# **CLINICIAN**INFORMATION

MUTE IS A NASAL BREATHING
DEVICE DESIGNED TO INCREASE
AIRFLOW THROUGH THE NOSE
DURING SLEEP BY GENTLY
OPENING THE AIRWAYS.

MUTE TARGETS THE EFFECTS OF NASAL OBSTRUCTION CAUSED BY A DEVIATED SEPTUM, CONGESTION OR NARROW AIRWAYS.







## **CLINICIAN** INFORMATION

### THE RHINOMED RANGE

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



Mute gently opens the nose to increase airflow during sleep to reduce the reliance on mouth breathing which is synonymous with snoring.

mutesnoring.com

## **MUTE**

Mute is an anatomically designed, discrete device that gently stents open the nasal airways to improve airflow during sleep by an average of 38%\*. Nasal airflow can be impeded by obstructions such as a deviated septum, narrow airways or congestion. Breathing more easily through the nose may reduce the reliance on mouth breathing; a known cause of disruptive snoring. Mute can be used by itself for simple snoring or may, when used in conjunction with other solutions, aid more complex snoring problems.



### **BREATHE MORE**

78%\*\* of users experienced an improvement in airflow through their nose



## **SNORE LESS**

75%\*\* of users reported a reduction in snoring



## **SLEEP BETTER**

Both snorers and their partners enjoyed a good night's sleep

## **MUTE** USERS BREATHE MORE, **SNORE LESS & SLEEP BETTER**

### THE LINK BETWEEN POOR **NASAL PATENCY AND SLEEP DISORDERS**

The case for nasal breathing over mouth breathing is mounting. Statistics show that 1 in 4 people have trouble breathing through their nose1.

With the nose responsible for the majority of upper airway resistance, these people are at risk of experiencing sleep disordered breathing, as any form of obstruction or congestion can have a dramatic impact on their nasal airway patency.2

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

Mute has been designed to specifically respond to this issue by stenting the airway and preventing the collapse of the nasal valve to provide an improved unrestricted airflow.

## **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 through the nose rather than the mouth<sup>3</sup>.

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 reasons for non-adherence to both oral and CPAP therapies<sup>6</sup>.

Rhinomed is pursuing 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.

## **CLINICAL TRIAL DEMONSTRATES INCREASED AIRFLOW**

#### THE OBJECTIVE

To study the nasal airflow with and without an intranasal stent device.

#### THE SUBJECTS

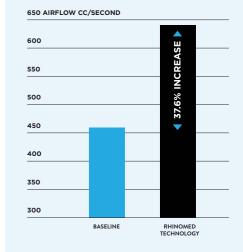
Group of 20 healthy individuals (male and female of varying ages).

#### PROOF OF CONCEPT TEST

Controlled rhinomanometry test where the amount of nasal airflow was measured objectively.

#### **FINDINGS**

On average the intranasal stent provided, on average, a 38%\* increase in airflow.



\*S. Braham, Proof of Concept Clinical Trial (Early Prototype), The Royal Victorian Eye and Ear Hospital, 2003. Financial sponsor ASAP Breatheassist. https://mutesnoring.com/38

IMPORTANT: Mute nasal device is not for the treatment of sleep apnea. If you think that your snoring may be a symptom of sleep apnea, you should consult your doctor or a sleep specialist

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<sup>\*</sup>S. Braham, Proof of Concept Clinical Trial (Early Prototype), The Royal Victorian Eye and Ear Hospital, 2003. Financial sponsor ASAP Breatheassist. https://mutesnoring.com/38 \*\*2014 User Trial N=118 couples. Results may vary. Marketing Moves. ASAP Breatheassist was the financial sponsor for this study. https://mutesnoring.com/75

<sup>1</sup> Stewart et al. Epidemiology and burden of nasal congestion. International Journal of General Medicine, 2010:3 37-45. | 2 Egan et al, Nasal Obstruction and Sleep Disordered Breathing. Operative Techniques in Otolaryngology (2006) 17, 268-272. 3 Fitzpatrick M. et al. Effect of nasal or oral breathing route on upper airway resistance during sleep. Eur. Respir. J. 2003: 22:827-832. 4 Lofaso F. et al. Nasal obstruction as a risk factor for sleep apnoea syndrome Eur. Respir. J. 2000 Oct;16 (4):639-43. | 5 McNicholas WT. 1982, Lavie P. 1981". | 6 Sugiura 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** IS COMFORTABLE, EFFECTIVE AND

**DESIGNED FOR THE RIGHT FIT** 

Hundreds of hours of careful research and design have been invested in Mute, resulting in a technology that is as effective as it is comfortable. Just as no human face is the same, so it is with the human nose. Mute's three sizes and patented gentle stent action allows for subtle adjustments from one nostril to the other, ensuring optimal airflow through both passages of the nose.

## 1: GENTLE STENTING ACTION

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

## 2: INCREASE AIRFLOW

Mute has been shown to increase air flow during sleep by an average of 38%\*.

## **3:** FULLY ADJUSTABLE FOR PERSONALIZED FIT

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

## 4: DESIGNED FOR COMFORT

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.

