

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY

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U.S. DISTRICT COURT  
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06-0368(KSH)

\_\_\_\_\_  
TOTAL GARD CORPORATION )  
 )  
175 Cedar Lane, Suite 1 )  
Teaneck, New Jersey 07666-4315 )  
 )  
Plaintiffs, )  
 )  
v. )  
 )  
SPLINTEK-PP, INC., and )  
POWER PRODUCTS, INC. )  
 )  
3325 Wyoming Street )  
Kansas City, Missouri 64111 )  
 )  
Defendants. )  
\_\_\_\_\_

Civil Action No. 06-0368(KSH)

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff, Total Gard Corporation (hereinafter, "Total Gard"), for its complaint against defendants, Splintek-PP, Inc. and Power Products, Inc. (hereinafter, collectively "Splintek"), alleges and states the following:

**PARTIES**

1. Plaintiff Total Gard Corporation is a New Jersey corporation having its principal place of business at 175 Cedar Lane, Suite 1, Teaneck, New Jersey 07666-4315.
2. Upon information and belief, Defendant Power Products, Inc. is a Missouri corporation having a place of business at 3325 Wyoming St., Kansas City, Missouri 64111.

3. Upon information and belief, Defendant Splintek-PP, Inc., a division of Power Products, Inc., is a Missouri corporation having a place of business at 3325 Wyoming St., Kansas City, Missouri 64111.

4. Upon information and belief, Splintek regularly does or solicits business in the State of New Jersey, engages in a persistent course of conduct in the State of New Jersey, or derives substantial revenue from its products used in the State of New Jersey, including the products at issue in this lawsuit.

#### **JURISDICTION AND VENUE**

5. Total Gard brings this action pursuant to the Patent Laws of the United States, codified at 35 U.S.C. § 1 *et seq.*

6. Jurisdiction is conferred upon this Court pursuant to 28 U.S.C. §§ 1331 (federal question jurisdiction) and 1338(a) (original jurisdiction under patent laws).

7. Venue of this action is properly laid in the United States District Court for the District of New Jersey pursuant to 28 U.S.C. §§ 1391(b),(c) (general venue statute) and/or 1400(b) (venue for patent infringement claims).

#### **PATENT IN SUIT**

8. On September 5, 1995, U.S. Patent No. 5,447,168 entitled "Mouthguard," issued with James J. Bancroft, DMD as the named inventor (hereinafter, the "Bancroft patent"). A true and correct copy of the Bancroft patent is attached hereto as Exhibit 1.

9. The Bancroft patent was duly and legally issued by the U.S. Patent and Trademark Office on September 5, 1995. The Bancroft patent is valid and subsisting.

10. Total Gard is the owner by assignment of all legal rights, title, and interests in and to the Bancroft patent, including the right to bring this suit for damages and injunctive relief for infringement thereof.

**CAUSE OF ACTION: PATENT INFRINGEMENT**

11. Total Gard incorporates by reference paragraphs 1-10 above as though fully set forth herein.

12. Total Gard designs and provides oral care products, including teeth protection devices called mouthguards that are covered by the Bancroft patent and marketed under the TOTALGARD and STRESSGARD names. The TOTALGARD product is an athletic protection device, while the STRESSGARD (hereinafter, "night guard") is a device used at night that prevents grinding and/or clenching (bruxism) of teeth during sleep. Both the TOTALGARD and STRESSGARD products are examples of commercial embodiments of mouthguards protected by the claims of the Bancroft patent.

13. Total Gard derives significant competitive advantages from the patented features of the Bancroft patent, including a stress release mechanism in the form of a groove defining a hinge permitting flexing of outward extensions of the mouthguard. These extensions are designed to extend into and be retained by the muscles of the buccal folds (cheeks). The stress relief groove allows the extensions to respond easily to the pressure of the muscles and lay comfortably in the buccal folds. (*See, e.g., Ex. 1 at column 1, lines 56 -61.*) In this manner, the patented products offer a comfortable fit, providing excellent retention in the mouth without the need for boiling or trimming as in prior art mouthguards.

14. Splintek originally marketed a low-profile night guard, sold under the EZ-Splint name, having small wings at its ends that did not extend above the upper gum line. (A photo of the original design of the EZ-Splint night guard is shown in the Splintek brochure attached hereto as Exhibit 2.) The EZ-Splint night guard is now marketed by Splintek as the low-profile SleepRight night guard.

15. Upon information and belief, the EZ-Splint night guard did not provide adequate retention for many of its wearers because the wings did not extend high enough so that the EZ-Splint night guard could not be readily held in place by natural oral tissues. This lack of retention probably caused the EZ-Splint to move around and/or become dislodged from its proper position when a wearer's mouth would open during sleeping.

16. Splintek subsequently introduced the EZ-Splint PM night guard, which was similar to the prior EZ-Splint version, but included horizontal grooves and extensions that projected upwardly above the upper gum line. The EZ Splint PM is now sold as the standard SleepRight night guard (hereinafter, "SleepRight night guard"). (Photos of the SleepRight night guard are shown in the Splintek product brochures attached hereto as Exhibit 3 .)

17. Upon information and belief, the SleepRight night guard provides improved retentive characteristics over the EZ-Splint night guard because the wings extend higher beyond the gum line so that the natural tissue of the buccal fold assists in holding the SleepRight night guard in place.

18. Splintek advertises the improved retentive characteristics of its SleepRight night guard on its website by stating that SleepRight night guard is held in place utilizing "natural tissue retention" and "[t]here are no need for clasps that attach to the teeth and you do not use the

teeth to hold the appliance in place.” (Splintek’s website description of its SleepRight night guard product is attached hereto as Exhibit 4.)

19. Just like the teachings of the Bancroft patent, the horizontal grooves in the SleepRight night guard function as stress release mechanisms that allow for extensions of the night guard to extend into the buccal folds to provide for better retention, comfort and fit, all without the need to boil or trim the night guard.

20. Splintek offers for sale and sells its SleepRight night guard in the State of New Jersey, including this District, through the Internet and by advertising in local media, including television, and in nationally published magazines circulated in this District, such as *Prevention*.

21. Total Gard has given the public, including Splintek, constructive notice of the Bancroft patent since 1997 by marking its patented products with patent number 5,447,168.

22. Splintek has been on actual notice of its infringement of the Bancroft patent since at least April, 2003.

23. Splintek has infringed and continues to infringe at least claim 1 of the Bancroft patent, in this District and elsewhere in the United States, by making, using, importing, offering for sale, and/or selling night guards having each and every element recited in claim 1 of the Bancroft patent, in violation of 35 U.S.C. § 271, including the EZ-Splint PM and SleepRight night guards.

