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(54) NASAL DILATOR WITH VARIABLE SPRING RATE

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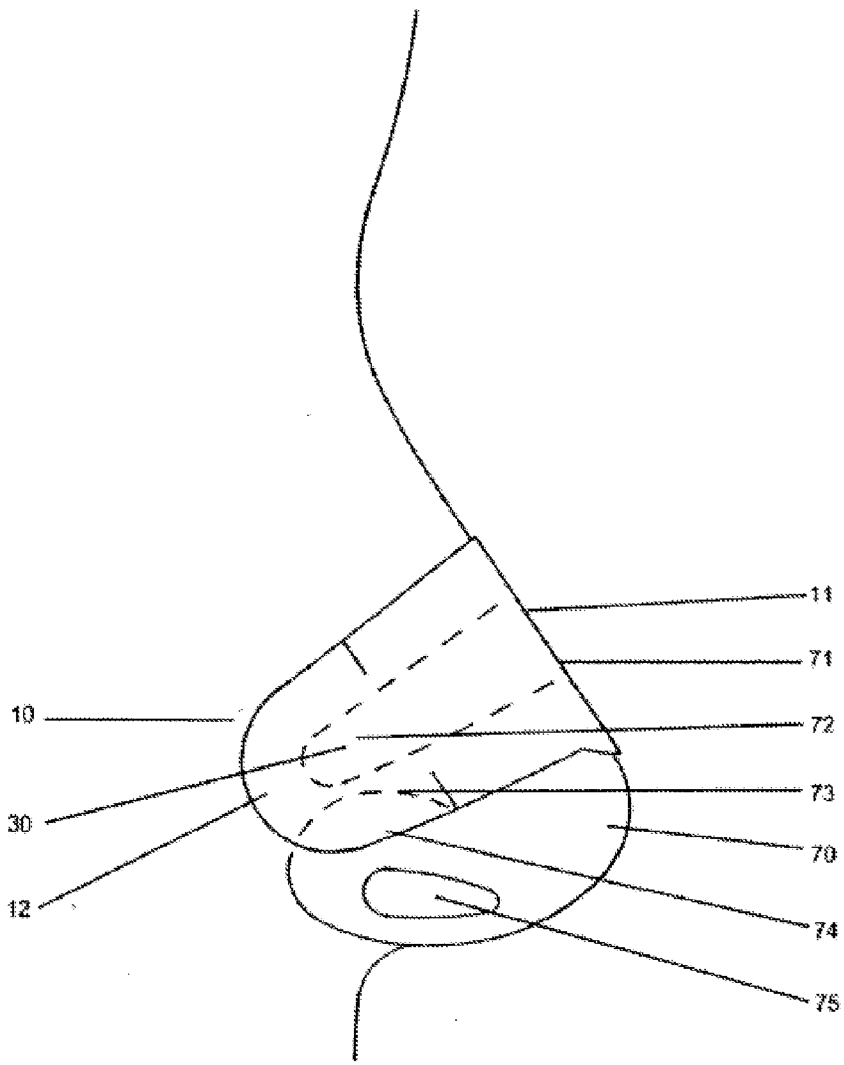
(57) ABSTRACT

A nasal dilator strip and methods, the strip including a first layer including a cover having adhesive on a surface thereof, the cover having a first edge with a convex locating feature and a second edge opposite the first edge, the second edge being an uninterrupted edge, and a second layer having opposite surfaces, one opposite surface of the second layer being secured to the first layer, at least a portion of the other opposite surface of the second layer having adhesive to hold the two-layer nasal dilator strip in place on a user's nose, the second layer including a substantially planar resilient member, the resilient member having a constant thickness and longitudinal sides which converge from a center of the resilient member to a pair of spaced apart ends.



