Stop Snoring with SleepPro

A complete range of stop snoring solutions

Better Sleep, Better Health, Better Life

Up to 40 times cheaper than dentally fitted devices

Trusted Worldwide and recommended by Doctors and Sleep Disorder Clinics

Easy to fit and adjustable — boil-and-bite technology
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The Company Profile and History

sleepPro is a British company and is the established market leader in the design, development and manufacture of high quality, affordable MAD’s — mandibular advancement devices for snoring.

We believe mandibular advancement splints, or jaw advancers have an important role to play in treating a range of sleep disorders, especially those that are associated with stopping snoring and alleviating upper airway obstructions. Success rates have run as high as 98 percent in tests.

Through our SleepPro range, we offer products that are priced to make mandibular (jaw) advancers affordable to everyone and they are available as both boil-and-bite and custom made mouthpieces. Since it was first established in 1998 the SleepPro range has moved on to become the leading UK brand.

SleepPro products are fully recommended by the NHS – which is the Government administered National Health Service of the United Kingdom – for which the product is approved for any patients with OSA. It is recommended throughout the UK by both by Dentists and Medical Practitioners alike.

Since that time SleepPro has extended its marketing into numerous other countries around the world particularly the USA, Canada, Australia, New Zealand and the countries of South America where OAT (Oral Appliance Technology) is widely regarded as a major contributor to the prevention of more serious health problems that are now clearly attributed to heavy snoring or sleep apnoea.
Snoring

Recent research in many medical establishments, Sleep Centres and the Universities around the world now firmly links snoring to the following serious health matters and recommends the use of anti-snoring splints such as those manufactured by SleepPro:

- **DIABETES TYPE II**
- **CARDIOVASCULAR DISEASE**
- **HYPERTENSION**
- **DANGEROUS FATIGUE**
- **ERECTILE DYSFUNCTION**

It must be also remembered that snoring is a major cause of road accidents, as well as those that may happen at work, due to the high levels of fatigue that comes from poor quality sleep. Additionally, major problems are caused in many personal relationships – snoring is the third highest factor listed for divorce.

The National Health Service in the United Kingdom clearly defines snoring as being caused by the vibration of the soft tissue in your head and neck as you breathe in.

While you are asleep, the airways in your neck and head relax and narrow, and it is thought that this narrowing of the airways increases the speed at which you are breathing out and changes air pressure in your airways. This causes the soft tissue to vibrate. The same effect can also be the result of partially blocked airways which may be caused by conditions such as enlarged tonsils and colds.

Evidence suggests snoring will get worse over time if left untreated. Vibrations that occur during snoring appear to damage blood vessels that supply muscles in the head and neck. This may, over many years, cause the muscles to weaken. If the muscles in your head and neck become weakened, their ability to keep the airway open will be affected, making you more likely to snore frequently and loudly.

THE TISSUE THAT CAN BE AFFECTED INCLUDES

- **NASAL PASSAGES**
- **SOFT PALATE** - a soft layer of tissue at the back of the roof of your mouth base of your tongue
- **TONSILS** - the two small glands above the tongue at the junction of the mouth and pharynx (the pharynx is the upper section of the throat)
- **UVULA** - a small cone-shaped section of tissue that hangs from the soft palate between your tonsils
Common Causes Of 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.

ALLEGIC 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, AND MEDICATIONS
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.

SLEEP POSTURE
Sleeping flat on your back causes the soft tissue of your throat to relax and block the airway.

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

When snoring is coupled with other areas such as obesity, excessive alcohol, smoking, and other similar lifestyle problems, the results are even more dramatic, particularly if the problem is obstructive sleep apnoea. To cure snoring problems, wherever possible, would solve the world’s Health services from a major waste of expenditure and save many lives, allowing the funds to be spent better — and all this from such a very small outlay — the cost of an anti-snoring mouthpiece. All these areas and problems are covered by the media of the world on a daily basis as the effect of the harmful effects of smoking is now being fully realised with the full knowledge that something must be done to resolve the issue — and fast.
People with severe snoring may have obstructive sleep apnoea (OSA) and this is a very dangerous condition where the airways become temporarily blocked during sleep and cut off the regular oxygen supply to the brain.

The following health problems are strongly linked to obstructive sleep apnoea:

**HIGH BLOOD PRESSURE.** Obstructive sleep apnoea contributes to high blood pressure in people who have it. The frequent night time wakings that plague people with sleep apnoea cause hormonal systems to go into overdrive, which results in high blood pressure levels at night. Low blood-oxygen levels, caused by the cut off of oxygen, may also contribute to hypertension in people with sleep apnoea.