24. On information and belief, Splintek’s infringement has been, and continues to be, deliberate and willful.

25. Total Gard has been damaged as a result of the above-referenced infringement of the Bancroft patent in amount to be determined at trial, and has suffered, and will continue to suffer, irreparable injury unless Splintek is enjoined from infringing the Bancroft patent.

**PRAYER FOR RELIEF**

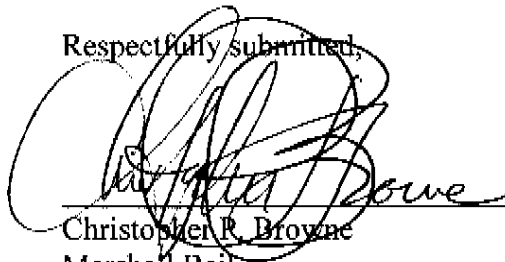
WHEREFORE, Total Gard prays for the following relief:

1. A preliminary and permanent injunction prohibiting Splintek from making using, importing, offering for sale, selling, and/or advertising night guards that infringe the '168 patent, and from otherwise directly infringing, contributing to, or inducing the infringement of the Bancroft patent; and for all further and proper injunctive relief pursuant to 35 U.S.C. §283;
2. A judgment that Splintek has infringed the Bancroft patent by making, using, importing, offering for sale and/or selling infringing night guards as claimed in the Bancroft patent;
3. A judgment that Splintek's infringement of the Bancroft patent is willful;
4. An accounting and award of damages against Splintek for any and all damages allowable by law, including but not limited to: (a) monetary damages sustained by Total Gard as a result of Splintek's acts of infringement, contributory infringement and active inducement of infringement; (b) treble damages pursuant to 35 U.S.C. §284; (c) costs and prejudgment interests; and (d) attorney's fees;
5. A finding that this is an exceptional case and an order awarding reasonable attorney's fees to Total Gard under 35 U.S.C. §285; and
6. Any and all such other and further relief as this Court may deem appropriate.

**JURY DEMAND**

Plaintiff Total Gard hereby demands trial by jury on all issues triable by jury.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Christopher R. Browne", is written over a horizontal line. The signature is somewhat stylized and overlaps the line.

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Attorneys for Plaintiff

DATED: January 24, 2006



US005447168A

**United States Patent** [19]

[11] **Patent Number:** 5,447,168

**Bancroft**

[45] **Date of Patent:** Sep. 5, 1995

[54] **MOUTHGUARD**

[76] **Inventor:** James J. Bancroft, 43 Mercer Ave., Englewood Cliffs, N.J. 07632

[21] **Appl. No.:** 316,866

[22] **Filed:** Oct. 3, 1994

[51] **Int. Cl.<sup>6</sup>** ..... A61C 5/14

[52] **U.S. Cl.** ..... 128/859; 128/861

[58] **Field of Search** ..... 128/848, 859-862; 2/2

[56] **References Cited**

**U.S. PATENT DOCUMENTS**

1,775,718	9/1930	Garvey	128/848
2,142,614	1/1939	Mitchell	128/859
2,424,533	7/1947	Falres	128/861
2,483,157	9/1949	Singer	128/861
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2,600,025	6/1952	Sage	128/860
2,627,268	2/1953	Leppich	128/861
3,187,746	6/1965	Gerber	128/859
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*Primary Examiner*—Michael A. Brown

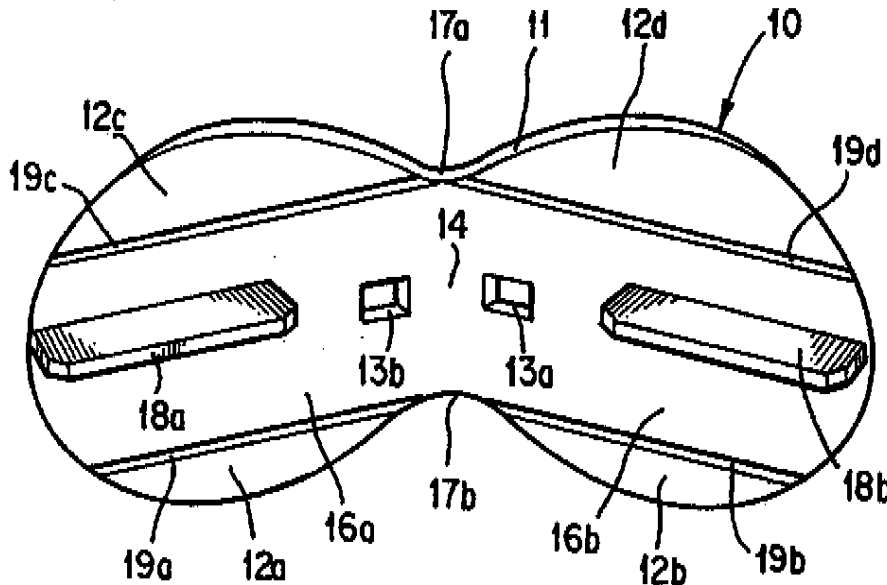
*Attorney, Agent, or Firm*—Howrey & Simon; Richard S. Meyer; Leo J. Jennings

[57] **ABSTRACT**

A mouthguard for protecting lips against impact trauma on orthodontic appliances (braces), protecting teeth

from sports trauma, protecting teeth from clashing together or grinding; and, protecting the temporomandibular joint (T.M.J.) from traumas due to a blow to the mandible. The mouthpiece comprises a curved flexible element, having two or more substantially central apertures extending therethrough and a notched portion on the upper and lower surface thereof. On the inner posterior surface of the element, an inwardly projecting portion extends at right angles thereto on each side of the aperture and designed to be grasped by the teeth. The mouthguard lays against the outer surface of the teeth with the curved flexible element and extends into the buccal folds superiorly and inferiorly of the cheek where the muscles hold it in place. A groove is positioned lengthwise along the posterior curved element above and below the right angle of the projecting portion for purposes of flexibility and to allow the muscles of the cheek to press the element close to the bone for better retention and comfort. The teeth engage both sides of the inwardly projecting element which prevent the teeth from clashing together and protects the temporomandibular joint (T.M.J.). The anterior central apertures permit easy breathing. The mouthguard is retained by the muscles of the lips and cheeks, causes no gag reflex and is simple, comfortable and protective.

