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(54) **Title**: NOISE-REDUCED NASAL DEVICES AND ADJUSTABLE RESISTANCE NASAL DEVICES

(57) **Abstract**: Described herein are nose-reduced nasal devices configured to reduce or eliminate noises associated with use of a nasal device. These noise-reduced nasal devices include a flap valve and a noise-reduction feature that is a noise-reduction element, a noise-reduction flap valve, or both. The noise-reduction feature typically prevents the flap valve from oscillating or vibrating and producing an audible sound during use, particularly during inhalation through the device. The method and devices described herein may prevent the flap, and particularly the edge region of the flap face or tip of the flap, from oscillating during inhalation. Also described herein are adjustable-resistance nasal respiratory devices which may include one or more resistance-modifying members for modifying the resistance of a nasal device. The adjustable- resistance nasal respiratory devices described herein may include a control or controls for adjusting the resistance to expiration. Methods of adjusting the resistance of a nasal device are also described.

NOISE-REDUCED NASAL DEVICES AND ADJUSTABLE RESISTANCE NASAL DEVICES

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to U.S. Provisional patent application serial no. 61/037,180, titled "NASAL DEVICES WITH NOISE-REDUCTION AND METHODS OF USE," filed on March 17, 2008, and U.S. Provisional patent application serial no. 61/061,918, titled "ADJUSTABLE RESISTANCE NASAL DEVICES," filed on June 16, 2008. These applications are herein incorporated by reference in their entirety.

BACKGROUND OF THE INVENTION

[0002] Nasal respiratory devices may be worn to treat many medical conditions, such as sleep disordered breathing (including snoring, sleep apnea, etc.), Cheyne Stokes breathing, UARS, COPD, hypertension, asthma, GERD, heart failure, and other respiratory and sleep conditions. Devices that provide a greater resistance to exhalation than to inhalation may be particularly useful, and may be worn by a subject when the subject is either awake or asleep. Indeed, many subjects may apply a nasal device before falling to sleep, so that the device may provide therapeutic benefits during sleep. However, these devices may produce noise during operation that some users (or their bedmates) may find annoying. For example, a nasal device including one or more flap valves may produce a buzzing, whistling, or other audible noise or vibration. In the worst case, the noise may disrupt the sleep of the user or others nearby. Thus, there is a need for noise-reduced (or "quiet") nasal devices which may be worn by a subject during sleep.

[0003] Examples of nasal respiratory devices have been well-described in the following US patents and patent applications, each of which is incorporated herein in its entirety: US Patent Application Serial No. 11/298,640 (titled "NASAL RESPIRATORY DEVICES") filed 12/8/2005; US Patent No. 11/298,339 (titled "RESPIRATORY DEVICES") filed 12/8/2005; US Patent Application Serial No. 11/298,362 (titled "METHODS OF TREATING RESPIRATORY DISORDERS") filed 12/8/2005; US Patent Application Serial No. 11/805,496 (titled "NASAL RESPIRATORY DEVICES") filed 5/22/07; US Patent No. 7,506,649 (titled "NASAL DEVICES") filed 6/7/07; US Patent Application Serial No. 11/759,916 (titled "LAYERED NASAL DEVICES") filed 6/7/07; US Patent Application Serial No. 11/811,401 (titled "NASAL RESPIRATORY DEVICES FOR POSITIVE END-EXPIRATORY PRESSURE") filed 6/7/07; US Patent Application Serial No. 11/941,915 (titled "ADJUSTABLE NASAL

DEVICES") filed 11/19/07; and US Patent Application Serial No. 11/941,913 (titled "NASAL DEVICE APPLICATORS") filed 11/16/07.

