# Report on clinical assessment of the medical device called NoSnorePLUS

## 1. Background Information

The object of the clinical assessment is the **NoSnorePLUS** nasal insert. Manufacturer: Plast-Med., 32-425 Trzemieśnia 565.

## 2. Description of the device and its intended use

The **NoSnorePLUS** nasal insert is a Class 1 re-usable medical device made from a high-quality colourless plastic material recommended for the production of medical devices, i.e. vinyl polychloride) ALFAVINYLGFM/4 - quality certificate no. 116/ŚJA/04/2011. The insert was microbiologically tested by TUVRheinland no. 266 22275/2012 - it is not toxic and is free from bacteria and fungi.

## 3. Intended therapeutic or diagnostic indications and the manufacturer's findings

The NoSnorePLUS nasal insert, which facilitates breathing, is recommended for snoring persons, who suffer from deviated nasal septum, a cold or hay fever and persons doing sports. It clears the nose, facilitates breathing, reduces snoring and ensures peaceful sleep [manufacturer's data].

## 4. The context of clinical assessment and selection of the type of clinical data

Devices (instruments) mechanically widening nostrils to reduce the resistance of air flowing through the nose, thus improving ventilation during effort, sleep quality and reducing snoring have been known for year. They can have the form of resilient strips glued across the bridge of the nose (external devices) or they can be put into the nasal vestibule in the form of flat inserts resilient to the outside (Novovent) or cylindrical inserts (Megavent) (internal devices).

Before reaching the lungs solids are removed from the air inhaled through the nose, the air is heated and humidified. Potentially hazardous elements are presented to the structures of the immune system within the nasal mucous membranes. It should not be forgotten either that the nose is responsible for the sense of smell and partly also for feeling flavours [Pevernagie 2005]. The air inhaled through the nose transports nitrogen oxide from the maxillary sinuses to the lungs, where it lowers the vascular resistance and increases saturation with oxygen. In persons with swollen mucous membranes who breathe through the mouth the functions mentioned above are not retained and, in addition, as a result of omitting the nasal breathing reflexes and reduced passage in the oral part of the throat caused by a mandibular shift, such persons have a tendency to snore.

The nasal valve area is the narrowest part of the nasal cavity, which is responsible for 50% of the total airway resistance for breathing during rest [Roithmann 1997|. As fluctuations in its diameter have a significant influence on the air flow, a range of devices have been invented which are aimed at increasing the air flow through the nose and protecting from the narrowing of the nasal valve area during inhalation. In a majority of published studies, external devices of the Breathe Right type and internal devices of the Nozovent type were assessed.

Mechanical devices widening the nostrils are widely used by snoring persons and strips gained additional popularity owing to their use by athletes at the Olympic Games in Atlanta in 1996. The principle of operation of the **NoSnorePLUS** nasal insert is similar to other internal nostril-dilating devices, such as Nozovent or Megavent [Ellegard 2006].

## 5. Summary pertaining to clinical data and their assessment

This clinical assessment of the **NoSnorePLUS** medical device is based on the results of the search of the Pubmed database of medical publications. The search included the term “nasal dilator” without time restrictions. The majority of quoted tests of strips (Breath Right) or inserts (Nozovent) were conducted on healthy patients of various races, during rest and effort. The research methods used for the assessment of the medical devices were based on subjective assessment on a point scale or on objective tests - acoustic rhinometry assessing the minimal cross-sectional area of the nose (MCA), anterior or posterior rhinomanometry assessing the dynamic air flow through the nose and air flow resistance. In studies assessing the effort efficiency, also the pulse, oxygen consumption and other function parameters were assessed. In a majority of studies examining the influence on sleep quality polysomnography was used, which assessed the wake index, the apnoea/shallow breathing and other snoring parameters.