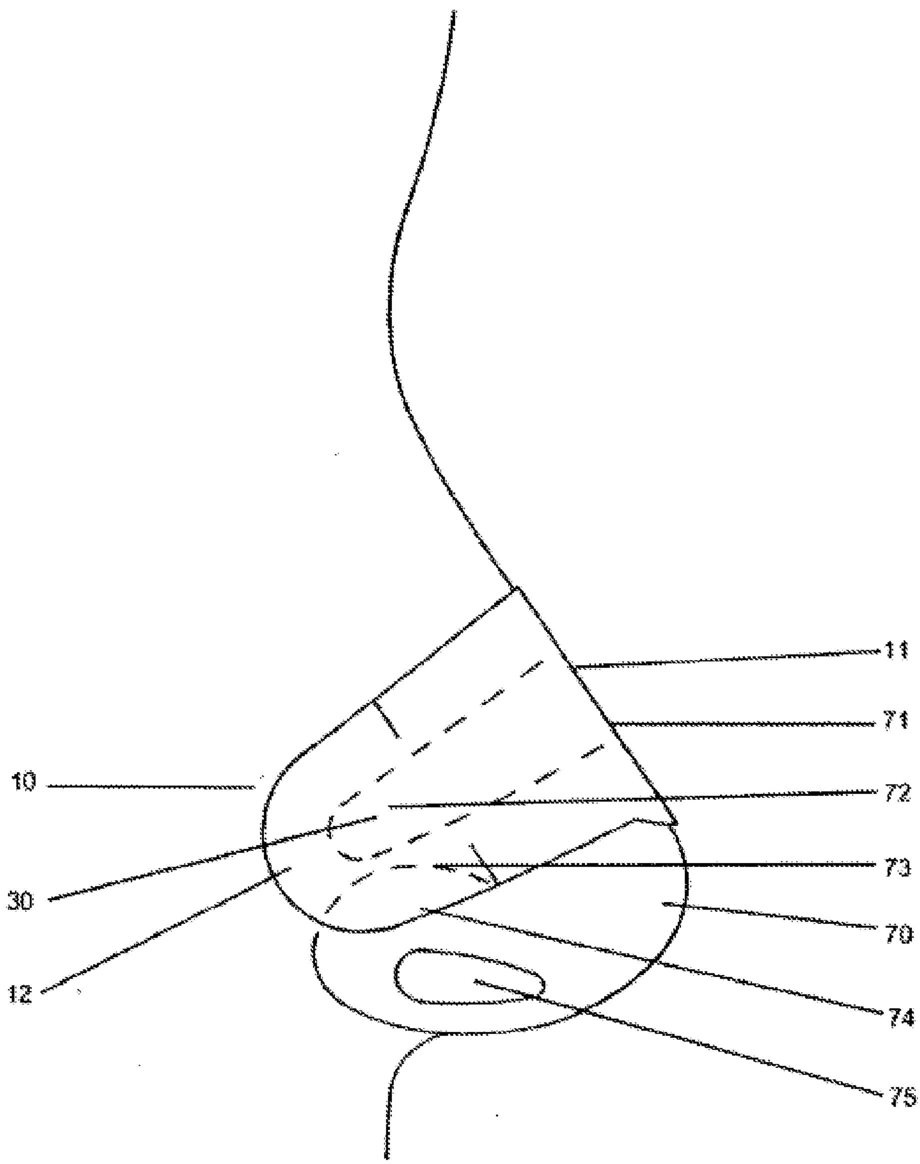


FIG 1

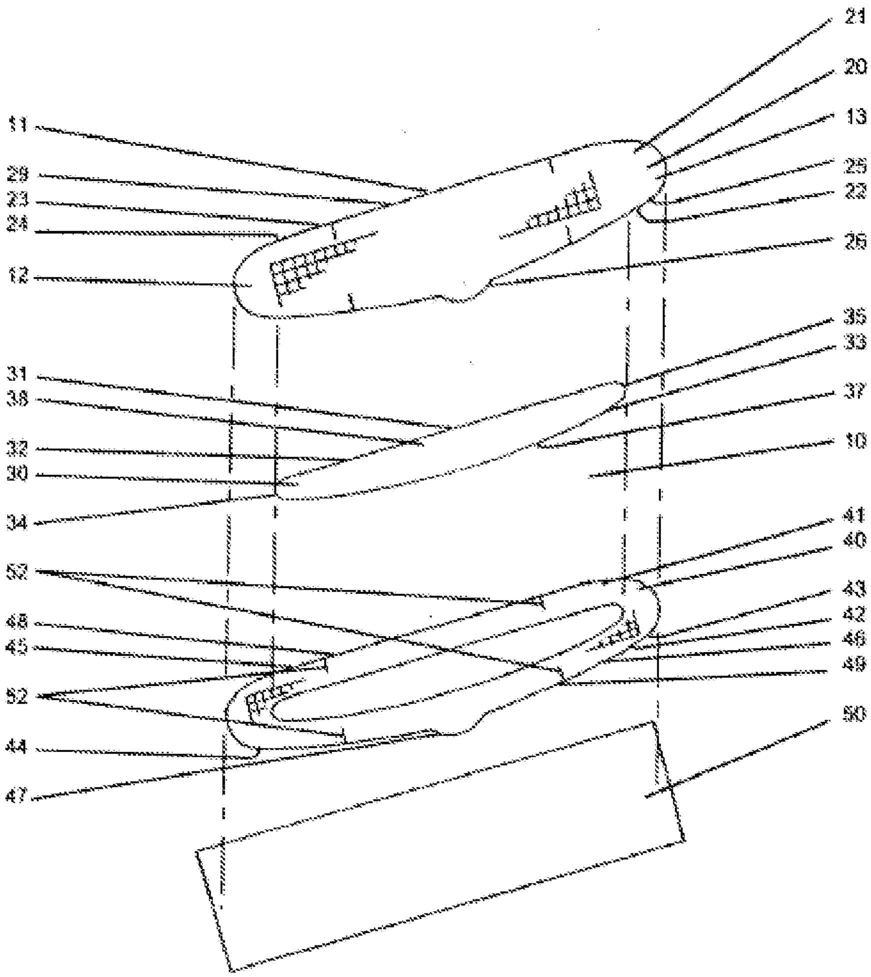

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FIG 2

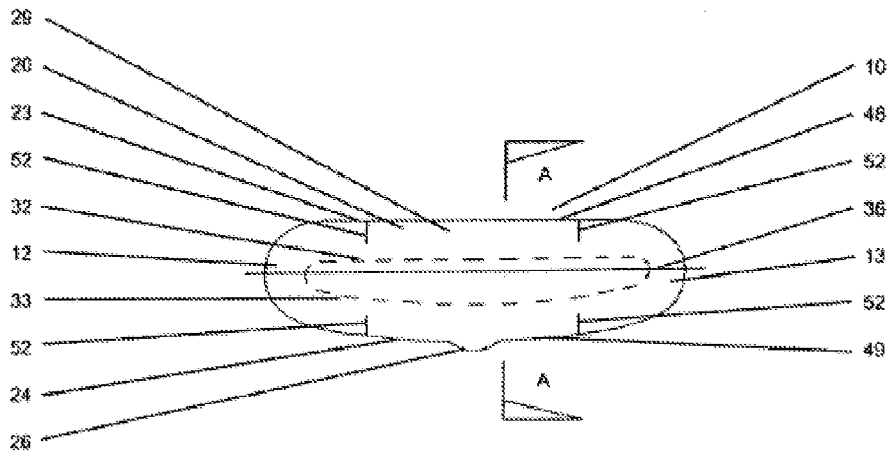
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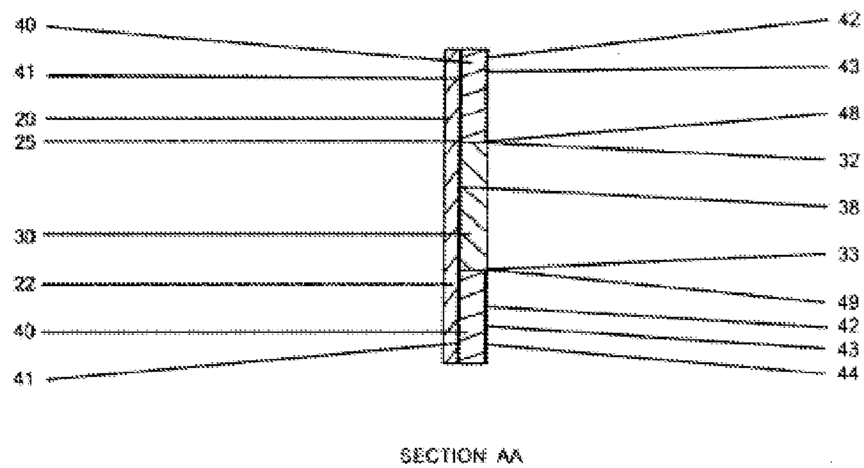
FIG 3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SECTION AA