[0004] Such nasal respiratory devices may passively induce positive end-expiratory pressure ("PEEP") or expiratory positive airway pressure ("EPAP"), and are adapted to be removably secured in communication with a nasal cavity. These devices act passively because they do not actively apply positive airflow, but instead regulate the subject's normal breathing, typically using one or more valves to inhibit expiration more than inspiration. These nasal respiratory devices are adapted to be removably secured in communication with a nasal cavity, and may include a passageway (which may just be an opening) through the device, a valve (or airflow resistor) in communication with the passageway, and a holdfast. The holdfast is configured to removably secure the respiratory device at least partly within (and/or at least partly over and/or at least partly around) the nasal cavity. The airflow resistor (which may be a valve) is typically configured to provide greater resistance during exhalation than during inhalation.

[0005] Examples of these devices are shown in FIGS. 1A-2B, and are briefly described below. Exemplary nasal devices may include an airflow resistor (e.g., a flap valve or multiple flap valves) providing a greater resistance to exhalation than to inhalation, a holdfast to secure the nasal device in communication with the subject's nose, and optionally a rim body forming a passageway in which the airflow resistor is positioned, and an aligner for aligning the device with respect to one or more of the subject's nostrils. In general, these nasal respiratory devices may be configured so that the airflow resistor provides a resistance to exhalation that is between about 10 cm H_2O*sec/L and about 250 cm H_2O*sec/L (e.g., 0.01 and about 0.25 cm H_2O/(ml/sec)) when measured at 100 ml/sec, and a resistance to inhalation that is between about 0.1 cm H_2O*sec/L and about 20 cm H_2O*sec/L (e.g., 0.0001 and about 0.02 cm H_2O/(ml/sec)) when measured at 100 ml/sec. For example, FIGS. 1A and 1B show front and back perspective views (respectively) of one variation of an adhesive nasal device.

[0006] The nasal device shown in FIGS. 1A and 1B are two single-nostril devices that have been joined to form a single device. In similar variations the two single-nostril devices are not joined by this bridge region 112, but are kept separate, and may be applied separately to each nostril. The front view of the nasal device shown in FIG. 1A illustrates the outward-facing side of this variation of a nasal device, when it is worn by a subject.

[0007] FIGS. 1A-2B show examples of nasal devices that may be adapted to include one or more noise-reducing features as described herein. The resulting noise-reduced nasal device may address the noise problem identified above. Nasal devices configured to include noise-

reduction features to help eliminate or reduce unwanted noise are described and illustrated below, along with methods of using and methods of forming such devices.

[0008] In addition to the problems associated with noise when operating these nasal devices, some users may benefit from adjusting the resistance to exhalation through the nasal device. Other examples of nasal devices including airflow resistors are shown in FIGS. 21A-21G. Each of these devices is configured so that it inhibits exhalation through the nose (one or both nostrils) more than it inhibits inhalation. In any of these devices, it would be useful to provide devices for which the resistance to expiration and/or the resistance to inspiration may be adjusted or adjustable. Described and illustrated below are nasal respiratory devices that may allow adjustable expiratory and/or inspiratory resistance.

SUMMARY OF THE INVENTION

[0009] Described herein are noise-reduced nasal respiratory devices and nasal devices having an adjustable resistance. The noise-reduction nasal respiratory devices are configured to reduce or eliminate unwanted buzzing, whistling or other noises associated with use of a nasal device. The adjustable resistance nasal devices may allow adjustment of either (or both) the resistance to inhalation and the resistance to exhalation. Adjustment of the resistance to exhalation ("expiratory resistance") is of particular interest. A nasal respiratory device may include both noise-reduction features and resistance-adjustment features.

