Concepts believes that class I (general controls) are sufficient to assure safety and effectiveness. The risks posed by the use of these devices are very minimal and it seems clear that lay users can follow simple instructions to self-fit the device to meet their personal needs. We conducted an extensive search of the published medical literature and were not able to find *any* evidence of injury or damage (*e.g.*, to the jaw, mouth, gum, teeth or intraoral tissues) associated with the use of dental mouthguards for bruxism. Moreover, devices of this type are similar to the athletic mouthguards that are used for protection against sports injuries, which are typically self-fitted and accepted as safe for consumer use. Finally, as further evidence of low risk, Dental Concepts has sold more than three million units of the NightGuard in the past several years and has not received even a single report of injury or damage (*e.g.*, to the jaw, mouth, gum, teeth or intraoral tissues) associated with the product.

Given that *dental mouthguards for bruxism* intended for personal use are not intended for a use that is of substantial importance in preventing impairment to human health, and do not present an unreasonable risk of illness injury, as class I devices they would be exempt from premarket notification (510(k) clearance) under the Act.

The proposed regulatory scheme would have the following impact on Dental Concepts' products: The NightGuard would fall under subparagraph (a) (personal use) and the BruxGuard would fall under subparagraph (b) (management of medical conditions). Thus, the NightGuard would be

class I, 510(k) exempt, while the BruxGuard would be class II, requiring 510(k) clearance and conformance with any special controls that FDA deems it necessary to promulgate.

VI. THE DENTAL MOUTHGUARD FOR BRUXISM FOR PERSONAL USE SHOULD CONTINUE TO BE AVAILABLE OVER-THE-COUNTER (OTC)

Section 520(f) of the FD&C Act requires that the labeling of a device bear adequate directions for use. FDA regulations define “adequate directions for use” to mean “directions under which the layman can use a device safely and for the purposes for which it is intended.” 21 C.F.R. § 801.5.

There is a legal presumption that a device will be sold OTC unless FDA affirmatively finds that a prescription only requirement is essential to the safe use of the device. A prescription only requirement is appropriate for a device only if there is a solid, evidence-based showing that the device would be unsafe if sold OTC and that adequate directions for safe lay use simply cannot be written.

In this case, the *dental mouthguard for bruxism* for personal use can clearly be sold OTC and used safely by consumers. For example, as mentioned above, more than three million units of the NightGuard have been safely sold OTC for the past several years without any reports of injuries associated with the product. The NightGuard product label was evaluated in a readability analysis and found to be written just below an eighth grade reading level. Moreover, the product label clearly identifies for the consumer when to completely refrain from using the NightGuard, when to seek advice from a dental professional before using the NightGuard, and when to stop using the product and seek attention from a dental professional.

Finally, as described in detail below, the potential risks from OTC dental mouthguards are mild compared to other currently available OTC dental products such as dental explorers and dental cement (**Appendix 3**).

VII. CONCLUSION

Dental Concepts is committed to manufacturing safe and effective products that meet the needs of both consumers suffering from bruxism and dental practitioners called on to manage the associated medical conditions. The regulatory scheme that the company proposes will continue to provide a reasonable assurance of safety and effectiveness of *dental mouthguards for bruxism* with an appropriate level of regulation tailored to their intended use.

APPENDIX 1

[BruxGuard labeling]



Brux Guard™
Bite Plate for
Professional Use.