15 Claims, 1 Drawing Sheet





U.S. Patent

Sep. 5, 1995

5,447,168

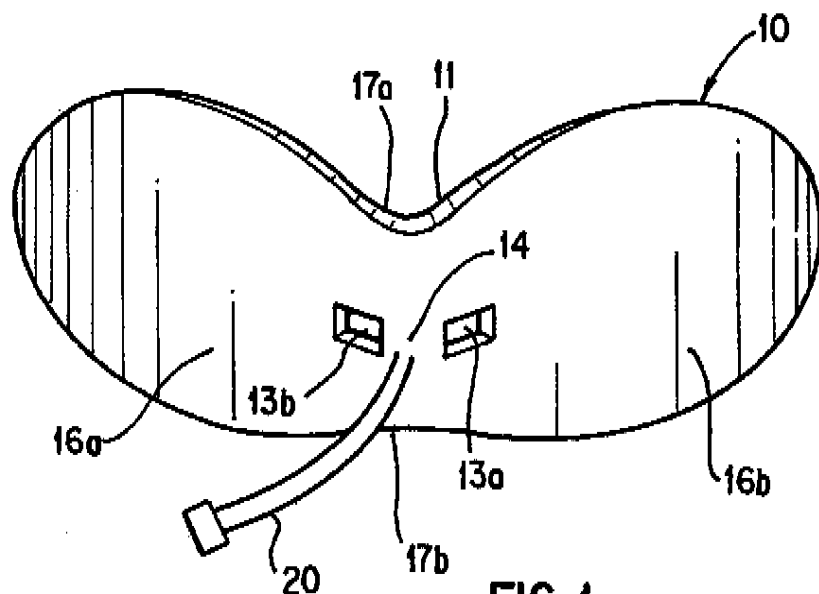


FIG. 1

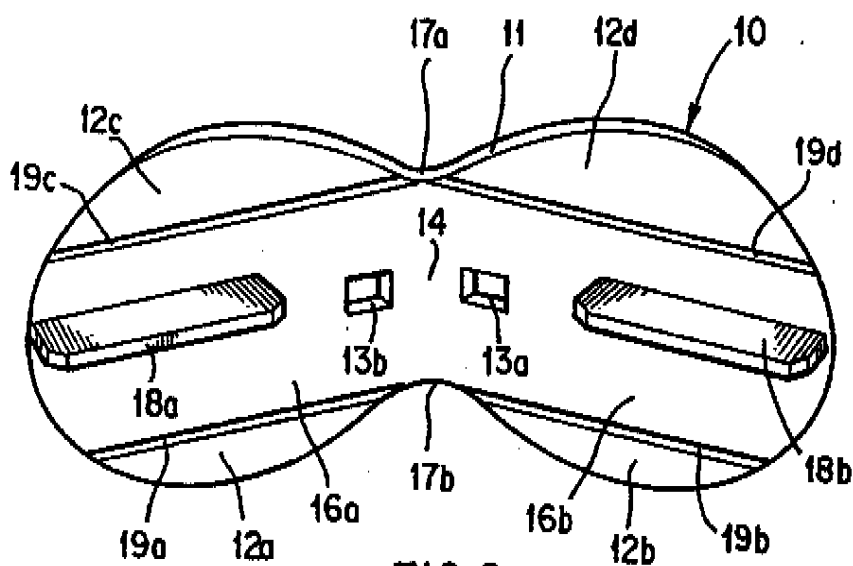


FIG. 2



FIG. 3

1

5,447,168

2

## MOUTHWARD

### BACKGROUND OF THE INVENTION

This invention relates to mouthguards and in particular to a new and improved mouthguard which is retained in position by the muscles of the lips and cheeks and produces no gag reflex. It is designed to fit comfortably over orthodontic appliances or to fit over the teeth naturally without orthodontic appliances of both maxillary and mandibular arches.

The prior art includes U.S. Pat. No. 2,590,118 to Oddo which discloses a mouthpiece having upper and lower channels for the teeth and pivotal front portions of the guard to permit opening of the mouth.

U.S. Pat. No. 4,114,614 to Kesling, discloses a mouthguard appliance comprising a pair of allochiral arch shaped members hinged together and made of a resilient material. The hinge permits folding of the arch shaped members together to retain the members in place on the arches. The teeth contact a plurality of ridges to hold the mouthguard in position.

The present patent discloses a device which is simple and comfortable and does not join across the rear of the mouth and includes an anterior aperture to facilitate breathing. The prior art patents do not disclose a similar structure.

### SUMMARY OF THE INVENTION

This invention relates to a new and improved mouthpiece, comprising a curved elongated frame member, having one or more anterior apertures in the central portion thereof and a central notch on the upper surface thereof. The mouthpiece frame further includes a first and a second outwardly projecting portion on the rear surface thereof, which can be grasped on both sides by the teeth to hold the mouthpiece in position. The mouthpiece as described protects one's teeth while eliminating the tendency to gag, which is a problem with most mouthguards. It also protects lips from impacting on the teeth or orthodontic appliances in the event of facial trauma. It further protects the temporomandibular joint (T.M.J.).

Accordingly, an object of this invention is to provide a new and improved flexible mouthguard.

Another object of this invention is to provide a new and improved flexible mouthguard which comprises a frame member which is held in position by the reflexes of the cheeks and lips against the teeth and includes outwardly projecting members which can be grasped on both sides by the teeth.

Another object of this invention is to provide flexible extensions of these buccal flanges via a stress relief groove (joint) so that these extensions can respond easily to the pressure of the muscles and lay comfortably in the buccal folds.

A further object of this invention is to provide a new and improved flexible mouthguard which is simple to use, inexpensive and readily used by the wearer since it is merely inserted into one's mouth and retained by the muscles and outwardly projecting portions which can be grasped by one's teeth without problems caused by the gagging reflex.

DESCRIPTION OF THE DRAWINGS The above and other objects and advantages of this invention may be more clearly seen when viewed in conjunction with the accompanying drawings wherein:

FIG. 1 is a front perspective view of the invention; FIG. 2 is a rear view of the invention with a curved frame element stretched out into a vertical plane; and FIG. 3 is a top view of the invention.

### DETAILED DESCRIPTION OF THE INVENTION

Referring now to the drawings, the invention comprises a mouthguard 10 having a curved frame member 11 which fits against the inside of the lips, cheeks and outside of teeth. The curvature is designed to accommodate the contour of the user's mouth. The mouthpiece includes two or more apertures 13a and 13b which facilitate breathing with the mouthpiece in place. In the drawings, a pair of rectangular apertures are shown with a portion 14 of the frame 11 separating the apertures. This arrangement provides additional strength although it is feasible to have a single aperture or a plurality of apertures to provide an opening for breathing. The frame member 11 basically includes two enlarged curved end members 15a and 16b which join at a central recessed slot 17a and 17b which is designed to provide additional comfort in using the mouthguard 10.

The rear portion of the mouthguard includes an inward extension 18a and 18b on each side of the apertures 13a and 13b. The extensions protrude inwardly at a right angle to from the rear of frame 11. The mouthguard 10 lays against the outer surface of the teeth which grasp both sides of the inwardly projecting elements 18a and 18b. This provides protection to the temporomandibular joint (TMJ) and posterior teeth against straight-on blows. The curved end members 16a and 16b have horizontally running flexible grooves (joints), which function as hinges 19a-d, which allow the muscles in the cheek to press the extensions 12a, 12b, 12c, 12d close to the bone for better retention and comfort. With the teeth engaged from both sides of the inwardly projecting elements the teeth are prevented from clashing together and the wearer is protected from TMJ. The mouthguard is retained by the muscles of the lips and cheek and causes no gag reflex and is simple, comfortable and protective.