[0010] In general, noise-reduced (or noise-reducing) nasal devices are nasal devices having flap valve airflow resistors that also include a noise-reduction feature such as a noise-reduction element, or a noise-reduction flap valve, or both. These noise-reduction features reduce whistling, rushing or turbulent sounds of air flowing through or around the airflow resistor, and may also reduce the sound of the flap valve opening/closing. For example, noise-reduced nasal devices may prevent the free end of the flap valve from oscillating or vibrating and producing an audible sound during use. In some variations the flap valve is a noise-reduction flap valve that prevents the free edge region of the flap face of the flap valve from orienting in parallel with the direction of airflow through the flap valve during inhalation. In some variations the device includes a noise-reduction element that controls or limits the oscillation of the flap, particularly the free edge region of the flap face and/or the tip of the flap during inhalation. The noise-reduction element may prevent a free edge region of a face of the flap valve from becoming oriented substantially in parallel with the direction of airflow through the opening during inhalation. As used herein, the "edge region of the flap face" typically refers to the region

of the flap valve face near the free edge of the flap valve. As described in greater detail below, a flap valve is generally a flat structure having two opposing faces and a minimal thickness.

[0011] A noise-reduced airflow resistor is typically an airflow resistor having a flap valve that is adapted in some manner to reduce the noises associated with the operation of the nasal device during respiration. A noise-reduced airflow resistor may also be referred to as a noise-reducing or noise-reduction airflow resistor. A noise-reduced airflow resistor may also be referred to as simply herein as an "airflow resistor." The noise-reduced airflow resistors described herein typically increase the resistance to expiration more than the resistance to exhalation. For example, any of the noise-reduced airflow resistors described herein may be configured to provide the nasal device with a resistance to exhalation that is between about 0.01 and about 0.25 cm H_2O/(ml/sec) when measured at 100 ml/sec, and a resistance to inhalation that is less than the resistance to exhalation, and may be between about 0.0001 and about 0.02 cm H_2O/(ml/sec) when measured at 100 ml/sec. These nasal devices may also have one or more leak pathways that are configured to remain open during both inhalation and exhalation. During operation of the nasal devices described herein, the flap valve(s) of the airflow resistor are typically at least partially closed during exhalation, increasing the resistance within the target range, and the flap valve(s) of the airflow resistor are typically at least partly open during inhalation.

[0012] Thus, a noise-reduced nasal respiratory device may include a noise-reduced airflow resistor comprising a flap valve, wherein the noise-reduced airflow resistor is configured to inhibit exhalation more than inhalation, and to inhibit oscillation of a free edge of the flap valve during inhalation when the flow rate is between about 20 and 750 ml/sec. The noise-reduced nasal respiratory device may also include a holdfast configured to secure the noise-reduced nasal respiratory device in communication with the subject's nasal cavity. Any appropriate holdfast may be used, including adhesive holdfasts and compressible holdfasts.

[0013] As mentioned, the noise-reduced airflow resistor typically includes one or more noise-reduction feature such as a noise-reduction flap valve or a noise-reduction element that acts on the flap valve (or both). For example, a nose-reduction flap valve may be a flap valve that is structurally adapted to prevent the edge of the flap valve from oscillating (e.g., vibrating) at flow rates present during inhalation and/or exhalation. In some variations a noise-reducing flap valve is adapted by having a thickness and/or durometer that is sufficient to prevent oscillation while allowing operation of the flap valve over a desired range of exhalation and/or

inhalation resistances. In some variations the flap valve is configured to have an open configuration that prevents noise.

[0014] A noise-reducing element may be used with a flap valve (including but not limited to noise-reducing flap valves) to reduce or prevent vibration or oscillation of the flap valve (and particularly the edge of the flap valve). As used herein, the phrase "oscillation" typically refers to vibration of all or a portion of the flap valve that may result in an audible sound (such as a buzzing). Any of the noise-reduced nasal respiratory devices described herein may include either a noise-reducing element (e.g., an element that acts on the flap valve) or a noise-reducing flap valve, or both.

[0015] For example, described herein are noise-reduced nasal respiratory devices including a noise reduced airflow resistor comprising a noise-reduction flap valve that is configured to inhibit exhalation more than inhalation. A noise-reduction flap valve may also be referred to as a "noise reduction flap" or a "noise reduced flap." The noise-reduction flap valve may be configured so that the edge of the flap does not oscillate during inhalation under a physiological range of inspiratory flow rates. As mentioned, these devices may include a holdfast configured to secure the device in communication with the subject's nasal cavity.

