



## OUR LOCATION



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# STOP SNORING WITH SLEEP PRO

*A complete range of stop snoring solutions*



## The Company Profile & History

Sleep Pro Ltd is a leader in the design, development and manufacture of affordable mandibular advancement splints to help control snoring and treat sleep apnea.

All SleepPro devices are manufactured in the UK to strictly controlled medical standards. We distribute through our specialist operations across Europe, North America, Australasia and Asia. With multiple stock locations we are able to service requests efficiently and effectively around the globe.

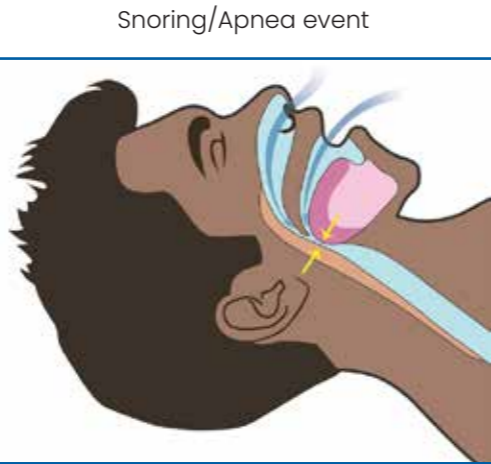
We believe mandibular advancement splints have an important role to play in treating a range of sleep disorders. Through the SleepPro brand, we have been working successfully with the professionals since 1998 to help to prevent snoring, bruxism and mild to moderate obstructive sleep apnoea – which continues to be a growing problem.

In Britain SleepPro products are recommended by many of the NHS and private hospitals who have specific treatment programs in sleep medicine and snoring. Globally our SleepPro range has been recognized as being a very cost effective first line choice in the treatment of specific respiratory conditions by professionals in medical centers, general practices, dental clinics, pharmacies, hospitals and many specialist centers that deal with snoring and other sleep disorders. Every year, tens of thousands of people benefit from the help of our products thanks to our global distribution networks.

# Snoring and Obstructive Sleep Apnoea

## Causes and Effects on Health

During sleep the throat and tongue relax and the structure that would normally be held taught and smooth become compresses, kinked and effectively reduce the size of the windpipe. Air passing through the restricted airways becomes turbulent causing vibration which creates the very familiar sound of snoring.



Airways is restricted



Once thought to be just a nuisance, research is now linking snoring to several serious medical conditions and the sound should now be seen as a warning which should initiate further investigation.

One of the most common and serious conditions that is associated with snoring is Sleep Apnea, this is where the airway is completely obstructed and there is a cessation of breathing. The accumulative effects of which can be life threatening!

### Untreated Sleep Apnea Multiple Risk

#### Prevalence:

- 20 million in the U.S.
- Children 1-2%
- Male: 24%
- Female: 9% (menopause)
- Elderly: 20%
- 40% of Americans go undiagnosed



#### Risks if untreated:

- Stroke – 4x more likely
- Heart disease – 4x more likely
- 3% risk of heart attack and stroke
- 50% have hypertension
- 38,000 deaths/yr

# So What Can Aggravate Snoring/Apnea

## Age

As you reach middle age and beyond, your throat becomes narrower, and the muscle tone in your throat decreases.



## Sleep Posture

Sleeping flat on your back causes the flesh of your throat to relax and block the airway.

## Allergic Rhinitis

A condition where the inside of the nose becomes swollen and inflamed due to an allergic reaction to substances such as dust or pollen.



## Alcohol, Smoking & Medicine

Alcohol intake, smoking, and certain medications can increase muscle relaxation leading to more snoring.