FIG 4

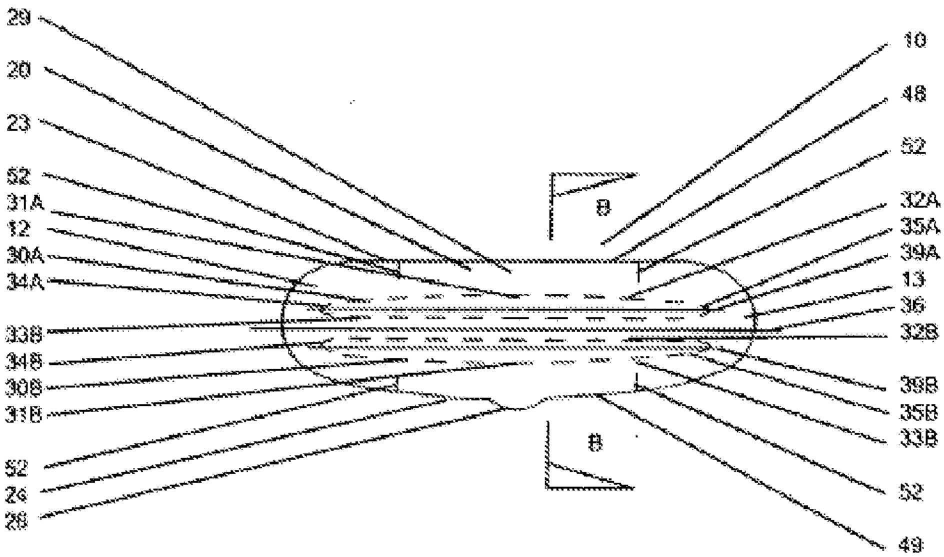
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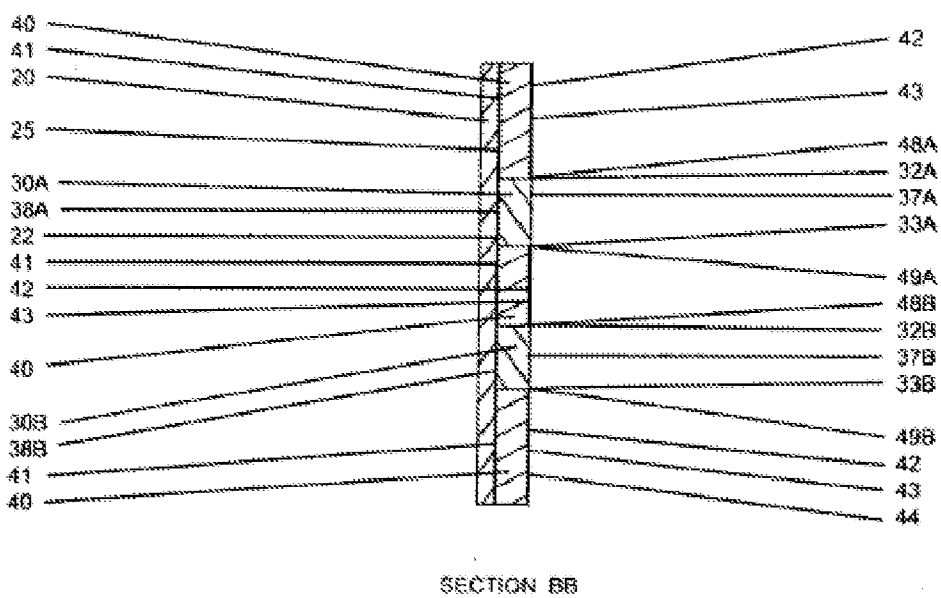
FIG 5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SECTION BB

FIG 6

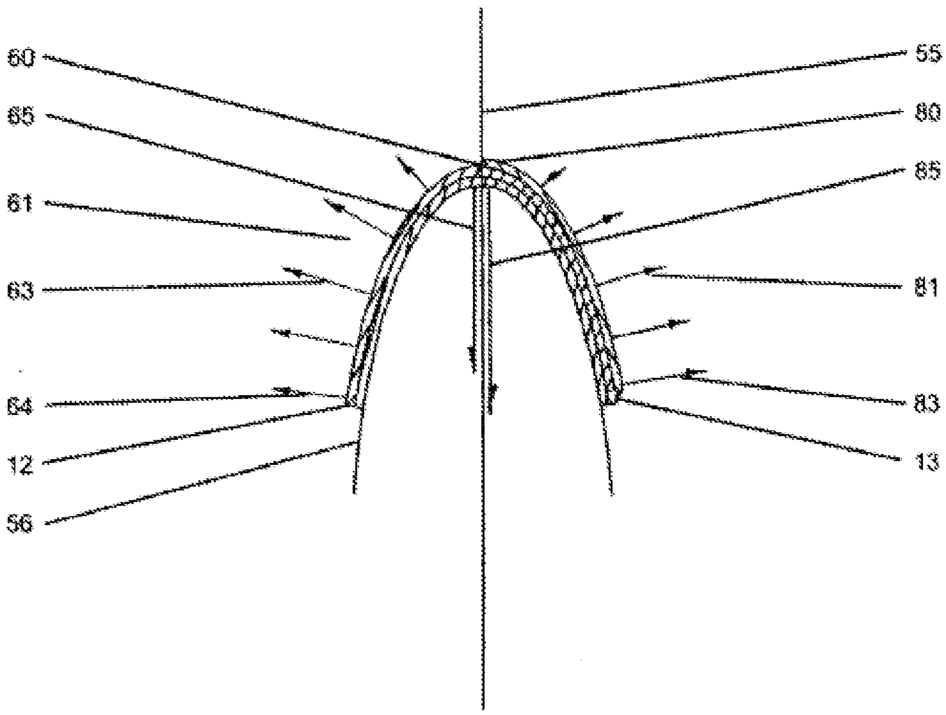

FIG 7

NASAL DILATOR WITH VARIABLE SPRING RATE

RELATED APPLICATION

[0001] This application is a continuation application of U.S. patent application Ser. No. 11/880,217, filed on Jul. 19, 2007, the entire contents of which are incorporated herein by reference.

BACKGROUND

[0002] This invention relates to an improvement to the configuration of nasal dilators such as those described in Spanish Patent No. 289,561 to Iriarti dated 15 Sep. 1986 and in the further patents discussed below. Generally speaking these dilators employ a resilient band which has an adhesive on the bottom side and sufficient length so that the resilient band can be bent over the bridge of the nose, and each end of the band becomes adhesively attached to the soft tissue on the lateral wall of the nasal passage.

[0003] Bending the resilient band from its initial planar state to its deformed state with its ends in contact with the lateral walls of the nasal passages and the center of the band overlying the bridge of the nose results in forces tending to pull out on the lateral wall tissues which stabilize the walls of the nasal passages during breathing.

[0004] The present invention improves nasal dilators by providing them with a resilient member which has a variable spring rate that decreases from the point where the resilient band crosses the bridge of the nose to the point where the resilient band terminates at the lateral wall of the nasal passage.

[0005] The nasal dilator of the present invention has a soft fabric cushion of the same or a slightly greater thickness than the resilient member. The soft fabric cushion is located in the same layer as the resilient member and covers the area of the soft fabric cover which is not in direct contact with the resilient member. The soft fabric cushion is in contact with edges of the resilient member and prevents the edges of the resilient member from pressing into the skin on the user's nose while using the nasal dilator.

[0006] The present invention further provides a convex protrusion on the side of the dilator at the center of the bridge of the nose facing the tip of the nose to indicate to the user the proper orientation of the dilator when applying it to the nose.

[0007] Blockage of the nasal passages from swelling due to allergies, colds and physical deformities can lead to breathing difficulty and discomfort. The nasal passages have mucus membranes which condition the air in the nasal passages prior to its arrival in the lungs. If the nasal passages are constricted due to swelling or minor deformities then the alternative is to breathe through the mouth. This means that the air bypasses the mucus membranes, losing the conditioning effects and causing irritation in the throat and lungs. At night, restrictions to breathing through the nasal passages can lead to snoring and/or sleep disturbances. In some cases, the restricted air supply can cause sleep problems brought on by a lack of oxygen.

[0008] For people with chronic blockages in the nasal passages, the alternative to correct the problem has been expensive surgery or medication. People with minor deformities and breathing problems brought on by swelling of the walls of the nasal passageways have been turning to various products fitted in or on the nose which claim to open the nasal passages.