[0016] During inhalation through the nasal device, the flow rate of air through the nasal device may be between a range of flow rates broadly within the range of between about 1 and about 750 ml/sec. The flow rate during normal inhalation may be within this broad range, or within a subset of this range. For example, the device may be configured so that the flow rate through the device during inhalation is typically less than about 100 ml/sec, less than about 200 ml/sec, less than about 250 ml/sec, less than about 500 ml/sec, less than about 750 ml/sec, etc., or between about 1 and 500 ml/sec, 20 and 750 ml/sec, or 20 and 500 ml/sec, or any other subset of this range. In particular, the noise-reduced devices described herein may be configured so that the oscillation of the flap valve (and thus some or all of the noise of the nasal device) is reduced or limited. The device may also be configured so that the noise due to opening and/or closing of the flap valve is limited.

[0017] There are many types of flaps that may be used and may be considered noise-reduction flap valves. One particular variation is a butterfly-type noise-reduction flap. In this variation, the flap is cut or otherwise arranged so that airflow from inhalation causes opposing (and optionally connected) flaps to open, and thereby limit each other's ability to fully open, or to open in parallel with the direction of airflow through the device. In the butterfly-type flap, the opposing pairs of flaps extend outward to form "wings" that push against each other, preventing

an edge region of the flap face from orienting in parallel with the airflow direction at reasonable physiological airflows, which might otherwise lead to oscillation of the flap. For example, a noise-reduction flap valve may have a plurality of cuts arranged so that the free edge region of the flap face of the flap valve cannot orient in parallel with the direction of airflow through the valve during inhalation within a physiologic range of inspiratory flow rates.

[0018] In some variations, noise-reduced nasal device include an airflow resistor with a flap having a dampened edge. For example, the dampened flap edge may be a thickened edge. The damped edge may prevent oscillation (vibration) of the free edge of the flap. In some variations, the edge region is stiffer than other portions of the flap, preventing or inhibiting oscillation. Thus, the edge may be thicker, or it may be made of different material (or both).

[0019] In some variations, a noise-reduced nasal device is a nasal device having a flap with a durometer that is greater than 40 (40 Shore A). For example, a noise-reduced nasal device may have a flap for the flap valve with a durometer of about 50. In some variations, the flap valve of the noise-reduced nasal device has a flap with a durometer of greater than about 40 and a thickness that is between about 1 mil and about 5 mil. In some variations, the flap has a durometer of greater than 40 and a thickness that is between about 2 mil and about 4 mil (e.g., the flap has a durometer of 50 and a thickness of 2 mil, 3 mil or 4 mil). The flap may be formed of silicone.

[0020] As mentioned above, the nasal devices described herein may include one or more leak pathways configured to remain open during both inhalation and exhalation, even as the airflow resistor opens and closes. These leak pathways may also be configured to reduce undesirable noise, including whistling. For example, the leak pathway may be sized or shaped to reduce whistling. In some variations the edges of the leak are smoothed to prevent whistling. Any of the surfaces through which airflow may pass through the nasal device may be smoothed to prevent or inhibit whistling as air moves over or across them. In some variations, the surfaces of the leak pathway (or other airflow pathways) may be treated or coated with a material to reduce noise. For example, the leak pathway may be coated with a material forming a surface that creates localized air turbulence.

[0021] Any of the nasal respiratory devices described herein may be configured to have a resistance to exhalation and/or inhalation that is within a desired range. For example, the resistance to exhalation may be between about 10 cm H_2O*sec/L and about 250 cm H_2O*sec/L (e.g., 0.01 and about 0.25 cm H_2O/(ml/sec)) when measured at 100 ml/sec. The airflow resistor, leak pathway(s), and also the noise-reduction flap and/or a noise-reduction element may all be

configured to achieve this target resistance to exhalation and/or inhalation. Examples of devices falling within this range of inspiratory and expiratory resistances are provided below.