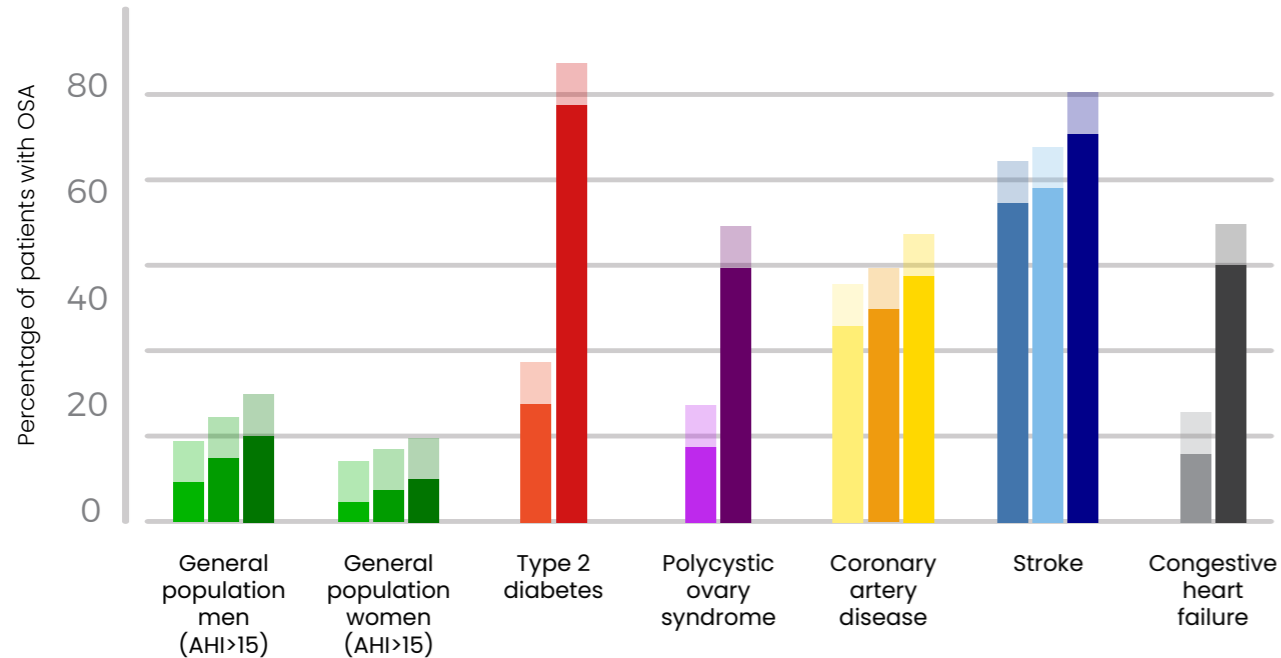
## Being Overweight or Out of Shape

Fatty tissue and poor muscle tone contribute to snoring.



### the way you're built..

Men have narrower air passages than women and are more likely to snore. A narrow throat, a cleft palate, enlarged adenoids, and other physical attributes that contribute to snoring are often hereditary.



**Figure 1.**

The prevalence of OSA (defined as either AHI  $\geq$  10 or 15) in various medical disorders. Compared to three population-based prevalence studies [20–23], patients with Type 2 diabetes [68,69], polycystic ovary syndrome [70,72], coronary artery disease [74–76], congestive heart failure [77–79], and stroke [80–82] have a much higher prevalence of OSA. Each bar in the figure represents an individual study.

## The Global Problem

The incidence of both snoring and sleep apnoea is increasing rapidly, mostly due to lifestyle factors such as alcohol, smoking and weight gain and this has resulted in major expansions of activity across the globe to combat the problem.

More and more evidence is being revealed on the severity of the problem and this will hopefully stimulate even further activity by health authorities, and the individual themselves to take simple steps towards reduction or elimination of the dangers.

It is a particular problem in the emergent economies, such as in the BRICS group of nations where awareness of these dangers is low as yet, but beginning to rise.

### Recent Research Findings In Europe, Australia And The U.S.A

A study published in June 2013, in the journal of the American College of Cardiology, found that in people (mean age=53 years) with severe obstructive sleep apnoea occurring more than 20 times per hour, there was a 60% increase in the risk of sudden cardiac death during sleep. In people with more than 20 episodes per hour, there was an 81% increase in risk, compared to those without apnoea.