**Table l. Influence on the physical**

| Author | Device type | Patients | Research methods | Result |
|---|---|---|---|---|
| Bahammam1999 | Strips | 18 (12m, 6k) * placebo | Polysomnography acoustic rhinometry | Significant decrease in the airflow resistance (AR) and increased TMCA |
| Di Somma 1999 | Strips, decongestant medication | 20 (7m, 13k) | spirometry | Significant increase in nasal inhalation parameters (FIF50% PIF, PEF/PIF) |
| Gehring2000 | Strips | 15 (6m, 9k) + placebo | Posterior rhinomanometry | Significant reduction in nasal air resistance during inhalation and/or exhalation |
| Griffin 1997 | Strips | 53 (33m, 20k) + placebo | Acoustic rhinometry | A statistically significant increase in TMCA (total minimal cross-sectional area) |
| Hoffstein 1993 | Inserts | 7 | Rhinomanometry | Significant decrease in the airflow resistance (AR) |
| Hoyvoll 2007 | Strips/decongestant medication | 89 (48m, 41k) | Acoustic rhinometry | Both for the strip and the decongestant medication, a significant decrease in the nasal airflow resistance (MCA), the peak nasal inhalation flow and improved nasal symptoms on a visual scale were observed |
| Kirkness 2000 | Strips | 20 (10m, 10k) + placebo | Posterior rhinometry | A decrease in the airflow resistance (RN) both during inhalation and exhalation |
| Lorino 1999 | \|Inserts/decongestant medication | 17 (9m, Sk) | Posterior rhinomanometry | A decrease in the airflow resistance (RN) both after the insert and decongestant medication |
| Meissner 1999 | Inserts | 17 (7m, 10k) | Rhinomanometry | A significant increase in intense inhalation flow for 50% of inspiratory volume (F1F50) |
| Metes 1992 | Inserts | 72 (46m, 26k) | Posterior rhinomanometry | Decrease in the airflow resistance (RN) |
| Peltonen 2004 | Strips/inserts | 27(15m, 12k) | Anterior rhinomanometry | In both cases, an increase in air resistance (AR) and an increase in TMCA |
| Pevernagie 2000 | Strips | 12 (11m, 1k) + placebo | Polysomnography, Anterior rhinomanometry | No statistically significant changes |
| Tong 2001 | Strips | 9 m | | A significant increase in peak inspiratory air flow (PNIF) before effort |
| Tong 2001 | Strips | 8 m | | A significant increase in peak inspiratory air flow (PNIF) before effort |

**Table 2. Influence on performance during physical effort**

| Author | Type of devices | Patients | Research methods | Result |
|---|---|---|---|---|
| Gehring 2000 | Strips | 15 (6m, 9k) + placebo | Measurement of nasal breathing. | No statistically significant differences were revealed. |
| Griffin 1997 | Strips | 30 (20m, 10k) + placebo | Exercise on a cycloergometer. Oxygen consumption measurement (VO2), heart rhythm and ventilation | Statistically significant reduction in oxygen consumption, ventilation and heart rhythm |
| Tong 2001 | Strips | 9 m +placebo | Treadmill. Measurement of breathing parameters during effort | An increase in the effort time (until exhaustion) was observed. No changes in the other parameters. |
| Tong 2001 | Strips | 8 m + placebo | Cycloergometer Measurement of breathing parameters during effort Measurement of the level of the perceived effort (RPE) and the level of perceived breathing difficulty (RPMBE) | Reduction in breathing muscle exhaustion, increase in the input power |
| Trocchio 1995 | Strips | 16m | Exercise on a cycloergometer. Measurement of basic parameters during effort | No statistically significant differences were revealed. |

**Table 3. Influence on sleep and**

| Author | Type of devices | Patients | Result |
|---|---|---|---|
| Harris 2009 | Inserts | 26 (12m, 14k) | The number of snoring episodes decreased by 52% as compared to the control group |
| Hoffstein 1993 | Inserts | 15 (9m, 6k) | No therapeutic effects were observed |
| Loth 1996 | Inserts | 42 m | Significant reduction in snoring and morning fatigue |
| Loth 1999 | Inserts | 42 m | Improved quality of life according to the Nottingham health profile and a visual analogue scale |
| Metes 1992 | Insert | 10 | No therapeutic effects were observed |
| Pevernagie 2000 | Strips | 12 (11m, lk) | Decrease in the snoring frequency without a significant influence on sleep quality, the apnoea index, shallow breath |
| Schonhofer 2003 | Inserts | 38 (31m, 7k) | Decrease in the continuous positive pressure in airways (in 50% of the patients) |
| Shinakawa 1998 | Inserts | 18 (12m, 6k) | Reduced snoring and apnoea were observed in 72% of the patients |
| Ulfberg 1997 | Strips | 35 (17m, 18k) | Significant decrease in snoring, mouth dryness and sleepiness according to the Epworth scale |