The lengthwise horizontal grooves 19a, 19b, 19c, 19d on each side of the posterior extension provide flexibility particularly during insertion of the mouthguard 10. The flexible mouthguard is also normally in a curved position to permit ease of installation in the user's mouth. If desired, a helmet strap attachment 20 can be molded to the central portion 14 of the outer frame element, as shown schematically in FIG. 1.

The mouthguard protects the lips against impact trauma particularly on orthodontic appliances. The use of mouthguards with orthodontic appliances or braces is extremely difficult with the present designs. The mouthguard 10 also protects the teeth from trauma and clashing together or grinding and protects the TMJ from traumas due to a blow to the mandible.

While the invention has been explained by a detailed description of certain specific embodiments, it is understood that various modifications and substitutions can be made in any of them within the scope of the appended claims which are intended also to include equivalents of such embodiments.

What is claimed is:

1. A mouthguard for insertion into a wearer's mouth to protect fine wearer's teeth and temporomandibular joint from trauma, said mouthguard comprising:

a generally curved, flexible member including a central portion for protecting the wearer's anterior teeth and two, end members each extending rearwardly from said central portion for protecting the wearer's posterior teeth, said flexible member having a front surface adjacent the wearer's lips and cheeks, a rear surface adjacent the wearer's anterior and posterior teeth when the mouthguard is inserted into the wearer's mouth, and a thickness defined by the distance between the front and rear surfaces;

a first groove extending into one of said front and rear surfaces a predetermined depth less than the thickness of said flexible member, said groove defining a first hinge permitting flexing of a portion of the flexible member about said hinge to conform to the wearer's mouth; and

a pair of opposed, bite tabs projecting inwardly from said end members and adapted to be engaged by the wearer's posterior teeth.

2. A mouthguard in accordance with claim 1, wherein said first groove extends generally horizontally across the rear surface of the mouthguard when placed in the wearer's mouth, and said portion of the flexible member being flexible about said first hinge comprises a first outward extension of the flexible member disposed above said first hinge.

3. A mouthguard in accordance with claim 2, further comprising a second groove extending generally horizontally across and into another portion of said rear surface a predetermined depth less than the thickness of said flexible member, said second groove defining a second hinge permitting flexing of a second outward extension of said flexible member disposed below said second hinge.

4. A mouthguard in accordance with claim 3, wherein said bite tabs are located between said first groove and said second groove.

5. A mouthguard in accordance with claim 4, wherein said first groove extends across the entire longitudinal extent of said central portion and end members in a position segregating said first outward extension into two distinct upper extensions having an outer perimeter conforming to the upper portion of a wearer's mouth.

6. A mouthguard in accordance with claim 5, wherein said second groove extends across the entire longitudinal extent of said central portion and end member's in a position segregating said second outward extension into two distinct lower extensions having an outer perimeter conforming to the lower portion of the wearer's mouth.

7. A mouthguard in accordance with claim 6, wherein said mouthguard is generally symmetrical about longitudinal and vertical axes and the distance between the outer perimeter of the upper extensions and the outer perimeter of the lower extensions is at a minimum at the center of the mouthguard.

8. A mouthguard in accordance with claim 1, further comprising at least one aperture in said flexible member providing an opening to facilitate breathing.

9. A mouthguard in accordance with claim 8, wherein said at least one aperture is provided in said central portion of said flexible member.

10. A mouthguard in accordance with claim 9, wherein said at least one aperture comprises two symmetrically disposed apertures.

11. A mouthguard in accordance with claim 1, wherein the wearer's teeth include orthodontic braces and said first hinge permits flexing to conform to the wearer's mouth and protect the lips against impacting the braces.

12. A mouthguard in accordance with claim 1, further comprising a helmet strap attachment connected to said front surface of said flexible member.

13. A mouthguard for insertion into a wearer's mouth to protect the wearer's teeth and temporomandibular joint from trauma, comprising:

a curved flexible member adaptable into a substantially u-shaped profile having a front surface and a rear surface, wherein said member has a first side portion, a second side portion, and a central portion, said first and second side portions separated in a lateral direction from each other by said central portion;

an aperture extending through said central portion; a first bite tab projecting inwardly from said rear surface of said first side portion;

a first groove extending along said rear surface of said first side portion, to facilitate flexing of said member along said first groove to conform to the wearer's mouth;

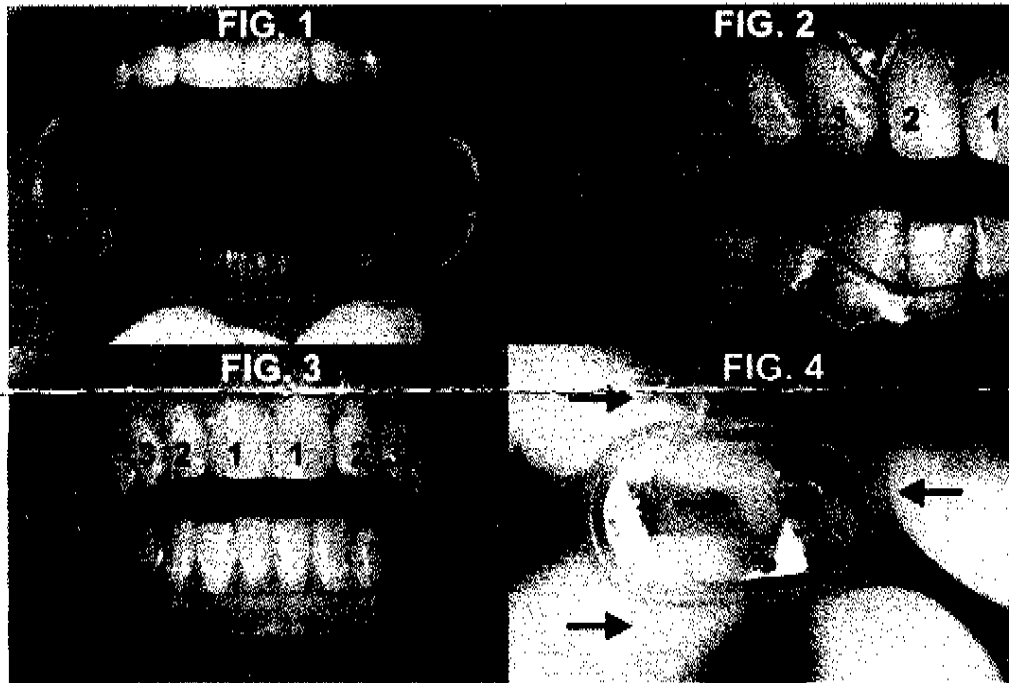
a second bite tab projecting inwardly from said rear surface of said second side portion; and

a second groove extending along said rear surface of said second side portion, to facilitate flexing of said member along said first groove to conform to the wearer's mouth.