## The Rising Cost Of Sleep Apnoea To Health Services

The global statistics say that the cost of untreated sleep apnoea reaches beyond just health issues. It is estimated that the average untreated Sleep Apnoea patient's health care costs \$1,336 more than that of an individual without Sleep Apnoea.

If current approximations are correct, there are over millions of untreated individuals who account for billions in health care costs a cost that could be much reduced if simple and inexpensive prevention steps are taken. Snoring is also the third most important contributory factor in marriage breakdown. Sleeping apart often happens as a result of the noise levels and erectile dysfunction is common in men.

**\$ 1,336**

The average untreated Sleep Apnoea patient's health care cost

## The Rising Cost Of Sleep Apnoea To Health Services

According to the report, one of the main drivers of this market is the high prevalence of sleep Apnoea disorders across the globe in adults and children, and the associated conditions such as hypertension, stroke, Type 2 diabetes or adult onset diabetes, weight gain, impotence and cardiovascular diseases.

Apnoea To Health Services the recently published report on the global sleep Apnoea Diagnostics and therapeutic Devices Market forecasts the overall market to grow at an annual average rate of 16.37 percent over the period up to 2017. The report covers the market in the Americas, the Middle East plus the Asia Pacific regions the report describes it as a 'Global Epidemic'.

**\$ 19,7 billion**

Value of the global Sleep Apnoea devices market in 2017

## Global Sleep Apnea Devices Market By Region



### Asia

Numerous studies have suggested that Asians are already more likely to have the disorder than Caucasians because of facial structures that result in smaller upper airways. One 2011 study published in the journal 'Sleep and Breathing' found that nearly 70 percent of Asian subjects had some form of sleep apnoea. Fatty tissue in the throat brought on by weight gain can bring on or can exacerbate the condition.

Changing eating habits in China have brought new health problems to the world's most populous nation, as the country's economic boom allowed millions of Chinese to add more meat and processed foods into their diets.

The combined rate of overweight and obese Chinese has increased by 54 percent from 2002, while the obesity rate alone has increased 208 percent over the same time. About 78 percent of U.S. adults meet the same standard of overweight or obese, according to WHO figures, with 46.2 percent having a BMI of 30 or greater.

The increased demand for sleep apnoea treatments can be traced to greater awareness of the problem and access to treatment. Doctors note that the increasing number of obese have led to corresponding higher cases of sleep apnoea. Millions of Chinese with sleep apnoea may not recognize that they have the disorder, doctors said, which makes accurate incidence reports hard to come by.

Studies generally show that at least five percent of the population in industrialized countries have some form of sleep apnoea, but it is thought to be more in China. If only 53, that translates into at least 70 million cases, he said. Nearly 20 percent of the U.S. population may have at least a mild form of sleep apnoea as a result of obesity, he noted. The true extent of the problem in China may not be known because relatively few doctors or patients are familiar with the disorder, it is the young who are most at risk of sleep apnoea due to high obesity levels.

Source: Reuters CHINA

# The treatment options available for snoring & sleep apnoea

There are many "treatments" offered on-line or over the counter, to date there are only 3 well established clinically proven methods to treat sleep apnea and snoring

## CPAP

There are several types of sleep therapy machines, but a CPAP (Continuous Positive Airways Pressure) machine is the most common. A CPAP machine a constant flow of airway pressure to the throat to ensure the airways stays open during sleep, effectively treating the spontaneous pauses in breath associated with sleep apnea. Recognized as the "gold standard" in sleep apnea treatment but has patient compliance issues



## Surgery

There are many surgical options for treatment sleep apnea, depending on how severe your sleep apnea is an your overall health. Radio frequency volumetric tissue reduction, Uvulopalatopharyngoplasty, Maxillomandibular advancement are just a few of the procedures available as with all surgical procedures there are inherent risks and outcomes are not guaranteed.

## MAD's

A mandibular repositioning appliance is a dental appliance, similar to a gum shield, which is worn in your mouth while you sleep. it is also known as mandibular advancement splint, mandibular advancement device, oral appliance or dental device. Wearing the device holds the airway open whilst you are sleeping, so that breathing becomes easier and oxygen levels in the blood are normalised.