**HEART DISEASE.** People with obstructive sleep apnoea are more likely to suffer heart attacks. The causes may be low oxygen or the stress of waking up often during sleep. Stroke and atrial fibrillation — a problem with the rhythm of the heartbeat — are also associated with obstructive sleep apnoea. The disrupted oxygen flow caused by sleep apnoea makes it hard for the brain to regulate the flow of blood in arteries and the brain itself.

**TYPE 2 DIABETES.** Sleep apnoea is very common among people with type 2 diabetes. Up to 80% of diabetics have some obstructive sleep apnoea. Obesity is a common risk factor for both disorders. Although studies haven’t shown a clear link between sleep apnoea alone and type 2 diabetes, sleep deprivation can cause insulin resistance, a precursor to diabetes.

**WEIGHT GAIN.** Adding weight raises your risk of sleep apnoea, and up to two-thirds of people with sleep apnoea are severely overweight. Obstructive sleep apnoea can often be cured if you lose enough weight, but that can be tough to do. Being very overweight causes fatty deposits in the neck that block breathing at night. In turn, sleep apnoea impairs the body’s endocrine systems, causing the release of the hormone ghrelin, which makes you crave carbohydrates and sweets. People with sleep apnoea who are tired and sleepy all the time may have lower metabolisms, which can also contribute to weight gain. Getting treatment for sleep apnoea can make you feel better, with more energy for exercise and other activities.

**ADULT ASTHMA.** Although the link to obstructive sleep apnoea is not proven, people who are treated for sleep apnoea may find they have fewer asthma attacks.

**ACID REFLUX.** There’s no absolute proof that sleep apnoea causes acid reflux or persistent heartburn, but many people with sleep apnoea complain of acid reflux, and treating it seems to improve apnoea symptoms, say sleep physicians.

**CAR ACCIDENTS.** Daytime fatigue can put people with sleep apnoea at increased risk of falling asleep behind the wheel. People with sleep apnoea are up to five times more likely than normal sleepers to have traffic accidents.

**OTHER SERIOUS HEALTH PROBLEMS** such as various forms of cancer, osteoporosis and erectile dysfunction are linked in recent research studies to sleep apnoea.

**SLEEP APNOEA IS A DISORDER THAT CAN AFFECT ANYONE BUT OFTEN GOES UNDIAGNOSED**

Recently it has received much attention. Nonetheless many people who have sleep apnoea have yet to have the “who me” moment. The reason the moment is so elusive for so many is that they don’t have a strong feeling that they have any problems sleeping. In some ways it’s like high blood pressure. You can have a serious problem, but can be completely unaware of it until you have your blood pressure checked.

People with sleep apnoea are most likely to be: men, overweight, over 50 years, those who consume alcohol or take sleep medicines, smoke, or have chronic rhinitis. Women of course are not excluded, or younger people, and having any combination of these items just makes it more likely. There is also evidence that it is more prevalent in some ethnic groups and at higher elevations above sea level.
The Treatment Options Available For Snoring and Sleep Apnoea

Snoring Treatments That Don’t Work

- Stop snoring tablets
- Devices that counteract the snoring noise
- Aromatherapy
- Will power training
- Wrist devices, rings
- Hypnosis

- Devices that flash a bright light when you snore
- Tongue retention devices have been reported as being too uncomfortable
- Sports gum shields or mouthguards

In our opinion, the following stop snoring options do not work or are best used in conjunction with one of the three treatment options that do work:

**SPRAYS** – people tell us that stop snoring sprays either do not work, or they only work for a short period before the effects wear off (saliva washes away the spray) and they are expensive if you need to keep buying more spray.

**NASAL STRIPS** make it easier to breathe through your nose, they don’t stop you snoring. Don’t be misled by claims to the contrary.

**ANYTHING THAT FORCES YOU TO BREATHE THROUGH YOUR NOSE** is useless when you have a cold, or allergies that give you a blocked nose. They will make you feel like you are being strangled.

**POSTURE** can play an important role in snoring, but is not a solution in itself.

It is also worth knowing there is no test or manoeuvre you can do when awake that determines how you snore or breathe when asleep. Anybody who says this is possible, does not understand snoring.