[0009] The structure of the nose limits the options available for the design of nasal dilators. The nose terminates at the nostril, which has a slightly expanded volume immediately above it known as the vestibule. Above the vestibule, the nasal passage becomes restricted at a point called the nasal valve. At the nasal valve, the external wall of the nose consists of soft skin known as the lateral wall, which will deform with air pressure changes induced within the nasal passage during the breathing cycles. Above the nasal valve the nasal passage opens up to a cavity with turbinates over the top of the palate and turns downward to join the passage from the mouth to the throat.

[0010] The external structure of the nose consists of a skin covering over the nasal bones which are part of the skull. This gives the top of the nose a rigid structure at its base. Beyond the rigid nose bones, there is thin cartilage under the skin which is attached to the septum, which in turn contributes to the outside shape of the nose. The septum forms the wall between the two nostrils and may, if it is crooked, contribute to breathing problems.

[0011] As an alternative to surgery, the structure of the nose and the current art leave two main alternatives for the design of nasal dilators. One alternative uses a tube or a similar structure which can be inserted into the nasal passage to hold it in the open position allowing the free passage of air. The disadvantage to this design is that the dilator structure covers up the mucus membranes which condition the air. Also dilators of this design are uncomfortable and can irritate the walls of the nasal passage.

[0012] Another alternative is a dilator design, taught by the Iriarti patent for example, where each end that attaches to the external lateral wall of each of the nasal passages has resilient means connecting the ends for developing an external pulling force on the lateral wall causing it to open the nasal passage. This design has the advantage over the first alternative because the nasal passages are not disturbed by an internal insert. This design has limited control over the resilient force on the lateral wall of each of the nasal passages, and the resilient members crossing over the bridge of the nose can cause discomfort.

[0013] The present invention is an improvement over earlier nasal dilator configurations because it redistributes the lifting forces within the resilient band by modifying the spring rate, so that they can provide optimum lift on the lateral walls of the nasal passage. In addition maximum comfort for the user is achieved by adding the cushion layer at the same level as the resilient member to prevent the edge of the resilient member from pressing into the skin on the user's nose.

[0014] There is prior art which permits for adjusting the spring rate of the resilient band in the nasal dilator. For example, U.S. Pat. No. 5,476,091 to Johnson employs two parallel resilient bands of constant width and constant thickness which cross over the bridge of the nose and terminate at the outer wall of each nasal passage. The Johnson patent shows a plurality of notches cut into the top of each end of the resilient band to reduce the spring rate, which in turn prevents the end of the resilient band from peeling away from the skin. Each notch is a single point reduction of the spring rate with the spring rate reduction determined by the depth of the notch.

[0015] U.S. Pat. No. 5,479,944 to Petruson and U.S. Reissue Pat. No. Re 35,408 to Petruson provide nasal dilators with a one-piece molded plastic strip, the ends of which carry tabs for insertion into the nostrils.

[0016] U.S. Pat. No. 5,611,333 to Johnson shows the same concept of single point reduction in the spring rate of the resilient band using the notches shown in U.S. Pat. No. 5,476,091 mentioned above. In addition, the '333 Johnson patent shows other designs for the resilient band with either holes or slots which are located at the ends of the resilient bands and are intended to reduce the spring rate at a single point to prevent the end of the resilient band from peeling away from the skin.

[0017] U.S. Pat. No. 6,029,658 to Voss shows a beam-shaped resilient band which extends from one side of the user's nose across the bridge of the nose to the other side of the nose. The resilient band is made of plastic and has a varying thickness and width over the entire span. The resilient band exhibits a rigidity increase from the center towards the two respective ends which attach to the sides of the user's nose, which is the exact opposite of what is attained with the present invention.

[0018] U.S. Pat. No. 6,453,901 to Ierulli discloses several nasal strip configurations where the cover member extends beyond the perimeter of the spring member, including one embodiment in which the strip has some degree of variation in the spring force over a portion of the length of the strip.

[0019] Some of the better known nasal dilator patents, such as U.S. Pat. No. 5,533,499 to Johnson, U.S. Pat. No. 5,533,503 to Doubrek et al., and U.S. Pat. No. 6,318,362 to Johnson, all teach of nasal dilators with a cushion layer between the resilient member and the user's skin. U.S. Pat. No. 6,058,931 to Muchin is similar to the Spanish Iriarti patent in that the resilient member is in direct contact with the user's skin and no cushion layer is provided. These nasal dilators differ from the current invention, which provides a cushion layer at the same level in the nasal dilator structure which prevents the edge of the resilient member from pressing into the user's skin, but at the same time does not prevent contact of the resilient member from the user's skin.

[0020] Even the most recent nasal dilator patents such as U.S. Pat. No. 6,694,970 to Spinelli, U.S. Pat. No. 6,769,428 to Cronk et al., and U.S. Pat. No. 6,769,429 to Benetti do not have the resilient member with a constantly varying spring rate which is diminishing from the centerline to each end of the resilient member in combination with the cushion layer located at the same level as the resilient member. U.S. Pat. No. 7,114,495 to Lockwood does have the resilient member with a constantly varying spring rate which diminishes from the centerline to each end of the resilient member. However, it has a cushion layer under the resilient member. In contrast, the cushion layer of the nasal dilator of the present invention is at the same level as, and surrounds, the resilient member.

BRIEF SUMMARY OF THE INVENTION

[0021] An object of this invention is to provide a nasal dilator which exhibits improved performance relative to the nasal dilator known from the prior art.

[0022] An important feature of the present invention is to provide a soft fabric cushion layer which is the same size and shape as the top soft fabric cover and has adhesives on both sides. The cushion layer is at the same level as the resilient member and equal to or slightly thicker than the resilient member. As a result, the cushion layer and the resilient member are substantially flush where they meet. Since the resilient member is attached to the bottom of the top fabric cover by adhesives, the cushion layer surrounds the edge of the resilient member and covers the remaining area of the top soft fabric cover not covered by the resilient member. The adhesive on the bottom of the cushion layer is in contact with the skin on the user's nose when the dilator is in use.

[0023] Another improvement feature of the present invention is to configure the resilient band to reduce the width gradually from the center of the resilient band towards each end in a way that gradually reduces the spring rate of the resilient band. The thickness of the resilient band remains constant over its entire length, which simplifies the structure while keeping costs low.

[0024] A further improvement of the present invention is that the new dilator has a relatively greater width at its center with the shape of the bottom edge provided with a slight convex protrusion which points to the tip of the nose when the dilator is in use. The outer shape of the dilator is configured to optimize the location of the resilient member over the soft tissues on the outer wall of the nasal passages where the dilating forces are most effective.

[0025] Other improvements provided by the present invention are the four slits in the top soft fabric cover and the cushion layer at the boundary that separates the ends of the dilator from the intermediate structure which connects the ends of the dilator. The four slits are close to perpendicular to the longitudinal axis of the dilator and allow the top soft fabric cover and cushion layer to conform to the many different shapes of the outer walls of the nasal passages.