	Easifit	Gel Fit	Contour	Custom	Custom Adjustable
Airway Aperture	120 sq mm	130 sq mm	140 sq mm	Custom	Custom
Polymer Construction	Monoblock	Dual Polymer	Dual Polymer	Monoblock	Dual Polymer
Adjustment	RE adapt	RE adapt	Adjustable straps	Fixed	Adjustable straps
Self Fit	✓	✓	✓	—	—
Fit Index	6	7	7	10	10
Suggested Replacement Period	6-12 months	6-12 months	9-15 months	12-18 months	12-18 months
Clinical Trial Data	✓	—	—	✓	—
Years in Market	20	4	6	20	10
GTIN	5060251570009	5060251570092	5060251570016	5060251570023	5060251570337
Annual Production Capacity	5m	5m	2m	250000	250000
Anti Microbial Version	✓	—	—	✓	—
Entry level product	✓	✓	✓	—	—
CPAP intolerant alternative	✓	✓	✓	✓	✓
Orthodontic stability	—	—	—	✓	✓
BPA free	✓	✓	✓	✓	✓
FDA compliant	✓	✓	✓	✓	✓
Best for long term use	—	—	—	✓	✓
Extensive Clinical use	✓	New Product	✓	✓	✓

## Fit Index

1 to 2	Falls out when mouth opened	7 to 8	Requires some effort to open the mouth, firm grip on all teeth, requires effort to remove
3 to 4	Remains on one arch when mouth opened but easily displace	9 to 10	very secure fit requires positive manual effort to remove from the mouth
5 to 6	Remains on one arch when mouth opened requires positive manual effort to remove		

# SleepPro System



## We offer

The unique SleepPro System for treating a range of sleep disorders, especially those that are associated with snoring and upper airway obstructions

## Up to 40 times

Cheaper than dentally fitted devices

## The System

Is comprised of 6 distinct and separate product that between them effectively cover snorers

## Trusted Worldwide

Recommended by Doctors and Sleep Disorder Clinics

## The Original

Stop Snoring Device - Helping People to Stop Snoring Since 1998

## Each performs

Effectively controlling snoring and apnoea events with unique designs developed in-house by specialists

## Easy to fit

And adjustable boil and bite technology

# SleepPro Easifit

The SleepPro Easifit is a custom developed mouthpiece to stop snoring that is up to 40 times more affordable than dentally fitted devices. It's easy to fit and adjust, medically recommended, and works immediately. The SleepPro Easifit uses special 'Boil and bite' technology to ensure it is comfortable to wear and easy to adjust. Although a SleepPro custom will offer maximum comfort and efficacy, many customers have found the Easifit is enough to stop their snoring without the need for a more specially formed bespoke oral appliance.

Easifit is now also available in an anti-microbial version and the am version will last longer and protect you from germs.



Up to 40 times cheaper than dentally fitted devices

Easy to fit and adjustable boil and bite technology

Recommended by Doctors and Sleep Disorder Clinics worldwide

Highly effective and with a 98% success rate

The original Stop Snoring Device helping people since 1998

# SleepPro Sleep Tight

Based on the long-established and proven SleepPro Easifit, this new custom developed mouthpiece is available worldwide after gaining stringent FDA clearance in the USA.

If you're looking for something that is highly effective, easy to adjust, and offering a tighter but still very comfortable fit, then the sleepPro Sleep Tight is the ideal oral appliance.

The SleepPro Sleep Tight uses special 'Boil and bite' technology to ensure it is comfortable to wear and easy to adjust. Although a SleepPro custom will offer maximum comfort and efficacy, many customers have found that the Sleep Tight is enough to stop their snoring without any need for a more specially formed bespoke oral appliance.



Based on the successful and proven Easifit with FDA clearance

Twin polymer technology makes it effective and comfortable

Fits more firmly to reduce rubbing or chafing

Improved ease of fit using boil and bite technology

Improved air intake - larger breathing hole - more tongue space

## SleepPro Contour

This special mandibular advancement device was developed due to a high volume of requests received from doctors and patients alike. It is medically proven to work, and it is highly cost effective in comparison with other more expensive, invasive treatments.