[0022] Also described herein are noise-reduced nasal respiratory devices including an airflow resistor comprising a noise-reduction flap valve that is configured to inhibit exhalation more than inhalation, wherein the noise-reduction flap valve is further configured so that the free edge region of the flap face does not orient in parallel (or substantially in parallel) with the direction of airflow through the flap valve during inhalation. The direction of airflow through the flap valve during inhalation generally refers to the average direction of airflow through the airflow resistor if the flap were completely removed (a hypothetical "completely open" state of the airflow resistor).

[0023] As previously mentioned, the noise-reduction nasal devices (including devices with noise-reduction flaps) may be configured to have a resistance to exhalation that is between about 0.01 and about 0.25 cm H_2O/(ml/sec) and a resistance to inhalation that is between about 0.0001 and about 0.02 cm H_2O/(ml/sec) when resistance measured at an air flow of 100 ml/sec.

[0024] Also described herein are noise-reduced nasal respiratory devices having an opening (or passageway) configured to communicate with the nasal cavity, an airflow resistor comprising a flap valve in communication with the opening, wherein the airflow resistor is configured to increase the resistance to air exhaled through the opening more than the resistance to air inhaled through the opening, a noise-reduction element in communication with the flap valve (wherein the noise-reduction element is configured to limit oscillation of the flap), and a holdfast configured to secure the opening in communication with the subject's nasal cavity. In general, the opening of the nasal device may be an opening or passageway through the nasal device.

[0025] The noise-reduction (or noise-reducing) element may be any element that reduces the oscillation of the flap valve during inhalation but does not substantially increase the resistance to inhalation. For example, the noise-reduction element may include a projecting surface at least partially into the opening that prevents an edge region of the flap face of the flap valve form orienting approximately in parallel with the direction of airflow during inhalation. The projecting surface (which may be referred to as a "projection") may be a rib or ribs extending at least partially across the opening through the nasal device.

[0026] In some variations, the noise-reduction element comprises a cone that is configured to prevent the edge region of the flap face of the flap from opening in parallel or

approximately in parallel with the direction of airflow during inhalation. The height of the cone may be greater than or equal to the height of the flap when the flap is fully opened during inhalation, and therefore permit control of the entire flap, including the free end or tip region. In some cases, the height of the cone may be less than the height of the flap when the flap is fully opened during inhalation. The tip region is generally the portion (or portions) of the flap that extend farthest from the closed position of the airflow resistor during inhalation. This may also be referred to as the portion of the flap that extends most proximally (into the nose) during inhalation when the device is worn.

[0027] A cone-type noise-reduction element may also include a plurality of cut-out regions for air passage along the perimeter of the cone. For example, the noise-reduction element may be a "castle-topped" cone, in which the cone is crenellated. The air passages may extend all the way to the top surface of the cone, or may be along the sides. In some variations, the noise-reduction element is a cage configured to prevent the edge region of the flap face from opening approximately in parallel with the direction of airflow during inhalation. For example, a cage-shaped noise-reduction element may be a dome formed of mesh or wire that does not substantially add to the airflow resistance through the nasal device.

[0028] In some variations a noise-reduction element includes a spacer configured to prevent the edge region of the flap face of the flap valve from opening in parallel with the direction of airflow during inhalation. For example, the projection into the opening through the nasal device may be a 'spacer' that keeps the tip of the flap from aligning in parallel with the direction of airflow, and thereby from stalling in the steam of air during inhalation. Multiple spacers may be used.

[0029] As mentioned, the noise-reduction element typically does not substantially increase the inspiratory resistance, and the resistance to exhalation for the nasal device including a noise-reduction element is generally between about 0.01 and about 0.25 cm H_2O/(ml/sec), and the resistance to inhalation is generally between about 0.0001 and about 0.02 cm H_2O/(ml/sec) when resistance is measured at 100 ml/sec. In some embodiments the noise-reduction element may minimally or negligibly increase the inspiratory resistance.

