



mu:te

BREATHE MORE
SNORE LESS

CLINICIAN INFORMATION

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RHINOMED

Rhinomed is a medical device technology company with a patented nasal technology platform that seeks to radically improve the way you breathe, sleep, maintain your health and take medication.

Rhinomed's first product was launched in February 2014 and the company now ships to over 36 countries worldwide.

► <http://rhinomed.global/>



BREATHE MORE, SNORE LESS, SLEEP BETTER

Mute is the latest offering in breathing technology from Rhinomed. Mute has been anatomically designed to increase airflow by holding open (stenting) nasal airways. This allows the snorer to breathe more easily through their nose and reduce the need to open their mouth during sleep, thus decreasing snoring.

MUTE HAS CLEAR BENEFITS:

1. SNORE LESS

75% of partners reported snoring was less/much less when their snorer used Mute, meaning both parties get a good night's sleep.

2. IMPROVE SLEEP

Three times as many snorers had reported improved sleep when using Mute. Four times as many partners had improved sleep when their snorer was using Mute.

Partners: 60% with Mute vs 14% without Mute

Snorers: 57% with Mute vs 21% without Mute

3. SLEEP COMFORTABLY

Mute has been anatomically designed to fit the exact curve of each nostril, gently holding open (stenting) the airway, at the nasal valve, for easier breathing through the nose.

Just as our faces are not symmetrical, neither are our noses. Mute allows for subtle adjustments from one nostril to the other ensuring optimal airflow through both sides.

* Rhinomed Product Trial, November 2014, n=118 couples

DESIGNED FOR THE 1 IN 4 PEOPLE WHO HAVE TROUBLE BREATHING THROUGH THEIR NOSE¹

The nose is responsible for the majority of upper airway resistance, so any form of obstruction or congestion can have a dramatic impact on nasal airway patency.

Many researchers have already identified the impact of poor nasal function on sleep-disordered breathing.

The patient population in which sleep-disordered breathing presents will commonly have a concurrent nasal obstruction².

The fully adjustable Rhinomed nasal dilator, Mute, has been designed to specifically respond to this issue by stenting the airway and preventing the collapse of the nasal valve - providing an improved unrestricted airflow.

| | EXISTING THERAPY | LIMITATIONS | MUTE DIFFERENCE |
|-------------------|---------------------------------------|---|--|
| CONGESTION | SPRAY | Short term use only Short acting drug | Mute is drug free May be used with a saline nasal wash Can be used up to 8 hours/night |
| NASAL OBSTRUCTION | STRIP SPRAY | Strips may cause skin irritation Does not address nasal valve collapse | No adhesives Stents the nasal valve from the inside |
| SNORING | STRIP MOUTHGUARD OTHER DILATORS | No adjustment Uncomfortable | Used on its own for nasal snoring May be combined with MAD |
| SLEEP APNEA | MAD | Uncomfortable | Mute improves nasal breathing and comfort |
| | CPAP | Low compliance | |

UPPER AIRWAY RESISTANCE AND ITS ROLE IN COMPLIANCE FOR OSA

Recent literature provides clear evidence that upper airway resistance during sleep and the incidence of obstructive sleep apnea are significantly lower while breathing nasally rather than orally³. Further, nasal obstruction has been shown to be a risk factor associated with sleep apnea syndrome⁴ and nasal obstruction due to allergic rhinitis is associated with OSA⁵.

Nasal congestion or obstruction are often cited as a potential reason for non-adherence to both oral and CPAP therapies⁶.

Rhinomed is conducting research on the use of Mute in combination with existing therapies as a possible front line solution to patients who find CPAP or oral devices uncomfortable due to nasal obstruction.

¹Stewart et al. Epidemiology and burden of nasal congestion. International Journal of General Medicine, 2010;3 37-45. | ²Egan et al, Nasal Obstruction and Sleep Disordered Breathing. Operative Techniques in Otolaryngology (2006) 17, 268-272. | ³Fitzpatrick M. et al. Effect of nasal or oral breathing route on upper airway resistance during sleep. Eur. Respir. J. 2003; 22:827-832

⁴Lofaso F. et al. Nasal obstruction as a risk factor for sleep apnoea syndrome Eur. Respir. J. 2000 Oct;16 (4):639-43 | ⁵McNicholas WT. 1982, Lavie P. 1981 | ⁶Sugiura T. Influence of nasal resistance on initial acceptance of continuous positive airway pressure in treatment for Obstructive Sleep Apnea Syndrome Respiration 2007;74:56-60

MUTE, COMFORTABLE & EFFECTIVE

Hundreds of hours of careful research and development have been poured into Mute, resulting in a technology that is as effective for nasal obstruction as it is comfortable.

MUTE, DESIGNED FOR COMFORT & FIT

1. STAYS IN ALL NIGHT

Mute is designed with retention fins to ensure the device stays comfortably in place all night.

2. INCREASE AIRFLOW

Mute has been anatomically designed to increase air flow during sleep (on average 38% in a clinical trial at Royal Victorian Eye & Ear Hospital in 2003).