For example, when a head and neck surgeon carries out a nasendoscopy to observe snoring, the procedure is done with the snorer sedated to induce sleep, rather than partially sedated and awake.
Sleep apnoea is a disorder where people stop breathing periodically when they sleep; a condition that affects around three million people in Britain, with many more undiagnosed cases. In the most severe cases the sufferer can stop breathing 30 times or more in an hour, with each pause lasting several seconds or even a few minutes.

Recent research released has revealed that people with snoring-related apnoea are more likely to develop deep vein thrombosis. While there is no known cure for sleep apnoea, it should always be brought to the attention of your GP as the condition can be managed and controlled. It might be as simple as wearing a simple mouthpiece to help your breathing at night.

There is then the more complex treatment using a Continuous Positive Airway Pressure (CPAP) device that the NHS is able to provide. This latter method doesn’t suit everyone as they find it really dries the throat.

Making sure that you consult your GP if you have a problem with snoring is a good first step. The reason why snoring occurs varies and until you know and understand the ‘category’ of snorer that you are, any treatment you invest in may prove to be simply a waste of money.

If you need more specialist advice, an ENT specialist will be able to tell you whether you fall into the nose, throat, palate or a ‘combination’ snoring category. You will then be in a better position to manage and treat the symptoms. Effective diagnosis will also stop you from investing money in the vast range of over-the-counter products that are probably quite inappropriate for your condition.

Keep it simple and stay with the proven and medically approved route. Take advice from your GP or Dentist and adjust your lifestyle. Try the type of mouthpiece recommended by the NHS. If all that fails then there are the more complex and expensive solutions of CPAP or Surgery.

Firstly You Should Try Out The Basic Ways To Stop Snoring

It’s true that shedding some of that excess weight, giving up smoking and alcohol and reducing the consumption of spicy foods and dairy products can all lower the likelihood of a person snoring. Investing in a good pillow that is not too large, not too soft and getting rid of any second pillow may also help, as will trying to sleep on your side rather than on your back. However, just how far these simple diet and lifestyle changes will go will really depend on the seriousness of the problem, and without getting to the real root of the problem, you will never banish snoring for good.

You also need to rule out sleep apnoea

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Independent Product Research

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 individuals 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 USA

A study published in June 2013, in the Journal of American College of Cardiology, found that in people (mean age = 53 years) with severe obstructive sleep apnoea i.e. 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.

In a presentation given at the American Thoracic Society May 2013 International Conference, a link was established between sleep apnoea and Alzheimer’s disease. It was noted that Alzheimer’s disease improved once treatment for sleep apnoea began and it may be that treatment for sleep apnoea might evolve into a form of treatment for Alzheimer’s disease.

Sleep apnoea has also been linked with elevated blood sugar levels, suggesting people with the condition could be at an increased risk of cardiovascular illness and mortality. The findings of a new study, published online (April 2014) in the European Respiratory Journal, add to a growing body of evidence that suggests that sleep apnoea is linked with diabetes. The research analysed 5,294 participants from the multinational European Sleep Apnoea Cohort.

People who have obstructive sleep apnoea are more likely to develop cancer, a new research study found. Moderate-to-severe OSA was associated with a 2.5-fold increase in cancer risk and a 3.5-fold rise in cancer death, according to a study by the University of Sydney in Australia.

“Mortality and morbidity in OSA seem to be driven by a combination of cancer and cardiovascular disease [particularly stroke],” wrote the researchers in a report on their study, published in the Journal of Clinical Sleep Medicine.

A new study presented at a European Heart conference explains that poor sleep and snoring doubles hospitalisations among individuals with the diagnosis of heart failure. Dr. Peter Johansson, first author of the study and a heart failure specialist at the University Hospital of Linkoping, Sweden, said, “Sleep is important for everyone and we all have to sleep to feel good. We know that sleep problems are common among patients with heart failure. But until now there was no data on whether poor sleep persists over time and how that relates to hospitalizations.”

He added, “Our study shows that some patients with heart failure have chronic sleep problems and this more than doubles their risk of unplanned hospitalisations.

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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 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.

Sleep Apnoea — The Growth Of The Problem

The recently published report on the Global Sleep Apnoea Diagnostic and Therapeutic Devices Market forecasts the overall market to grow at an annual average rate of 16.37% over the period up to 2017. The report covers the market in the Americas, the Middle East plus the Asia Pacific regions and describes it as a ‘Global Epidemic’.

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 II diabetes or adult onset diabetes, weight gain, impotence, and cardiovascular diseases.

Studies suggest that about 105 million people worldwide are suspected to have OSA — obstructive sleep apnoea, of which more than 80% remain undiagnosed.