14. A mouthguard in accordance with claim 13, wherein said first side portion further comprises a third groove extending across said rear surface of said first side portion and said second side portion further comprises a fourth groove extending across said rear surface of said second side portion.

15. A mouthguard in accordance with claim 14, wherein said first bite tab is located between said first groove and said third groove, and said second bite tab is located between said second groove and said fourth groove.

\* \* \* \* \*



CE Splintek  
Batch #N-1198-03  
EEA: Authorized Rep.



**CARE AND FITTING INSTRUCTIONS**

1. Use mouthwash or antibacterial soap with warm water for initial cleaning and lubrication of the EZ-splint™ adjustable feature. Rinse with warm water and avoid extreme temperatures.
2. Your EZ-splint™ has been preadjusted to fit most individuals. Try your EZ-splint™ and use a mirror to check the bitepad position (FIG.1,2).
3. The front edge of the bitepads should rest between the upper third tooth (cuspid) and fourth tooth (premolar) from the front midline providing solid posterior support (FIG.2,3).
4. The pinch and slide feature makes adjustments easy. Simply hold the bitepad firmly between your first finger and thumb, while **GENTLY PUSHING** the bitepad and strap together as shown. Never pull the bitepad against the strap always push the bitepad into the desired slot position. (FIG.4).
5. Rinse with warm water or mouthwash after each use. For thorough cleaning, use toothbrush and toothpaste. Always store EZ-splint™ wrapped around foam tray in case for shaping.

**ADJUSTMENT PERIOD**

- Your goal is to concentrate on lips together and teeth apart. You must become a participant in starting and managing the jaw muscle relaxation process.
- The "grind zone" was coined to explain how jaw muscles fall into regular and easily accessible clenching activity due to habit, stress relief, anatomy, etc.
- Your brain will immediately become aware of the EZ-splint™ bitepads between your teeth. The jaw muscles will react naturally by contracting to start a clenching or grinding cycle searching for a grind zone. This is normal.
- It is natural to experience jaw muscle fatigue, soreness, pain or even headache symptoms when uncontrolled jaw muscle activity builds tension in the grind zone. For bruxers a neuromuscular response is needed to break the clenching cycle and bring the jaw muscles out of their grind zone. When used consistently the EZ-splint™ resilient yet firm bitepads provide the necessary break in the muscle clenching cycle to disrupt the grind zone.
- Part of managing the jaw muscle relaxation process is fighting the natural urge to clench.
- Patients suffering from TMJ discomfort may experience immediate relief due to the instant unloading and protection of the joint.
- EZ-splint™ requires no boiling or mix and easily accommodates dental work and braces.
- Do not use over 12hrs continuously, or by children under 6yrs of age unless directed by a doctor.

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Splintek a division of PPI.



Liberty, Mo. 64068  
for technical support (816) 792-8TMJ



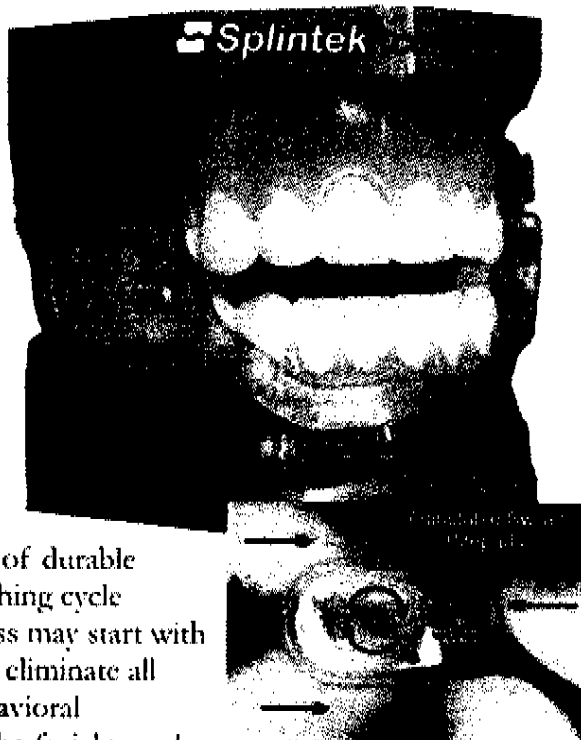
# EZ-Splint Information

- Adjustable night guard for the treatment of bruxism (teeth grinding) and TMJ (TemporoMandibular Joint) tension and headaches.
- EZ-Splint, used by professionals worldwide, yields successful treatment for thousands.
- EZ-Splint bitepads are guaranteed for six months and have a muscle deprogramming resilience.



## How Does it Work?

Bruxism is caused by excessive muscle activity. When placed between the teeth, EZ-Splint interrupts the clenching and grinding cycle. Most night guard materials tend to breakdown, stimulating excessive muscle activity. EZ-Splint bitepads, made of durable Kraton® material, provide a constant resilient break in the clenching cycle deprogramming the muscles. The muscle deprogramming process may start with muscle soreness. It is important to understand that no splint will eliminate all problems. The EZ-Splint will increase awareness. Through behavioral modification, the patient must make a conscious effort to relax the facial muscles.



## How Does it Fit?

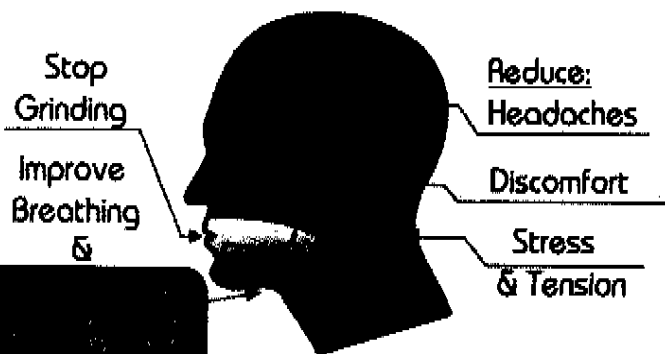
This appliance utilizes adjustable swivel bitepad technology to fit the arch of each individual. Bitepads can always be adjusted forward or backward to shorten or lengthen the fit of the appliance. If desired, this can change the space between your upper and lower teeth. The patented bitepads are manufactured with a dual injection process providing unparalleled durability. This technology begins by manufacturing a hardcore infrastructure, encapsulated by Kraton®, the firm bite surface developed to accommodate individual teeth. The U shaped arch of the appliance is made with a thermal sensitive strap which forms to the gum surface as worn. The U shaped arch is also smooth, soft and flexible. Because of its adaptability and comfort, it feels like one's natural anatomy.