Just as no human face is the same, so it is with the human nose. Mute's three sizes and patented independent gentle stent action allows for subtle adjustments from one nostril to the other, ensuring optimal airflow through both passages of the nose.

3. COMFORTABLE

Mute is made from ultra-soft medical grade polymers and is anatomically designed to hug the internal structure of the nose for ideal comfort and fit. Mute is latex free and drug free.

4. PERSONALIZED FIT

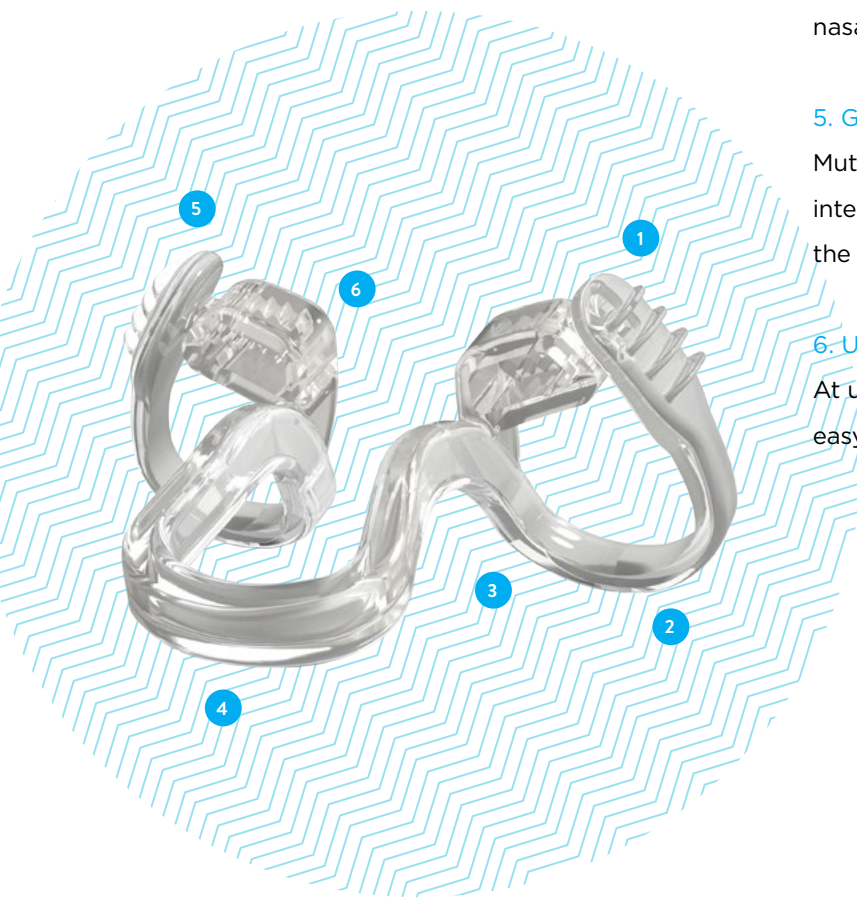
Mute is the only nasal stent (dilator) that uses a patented dilation technology to further personalize the fit. Mute can be adjusted independently on each side to overcome nasal asymmetry.

5. GENTLE STENT ACTION

Mute gently stents (holds open) the airway from the internal side wall of the nose, minimising pressure on the septum.

6. UNDER \$1 A DAY

At under \$1 per day, Mute is cost effective, discreet and easy to use.



MUTE RANGE

Mute is available in a Trial Pack and three sized packs, Small, Medium and Large

The Trial pack contains one small, one medium and one large device allowing users to try each size to find the optimal fit.

Each size pack provides one month's supply at \$1 per day.

MUTE SHOULD BE CHANGED AFTER 10 NIGHTS FOR THE FOLLOWING REASONS:

1. Moisture may discolour and stiffen the ultra-soft polymers of the device, compromising the soft and comfortable fit.
2. The unique patented dilation system (adjustable paddles) will wear and may not retain position in the nose.
3. The risk of compromising hygiene standards increases.



TRIAL PACK
ONE SMALL, ONE MEDIUM,
ONE LARGE



3 SMALL



3 MEDIUM



3 LARGE

FREQUENTLY ASKED QUESTIONS

What is Mute?

Mute is a respiratory technology designed to gently open the nasal airway during sleep to increase airflow through the nose and thereby reduce mouth breathing and the severity of snoring.

Why is Mute going to work?

Using the anatomy of the nose, Mute has been designed to sit comfortably in the nose whilst gently stenting the airway and making it easier to breathe. By breathing easier through the nose, there is no need to breathe through the mouth, a common cause of snoring.

Mute also has an independent dilation system to further personalize the fit to each nostril.

Why is it important for patients to find the right size product?

We have developed a sizing tool that will allow you to size your patients for maximum comfort and the best results. This sizing tool can be supplied as part of your clinic pack.

When Mute is the right size it will fit snugly and be comfortable to wear throughout the night. If it's too small then it may fall out and/or not open the nose enough to benefit snoring.