The global sleep apnoea devices market was valued at $7.96 billion in the year 2011 and is expected to reach $19.72 billion by the year 2017.

North America is the largest sleep apnoea devices market, followed by Europe and Asia. North America will continue to lead the sleep apnoea device market in the next few years, followed by Europe.

The Asian region’s contribution to the global sleep apnoea device market is expected to pick up in the coming years, as the medical condition gets more recognition. This requires
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 5%, 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.
SleepPro System

We Offer The Complete Solution

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

The System

Compromises of 6 distinct and separate products that between them effectively cover snorers.

Consistency

Each performs guaranteed performance, variable customization.

Affordable

Cheaper than dentally fitted devices.

Highly Effective

Clinically proven results.

Easy To Fit

Adjustable and remouldable in most cases, except Custom bespoke mouthpieces, due to the Boil and Bite technology.

The Original

Stop Snoring Device — Helping People to Stop Snoring Since 1998.

Trusted Worldwide

Recommended by Doctors and Sleep Disorder Clinics.

www.sleeppro.com
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
- Highly effective and with a 98% success rate
- Easy to fit and adjustable – boil-and-bite technology
- The original Stop Snoring Device – helping people since 1998
- Recommended by Doctors and Sleep Disorder Clinics worldwide
- Get the sleep you deserve – 30 days money back guarantee

SleepPro Sleep Tight

Based on the long-established and proven sleepPro Easifit, this recently 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
- It carries the same 30 day money back guarantee
- Twin polymer technology makes it effective and comfortable
- Improved ease of fit using boil-and-bite technology
- Fits more firmly to reduce rubbing or chafing
- Improved air intake – larger breathing hole – more tongue space

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SleepPro System

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 and adjustability in mind
- Highly effective and works immediately
- Unique advancement straps with easy attachment and removal
- Ergonomic trays to fit both the upper and lower dental arches
- 7 different settings for precise variable advancement
- 50% refund if you are not satisfied within 30 days

BPA and Latex Free

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
- Highly effective for both snoring and sleep apnoea
- Fits perfectly and custom made to fit your jaw exactly
- Recommended by Doctors and Sleep Disorder Clinics worldwide
- Comfortable and easy to use
- Get the sleep you deserve – Stops snoring immediately

www.sleeppro.com
No woman likes to think that she snores, because of the stigma that is attached to it, but at the end of the day the statistics show that women who snore account for 40% of all snorers. Recent UK research shows that women are heading in increased numbers for their GP, Dentist, or Sleep Centre to find a solution to resolve this major sleep disorder and the related dangerous health situation.

SleepPro offer a range of high quality approved mouthpieces to help to prevent serious health problems that may be caused by heavy snoring and obstructive sleep apnoea and SleepPro Woman has been specially produced with this in mind.

### SleepPro Woman

- Designed especially for women and NHS Approved
- Highly effective and with a 98% success rate
- Easy to fit and re-adjustable for extra comfort
- Fits snugly and unobtrusively and stays firmly in place
- Recommended by Doctors and Sleep Disorder Clinics worldwide
- Get the sleep you deserve – 30 day money back guarantee

### SleepPro Chin Support Strap

The SleepPro stop snoring chin support strap is a specialised treatment for open mouthed snoring and is a well proven solution to minimise the problem of dryness of mouth during sleep. With the chin strap on, you can sleep peacefully and without any unnecessary discomfort or pain. 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.

- A simple, affordable anti-snoring device
- Fits easily across the chin and around the top/back of head
- Comfortable to wear and brings instant results
- The usual treatment for open mouthed snoring
- Proven to vastly reduce the problem of dry mouth during sleep
- Easy to clean using either a hand or a machine wash
- Affordable, long lasting and one size fits all
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."1

United States Food and Drug Administration (FDA) regulations allow using Elvax® in contact with food.2 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.3

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.4

DuPont, which does not warrantee 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.5

TOTAL HIPS 4440

Polystyrene is a resin produced by polymerizing styrol, a thermoplastic resin used in dentures.5 It is one of the most widely used plastics, whose use is said to reach billions of kilograms a year.6


Class 1

medical devices as specified by EU Directive 93/42/EEC
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 health effects of styrene exposure. 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 AND TOTAL HIPS 4440

Whereas no controlled clinical studies have been advance 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, 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.