## 6. Analysis of clinical data 6.1.

### 6.1 Effectiveness

In the published studies, the devices used decreased nasal resistance by 22-50% (Breathe Right) and 35-45% (Nozovent) and increased the airflow through the nose by 10-23% (Breathe Right) and 29% (Nozovent). In one study comparing the effect of Breathe Right and Nozovent, improved MCA was observed if both devices were used - the effect of Breathe Right was greater - while there was no difference in the reduction in nasal resistance between the devices [Peltonen 2004]. During free or increased breathing, **7** out of 20 and **8** out of **1 7** patients using the strips responded by a significant decrease in nasal inspiratory resistance [Kirkness 2000]. As Breathe Right peak inspiratory airflow (nPIF) and it did not influence peak expiratory airflow (nPEF), Di Somma et al. concluded that this device does not only dilate the narrow nasal cavity but it also stabilizes the nasal valve area, thus preventing its narrowing during inhalation [Di Somma 1999]. In a study by Lorino et al., owing to the use of Nozovent and local decongestion of the nasal mucous membranes, a reduction in the mean nasal resistance was obtained [Lorino**1998].**In the next experiment, the final effects were not quite additive, which could indicate a small dilating influence of the device on the nasal concha and/or a small decongestive influence of the device in the nasal valve area [Lorino 1999]. In an analysis of the flow-volume loop **(FVL),** Meissner et al. showed that Nozovent improved the nasal airflow in patients with extrapulmonary variable resistance [Meissner 1999]. In summary, both Breathe Right and Nozovent dilate the nasal valve area, decrease the nasal resistant and improve the airflow through the nose. The airflow is mostly improved during inhalation as the nasal valve is stabilized and protected against narrowing. The response differs significantly between patients and it can big.

**Influence on performance during physical effort**

During increased effort, a majority of persons automatically switch from nasal breathing to oral and nasal breathing. Mechanical nasal dilators can extend the period of nasal breathing with increasing effort, it was shown that Breathe Right increased the ability to endure moderate effort with nasal breathing only, while maintaining heart and breathing parameters at the placebo control group level [Tong 2001]. In a physical load situation forcing the switch to oral breathing or oral and nasal breathing, an improvement of the airways at the nasal section had a small [Tong 2001-1] or no influence [O'Kroy 2000 O'Kroy 2001, Trocchio 1995] on the final result. In one study in which placebo strips applied by a technician were used, the oxygen consumption and pulse were reduced at specific intensity of exercise, while the ventilation level increased when using Breathe Right [Griffin 1997], the other tests did not show any improvement as compared with the placebo group [O'Kroy

2000 O'Kroy 2001, Tong 2001]. After using Breathe Right **1 1** /15 persons were considered to respond to the nasal dilator, during exclusive nasal breathing and the progressing level of work on the cycloergometer, increased ventilation was observed with a significant decrease in nasal resistance during the peak airflow and reduced nasal breathing effort [Gehring 2000]. Nasal dilators delay oral and nasal breathing and have a small influence on its further efficiency. Nasal breathing is particularly important for asthma sufferers, especially during physical effort or activities in the open air at very low temperatures. It is very beneficial for athletes who feel less dryness in the throat and larynx, lose less water, which is very important in many sports.

