

# The Next Generation Mouthguard

## Finally: A Custom Fit Boil-and-Bite Mouthguard Without the Need of a Dentist Impression

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CustMbite

### Summary

This article introduces the latest mouthguard material innovation – the CustMbite MVP – which offers all the positive features of a custom-fabricated mouthguard in a boil-and bite format. Athletes can now fit their own mouthguard – *without the assistance of a dentist* – which will give a precise, comfortable fit with no impairment of speech or breathing and the much needed protection to the teeth, jaws and cranial structures. The CustMbite mouthguard is made from the “new to the world” Vistamaxx™ family of polyolefin elastomers manufactured by ExxonMobil Chemical. The material is biocompatible, hydrophobic and exhibits step-out properties and performance superior to the currently used boil-and-bite ethylene-vinyl acetate (EVA) copolymers. The CustMbite mouthguard has excellent retention with an exceptionally soft feel, is odorless, tasteless and has good shock absorbing/dissipative properties and sufficient thickness protection in all areas. The mouthguard can be fitted using the conventional boiling water or microwave. The same positive features can be seen with fixed Orthodontic appliances.

**Keywords:** boil-and-bite mouthguard, custom-fabricated mouthguard

### Introduction

The material of choice for manufacturing mouthguards over the last 50 years has been ethylene-vinyl acetate copolymers (EVA) [1]. While the mechanical and physical properties of EVA generally fulfill the safety requirements for a custom-fabricated mouthguard [2], attempts to mass-produce EVA as a boil-and-bite, “fit-it-yourself” mouthguard have had limited success and acceptance [3]. Elkin has witnessed athletes shockingly cutting the posterior part of their mouthguards for comfort and relief. These mouthguards do not fit well and their poor retention and lack of proper extension into the buccal vestibule have led Park, *et al* to state [4]: “...unless dramatic improvements are made, they should not be promoted to customers as they are now.”

Currently, commercially available EVA mouthguards are classified as [5]:

- Type I: Stock mouthguards – one size fits all! They must be held in place by clenching the teeth together.
- Type II: Mouth formed boil-and-bite mouthguards. They are made from pre-formed EVA.

The Type I mouthguard is inexpensive and ready-made but little can be done to adjust their fit. It is bulky and makes breathing and talking difficult.

The Type II boil-and-bite mouthguard is softened in boiling water and shaped around the teeth using finger and biting pressure. However, when athletes attempt to fit these mouthguards, the resulting fit is often inadequate, loose, and uncomfortable. These mouthguards often lack proper thickness, especially in the occlusal area, due to an excessive biting down during the form-fitting.

Tremendous progress has been made in engineering the boil-and bite EVA mouthguard for better fit, comfort and protection. This includes sophisticated multilayer composites with a different softening temperature [6], custom gel fit liner [7], grip fit technology [8], OPROfin™ retention system [9], or blending EVA with various polymers such as Kraton [9] and polyurethane [10]. Despite these tremendous efforts, a properly fitted boil-and-bite mouthguard is still difficult to achieve and many athletic trainers and sports participants still prefer the custom-fabricated mouthguards (Type III), i.e. from dentist-made stone casts of the athlete’s upper dental arches. They are comfortable, fit better with good retention and allow the user to breathe and speak easily [3]

This paper introduces an alternative material to EVA. This novel material combines the simplicity and low cost of a boil-and-bite with the comfort, snug fit and protection of a custom-fabricated mouthguard without the high cost and time consuming visits to the dentist.

## Limitations of EVA as “boil and bite” mouthguard

From a material perspective, the *main limitation* of EVA when used as a boil-and-bite mouthguard is its *fast crystallization* – this is an intrinsic property of EVA one has to live with. The mouthguard is softened in boiling water and cooled to a workable temperature of around 60°C (140° F) – this is the maximum temperature the mouth can tolerate. Unfortunately, once this temperature is reached, the material (28% vinyl acetate) hardens and stiffens within seconds giving the user *absolutely* no time to fit the mouthguard.