Brux Guard™
Bite Plate for
Professional Use

RIVAL

Low High

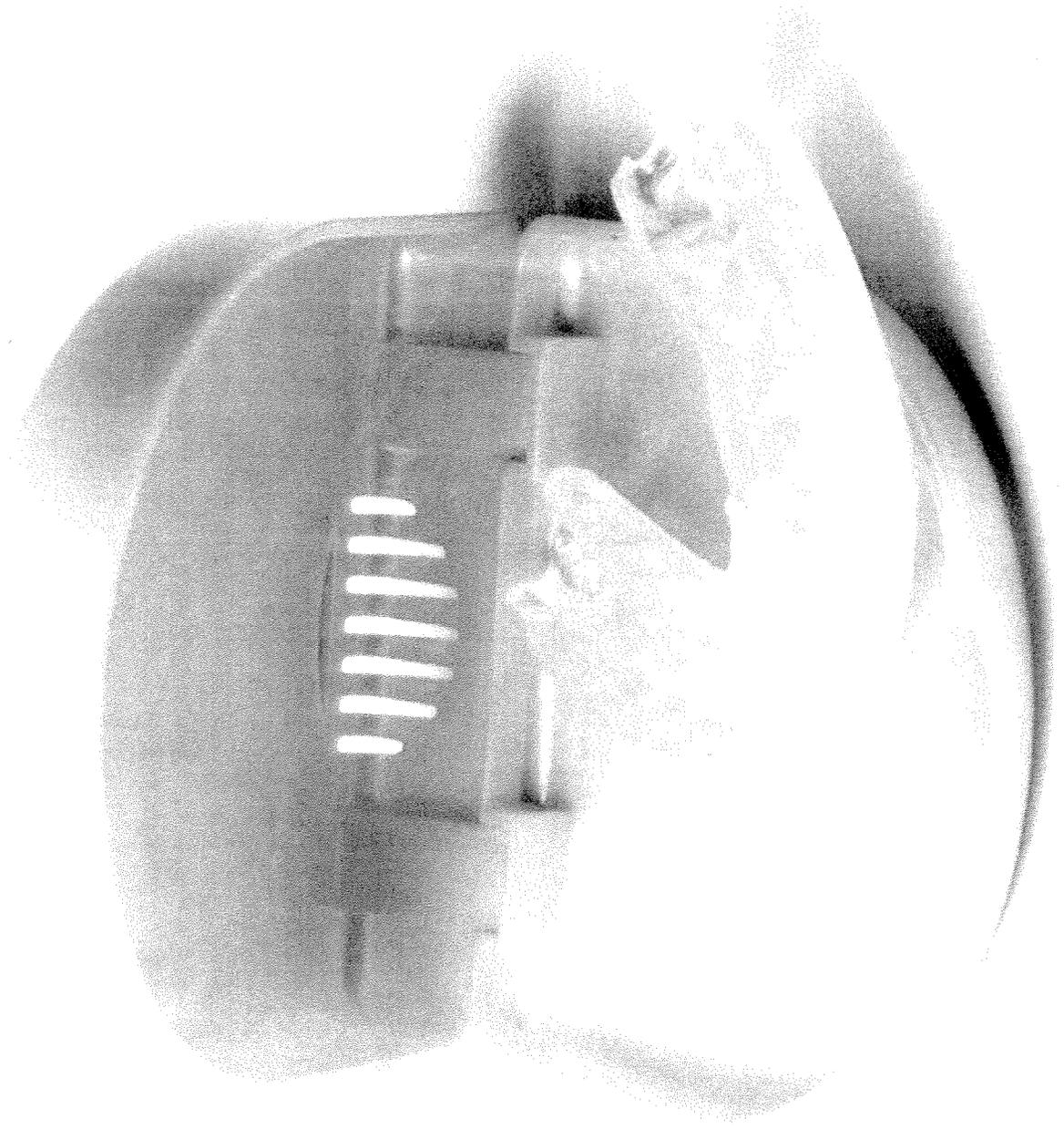
NEW

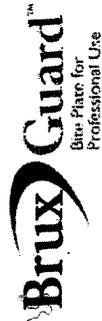
Brux Guard™
SMALL TRAY

MEDIUM

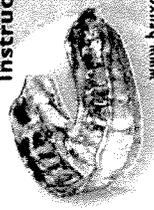
Brux Guard™
LARGE TRAY

GUARD THE PAIN
OF BRUXISM
USE WITH YOUR
BRUX GUARD





Dentist Fitting Instructions



www.bruxguard.com

Use:
The BruxGuard is indicated for protection against bruxism (nighttime teeth grinding), jaw clenching during sleep, short-term pain relief from muscle spasm due to occlusal interference, and prevention of chronic tension and temporal mandibular joint (TMJ) syndrome that is caused by chronic jaw clenching or the posterior mandibular and maxillary teeth by the temporalis muscle.

Warnings

- This product is contraindicated for patients:
- Who wear braces, dentures, or other dental appliances
 - With TMJ problems or clicking of the joint
- This product may not be suitable if the patient:
- Has sores on the inside of the mouth
 - Has gum disease or loose teeth

A physician should be consulted prior to prescribing this device for patients with respiratory problems or other serious health problems. The BruxGuard is not to be fitted by the patient. Review the patient instructions with the patient after fitting, including reasons to contact a dentist.

Questions?