Still using the original 'boil and bite' technology, the SleepPro Contour allows you to adjust and experiment with the amount of advancement needed to stop your snoring by using interchangeable straps, whilst still ensuring maximum comfort and the closest fit without selecting a mouthpiece like Custom which has full customisation.



Designed with comfort, fit & adjustability in mind

Unique advancement straps with easy attachment and removal

7 different settings or precise variable advancement

Highly effective and works immediately

Ergonomic trays to fit both the upper & lower dental arches

## SleepPro Custom

The SleepPro Custom is a bespoke mouthpiece to stop snoring and to prevent sleep apnoea and it is much more affordable than any dentally fitted device. It has the highest possible medical recommendation in the research conducted by the Sleep specialists at Papworth Hospital whose findings were published in Autumn 2014 in 'The Lancet'.

The SleepPro custom will offer maximum comfort and efficacy, and it will stop you snoring immediately. Safeguarding your future health.

Custom is now also available in a new anti-microbial version which will last longer and will protect you from germs.



Nearly half the price of costly alternatives

Fits perfectly and custom made to fit your jaw exactly

Comfortable and easy to use

Highly effective for both snoring and sleep apnoea

Recommended by Doctors and Sleep Disorder Clinics worldwide

Get the sleep you deserve  
Stops snoring immediately

## SleepPro Custom Adjustable

The SleepPro Custom Adjustable is a bespoke mouthpiece that offers the ultimate in sleek low profile contouring. With adjustable tension straps it enables easy adjustment and allows full lateral movement of the lower mandible. This makes it one of the most comfortable and effective devices within the SleepPro product portfolio.

The SleepPro Custom Adjustable will offer maximum comfort and efficacy, and it will stop you snoring immediately, safeguarding your future health.

Unlike the basic Custom, the adjustable can be made direct from impressions without the need for an intermediary appliance to record the position. This makes it a quicker product to access and provides a fast track solution to snoring and apnoea management.



Advanced Custom design offering comfort and effective control of snoring and apnoea

Simple one step impression process Fits snugly and unobtrusively and stays firmly in place

Recommended by Doctors and Sleep Disorder Clinics worldwide

## SleepPro Chin Support Strap

The SleepPro stop snoring chin support strap is a specialised option for open mouthed snoring and is a well proven solution to minimize the problem of dryness of mouth during sleep. With the chin strap on, you can sleep peacefully. This anti snore chin strap is designed for easy use and has an easily adjustable, sleek design.

Wrapping around the chin and top/back of head, the chin strap ensures that the mouth of the person snoring remains closed all night without coming off. The exclusive one-piece, two strap design ensures comfort, whilst firmly remaining in position throughout the duration of your sleep.



Fits easily across the chin and around the top back of head

The usual treatment for open mouthed snoring

Easy to clean using either a hand or a machine wash

comfortable to wear and brings

Proven to vastly reduce the problem of dry mouth during sleep

Affordable, long lasting and fits the majority of sizes



# Technical data

All SleepPro products are constantly being reviewed and developed to ensure we are always providing the very best product for our customers and referral partners, both in terms of efficacy and cost, an important consideration for purchasing and supply chain providers.

A frequently asked question "What are your products made of?" is one we welcome, we like to be open and as transparent as possible regarding biocompatibility and safety. All of our products meet if not exceed all required tests and checks for Class 1 medical devices as specified by EU Directive 93/42/EEC.

We recently commissioned a report to gather together all documents positive and negative relating to our product materials, that report appears in full below

## Biocompatibility of Elvax 150w and total hips 4440 polymers

This report reviews the industrial, health and scientific literature concerning the two polymers, Elvax® 150w and Total HIPS 4440, which our device uses to yield a safe and effective product

### HISTORY

The device is composed of two polymers, Elvax® 150w and Total HIPS 4440, used for a variety of purposes for decades. Since developing the first synthetic fiber, nylon, from research on large molecules called polymers, DuPont has led polymer research. In addition to Elvax®, DuPont manufactures high impact polystyrene (HIPS), which is also produced by other manufacturers. Each of these two components of our new oral device is examined in the following sections.