Furthermore there are two major disadvantages of very quick crystallization: (i) the inability of the mouthguard to shrink; (ii) heated mouthguards become limp and completely lose their shape upon heating [12]. Note that these limitations are irrelevant in a custom fabricated mouthguard because the dentist can work at a high temperature to keep the material soft as he/she molds the mouthguard over the study cast. These mouthguards have a snug, comfortable fit that allows the device to stay on the upper teeth when the wearer’s mouth is open. The dentist can also control the thickness by laminating two or three layers of EVA material [13].

For a boil-and-bite mouthguard to achieve the same level of fit/comfort as a custom-made one, the time-temperature-softness (TTS) window must be widened. This is a very demanding material property that is definitely *outside the property range* of EVA and new materials must be developed. Briefly, the next generation of material must (i) give the user ample time – two to three minutes – to properly fit the mouthguard at a workable temperature below 60°C, during which the material must remain soft and elastic/extensible to conform the contour of dentition; (ii) shrink without any distortion once the mouthguard is comfortably in place; and (iii) possess a good balance of hardness, soft feel and shock absorbing power.

Cook recently introduced a promising low-density polyethylene [14]. These materials, however, exhibit similar TTS as EVA because the major component of the material – polyethylene – is similar to EVA.

With the recent development in the field of metallocene catalyst and polymerization reactor technologies [15], it is now possible to develop and design alternative polyolefins with controlled microstructure that will widen the TTS window.

## The CustMbite MVP Mouthguard: Combining boil-and-bite simplicity with custom-fabricated efficacy

The CustMbite MVP mouthguard is made from a novel specialty polyolefin elastomer called Vistamaxx™, which is manufactured by ExxonMobil Chemical. Vistamaxx™ is a semicrystalline *all polyolefin* propylene -ethylene copolymer (PEC) [15], the majority component – more than 80% – being *isotactic* polypropylene. The unique properties of these polymers are derived from the controlled level of the propylene crystallinity, enabled by the Exxpol® metallocene catalyst technology which provides 3 to 30 percent crystallinity[14]. Vistamaxx™ offers unique balance of elasticity, softness, toughness, flexibility and durability superior to the current EVA mouthguard material. Table 1 displays the characteristics and physical property range of Vistamaxx™– data provided by Exxon – with the most commercially available mouthguard material, EVA 18-28% vinyl acetate. The data on EVA are compiled from published literature [16]. It is clear from the table that Vistamaxx™ and EVA exhibit similar physical and mechanical properties. The main difference between the two materials is their rate of crystallization - or fitting time, i.e. the time interval before the material stiffens at body temperature. EVA hardens and sets within 10 to 20 seconds; *this is the main reason why EVA does not work as a boil-and-bite mouthguard*. Any attempt to fit the mouthguard within this time interval usually results in an ill-fitted mouthguard with poor retention.

The slow crystallization of Vistamaxx™ – 2 to 3 minutes – has several advantages:

- There is no need to rush to fit the mouthguard
- During this time interval, the material remains soft/extensible and easily mold to the contour of the mouth
- The slow crystallization allows the mouthguard to shrink naturally, giving a snug fit with excellent retention to the teeth and jaw within 5 minutes
- The mouthguard does not collapse or lose its shape during heating. (quasi-equilibrium crystallization)

Table I. Physical and mechanical property range of Vistamaxx™ and EVA (18-28 wt% vinyl acetate)

<b>Characteristics and Physical Properties</b>	<b>CustMbite Mouthguard Vistamaxx™</b>	<b>Standard Mouthguard EVA (18-28% Vinyl acetate)</b>
Biocompatibility	Yes	Yes
Water sorption (wt%)	No water sorption (hydrophobic)	< 0.3 wt%
Density, g/cm <sup>3</sup>	0.86-0.89	0.80-0.95
Melting Point (°C)	55-100	60-80
Hardness (Shore A)	50 -90	70-90
Tensile Strength (MPa)	15-30	13-27
Die C Tear Strength (kN/m)	30-50	30-50
Elongation at Break (%)	100-1500	200-1000
Impact strength (J) (ASTM D3763)	5-20	5-20
Impact reduction (%)	5- 50	5-50
Flexural Modulus (MPa)	10 - 40	9-30
Fitting time	2 - 3 minutes	10 - 20 seconds
Shrinkage to teeth	Excellent	Poor

The mouthguard is pre-formed by injection molding using the following recommended specifications [17]: labial thickness of 3 mm, palatal thickness of 2 mm, and occlusal thickness of 4 mm. The mouthguards may be colored with various bright, clean, transparent colors – red, green, blue, yellow, smoke for aesthetic.