If Mute is too large then it may not fit inside the nose at all, or it may feel uncomfortable.

You can direct your patients to tips.mutesnoring.com for sizing and fitting instructions.

How long should patients use Mute for before they start to feel better?

Whilst it may take them a couple of nights to get used to wearing Mute, your patient and their sleeping partner may start to feel the benefits of better sleep almost immediately.

Once the snorer has correctly fitted the device, they should be able to feel more air entering through the nose from the first moment the device has been fitted.

Both the snorer and their sleeping partner may begin to enjoy the benefits of uninterrupted sleep from the very first night they use Mute.

Ongoing sleep interruptions due to snoring can interfere with the natural 90 minute sleep cycle, stopping snorers from reaching the deep sleep phase. The deep sleep phase is important for the body to physically and mentally repair from the day's activities.

Researchers are suggesting that better sleep may result in many performance and health benefits specific to each individual. These can include a reduction in daytime drowsiness and improvement in mood, concentration and memory.

What is Mute made from?

Mute is made from ultra-soft medical grade polymers to ensure a comfortable fit throughout the night.

Why does Mute have adjustable paddles?

Just like the rest of our faces, our nose is not symmetrical. There are small differences between the size, shape and structure of our two nasal passages. These small differences can be genetic or caused by trauma to the nose. Mute's independent dilation system (adjustable paddles) allows snorers to counteract any of these differences by personalising the fit of Mute for maximum airway dilation and comfort.

Why does Mute have ribbed paddles?

The soft ribbed paddles (retention fins) on Mute's dilation system not only helps Mute stay in place throughout the night, minimizing the chance of the device shifting its position during sleep, but also provide a cushioning effect where Mute is in contact with the internal walls of the nose.

How long should patients use Mute for?

Each Mute device can be worn for up to 8 hours each night, recommended for a maximum of 10 nights.

Should patients clean Mute?

Mute should be cleaned in warm soapy water, rinsed well and completely dried before storing in between uses.

Why should patients change Mute after 10 nights?

In order to maintain optimal device performance, comfort and fit, it is recommended that Mute is replaced after 10 uses.

The device has been tested and shown to be effective for up to 10 uses. Whilst the Mute may appear fit for use beyond 10 nights, optimal device performance cannot be guaranteed because:

1. Of the risk of compromising hygiene standards.
2. The device may discolour or the ultra-soft polymer may begin to harden, compromising the perfect, soft fit of Mute.
3. The dilation mechanism will wear and may not hold its position in the nose or dilate effectively.

Who can use Mute?

Mute has been designed for use in adults who snore due to nasal night time congestion and / or obstruction.

Mute is not appropriate for use in people under 12 years old.

When should patients use Mute?

Please ask patients to view the online instructional video or enclosed instructions for the most comfortable, personalized fit of Mute.

When first using Mute, it is suggested that patients fit the device and wear it for a couple of hours (during the day or before bed) to ensure they have the right fit and to familiarise themselves with the feeling of dilated airways.

Will Mute fall out during the night?

Along with the soft ribs on the paddles to aid retention, Mute has been designed to use the natural anatomy of the nose to keep it in place throughout the night, however finding the right size is key.

If Mute is too small, the retention structures of the device will not hold it in as well. It is the right size when the user can feel the arms of Mute hugging the internal curve of their nostrils, with the retention fins finishing in line with the top of the nostril crease. If the paddles finish below this crease, we suggest to try a larger size.

The other reason patients may wake up without Mute is that when they start using the device, they may find that during the first few nights, they may unconsciously remove it because it is a new sensation. We recommend that they periodically wear Mute during the day for a couple of hours or before bed to get used to the feeling.

If the patient is experiencing a dry nose, products such as Nozoil™, as used with CPAP, may be useful.

They're still snoring even though they report using Mute (the correct size, fitted correctly).

We realise that snoring is a complex issue and so Mute alone may not be enough for some patients. Anecdotally, we have received feedback from some users that they've had great results when they've used Mute as a companion therapy to other products like MADs, therapeutic pillows and throat sprays.

RHINOMED BRANDS

mu:te
BREATHE MORE
SNORE LESS

MUTE

(SNORING & SLEEP)

Snoring disrupts the sleep and the lives of millions of people worldwide. Mute has been designed to give snoring the silent treatment. Mute is a unique respiratory technology that will help you to breathe more and snore less.

Mute is easy to use and discreet. It has been designed to fit the anatomy of your nose and to gently expand each nostril, giving you more air.

TURBINE
SPORTS BREATHING TECHNOLOGY

TURBINE

(SPORT & EXERCISE)

Turbine gives you extra air when you need it most. On the track or on the field, on the bike or during a workout, Turbine has been shown to deliver on average 38% more air.

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RHINOMED MUTE MARKET RESEARCH

Rhinomed conducted formal market research in November 2014 in order to further understand our snoring consumers, customers and their behaviour in the snoring category. The research conducted was both qualitative (focus groups) and quantitative (in home product trial with 118 couples), and excluded OSA, high BMI or chronic throat snoring patients.