Call 1-877-BRUX-123 between 9 a.m. and 5 p.m. Eastern Standard Time

What you will need:

- The BruxGuard with fitting instructions
- The BruxGuard heater or other heat source
- A cup of cold water
- Spoon to remove guard from hot water

Preparation:
Center the BruxGuard in the patient's mouth and instruct the patient to bite down slightly. The hard portion of the bite plate faces downward.

Determine if the BruxGuard is the appropriate size. If the BruxGuard extends more than past the rear molars, trim the guard using a bur. (See picture A)

The BruxGuard may appear too wide or narrow for the patient's mouth. When the BruxGuard is heated, you can easily adjust its shape.



Fitting:

Note: Each of these steps must be done without pausing between them. It is very important to be familiar with the fitting process before you begin. Refer back to the instructions as you fit the BruxGuard. If you are having difficulty, repeat the fitting process from the beginning.

1. Heat water (at least 4" deep within appliance) to a rolling boil.
2. Allow the water to maintain a rolling boil for one full minute. Place the BruxGuard in the water.
3. Allow the BruxGuard to sit in the water for 45 seconds. After 45 seconds, remove the BruxGuard from the water with a spoon.
4. Drop the BruxGuard into a cup of cold water for one second and then remove it with your fingers. The clear material (impression material) is now soft enough to mold to the patient's mouth. The

BruxGuard should be warm to the touch before fitting. If it is cool to the touch, start over at Step 1.

WARNING:

Do not put the BruxGuard in the mouth if it is hot.

5. Position the BruxGuard comfortably in the patient's mouth (as you did in your preparation) and have them bite down firmly. The patient should be able to feel the difference between the soft, clear impression material and the hard, clear tray. It is okay for the teeth to contact the hard, clear tray, but they should not bite into it.
6. Immediately after the patient bites down, use your fingers to firmly push the clear impression material on the outside surfaces of the teeth up towards the gums. Press evenly on both sides, all the way back to the patient's rear molars. The patient should hold it in place for approximately 5 seconds.

7. Remove your fingers from the BruxGuard, and then instruct the patient to close their mouth, place the tongue on the roof of the mouth, and suck in. The suction will help mold the clear impression material further.

8. Once the clear impression material has been molded to the outside surfaces of the teeth, use your thumbs to press the clear impression material towards the roof of the mouth on the inside surfaces of the teeth. This should also take approximately 5 seconds.

9. Instruct the patient to bite down firmly once again.
10. Remove the BruxGuard from the patient's mouth and place it into a bowl of cold water for 30 seconds.

The BruxGuard should now contain an exact impression of the patient's teeth. To test it, instruct the patient to place it back into their mouth and close their mouth comfortably. About 1-2 mm of material should be left between the upper and lower teeth when the patient bites down.

If there is too much material, the bite plate will feel uncomfortable or will fall out of the patient's mouth. Start at Step 1 again.

This product does not contain latex or silicone.

Review the patient instructions with the patient after fitting, including reasons to contact a dentist.

APPENDIX 2

[NightGuard labeling]

The Doctor's NightGuard dental protector is not recommended for people who experience "clicking" of the jaw and/or who have been diagnosed with temporomandibular joint problems.

This product is not to be used by children under the age of 12.

Guaranteed Fit:

Most of our customers are able to obtain an excellent fit the first time they try. However, if you are not completely satisfied with the fit and comfort of this product, or if you purchased the wrong size for your mouth, we'll send you a new one. We offer this to provide you with a comfortable and effective bite plate.

Please send the following survey indicating the size of your needed replacement product along with the cash register receipt to:

Resolve Corporation
C/O Dental Concepts 2305
1001 South Trooper Road
Norristown, PA 19003

Note: There is no need to send the NightGuard box or container back, just the survey and cash register receipt.

We want you to have relief from night time teeth grinding and promise to make the exchange as rapidly as possible. At the longest however, it may take as much as three weeks to process your request.

www.doctorsnightguard.com

You have just made a significant advance in the relief of night time grinding with the purchase of The Doctor's NightGuard. We value our customers and the input we receive from users like you. We would love to hear from you using the survey below or visit our website at www.doctorsnightguard.com.

Name _____
Address _____
Apt. # _____ City _____
State/Zip Code _____

If you are taking advantage of our fit guarantee, please check the replacement size you need mailed to you below.

Is this your first purchase of The Doctor's® NightGuard?
 Yes No
 Small Medium Large

Where did you purchase The Doctor's® NightGuard?