1 – DuPont Industrial Polymers: Elvax® Grade Selection Guide.
5 – DuPont Medical Caution Statement, H-50102.
7 – http://en.wikipedia.org/wiki/Polystyrene#cite_ref-28
8 – Cohen, Joshua T.; Carlson, Gary; Charnley, Gail; Coggan, 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: Critical Reviews 5:1
Conclusion

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

<table>
<thead>
<tr>
<th>Material Composition and Manufacture/Construction</th>
<th>EVA</th>
<th>HIPPS</th>
<th>Manufacture / Construction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Easifit /Woman</td>
<td>Yes</td>
<td>No</td>
<td>Single shot injection moulded part</td>
</tr>
<tr>
<td>Contour</td>
<td>Yes</td>
<td>Yes</td>
<td>Two shot injection moulded</td>
</tr>
<tr>
<td>Sleep Tight</td>
<td>Yes</td>
<td>No</td>
<td>Two shot injection moulded</td>
</tr>
<tr>
<td>Custom</td>
<td>Yes</td>
<td>No</td>
<td>Custom produced pressure thermoformed</td>
</tr>
</tbody>
</table>

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".
I don’t snore anymore!
After years of sleeping in the spare room and a failed marriage, I can finally say that I don’t snore! In the past I have tried nasal strips, sprays and even a hairbrush strapped to my back in an attempt to stop me from rolling over!
SleepPro Easifit has changed all that. I used an app on my phone called Sleep Recorder. Each morning there would be a recording of over an hour of loud snoring, but now all I get is just a couple of minutes of my noisy central heating firing up!
SleepPro Easifit has been 100% successful for me and I would tell everyone who snores to try this Full stop Cap Leader. You’ll be delighted with the results.
— VH about SleepPro Easifit

At last, someone has realised that lots of women snore too and has created a suitable product for the girls. Not only has it stopped me snoring, but I now wake up feeling like I’ve had a decent night’s sleep. My other half uses an Easifit so the different colours means no confusion.
— SUSAN GREAVES about SleepPro Woman

My experience with the SleepPro Custom is going very well indeed, so much so that I am now recommending it to friends and medical colleagues.
I found it easy to use and no longer snore. This problem often affects younger people too, but inevitably with age, people find themselves having to face annoying snoring, which is especially difficult for those who sleep next to them. Because of my strength of feeling that this is a very serious problem, not just a laughing matter, I am very happy to help you spread the word and encourage people to use a SleepPro.
— DR BRUNO INNOCENTI about SleepPro Custom

This has really helped me. Having seven different settings to fine tune the original fit of the mouthpiece is a godsend.
— MARGARET STEVENS about SleepPro Contour

Had a remarkable result from my first night with a SleepPro. Many thanks.
— MR DAVID GARDINER about SleepPro Easifit

I received my SleepPro Custom this morning and it fits perfectly so thank you. Taking one’s own impressions was very simple with your very easy to follow instructions and I am very impressed with the quality of the finished article.
After I started to use the SleepPro Custom my sleep quality has now improved dramatically. I don’t snore, grind my teeth or bite my tongue and I feel so much better the following morning.
— RAY OAKLEY about SleepPro Custom

I am so pleased with my SleepPro Contour. I don’t snore anymore and so I’m sleeping well – but importantly I can adjust it to what seems the most comfortable fit at that time – it makes all the difference to be able to do that as it seems to vary over time. The different settings solve the problem.
— TONY STYLES about SleepPro Contour

I have recently changed from an Easifit to the Sleep Tight. Although it had stopped my snoring it sometimes fell out during the night as my jaw is quite narrow. The Sleep Tight is a snugger fit and I no longer have the problem.
— MR STEPHEN MARKHAM about SleepPro Sleep Tight

My snoring problem is fixed – and for next to no money. When I fell asleep my mouth was forever open according to my wife, and the noise was deafening.
She’s so pleased that she now gets a great night’s sleep, as I do, that she’s just bought me another two as back up.
— JIM RUSHTON about SleepPro Chin Support Strap
Feel free to get in touch with us in the following ways

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Monday to Friday 9am – 4.30 pm

info@sleeppro.com

www.sleeppro.com

Post — MEDI'TAS Ltd.
5 Broadpiece, Pennyland, Milton Keynes
MK15 8AT, United Kingdom

Contact us for support and advice

We use our expertise to your advantage at sleepPro. Our consultants can offer some of the best advice available about the products we have on offer. If you’re uncertain about which product will bring you the best results, our consultants are on hand to guide you in the right direction.

Email for Help and Support: help@sleeppro.com