## 5: UNDER \$1 A DAY

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

#### **6:** STAYS IN ALL NIGHT

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

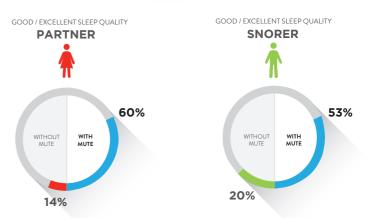


## **MUTE** USERS BREATHE MORE, SNORE LESS & SLEEP BETTER

MUTE USERS EXPERIENCED IMPROVEMENTS IN SLEEP HYGIENE



MUTE USERS AND THEIR PARTNERS EXPERIENCED IMPROVED SLEEP QUALITY



## THE **MUTE**DIFFERENCE

Mute is designed for those who suffer from nasal obstruction due to problems such as a deviated septum or narrow airways or from chronic night time congestion. Mute can be used on its own for those with limited nasal patency or in conjunction with other solutions, where

nd even compliance may be improved by being

Mute Snoring Product User Trial, 2014 User Trial N=118 couples.

Results may vary. Marketing Moves. ASAP Breatheassist was the

financial sponsor for this study. https://mutesnoring.com/75

comfort and even compliance may be improved by being able to breathe more easily through the nose. Mute is a simple and effective first line of defence, drug free, comfortable and easy to use.

PROBLEM	EXISTING	LIMITATIONS	THE MUTE DIFFERENCE
SNORING	STRIPS	Strips may cause skin irritation	Drug free Supports nasal valve
NASAL OBSTRUCTION	OTHER DILATORS	Uncomfortable No adjustment	Fully adjustable to each nostril
CONGESTION	SPRAYS	Short term use only	May be combined with oral appliance
SLEEP APNEA	ORAL APPLIANCES CPAP	Poor nasal patency causes discomfort when using MADs or masks, which may lead to lower compliance	Supports the nasal valve  Adjustable for each nostril

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<sup>\*</sup>S. Braham, Proof of Concept Clinical Trial (Early Prototype), The Royal Victorian Eye and Ear Hospital, 2003. Financial sponsor ASAP Breatheassist. https://mutesnoring.com/38

## THE **MUTE** RANGE

PATIENTS ARE ENCOURAGED TO START WITH THE TRIAL PACK TO FIND THEIR OPTIMAL FIT.



: Each size pack contains three devices or one month's supply of Mute for under \$1 per day.

#### **AVAILABLE IN**

TRIAL PACK 1 x SMALL, 1 x MEDIUM, 1 x LARGE

SMALL MEDIUM 3 x PACK (30 NIGHT SUPPLY) (30 NIGHT SUPPLY)

## LARGE

3 x PACK

3 x PACK (30 NIGHT SUPPLY)

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

- : Moisture may discolour and stiffen the ultra-soft polymers of the device, compromising the soft and comfortable fit
- : The unique patented dilation system (adjustable paddles) will wear and may not retain position in the nose or dilate effectively
- : The risk of compromising hygiene standards

## BECOME A **REFERRER** OR **RESELLER**

## **REFER**

## **BECOME A** REFERRING CLINIC

If you would like to refer Mute to your patients, we will send you a Referral Kit which includes.

- : Product samples
- : Sizing guides so you can size the patient in clinic
- : Referral pads detailing retail outlets and online sites for purchasing Mute
- : Patient Information brochure



▶ 6 UNIT PACK DISPLAY







SLIMLINE BROCHURE





SIZING GUIDE

## RESELL BFCOMF A **RESELLING CLINIC**

Open a wholesale account at

mutesnoring.com/wholesale-registration/

You will have access to our custom online wholesale ordering portal to place orders.

- : Product at wholesale margins
- : Sizing guides so you can size the patient in clinic
- : Mute display trays

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#### Why Mute?

Mute is a nasal breathing device designed to increase airflow through the nose during sleep by gently opening the airways. By increasing airflow, Mute may reduce the reliance on mouth breathing, a common cause of snoring.

#### Who can use Mute?

Mute has been designed for use in adults who snore due to nasal obstructions such as a deviated septum, night time congestion or narrow airways. Mute is not appropriate for use in people under 12 years of age.

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

When Mute is the right size it will fit snugly in the nose and be comfortable to wear throughout the night. If Mute is too small then it may fall out and/or not open the nose enough to reduce snoring. If Mute is too large then it may not fit inside the nose at all, or it may feel uncomfortable.

Using the Trial pack (contains one small, one medium and one large device) is the best way to find the ideal size. Alternatively, we have developed a sizing tool that can be supplied as part of your clinic pack so that you can size your patient in clinic.

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

#### What is Mute made from?

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

## Why does Mute have adjustable paddles?

Just like the rest of your face, your nose is not symmetrical. There are small differences between the size, shape and structure of our two nasal passages.

Mute's independent dilation system (adjustable paddles) allows snorers to counteract any of these differences by personalizing the fit of Mute to each nostril for maximum airway dilation and comfort.

#### Why does Mute have ribbed paddles?

The soft ribbed paddles on Mute's dilation system not only help Mute stay in place throughout the night 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, 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?

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 performance cannot be guaranteed because:

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

#### Using Mute for the first time?

Please ask patients to view the online instructional video (at tips.mutesnoring. com) or instructions inside the pack 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 familiarize themselves with the feeling of dilated airways.

#### Will Mute fall out during the night?

Mute may fall out during the night if it is too small, and if this happens, we suggest the paddles be adjusted to increase the size of the loop or alternatively to move up to a larger size. Sometimes, people unconsciously remove Mute during sleep 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 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 in conjunction with other products like Mandibular Advancement Therapy, therapeutic pillows and throat sprays.