[0030] Also described herein are noise-reduced nasal respiratory devices including an opening (or passageway) configured to communicate with the nasal cavity, an airflow resistor comprising a flap valve in communication with the opening, wherein the airflow resistor is configured to increase the resistance to air exhaled through the opening more than the resistance to air inhaled through the opening, a noise-reduction element configured to prevent a free edge

region of the flap face from orienting itself roughly or substantially in parallel with the direction of airflow through the opening during inhalation, and a holdfast configured to secure the opening in communication with the subject's nasal cavity. Any of the noise-reduction elements previously described may be used with these noise-reduction nasal devices.

[0031] Also described herein are noise-reduced nasal respiratory devices including an opening (or passageway) through the nasal device configured to communicate with the nasal cavity, an airflow resistor comprising a flap valve in communication with the opening, wherein the airflow resistor is configured to increase the resistance to air exhaled through the opening more than the resistance to air inhaled through the opening, a noise-reduction element projecting into the opening configured to prevent the edge of the flap valve from oscillating, and a holdfast configured to secure the device in communication with the subject's nasal cavity. Any of the noise-reduction elements previously described may be used with these noise-reduction nasal devices.

[0032] Also described herein are methods of decreasing the noise of operation of a nasal device having a flap valve airflow resistor. These methods may include the steps of: placing a nasal device at least partially into or at least partially over a subject's nasal cavity, wherein the device includes a flap valve airflow resistor configured to inhibit exhalation more than inhalation; and inhibiting the flap valve from oscillating during inhalation through the nasal device. In some variations, the method includes inhibiting the flap valve from oscillating by preventing an edge region of the flap face of the flap valve from orienting itself in a direction that is roughly or substantially parallel with the direction of inspiratory airflow through the nasal device. Alternatively the oscillation of the flap may be inhibited by using a noise-reduction flap valve, as described herein.

[0033] The flap valve may be inhibited from oscillating by limiting the motion of the distal tip of the flap valve. The distal tip is also referred to as the portion of the flap that extends most proximally (into the nose) during inhalation when the device is worn.

[0034] These methods may also include the step of adhesively securing the nasal device at least partly within or at least partly over the subject's nasal cavity.

[0035] Also described herein are methods of decreasing the noise of operation of a nasal device that include the steps of: placing a nasal device at least partially into or at least partially over a subject's nasal cavity, wherein the device includes an opening, a flap valve airflow resistor in communication with the opening, and a noise-reduction element projecting at least

partially into the opening, wherein the flap valveairflow resistor is configured to inhibit exhalation more than inhalation; and inhibiting the oscillation of the flap valve during inhalation through the nasal device by contacting at least a portion of the flap valve to the noise-reduction element during inhalation. For example, the oscillation may be preventing the edge region of the flap face from orienting in a direction that is roughly or substantially parallel with the direction of airflow.

[0036] Also described herein are fluttering or vibrating nasal devices. Fluttering or vibrating valves that are configured specifically to oscillate are also described herein. These devices may be referred to as "fluttering" or "vibrating" passive nasal devices. Such nasal devices typically promote oscillation during inhalation and/or exhalation, and may promote oscillation of the edge region of the flap face and/or tip of the flap during inhalation and or exhalation. These devices may also utilize any of the previously described device features which may be used to prevent oscillation and noise in one direction while promoting oscillation in another direction of airflow. In some variations, the devices are configured so that the flap valve oscillates at certain (desirable) frequencies. For example, it may be desirous for the flap valve to oscillate in a range of frequencies that does not produce audible noise, but does produces the sensation (tactile) of vibration. An oscillating or vibratory flap valve may be used as part of a method for treatment of disorders which would benefit from the use of nasal vibration, including the treatment of cystic fibrosis or other respiratory disorders.