### ELVAX® 150W

Manufactured by DuPont, Elvax® is a copolymer of ethylene and vinyl acetate (EVA). It is flexible, resilient, tough, and resistant to ozone or environmental stress cracking. Elvax® can be used alone or as an additive to improve other resin or elastomer performance. With no plasticizer to migrate and minimal odor, Elvax® offers advantages over plasticized polyvinyl chloride and natural or synthetic rubbers. Elvax®'s flexibility spans a broad temperature range, and recovers rapidly under repeated instantaneous load. For resins in the melt index range below 30, toughness increases with vinyl acetate content. Elvax® 150w, which contains 32% vinyl acetate, but a melt index above 30, is still significantly tougher than low density polyethylene.

As a blending resin, Elvax® improves flexibility, resilience and toughness in many resins and rubbers, easily compounding with polyethylene, polypropylene, ABS, thermoplastic, nitrile, natural and compounded rubbers, as well as elastomers. DuPont notes the "broad compatibility of Elvax® resins with other resins and their ability to accept high pigment and filler loadings."

United States Food and Drug Administration (FDA) regulations allow using Elvax® in contact with food. As a non-biodegradable, non-inflammatory sustained-release polymer, Elvax® has been used for decades as a sustained-release delivery medium for drugs in human implants.

More germane to its use in our new oral device, moreover, Elvax® resins have been used safely in the local delivery of various substances through sustained-release human dental implants.

DuPont, which does not warrant Elvax® for human implants, contact with body fluids or tissue (obviously for legal reasons), states it has not performed clinical testing for implantation, has not sought FDA approval for such use, and will not provide data for its use in medical devices.

### TOTAL HIPS 4440

Polystyrene is a resin produced by polymerizing styrol, a thermoplastic resin used in dentures. It is one of the most widely used plastics, whose use is said to reach billions of kilograms a year.

Total Petrochemicals Polystyrene 4440 (Total HIPS 4440) is high-impact polystyrene used in the injection molding of parts requiring superior dimensional stability. Total HIPS 4440, like other high-impact polystyrene, is used in the manufacture of, among other things, sporting equipment.

A decade ago, an international panel of experts in the fields of toxicology, epidemiology, medicine, risk analysis, pharmacokinetics and exposure assessment, selected by the Harvard Center for Risk Assessment, performed an extensive study on any potential

At its conclusion in 2002, finding no health risk, the Harvard study noted styrene is naturally present in a number of foods, including strawberries, beef and spices, and is also produced naturally in the processing of certain foods, such as wine and cheese. The Harvard study also reviewed styrene's contribution to the diet through food packaging and disposable food contact items, finding no cause for concern from exposure to styrene from foods or from styrene-based materials used in food service, such as polystyrene packaging or food containers.

More recently, after more than fifty years of clinical testing, government safety authorities have determined polystyrene is safe for use in foodservice products. Polystyrene meets the standards of both the European Commission/European Food Safety Authority, and the United States Food and Drug Administration (FDA) for use in packaging in order to store and serve food.

The FDA's regulations, in fact, specifically state polystyrene "may be safely used as components of articles intended for use in contact with food."

## ELVAX® 150W & Total HIPS 4440

Where as no controlled clinical studies have been advanced to specifically determine the safety of combining Elvax® with Total Hips 4440, there remains absolutely no reason to believe that any adverse health effect would arise from such a marriage. Independently, both Elvax® 150w and Total HIPS 4440 have been used in the construction of human dentures for several decades. Also, the FDA's regulations approve Elvax® for regular contact with commonly used food products and food contact surfaces and polystyrene itself exists naturally in foods, has been rigorously tested by an international panel of experts, and has, in response to previously expressed health concerns, universally received a clean bill of health. In short, both Elvax® and Total Hips 4440 polymers are free of objectionable taste or odor, and are safe for use in the human mouth, lending to their ready use in our oral device.