How did you hear about The Doctor's® NightGuard?
 Friend Saw in the Store
 Radio Advertising Other
 Drug Store Advertisement Identify Other

What could we do differently to help you have an easier time custom fitting The Doctor's® NightGuard?

Would you recommend The Doctor's® NightGuard to other sufferers of night time teeth grinding?

Yes No

Share your success story here:

Thank you. We truly value your input on our products.

Please mail this survey along with your receipt to:

Resolve Corporation
C/O Dental Concepts 2305
1001 South Trooper Road
Norristown PA, 19003

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T H E D O C T O R ' S ®

Night Guard

Dental Protector
For Night Time Teeth Grinding

Fitting Instructions



www.doctorsnightguard.com

Congratulations!

You have purchased a superior product for night time teeth grinding. The Doctor's® NightGuard is a custom-fit dental protector to cushion your teeth against night time teeth grinding.

For Best Results

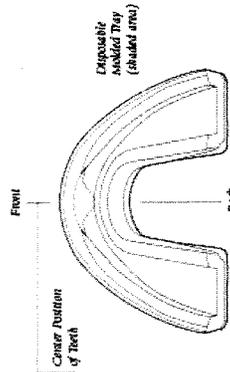
Read and follow instructions BEFORE AND DURING custom fitting of the dental protector. The dental protector can be fitted on the upper or lower teeth, but upper is preferred.

What You Need to Begin:

- A cup of cold water
- A pot to boil water
- A kitchen fork or spoon
- A mirror
- A clock with a second hand to time fitting steps in seconds



Custom Fitting Instructions



Test Fitting

1. Position The Doctor's® NightGuard into your mouth to determine if the sizing is correct. You will know the sizing is correct if your teeth fit comfortably into the "channel" of the dental protector and fit the "arms" of the "U" shape reach only to the end of your last molar.
2. If the arch (U-shape) of the dental protector is too narrow or too wide to fit the arch of your mouth, the dental protector can be altered during the fitting.
3. If the length of the dental protector extends beyond your back molars in the test fitting, the dental protector can be shortened by using a single-edge razor blade or a sharp knife.

For extra help with the fitting process, go to www.doctorsnightguard.com or call 1-800-592-6661 between 9am and 5pm Eastern Standard Time.

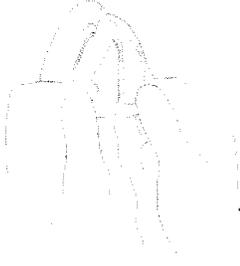
Relieve the nightly grind™

Boiling and Fitting

1. Fill a pot with approximately 3" of water. Boil water until you see a rolling boil and boiling bubbles. Let boil for 1 minute before starting.
2. Submerge the dental protector into the boiling water with the blue tray facing down for 35 seconds.
3. Using a fork or spoon, remove the dental protector from the boiling water and submerge in the cup of cold water for 1 second to remove the heat from the dental protector.
4. Position the dental protector comfortably into your mouth. You can widen or narrow the dental protector at this point in the process by up to 1/2 inch. Bite into the dental protector just enough to make a slight impression.

Press in along the gum line using equal amounts of pressure on both sides of the "U" shape from the front of the dental protector to the rear molars. Be sure to use your fingers to mold the soft impression material up and around the teeth.

5. Suck in to remove excess moisture and create the suction that will allow the dental protector to stay comfortably on your upper teeth.
6. Once you feel you have attained a comfortable fit, remove the dental protector and place into the cup of cold water to "set" the mold.
7. Peel off and discard the blue tray and you're finished.



Store The Doctor's NightGuard in the container provided when not in use.

Congratulations!

You now have a safe, comfortable The Doctor's® NightGuard for night time teeth grinding.

Longevity of the Dental Protector-

The life of your dental protector will vary based on the force of your teeth grinding. The average dental protector lasts from 6 months to one year with normal night time wear.

Important Note:

The Doctor's NightGuard dental protector is designed to feel comfortable all night long. However, should any pain occur, remove immediately and consult your dental professional. It may take you a week or two to get used to wearing the dental protector.

Does not contain latex or silicone.

Care and Maintenance:

- After each use, simply rinse the dental protector in cool water or mouth wash. Store the dental protector in the container provided.
- Proper care of your dental protector will extend its life.

Caution

- If you wear braces or any other dental appliances, consult your dental professional before using the dental protector.
- This product is not to be used to diagnose, cure, mitigate, treat or prevent disease or other medical condition, or to affect the structure or function of the body.