[0026] An additional improvement of the present invention is the use of transparent materials for the top soft fabric cover, the resilient member, and the cushion layer. Here too the cushion layer has a thickness that is equal to or slightly thicker than the resilient member. The normal color for the top soft fabric cover is tan; however, for sports applications the cover may be black or some other dark color.

[0027] The nasal dilator of the present invention is a significant unobvious improvement over the prior art. Nasal dilators that have been in the market for more than 10 years have a resilient member held in place on the user's nose by a top cover that defines the length and width of the dilator as well as adds additional adhesive surface to overcome the stresses developed by the resilient member. Another nasal strip that has been sold in the past has a resilient member sandwiched between a top surface which defines the length and width of the dilator and a cushion layer that covers the entire bottom surface of the top layer. Both of these dilators use current converting technology in their manufacturing process.

[0028] The improved nasal dilator of the present invention uses a new converting technology that has not been available until now. The new converting process requires that the resilient member be formed and located on the bottom surface of the top cover in a precise location. At the same time the cushion layer must have an opening cut and be precisely indexed, so that the edges of the cushion layer match up to the respective edges of the resilient member in order to achieve the contiguous bottom surface required by the improved dilator. This improvement in precision in the converting process is due to computer-controlled indexing, as well as a special webbing, which do not form part of the present application.

[0029] The improvements summarized above enhance the performance of the dilator and make the dilator more comfortable for the user as compared to prior art dilators in general and the Iriarti dilator in particular. In another embodiment the invention provides a method of {text}.

BRIEF DESCRIPTION OF THE DRAWINGS

[0030] The unique advantages of the present invention will become apparent to one skilled in the art upon reading the following specification and by reference to the following drawings:

[0031] FIG. **1** is a side view of the dilator on the nose;

[0032] FIG. **2** is an exploded perspective top view of the components making up the dilator;

[0033] FIG. **3** is a top view of the dilator with a single resilient band;

[0034] FIG. **4** is a sectional view of the dilator in FIG. **3** showing the layers of the components that make up the dilator;

[0035] FIG. **5** is a top view of the dilator with two resilient bands;

[0036] FIG. **6** is a sectional view of the dilator in FIG. **5** showing the layers of the components that make up the dilator; and

[0037] FIG. **7** is a drawing showing the force vectors of the dilator in this invention compared to the force vectors in other, known dilators.

DETAILED DESCRIPTION

[0038] The specific improvements provided by this invention over past nasal dilators described in the prior art are best seen in the attached drawings.

[0039] Referring to FIGS. **1-4**, the new nasal dilator **10** is mounted on the nose **70** of the user. The nasal dilator **10** has a center **11** that is bent over the bridge **71** of the nose **70**, and each end **12** and **13** of the nasal dilator **10** is positioned over the lateral wall **72** of the nose **70**.

[0040] The lateral wall **72** of the nasal passage **75** is located in the soft tissue **73** above the nostril flare **74**, which in turn is adjacent to the entrance of the nasal passage **75**. When the nasal dilator **10** which contains a resilient band **30** is deformed from its normally planar state by being bent over the bridge **71** of the nose **70**, the ends **12** and **13** which are attached to the lateral wall **72** of the nasal passage **75** tend to pull on the lateral wall **72** in a way that opens the nasal passage **75** and improves the air flow through the nasal passages **75** during breathing. This invention shows improvements to the performance of the nasal dilator **10**, makes the nasal dilator **10** easier to use, and increases the comfort of the nasal dilator **10** when it is used to dilate the lateral walls **72** of the nasal passages **75**.

[0041] The new nasal dilator of the present invention has a top cover **20** which establishes the length and width of the nasal dilator **10**, a resilient member **30** which is attached to the bottom surface **22** of the top cover **20**, and a cushion layer **40** which is equal in thickness to the resilient member **30** and covers all of the bottom surface **22** of the top cover **20** that is not in contact with the top surface **38** of the resilient member **30**. The dilator is flat in its natural state with the thickness of the nasal dilator **10** that is constant over the entire surface of the top cover **20** including surfaces in contact with the resilient member **30** and the cushion layer **40**. The cushion layer **40** has an adhesive **43** which is in contact with the skin on the user's nose **70** when the nasal dilator **10** is in use. The bottom surface **37** of the resilient member **30** does not have an adhesive which is in contact with the skin on the user's nose **70**. The top cover **20** does not contact the skin on the user's nose **70** when the nasal dilator **10** is in place, which is a unique feature of the nasal dilator of the present invention.

[0042] As is best seen in FIG. **2**, the nasal dilator **10** is made up of several layers. The first layer is the top cover **20** which is made from a non-woven polyester cellulose fabric or equal which is usually tan in color on the top surface **21**. The top surface **21** of the top cover **20** can be dyed in any color or imprinted with a brand, logo or other information. The top cover **20** also has a bottom surface **22** which is coated with a 3 mils acrylic hypoallergenic medical grade pressure-sensitive type adhesive **25** or equal. The adhesive **25** covers the entire bottom surface **22** of the top cover **20**.

[0043] The top cover **20** has two sides **23** and **24** which run over the length of the top cover **20** with the exception of an approximately 0.5-inch wide section at the center **11** of the nasal dilator **10**. On one side **23** of the top cover **20**, there is a convex protrusion **26** which is configured to indicate the proper orientation of the nasal dilator **10** when it is in use. When the nasal dilator **10** is properly positioned on the user's nose, the convex protrusion **26** at the center **11** of the nasal dilator **10** is pointed towards the tip of the user's nose **70**.

[0044] The second layer is the resilient member, **30**, a plastic layer, which is made from a polyester sheet which is about 0.010 inch to about 0.015 inch thick, depending on the required strength of the nasal dilator **10**. The thickness selected of the resilient member **30** is constant over the entire length of the resilient member **30**, and the width of the resilient member **30** is greatest at the center **31** where the nasal dilator **10** passes over the bridge of the nose **71**. The bottom edge **33** of the resilient member **30** curves toward the top edge **32** as the distance from the center **31** of the resilient member **30** is increased. This reduction of the width of the resilient member **30** causes a reduction of the spring rate in the resilient member **30** over the span from the center **31** to each of the ends **34** and **35** of the resilient member **30**. The width at the center **31** of the resilient member **30** is less than half of the width of the top cover **20**, and the width of the resilient member **30** at each of the ends **34** and **35** is approximately half of the width of the center **31**.

[0045] The bottom edge **33** of the resilient member **30** between the center **31** and the respective ends **34** and **35** is curved over the length of the strip and is asymmetrical in relation to the longitudinal center line **36** (see FIG. **3**) of the resilient member **30**. Other curves for edges **32** and **33** are possible as long as the maximum width of the resilient member **30** is at the center **31** and the spring rate is reduced as the distance from the center **31** is increased until reaching ends **34** and **35**. To attain the desired force distribution and to prevent the development of torsional forces, the radius of curvature of the edges **32** and **33** of the resilient member **30** is greater than 1.5 inches. In addition, the thickness of the resilient member **30** is 3% or greater than the width of the resilient member **30** at the longitudinal center line **36** in order to establish a baseline spring rate at the centerline of the resilient member **30** and allow for the reduction of width of the resilient member **30** over the span to the ends **34** and **35** in which the polyester of specified thickness will achieve a lifting force of 25 to 30 grams. This ratio increases as the distance from the center **31** is increased, and the width of the resilient band decreases until reaching ends **34** and **35**.