DuPont Industrial Polymers: Elvax® Grade Selection Guide

Title 21 Code of Federal Regulation Section 177.1350 (accessed 04/04/2012), available at:

[http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFR-Search.cfm?fr=177.1350&utm\\_source=fdaSearch&utm\\_medium=website&utm\\_term=177.1350&utm\\_content=1](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFR-Search.cfm?fr=177.1350&utm_source=fdaSearch&utm_medium=website&utm_term=177.1350&utm_content=1)

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Dolce C, Vakani A, Archer L, Morris Wiman JA, Holliday LS: Effects of echistatin and RGD peptide on orthodontic tooth movement. J Dent Res; 2003 Sep;82(9):682-6 (Elvax® loaded with RGD peptide or echistatin surgically implanted next to maxillary molars inhibited orthodontic tooth movement); Holliday LS: Dental applications for novel osteoclast inhibitor. NIH Reporter; 2010 08 (method for sustained local release of enoxacin and Binhib16 using Elvax®, noting: "[n]umerous studies have utilized Elvax for similar applications"); Holliday LS, Vakani A, Archer L, Dolce C: Effects of matrix metalloproteinase inhibitors on bone resorption and orthodontic tooth movement. J Dent Res; 2003 Sep;82(9):687-91 (orthodontic tooth movement inhibited by delivery of Ilomastat, a general matrix metalloproteinase inhibitor, using ethylene vinyl acetate (Elvax®), as a non-biodegradable, non-inflammatory sustained release polymer).

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Dorland's Medical Dictionary for Health Consumers (2007) Saunders, imprint of Elsevier, Inc.

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Cohen, Joshua T.; Carlson, Gary; Charnley, Gail; Coggon, David; Delzell, Elizabeth; Graham, John D.; Greim, Helmut; Krewski, Daniel et al (2002). "A comprehensive evaluation of the potential health risks associated with occupational and environmental exposure to styrene". Journal of Toxicology and Environmental Health Part B:

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<http://plasticfoodser-vicefacts.com/main/Safety/Californias-Proposition65/Q-A-on-the-Safety-of-Polysty-rene-Foodservice-Products.GMEditor.html>. Accessed 04-04-12.

Title 21 Code of Federal Regulation Section 177.1640 (accessed 04/04/2012), available at:

[http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFR-Search.cfm?fr=177.1640&utm\\_source=fdaSearch&utm\\_medium=website&utm\\_term=polystyrene&utm\\_content=5](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFR-Search.cfm?fr=177.1640&utm_source=fdaSearch&utm_medium=website&utm_term=polystyrene&utm_content=5)

Though some investigation has been made into the physical properties of compounds created by combining these polymers, e.g., Moreira, A, Cario J, Francisco O & Soares, B. Continuous Morphology in Polystyrene/Ethylene Vinyl Acetate Copolymer Blends. Polímeros. 2002, vol.12, n.3, pp. 138-146; and J Appl Polym Sci 65: 2141-2149. John Wiley & Sons, Inc. (1997), no study concerning the health and/or safety effects of such a marriage appears in the literature.

## Conclusion

Our oral device's use of Elvax® 150w and Total HIPS 4440 yields a product safe and effective for its intended use.

## Material Composition & Manufacture/Construction

	EVA	HIPPS	Manufacture/Construction
Easifit	✓	—	Single shot injection moulded part
Contour	✓	✓	Two shot injection moulded part
Sleep Tight	✓	—	Two shot injection moulded part
Custom	✓	✓	Custom produced pressure thermoformed

## Continuous Development

The most recent development has been the introduction of Silver Ion Technology to introduce Anti-Microbial properties to the product. This has been introduced into the Easifit, this is a well proven technology provided by the world's leader in this field BioCote® it is planned to extend the addition of this additive to the whole range of products by 2017.

## Certification

"The products may also be supplied to sales agents, including national distributors, and where applicable marketed under other brand names to be advised by production of one or more supplements to this technical file".