### **Fitting the CustMbite MVP Mouthguard in Boiling water or microwave**

The working time to fit the mouthguard is about 2 minutes as compared to the 20 seconds with currently available boil-and-bite products. *There is therefore no need to rush to carry out the following simple procedure:*

#### **Boiled Water**

What you need: pot, bowl of cold tap water, slotted spoon/fork, heater/gas or electric stove.

1. Fill a 4-6” pot with approximately 3” of water. Let the water come to a rolling boil. If using a gas stove, simply turn the heat off, if using an electric stove, turn the heat off and remove the pot from the heat source. Have a bowl of cold tap water nearby.
2. Place the MVP face down in the boiled water for 15 seconds.
3. Remove the mouthguard from water with a slotted spoon and dip into the cold water for 3 seconds.
4. Carefully place the mouthguard in the mouth, lining up the mouthguard with the centerline of the upper teeth. **Do not bite** the mouthguard into place.
5. Close your mouth and gently suck on the mouthguard until it has molded into the shape of your upper teeth. In 45 seconds to one minute, you should be able to open your mouth and the mouthguard should remain securely in place. Leave in your mouth for 2 additional minutes. You may then continue to leave the mouthguard in your mouth or remove it and leave in the cold water. In 5 minutes you will have a final snug fit comparable to a dentist-office custom made mouthguard.

#### **Microwave**

What you need: Microwave on the highest setting, bowl of cold tap water, large paper towel, slotted spoon/fork.

1. Wrap the MVP in a wet paper towel. Have a bowl of cold tap water nearby.
2. Place the wrapped mouthguard in a microwave on high setting for 1 minute – be careful because the paper towel will get hot. Do not remove the mouthguard with your hands.

3. Remove the MVP with a slotted spoon and cool it – still wrapped in the paper towel – in the cold water for 3 seconds.
4. Unwrap the MVP from the paper towel.
5. Carefully place the mouthguard in the mouth, lining up the mouthguard with the centerline of the upper teeth. **Do not bite** the mouthguard into place.
6. Close your mouth and gently suck on the mouthguard until it has molded to the shape of your upper teeth. In 45 seconds to one minute you should be able to open your mouth and the mouthguard should remain securely in place. Leave in your mouth for 2 additional minutes. You may then continue to leave the mouthguard in your mouth or remove it and leave in the cold water. In 5 minutes you will have a final snug fit comparable to a dentist-office custom made mouthguard.

If fitting over orthodontic braces, follow the same directions as above.

Since biting is not necessary during the fitting, there is no thinning of the material in the area of the occlusal pad – the most critical area. The posterior thickness will vary from 3 to 4 millimeters after the final fitting.

## Discussion

As participation in sports continues to gain popularity and intensity, dental injuries on the athletic fields are alarmingly increasing [18]. Experts in the medical, dental and sports professions are recommending the custom-fitted mouthguard as the best choice for fit and protection [3]. Unfortunately, cost and time prohibit their mass production and there are definitely not enough dentists to meet the needs of the millions of mouthguards that would be required. It is therefore imperative to have an over-the-counter true mouth-formed mouthguard comparable to a custom-fabricated guard. We believe that the CustMbite MVP mouthguard achieves this goal. The ease of fitting and the low cost of the mouthguard now make it possible to recommend/mandate the use of mouthguards in many other sports [19]. Currently, the American Dental Association and the International Academy of Sports Dentistry recommend mouthguards for the following sports:

Football	Basketball	Rugby
Soccer	Volleyball	Equestrian
Martial Arts	Softball/Baseball	Track and Field
Ice Hockey	Field Hockey	Inline Skating
Lacrosse	Weight Lifting	Racquetball
Boxing	Gymnastics	Water Polo

## Conclusion

The CustMbite mouthguard offers all the positive features of a custom-made study cast mouthguard in a boil-and-bite format. We are well aware that the actual performance of a mouthguard not only depends on the material properties but also on the design parameter such as thickness and shock absorbing/dissipating properties. These require a delicate balance between thickness and elastic modulus to absorb and spread the impact energy. These studies are in progress.

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