[0046] In the same layer as the resilient member **30**, there is a cushion layer **40** which is equal to or slightly thicker than the resilient member **30** and surrounds the edges **32** and **33** of the resilient member **30**. In this embodiment the edges **48** and **49** of the cushion layer **40** that are adjacent to the respective edges **32** and **33** of the resilient member **30** have the same curvature as the resilient member **30** in order to form a contiguous surface between the bottom **42** of the cushion layer **40** and the bottom **37** of the resilient member **30**. This will prevent the edge of the resilient member **30** from pressing into the user's skin while the nasal dilator **10** is in use.

[0047] The cushion layer **40** is made from non-woven polyester cellulose fabric which is about 0.010 inch to about 0.015 inch thick. The cushion layer **40** is attached to the bottom surface **22** of the top cover **20** which is not covered by the resilient member **30**. As a result, the bottom **37** of the resilient member **30** and the bottom **42** of the cushion layer **40** are in contact with the skin on the user's nose **70**, while the top cover **20** cannot come in contact with the user's nose **70** when the nasal dilator **10** is in use. This also distinguishes this present invention from the prior art because all known nasal dilators either have a cushion layer **40** that prevents the resilient member **30** from contacting the skin on the user's nose **70** or have no cushion layer **40** which allows both the bottom surface **22** of the top cover **20** and the bottom surface **37** of the resilient member **30** to have direct contact with the skin on the user's nose **70**.

[0048] The bottom **42** of the cushion layer **40** is coated with a 3 mils acrylic hypoallergenic medical grade pressure-sensitive type adhesive **43** or equal that is designed to hold the nasal dilator in place on the user's nose **70**. The adhesive **43** on the bottom **42** of the cushion layer **40** has sufficient strength when adhering to the user's nose **70** to overcome the stresses developed by the resilient member **30** when the resilient member **30** is deformed to conform to the surface of the skin of the user's nose **70**. The cushion layer **40** has two sides **45** and **46** which match the two respective sides **23** and **24** of the top cover **20**. The cushion layer **40** also has a convex protrusion **47** which matches the convex protrusion **26** of the top cover **20**.

[0049] A release liner **50** is provided to protect the adhesive surface **43** on the bottom side of the cushion layer **40**. This release liner **50** is removed from the nasal dilator **10** prior to applying the nasal dilator **10** to the skin of the user's nose **70**.

[0050] FIGS. **3** and **4** show a top view of the first embodiment of the nasal dilator **10** and a cross-sectional view (AA) which is perpendicular to the longitudinal axis **36** of the nasal dilator **10**. The cross-sectional view shows the top cover **20** with adhesive **25** on the bottom surface **22** which is in direct contact with the top surface **38** of the resilient member **30** and the top surface **41** of the cushion layer **40**. The edges **32** and **33** of the resilient member **30** are in direct contact with the edges **48** and **49** of the cushion layer **40** forming a contiguous bottom surface **44** which prevents the edges **32** and **33** of the resilient member **30** from pressing into the skin on the nose **70** of the user when the nasal dilator **10** is in use.

[0051] FIGS. **5** and **6** show a top view of another embodiment of the nasal dilator **10** and its respective cross-sectional view (BB) which is perpendicular to the long axis of the nasal dilator **10**. The edges **32** (A&B) and **33** (A&B) of two resilient members **30** (A&B) are shown. The cross-sectional view (BB) shows the top cover **20** with adhesive **25** on the bottom surface **22** which is in direct contact with the top surface **38** (A&B) of the resilient members **30** (A&B) and the top surface **41** of the cushion layer **40**. The top cover **20** is made from non-woven polyester cellulose fabric or equal and the top cover **20** defines the length and width of the nasal dilator **10**.

[0052] The second layer has two or more resilient members **30** (A&B) which are made from a polyester sheet which is about 0.010 inch to about 0.015 inch thick, depending on the required strength of the nasal dilator **10**. The thickness selected of the resilient members **30** (A&B) is constant over the entire length of the resilient members **30** (A&B), so the nasal dilator **10** can be manufactured in a converting process. The width of the resilient members **30** (A&B) is constantly decreasing from the center **31** (A&B) of the resilient members **30** (A&B) to each end **34** (A&B) and **35** (A&B) in this particular embodiment, and the thickness of the resilient members **30** (A&B) is 3% or greater than the width of the resilient member over the length of the nasal dilator.

[0053] As can be seen in FIG. **6**, the resilient members **30** (A&B) are attached to the bottom surface **22** of the top cover **20** with the adhesive **25** that is applied to the bottom surface **22** of the top cover **20**. The resilient members **30** (A&B) are parallel to the longitudinal axis **36** of the top cover **20** with each of the ends **34** (A&B) and **35** (A&B) terminating short of the end edges of the top cover **20**. The resilient members **30** (A&B) have no adhesive on the bottom surface which is in contact with the user's skin when the nasal dilator **10** is in use.

[0054] Each of the resilient members **30** (A&B) can be symmetrical or asymmetrical to the longitudinal axis **39** (A&B) of the resilient members **30** (A&B). Symmetry is achieved by using identical curves for sides **32** (A&B) and **33** (A&B) between the center **31** (A&B) and the ends **34** (A&B) and **35** (A&B) of the resilient members **30** (A&B). The concept of using a reduction of the width in the resilient members **30** (A&B) that causes a reduction of the spring rate in the resilient members **30** (A&B) can be used in nasal dilator **10** with one or more parallel resilient members **30** (A&B) that extend parallel to the longitudinal axis **36** of the nasal dilator **10**.

[0055] In the same layer as the resilient members **30** (A&B), there is a cushion layer **40** which is equal to or slightly thicker than the resilient members **30** (A&B) and surrounds the edges **32** (A&B) and **33** (A&B) of the resilient members **30** (A&B). The cushion layer **40** is designed to form a contiguous surface between the bottom **42** of the cushion layer **40** and the bottoms **37** (A&B) of the resilient members **30** (A&B) to prevent the edges **32** (A&B) and **33** (A&B) of the resilient members **30** (A&B) from pressing into the user's skin while the nasal dilator **10** is in use. The cushion layer **40** is made from non-woven polyester cellulose fabric which is about 0.010 inch to about 0.015 inch thick including the thickness of the attached adhesive **43**. The cushion layer **40** is attached to the bottom surface **22** of the top cover **20** which is not covered by the resilient members **30** (A&B), and the edges **48** (A&B) and **49** (A&B) of the cushion layer **40** are in contact with the respective adjacent edges **32** (A&B) and **33** (A&B) of the resilient members **30** (A&B).

[0056] The bottom **42** of the cushion layer **40** is coated with a 3 mils acrylic hypoallergenic medical grade pressure-sensitive type adhesive **43** or equal capable of withstanding the stresses caused by the resilient members **30** (A&B) and holding the nasal dilator **10** in place on the user's nose **70**. Depending on the specific converting process used to manufacture the nasal dilator **10**, the cushion layer **40** may also have the same 3 mils acrylic adhesive on the top surface **41** to control any stretch in the fabric during manufacturing.