## How Does it Stay in Place?

EZ-Splint was designed by a team of doctors along with years of research and clinical study to utilize ones natural anatomy, tissue retention (lips and cheeks), body temperature and even gravity to hold the appliance in place. When run under hot water the thermal strap will form easily to the mouth's shape. Refer to the dental model, notice the way the appliance wraps around the lower gum, takes on its form, and uses front and side facial tissue retention to aid in fitting. Within a few minutes anyone can quickly learn how to position the EZ-Splint making it very user friendly. Simply move the jaw, tongue or facial muscles.

## Important Statistics

Recent literature reports that research being done on bruxism has classified it as a sleep disorder. Up to 220,000,000 people (80%) of the US population have this disorder at some point. Only 80-110,000,000 (30% to 40%) people are actually aware they have this damaging nighttime disorder. Teeth grinding can cause tooth enamel loss and may cause irreversible damage to the TMJ. Always consult a professional with all TMJ concerns.



- **Reduces:** head neck and shoulder tension, myofacial tension, and headaches associated with teeth grinding and clenching jaw muscles
- Instantly unloads TMJ allowing relief and healing
- Used in some treatments of scoliosis
- Clinically proven to start treating bruxism immediately, effectively and safely

**Indicações Para La Dura e La Sistemazione Dell'Impressione**

1. Utilizzare un collutorio o un sapone antibatterico per la pulizia e la lubrificazione iniziale dell'apparato EZ-splintPM regolabile. Risciacquare con acqua calda evitando estreme temperature.
2. Il vostro EZ-splintPM è stato pre-regolato per adattarsi alla maggior parte degli individui. Provare il vostro EZ-splintPM e controllate allo specchio la posizione del cuscinetto. (FIG. 1, 2).
3. L'entità e l'angolo dei cuscinetti deve restare tra il terzo dente superiore (canino) e il quarto (premolare) della linea mediana superiore per fornire un solido supporto nell'area posteriore. (FIG. 2, 3).
4. La possibilità di comprimere e far scivolare facilmente la base di adattamento. Occorre semplicemente tenere saldo il cuscinetto tra il pollice e l'indice e contemporaneamente spingere leggermente il cuscinetto e la fascetta come mostrato. Non tirare mai il cuscinetto contro la fascetta, ma spingerlo sempre verso la posizione desiderata.
5. Risciacquare con acqua calda o collutorio dopo ogni utilizzo. Per una pulizia più accurata fare uso di spazzolino e dentifricio. Conservare sempre EZ-splintPM avvolto nel suo cuccio in gomma piena.

**Indicazioni Per l'Uso dell'EZ-splintPM**

1. Per abituarsi all'uso dell' EZ-splintPM, portatelo 1 ora prima di coricarvi.
2. Il vostro obiettivo è di concentrarvi in modo tale da sentire le labbra urite e i denti separati dalle stesse. Dovete orientare la parte attiva del processo di rilassamento dei muscoli masticatori.
3. La zona di diginamento è stata creata per spiegare in che modo i muscoli mandibolari tendono facilmente ad attivare una contrattura dovuta ad abitudini, stress, ansietà, ecc.
4. Il vostro bersivo diventa immediatamente consapevole della presenza del EZ-splintPM. I muscoli mandibolari reagiscono naturalmente contraindoss nel tentativo di ritrovare una posizione di diginamento. Ciò è del tutto normale.
5. E' naturale provare una certa fatica del muscolo mandibolare, irritazioni, dolori o sintoni di cefalalgia quando l'attività incontrollata dei muscoli mandibolari crea tensione nella zona di diginamento. Per i bruxisti occorre una risposta neuromuscolare per rompere il ciclo di diginamento e portare i muscoli mandibolare fuori dalla loro zona. Se usati costantemente gli EZ-splintPM aiutano a bloccare il ciclo di contrattura muscolare per sbloccare la zona di diginamento.
6. Il processo di rilassamento muscolare in parte e' in grado di bloccare il naturale istinto a contrarre i muscoli che soffrono di disturbi all'ATM possono provare subito sollievo grazie alla protezione ed all'immediato scarico dell'articolazione.
7. EZ-splintPM non richiede bollitura e può essere portato con gli attacchi ortodontici e le protesi dentali.
8. Avvertenze: Non utilizzare l'EZ-splintPM per più di 12 ore consecutive. I bambini con meno di 8 anni possono usarlo solo dietro prescrizione medica.

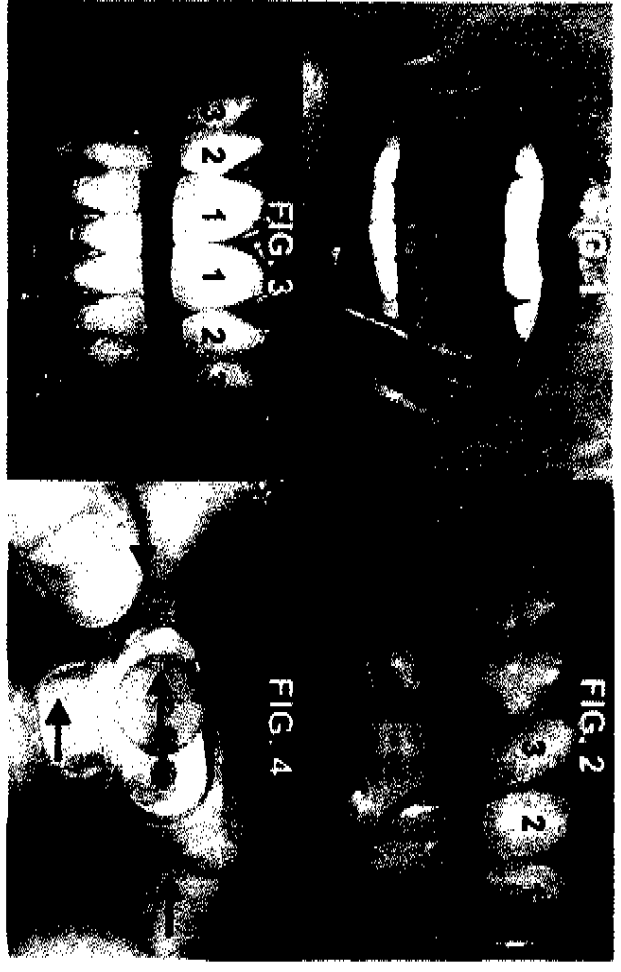
**EZ-Splint PM**

**Indicazioni Generali**

1. Usa antiseptico buccale ou sabão antibacterico com água morna para limpeza inicial e lubrificação do EZ-splintPM. Enxágue com água morna evitando que esfrie, muito quente.
2. Seu EZ-splintPM foi pré ajustado para se adaptar à maioria das pessoas. Coloque seu EZ-splintPM e use um espelho para verificar a posição da mordida de mordida (FIG. 1, 2).
3. As enteadades anteriores das almofadas de mordida devem se posicionar entre o terceiro e o quarto dente (pre-molar) superiores a partir da linha média, promovendo sólido apoio posterior (FIG. 2, 3).
4. Se houver necessidade de fazer um ajuste de posição da almofada de mordida, segure-a firmemente entre seu dedo indicador e o polegar enquanto empurra delicadamente a almofada e a peça juntas. Nunca puxe e almofada estranada a peça (FIG. 4).
5. Enxágue com água morna ou antiseptico buccal após cada uso. Para uma limpeza mais profunda use creme e escova dental. Guarde sempre seu EZ-splintPM em sua caixa com suporte apropriado, guardando seu formato.