APPENDIX 3

Examples of other OTC Dental Products

Consumer Products	Intended Use	Warnings
Dentemp® Custom Temporary Filling Mix	Fast, temporary relief of pain and discomfort. Replaces lost fillings and may be used to temporarily cement loose crowns.	Keep out of the reach of children. Do not use if you are allergic to Eugenol. If burning sensation occurs, remove Dentemp materials from mouth and rinse affected areas with vegetable oil. This product should not be used if throbbing pain or swelling in the affected areas exists. Consult your dentist immediately. This product is sold only as a temporary remedy. You must see a dentist as soon as possible for permanent work to be performed. Failure to do so may cause infections and/or serious injury.
DenTemp® O.S. Max Hold	Provides fast relief of pain and discomfort until you can see your dentist. Clinically tested, Dentemp® O.S. is pleasant tasting, safe and so effective, “you can eat on it.”	Keep out of reach of children. Caution: This product should not be used if throbbing pain or swelling in affected area exists. Consult your dentist immediately. This product is sold as a temporary remedy. See your dentist as soon as possible for permanent work to be performed. Failure to do so may cause infections and/or serious injury.
Red Cross® Toothache	Temporarily relieves throbbing, persistent toothache due to a cavity until a dentist can be seen.	Warnings: For external use only – Do not use if you are allergic to eugenol (clove oil). When using this product, use only in teeth with persistent throbbing pain; avoid touching tissues other than tooth cavity, do not swallow, do not use for more than 7 days; do not exceed recommended dosage. Stop use and ask a dentist or doctor if irritation persists, inflammation develops, or if fever and infection develop. Toothaches and open cavities indicate serious problems which need prompt attention by a dentist.
Recapit® Cement	Unique, no mix cement made especially for replacing loose caps and crowns. Clinically tested and guaranteed, Recapit is safe and so effective “you can eat on it.”	Keep out of reach of children. Caution: This product should not be used if throbbing pain or swelling in affected area exists. Consult your dentist immediately.
DenTek® Thin Set Cap & Crown Cement	Designed to temporarily secure dental restorations (loose crowns, caps, laminates and bridges). This is a temporary remedy meant to secure your dental restoration until you have had a chance to visit your dentist.	Keep out of reach of children. To avoid injection and/or serious injury, this product should not be used if there is throbbing pain, ulceration or swelling in the affected area. In this situation, consult your dentist immediately. This product should not be placed on open wounds.
DenTek® Temparin® Filling Material	Designed to repair lost fillings with the same ingredients dentists use. This is a temporary remedy meant to replace a lost filling or inlay until you have a chance to visit your dentist.	Keep out of reach of children. Caution: To avoid infection and/or serious injury, this product should be used if there is throbbing pain, ulceration, or swelling in the affected area. If any of the symptoms exist, consult your dentist immediately. This product should not be placed on open wounds.
D.O.C.® (Dentist	Repair broken dentures and	Keep out of reach of children. Warning: For emergency

<p>On Call) Emergency Denture Repair Kit</p>	<p>denture teeth in minutes. Fix breaks, replace loose teeth, mend cracks.</p>	<p>repair only. Long term use of an improperly repaired denture may cause serious problems. See your dentist as soon as possible. Caution: Do not use near fire or flame. Protect from heat or direct sunlight. Store in a cool, dry place.</p>
<p>EZO® Denture Cushions</p>	<p>Temporary aid to hold loose dentures.</p>	<p>Use not to exceed 6 weeks duration. For temporary use until a dentist can be seen. EZO cushions should be changed daily. Use only 1 cushion on each denture. EZO cushions should only be used with full upper dentures. Consult your dentist: Use of ill-fitting dentures may seriously impair health, causing permanent bone loss and irritation.</p>
<p>Dentek® Explorer Professional Quality Interdental Pick</p>	<p>Professional quality interdental tool used to remove impacted food particles, remove plaque and help prevent gingivitis.</p>	<p>Certain elements found in dental plaque may cause clotting and an increased risk of heart disease in some people. Regularly rinse mouth thoroughly during the use of the explorer. Do not swallow the material removed. If bleeding of the gums occurs, stop and consult your dentist. For additional instructions, consult your dentist.</p>
<p>Dentek® Tongue Cleaner</p>	<p>Removes germs that cause bad breath.</p>	<p>If bad breath persists, please contact your dentist. (85% of bad breath is the result of volatile sulfur compounds (VSCs) produced by bacteria on the back of your tongue where your toothbrush can't reach.)</p>