[0057] To protect the adhesive surface **43** on the bottom surface **42** of the cushion layer **40**, a release liner **50** is provided as shown in FIG. **2**. This release liner **50** is pealed away exposing the adhesive **43** on the bottom of the cushion layer **40** when the nasal dilator **10** is ready to be placed on the nose **70**.

[0058] The nasal dilator **10** in both embodiments is normally in a planar state when it is removed from the release liner **50** and has no stresses. When the nasal dilator **10** is bent over the bridge **71** of the nose **70** and the ends **12** and **13** are engaged with the lateral wall **72** of the nasal passage, then the stresses introduced in the resilient member **30** cause the ends **12** and **13** of the nasal dilator **10** to pull outwardly and upwardly on the lateral wall **72** to improve the breathing of the user.

[0059] The nasal dilator **10** in both embodiments can also be provided as a clear nasal dilator **10**. In this case, the top cover **20** is made from a 3 mil polyethylene with the bottom surface **22** coated with 2 mils acrylic hypoallergenic medical grade adhesive **25**. The resilient member **30** in both embodiments is made from the clear polyester and the cushion layer **40** is made from 8 mil polyethylene with both the top surface **41** and the bottom surface **42** coated with 2 mils acrylic hypoallergenic medical grade adhesive **43**.

[0060] Referring to FIGS. **1**, **2**, **3** and **5** there are four slits **52** in the top soft fabric cover **20** and the cushion layer **40** at the boundary of the ends **12** and **13** of the nasal dilator **10** and the intermediate structure **29** which connects the two ends **12** and **13**. The four slits **52** are shown to be perpendicular to the longitudinal axis **36** of the nasal dilator **10**, and they allow the top soft fabric cover **20** and the cushion layer **40** to conform to the many different shapes of the outer wall tissue **73** of the nasal passages **75**. In some cases the slits **52** may be cut at an angle to the longitudinal axis **36** of the nasal dilator **10**.

[0061] The use of a resilient band **30** with a decreasing spring rate in a nasal dilator **10** has a positive effect on the nasal dilator **10** performance. FIG. **7** shows a comparison of the performance of a nasal dilator **10** with a decreasing spring rate **60** on the left side of the vertical centerline **55** and a nasal dilator with a constant spring rate **80** on the right side of the vertical centerline **55**. The nasal dilator **10** is shown bent over an elliptical surface **56** which represents the skin **76** of the user's nose **70**.

[0062] The nasal dilator **10** with the decreasing spring rate **60** has a series of vectors **61** pulling out on the elliptical surface **56**. Vectors **61** which are further away from the vertical centerline **55** increase to vector **63**. Then they begin to decrease to vector **64** at the end **12** of the nasal dilator **10**. The vectors **61** on the side with the decreasing spring rate **60** cause the lateral wall **72** to be pulled up and out at the center of the nasal passage **75**, which improves the air flow in the nasal passage **75**. A reactive vector **65** provides an opposing force to vectors **61**.

[0063] The right-hand side of FIG. **7** illustrates the forces generated by a nasal dilator **10** with a constant spring rate **80**. It generates a series of vectors **81** pulling out on the elliptical surface **56**. As the vectors **81** move away from the vertical centerline **55**, they increase until the last vector **83**. This means that the pull on the lateral wall **72** is outward and that the maximum vector **83** is pulling out on the lateral wall **72** at the edge of the nasal passage **75**. Although air flow is improved, the nasal dilator **10** with the decreasing spring rate **60** provides better performance because it opens the lateral wall **72** adjacent to the center of the nasal passage **75** where the maximum air volume flows. Also the reactive vector **85** is greater than the reactive vector **65** for the decreasing spring rate **60** nasal dilator **10**, which renders the constant spring rate **80** nasal dilator **10** less comfortable for the user.

[0064] The description of the preferred embodiment described herein is not intended to limit the scope of the invention, which is properly set out in the claims.

What is claimed is:

1. A two-layer nasal dilator strip comprising:

a first layer including a cover having adhesive on a surface thereof, the cover having a first edge with a convex locating feature and a second edge opposite the first edge, the second edge being an uninterrupted edge; and

a second layer having opposite surfaces, one opposite surface of the second layer being secured to the first layer, at least a portion of the other opposite surface of the second layer having adhesive to hold the two-layer nasal dilator strip in place on a user's nose, the second layer including a substantially planar resilient member, the resilient member having a constant thickness and longitudinal sides which converge from a center of the resilient member to a pair of spaced apart ends which, if forced together from initial positions to reduce direct spacing between the ends, results in restoring forces in the resilient member to restore the direct spacing between the ends.

2. The two-layer nasal dilator strip of claim **1** wherein the second layer also includes a cushion member.

3. The two-layer nasal dilator strip of claim **2** wherein the opposite surface of the cushion member has adhesive.

4. The two-layer nasal dilator strip of claim **2** wherein the opposite surface of the resilient member does not have adhesive.

5. The two-layer nasal dilator strip of claim **1** wherein the second edge of the cover is an uninterrupted linear edge.

6. The two-layer nasal dilator strip of claim **1** wherein the resilient member is made of plastic.

7. The two-layer nasal dilator strip of claim **6** wherein the resilient member is made of polyester sheet material.

8. The two-layer nasal dilator strip of claim **1** wherein the resilient member has a thickness of about 0.010 of an inch to about 0.015 of an inch.

9. The two-layer nasal dilator strip of claim **1** wherein the cover and the resilient member are fabricated from transparent materials.

10. The two-layer nasal dilator strip of claim **1** wherein the resilient member is symmetrical with respect to a lateral centerline of the resilient member.

11. The two-layer nasal dilator strip of claim **1** wherein the resilient member is asymmetrical with respect to a longitudinal centerline of the resilient member.

12. The two-layer nasal dilator strip of claim **1** wherein the longitudinal sides of the resilient member converge from a lateral centerline to the ends.

13. The two-layer nasal dilator strip of claim **1** wherein the resilient member has a spring rate which diminishes from the center to the ends.

14. The two-layer nasal dilator strip of claim **13** wherein the resilient member has a constantly varying spring rate which diminishes from a lateral centerline of the resilient member to the ends.

15. The two-layer nasal dilator strip of claim **1** wherein the resilient member generates restorative forces capable of supporting a load of 25 to 30 grams applied to an end of the resilient member.

16. A nasal dilator strip comprising:

a cover having adhesive on a surface thereof, the cover having a first edge with a convex locating feature and a second edge opposite the first edge, the second edge being an uninterrupted edge; and

a substantially planar resilient member secured to the cover, the resilient member having a constant thickness and longitudinal sides which converge from a center of the resilient member to a pair of spaced apart ends which, if forced together from initial positions to reduce direct spacing between the ends, results in restoring forces in the resilient member to restore the direct spacing between the ends.