**Preceda o uso diário**

1. Para se acostumar ao seu EZ-splintPM, comece a usá-lo 1 hora antes de dormir.
2. Sua meta é concentrar-se em deixar os lábios juntos e os dentes separados. Você deve tornar-se um participante no processo de relaxamento muscular.
3. A denominada "zona de trituração" é um termo criado para explicar como os músculos da mandíbula entram em regular e facilmente acessível atividade de apertamento devido ao hábito, para alívio do stress, por causa da anatomia, etc.
4. Seu cérebro imediatamente perceberá a presença das almofadas do EZ-splintPM entre seus dentes e os músculos da mandíbula naturalmente se contrairão para iniciar o ciclo de apertamento ou trituração, procurando a "zona de trituração". Isto é normal.
5. E' natural experimentar uma fadiga dos músculos da mandíbula sensação de dor local, dor de cabeça, quando a atividade descontrolada da musculatura mandibular provoca tensão na "zona de trituração". Usado de forma consistente, as estruturas podem firmes amortadas de mordida do EZ-splintPM interrompem o ciclo de apertamento dental, promovendo a resposta neuromuscular necessária para levar os músculos da mandíbula para fora da "zona de trituração", o que é necessário no tratamento das pessoas com bruxismo.
6. Parte do processo para promover o relaxamento da musculatura mandibular consiste em romper o hábito de apertar.
7. Pacientes que sofrem de desconforto da ATM podem experimentar um imediato bem estar devido ao instintivo alívio e proteção da articulação.
8. EZ-splintPM não requer qualquer aquecimento físico ou mistura, acomodando-se ao tratamento ortodôntico por dentes ou dentes livres para movimentação.
9. Não use o EZ-splintPM por mais de 12 horas seguidas. Crianças menores de 8 anos também não devem usá-lo, a não ser com explicata recomendação.



Splintek  
Borch #14-06-01  
EZA: Authorized Rep.



**CARE AND FITTING INSTRUCTIONS**

1. Use mouthwash or antibacterial soap with warm water for initial cleaning and lubrication of the EZ-splintPM adjustable feature. Rinse with warm water and avoid extreme temperatures.
2. Your EZ-splintPM has been preadjusted to fit most individuals. Try your EZ-splintPM and use a mirror to check the bitted position (FIG. 1, 2).
3. The front edge of the bitpads should rest between the upper third tooth (cuspid) and fourth tooth (premolars) from the front middle providing solid posterior support (FIG. 2, 3).
4. The pinch and slide feature makes adjustments easy. Simply hold the bitpad firmly between your first finger and thumb, while GENTLY PUSHING the bitpad and strap together as shown. Never pull the bitpad against the strap always push the bitpad into the desired slot position. (FIG. 4).
5. Rinse with warm water or mouthwash after each use. For thorough cleaning, use toothbrush and toothpaste. Always store EZ-splintPM as it was shipped, in the case around the foam tray.

**ADJUSTMENT PERIOD**

1. To become accustomed to the new feeling of your EZ-splintPM, begin wearing 1 hour before sleep.
2. Your goal is to concentrate on lips together and teeth apart. You must become a participant in starting and managing the jaw muscle relaxation process.
3. The "grind zone" was coined to explain how jaw muscles fall into regular and easily accessible clenching activity due to habit, stress, relief, anatomy, etc.
4. Your brain will immediately become aware of the EZ-splintPM bitpads between your teeth. The jaw muscles will react naturally by contracting to start a clenching or grinding cycle searching for a grind zone. This is normal.
5. It is natural to experience jaw muscle fatigue, soreness, pain or even headache symptoms when uncontrolled jaw muscle activity builds tension in the grind zone. For bruxers a neuromuscular response is needed to break the clenching cycle and bring the jaw muscles out of their grind zone. When used consistently the EZ-splintPM resilient yet firm bitpads provide the necessary break in the muscle clenching cycle to disrupt the grind zone.
6. Part of managing the jaw muscle relaxation process is fighting the natural urge to clench. Patients suffering from TMJ discomfort may experience immediate relief due to the instant unloading and protection of the joint.
7. EZ-splintPM requires no boiling or mix and easily accommodates dental work and braces. Do not use over 12hrs continuously, or by children under 8yrs of age unless directed by a doctor.



Kansas City, MO 64111  
for technical support (816) 531-1500

Eliminate the detrimental effects of teeth grinding with our night guard

# SleepRight<sup>®</sup>

## Adjustable Night Guard

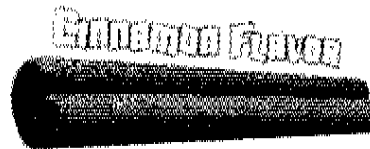
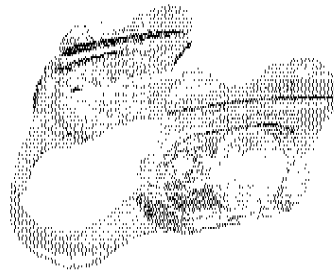


Splintek's Philosophy  
30-Day Money Back Guarantee!

Orders placed after 1pm CST for products listed below, will be shipped out the next business day. Orders placed Friday after 1pm CST, Saturday, or Sunday will be shipped the following Monday, despite the chosen shipping method.

If you are ordering online and would like your purchase to be shipped **outside of the United States**, you must choose the Express Mail shipping option. Please provide your email address in case problems with shipping occur.

**SleepRight System:** When you purchase both the SleepRight Night Guard and a SleepRight Side Sleeping Pillow, you get a discount on the pillow. Purchase a night guard and a 16" pillow for \$99.95, or a night guard and a 24" pillow for \$119.95. You must call and place your order to get this discount, 1-888-792-0865. All sales are final on the SleepRight Side Sleeping Pillow.