**Influence on snoring and sleep**

In persons who breathe properly through the nose, difficulties in nasal breathing may occur after lying down. It is caused by physiological hyperaemia of venous sinuses in the mucous membrane of the nasal concha. The degree of nasal patency is regulated by reflex dilation of the opposed nasal tract in the side lying position and by the nasal cycle [Pevemagie 2005]. Measurements in the supine position showed a 54% increase in the MCA while using Breathe Right as compared to the placebo group and a 60% decrease in the nasal resistance while using Nozovent [Metes 1992]. Polysomnography in snoring persons, some of whom also suffered from apnoea,
an increased nasal airflow was observed after 10 nights of using Nozovent. In all patients, except for one, the apnoea index (AI) decreased during the use of the device and the minimum oxygen saturation increased [Hoijer 1992]. Good tolerance and effectiveness is shown by the fact of using the Nozovent by men with severe snoring at a level of 88% after 1 month, 60% after 6 months [Loth 1996] and 21% after 5 years [Petruson 2000]. Less severe morning fatigue was observed in a group of men and their partners noticed reduced snoring during the use of the device [Loth 1996]. In other studies, an improvement in the total assessment and an improvement in responses provided in the part concerning energy in the Nottingham Health Profile questionnaire already after month [Loth 1999]. Among men “who snored less and felt less tired in the morning” already after 1 month after the use of the Nozovent device an increase in the insulin like growth factor 1 (IGF-1) in the blood serum was observed. An increased IGF-1 lever was observed also in apnoea treatment during sleep using continuous positive airway pressure (CPAP) and after adenotonsillectomy, which probably was caused by an increased secretion of growth hormones induced by deep sleep [Loth 1998|. In the group of persons with severe snoring without apnoea, an improvement in snoring intensity, mouth dryness and the Epworth Sleepiness Scale was observed after using Breathe Right for 2 weeks [Ulfberg 1997]. A beneficial influence of the Nozovent device was observed in patients suffering from OSAS ( obstructive sleep apnoea syndrome) who received the continuous positive airway pressure therapy (CPAP). The required level of the pressure was reduced by o>1cm H20 in 50% of patients who required pressure above 9 cm H2O [Schonhofer 2000]. After a report of the American Academy of

Sleep Medicine in 2003 that despite limited scientific evidence, after the application of nasal dilators, snoring can be reduced, there appear further studies showing that Nozovent and Breathe Right improve disturbed breathing during sleep in some patients [Meoli 2003 ]. As snoring can be caused by numerous physical factors which can occur simultaneously in one person, such as BMI, throat or nose obstruction and pathology within the mandible, it is difficult to predict the influence of an intervention aimed against one of these factors.

### 6.2. Safety

In the available scientific literature, virtually no adverse effects of nasal dilators are observed [Jungmark 2012]. The adhesive under the Breathe Right strip can irritate the skin of the bridge of the nose, while the pressure of Nozovent can irritate the skin in the nasal vestibule, especially if a large-size device is used. One of the reasons for discontinuation of the use of the device is a sense of discomfort. Such cases were observed in 3 out of 18 Japanese men [Shinakawa 1998]. In none of 38 patients with OSAS treated with CPAP, no sleep disturbance was observed as a result of using Nozovent for  1 night [Schonbofer 2003]. From the aesthetic point of view, neither strips nor inserts seem very attractive. 5 out of 26 snoring Japanese men did not decide to use Nozovent because of its appearance [Shinakawa 1998]- The Nozovent-type nasal insert can fall out, in 3 out of 26 Caucasian patients, it fell out during the night [Schonhofer 2000].

In the available literature, only one case of a 48-year-old patient suffering from right-sided sinusitis for 5 weeks was recorded. Rhinoscopy showed effusion and redness of nasal mucous membrane. The reason was a part of a nasal dilator left in there - a silicone cylinder. After its removal, slight ulceration without granulation lesions was observed and the patient's condition improved quickly (Jungmark 2012).

### 6.3. Labelling, instructions for use and promotional materials pertaining to the product

Proposed by the manufacturer, the Plast-Med company. Labelling, instructions for use and promotional materials are consistent with the clinical data and contain information about all hazards.

## 7. Conclusions

Based on the international literature review pertaining to research on nasal dilators, it can be concluded that:

- these devices (just like the product under assessment) showed effectiveness in the improvement of nasal ventilation, improved efficiency during physical effort, improved sleep quality and snoring reduction
- when used properly, these devices are characterised by high safety,
- no hazards were identified in the quoted clinical data which resulted from the use of the medical device under assessment
- the **NoSnorePLUS** nasal insert is a medical device which can be fully used in the way declared by the manufacturer.

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