17. The nasal dilator strip of claim 16 wherein the nasal dilator strip is a two-layer nasal dilator strip, a first layer including the cover and a second layer including the resilient member.

18. The nasal dilator strip of claim 17 wherein at least a portion of a surface of the second layer opposite the cover has adhesive to hold the two-layer nasal dilator strip in place on a user's nose.

19. The nasal dilator strip of claim 18 wherein the second layer also includes a cushion member, the cushion member having the adhesive to hold the two-layer nasal dilator strip in place on a user's nose.

20. The nasal dilator strip of claim 16 wherein the resilient member is symmetrical with respect to a lateral centerline of the resilient member.

21. The nasal dilator strip of claim 16 wherein the resilient member is asymmetrical with respect to a longitudinal centerline of the resilient member.

22. A two-layer nasal dilator strip comprising:

a first layer including a transparent cover having adhesive on a surface thereof, the cover having a first edge with a convex locating feature and a second edge opposite the first edge, the second edge being an uninterrupted edge; and

a second layer having opposite surfaces, one opposite surface of the second layer being secured to the first layer, at least a portion of the other opposite surface of the second layer having adhesive to hold the two-layer nasal dilator strip in place on a user's nose, the second layer including a substantially planar transparent resilient member, the resilient member being made of polyester sheet material, the resilient member having a constant thickness of about 0.010 of an inch to about 0.015 of an inch, the resilient member having longitudinal sides which converge from a center of the resilient member to a pair of spaced apart ends which, if forced together from initial positions to reduce direct spacing between the ends, results in restoring forces in the resilient member to restore the direct spacing between the ends, the resilient member being symmetrical with respect to a lateral centerline of the resilient member, the resilient member being asymmetrical with respect to a longitudinal centerline of the resilient member, the resilient member having a spring rate which diminishes from the center to the ends.

23. The two-layer nasal dilator strip of claim 22 wherein the second layer also includes a cushion member.

24. The two-layer nasal dilator strip of claim 23 wherein the opposite surface of the cushion member has adhesive.

25. The two-layer nasal dilator strip of claim 23 wherein the opposite surface of the resilient member does not have adhesive.

26. The two-layer nasal dilator strip of claim 22 wherein the second edge of the cover is an uninterrupted linear edge.

27. The two-layer nasal dilator strip of claim 22 wherein the longitudinal sides of the resilient member converge from the lateral centerline to the ends.

28. The two-layer nasal dilator strip of claim 22 wherein the resilient member has a constantly varying spring rate which diminishes from a lateral centerline of the resilient member to the ends.

29. The two-layer nasal dilator strip of claim 22 wherein the resilient member generates restorative forces capable of supporting a load of 25 to 30 grams applied to an end of the resilient member.

30. A method of manufacturing a two-layer nasal dilator strip, the method comprising:

forming a first layer including a cover having a first edge with a convex locating feature and a second edge opposite the first edge, the second edge being an uninterrupted edge;

forming a second layer having opposite surfaces, the second layer including a substantially planar resilient member, the resilient member having a constant thickness and longitudinal sides which converge from a center of the resilient member to a pair of spaced apart ends which, if forced together from initial positions to reduce direct spacing between the ends, results in restoring forces in the resilient member to restore the direct spacing between the ends;

applying adhesive to a surface of the first layer;

securing one opposite surface of the second layer to the first layer; and

applying adhesive to at least a portion of the other opposite surface of the second layer to hold the two-layer nasal dilator strip in place on a user's nose.

31. The method of claim 30 further comprising applying a release liner to the other opposite surface of the second layer to protect the adhesive.

32. The method of claim 30 wherein securing includes securing the resilient member substantially centered on the cover.

33. The method of claim 30 wherein forming the second layer includes forming a second layer including the resilient member and a cushion member.

34. The method of claim 33 wherein applying adhesive to at least a portion of the other opposite surface of the second layer includes applying adhesive to the opposite surface of the cushion member.

35. The method of claim 33 wherein applying adhesive to at least a portion of the other opposite surface of the second layer includes not applying adhesive to the opposite surface of the resilient member.

36. The method of claim 30 wherein forming the first layer includes forming a cover with an uninterrupted linear second edge.

37. The method of claim 30 wherein forming the second layer includes forming the resilient member of plastic.

38. The method of claim 37 wherein forming the resilient member includes forming the resilient member of polyester sheet material.

39. The method of claim **30** wherein forming the resilient member includes forming the resilient member with a thickness of about 0.010 of an inch to about 0.015 of an inch.

40. The method of claim **30** wherein forming the first layer includes forming the cover of a transparent material, and wherein forming the second layer includes forming the resilient member of a transparent material.

41. The method of claim **30** wherein forming the second layer includes forming the resilient member asymmetrically with respect to a longitudinal centerline of the resilient member.

42. The method of claim **30** wherein forming the second layer includes forming the resilient member symmetrically with respect to a lateral centerline of the resilient member.

43. The method of claim **42** wherein forming the resilient member includes forming the resilient member with the longitudinal sides converging from the lateral centerline to the ends.

44. The method of claim **30** wherein forming the second layer includes forming the resilient member with a spring rate diminishing from the center to the ends.

45. The method of claim **44** wherein forming the resilient member includes forming the resilient member with a constantly varying spring rate diminishing from a lateral centerline of the resilient member to the ends.

46. The method of claim **30** wherein forming the second layer includes forming the resilient member to generate restorative forces capable of supporting a load of 25 to 30 grams applied to an end of the resilient member.

47. A method of introducing separating stresses in nasal outer wall tissues of a user's nose, the method comprising:

providing a two-layer nasal dilator strip including

a first layer including a transparent cover, the cover having a first edge with a convex locating feature and a second edge opposite the first edge, the second edge being an uninterrupted edge, and

a second layer having opposite surfaces, one opposite surface of the second layer being secured to the first layer, at least a portion of the other opposite surface of the second layer having adhesive, the second layer including a substantially planar transparent resilient member, the resilient member being made of polyester sheet material, the resilient member having a constant thickness of about 0.010 of an inch to about 0.015 of an inch, the resilient member having longitudinal sides which converge from a center of the resilient member to a pair of spaced apart ends which, if forced together from initial positions to reduce direct spacing between the ends, results in restoring forces in the resilient member to restore the direct spacing between the ends, the resilient member being symmetrical with respect to a lateral centerline of the resilient member, the resilient member being asymmetrical with respect to a longitudinal centerline of the resilient member, the resilient member having a spring rate which diminishes from the center to the ends;

orienting the two-layer nasal dilator strip on the user's nose with the other opposite surface of the second layer facing a surface of the nose, with the first edge having the convex locating feature pointing toward a tip of the nose and with the second uninterrupted edge pointing away from the tip of the nose;

bending the two-layer nasal dilator strip over a bridge of the nose; and

attaching the adhesive to the surface of the nose.

48. The method of claim **47** wherein bending includes generating in the resilient member restoring forces capable of supporting a load of 25 to 30 grams applied to an end of the resilient member.

49. The method of claim **48** wherein attaching includes resisting the restoring forces generated in the resilient member.

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