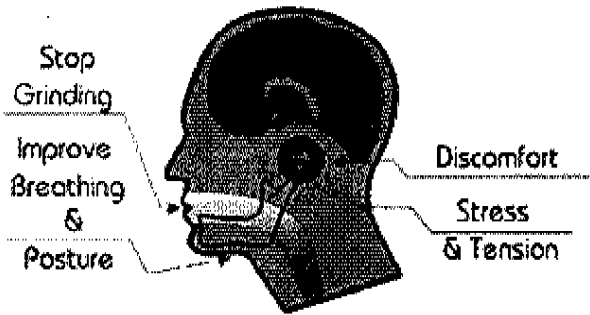
**Adjustable night guard.**  
**\$69.95**

Select Flavor

### What is the SleepRight Night Guard?

The SleepRight Adjustable Night Guard was designed by a specialist in dentistry and has been used by thousands of doctors worldwide. The SleepRight Night Guard's state-of-the-art technology is designed specifically to protect teeth from clenching and grinding. Studies have reported that chronic jaw clenching and grinding have been associated with head, neck, and back tension.



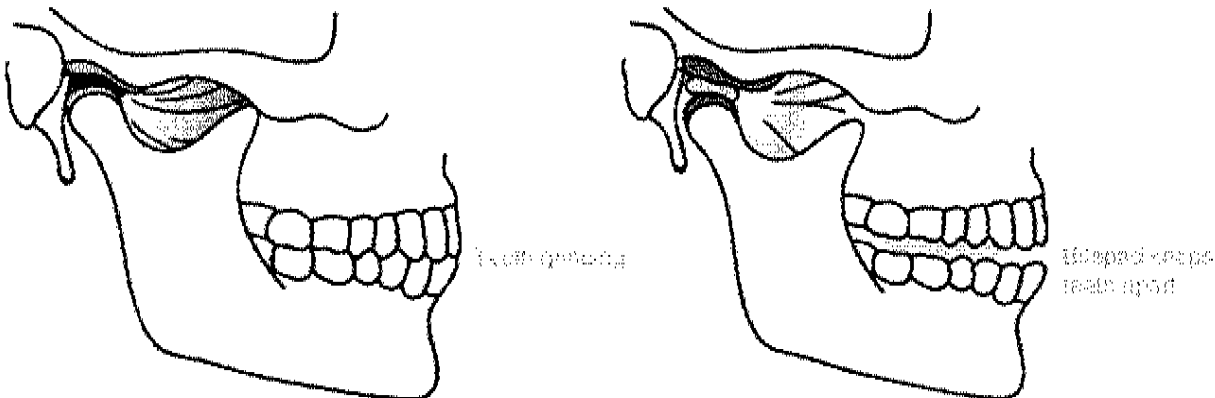


**Benefits of using the SleepRight Night Guard**

- No boiling required
- Protects teeth and dental work from damage caused by clenching and grinding
- Easy to fit in seconds using the provided care and fitting instructions
- Economically priced compared to night guards from health care professionals
- Can also be worn for performance enhancement during non-contact sporting activities where the natural tendency to clench and grind the teeth may occur, such as: golf, weightlifting, tennis, cycling, bowling, archery, skeet shooting, etc.
- Does not contain latex or silicone and is hypoallergenic.

**How does the SleepRight night guard work?**

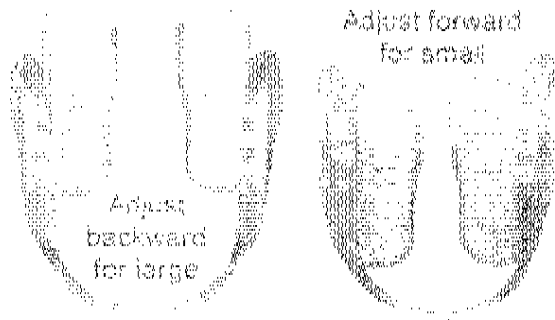
Clenching and grinding teeth has been classified as a neuromuscular disorder. Overactive muscles can cause chipping, fractures, excessive wear and loosening of the teeth. Some studies report that stress to the head and neck system, causing muscle tension and pain in the jaw joints, may be related to chronic jaw clenching and grinding. The SleepRight's articulating bitepads, made of a hybrid resilient material, slip comfortably between your teeth and are designed to re-establish your natural freeway space. While the SleepRight protects teeth from clenching and grinding, we emphasize and strongly encourage our customers to concentrate on, "lips together, teeth apart" to initiate the muscle relaxation learning process. Muscles at ease, will allow the teeth to rest on the bitepads. Do not bite down, although the natural urge to do so will test your mental approach to this learning process.



**How does the SleepRight night guard fit?**

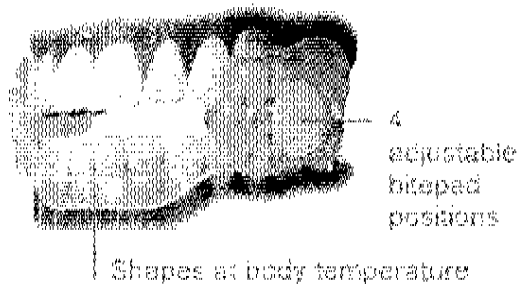
Detailed pictures are included with easy to follow care and fitting instructions. With SleepRight's patented adjustable technology, you have four bitepad positions, making it easy to customize the size to fit most people. The thermal sensitive strap, which is positioned between your lower lip and teeth, will adapt to your gums when heated under hot water. Do not boil the SleepRight night guard.





### How does the SleepRight night guard stay in place?

The SleepRight night guard utilizes natural tissue retention between your lips, cheek, and tongue to be held in place. There are no clasps that attach to the teeth and you do not use the teeth to hold the appliance in place. While the bitepads are made of a tough and resilient material, the heat sensitive memory strap is smooth, soft, and flexible. This enhances the adaptation to each individual's anatomy.



### Can I wear the SleepRight during the day?

Yes! In fact, we encourage our customers to wear it when they are not sleeping, especially during the initial adjustment period. You are at your best to change a bad habit while awake and in the conscious state of mind. Clenching and grinding teeth can occur at any time, especially during stressful situations at school, in sports, on the job or on the go, such as lengthy computer work, driving a car or routine chores around the house.

### What if I have a small mouth?

For those with a small mouth or sensitive gums, Splintek has designed a Low-Profile SleepRight. Except for the smaller, streamlined version of the wings on the sides, it is identical to the Standard SleepRight. It can also be worn during the day.

### Can the SleepRight night guard help reduce snoring?

The SleepRight night guard was not designed to reduce snoring.

### Do I need to boil the SleepRight night guard?

No, there is no boiling involved in fitting the SleepRight. The SleepRight night guard is different from all other night guards because it utilizes adjustable technology. Simply slide the bitepads forward or backwards to get the appropriate fit.

### How do I clean the SleepRight night guard?

You can clean the SleepRight night guard with a toothbrush and toothpaste or with mouthwash. The SleepRight comes in a convenient storage case.

Eliminate the detrimental effects of teeth grinding with our night guard



For more information about the Low-Profile SleepRight click here.

*Do not use for more than 12 hours in a 24 hour period. Not for children under 12 years of age. Discontinue use and replace if breakage occurs. For all TMJ concerns consult a professional.*