[0037] Also described herein are nasal respiratory devices configured to have an adjustable resistance, which may be referred to as "adjustable-resistance nasal devices." In general, adjustable-resistance nasal respiratory devices have a resistance to expiration that is greater than the resistance to inspiration. In some variations, the resistance to inspiration is relatively constant (i.e., pre-set), while the resistance to expiration may be adjusted. In other variations, both the resistance to expiration and the resistance to inspiration are adjustable. In still other variations, the resistance to inspiration is adjustable while the resistance to exhalation is pre-set. Although the majority of examples provided herein refer only to devices and methods for adjusting the expiratory resistance, many of the same principles and techniques described may be applied to allow adjusting of the inspiratory resistance.

[0038] As used herein, the term "adjusting" or "adjustable" typically refers to modifying or changing the resistance of a nasal respiratory device. An adjustment may be made dynamically (e.g., while the device is being worn), or it may be made prior to applying the device to a subject or patient. An adjustable device may be continuously adjustable, so that the resistance (e.g., to expiration) may be transitioned continuously over a range, or it may be

discretely adjustable, so that the resistance may be transitioned in steps. The adjustable devices may be user- or subject-adjustable, and may include one or more controls (e.g., knobs, buttons, dials, wheels, etc.). Adjustable devices may be adjusted by the application of modifying member or component (e.g., a snap-on resistance modifying member, an adhesive resistance modifying member, etc.). Any of the resistance modifying members that attach to the nasal device may also be attached to a nasal cannula or sensor (e.g., thermister) or may be adapted for use with such a sensor or sensing element.

[0039] The resistance to expiration may be modified by controlling the size and/or shape of a leak pathway (or pathways) through the device. As used herein, the term "leak pathway" may refer to an opening or channel through the device that is open when the airflow resistor is closed.

[0040] In general, the nasal devices having an adjustable resistance typically include an airflow resistor (which may comprise, for example, a flap valve) that is configured to inhibit expiration more than inhalation, and a holdfast configured to secure the nasal device in communication with one or more of the subject's nostrils. The nasal devices may also include one or more leak pathways or openings that are typically open during both expiration and inhalation. An adjustable-resistance nasal device may include any appropriate airflow resistor, including (but not limited to) flap or diaphragm valves, ball valves, duckbill valves, hinge-less valves, balloon valves, stepper valves, slit valves, PEEP valves, threshold valves, etc., or the like. In addition, any of the adjustable-resistance nasal devices described herein may include any appropriate holdfast for securing the device in communication with the subject's nose. For example, any of these devices may be adhesive nasal devices, which include one or more adhesive holdfasts or may be mask devices that fit over the nose and/or the mouth.

[0041] The adjustable resistance nasal devices described herein may be adjustable within any appropriate treatment range, including those described above. For example, an adjustable resistance nasal device may be adjustable so that the resistance to expiration can be set to between about 1 and about 250 cm H_20/(l/sec). In some variations, the resistance to expiration can be set between about 5 and about 250 cm H_20/(l/sec). The nasal devices described herein may have a very low resistance to inspiration. For example, the resistance to inspiration may be between about 0.01 and about 5 cm H_2O/(l/sec) (and in adjustable resistance nasal devices configured to allow adjustment of the inhalational resistance, the resistance to inhalation may be varied within this range). As mentioned below, the adjustment may be continuous (over a range or resistances) or it may be discrete (in steps), or some combination of the two. The adjustment may be linear or non-linear.

[0042] In some variations, an adjustable resistance nasal device includes a leak pathway that can be plugged or covered. The leak pathway cover may be integrated as part of the nasal device, or it may be a separate component or structure that can be applied to the nasal device to occlude or partially occlude the leak pathway and thereby increase the resistance to expiration (or be removed from the nasal device to decrease resistance to expiration). For example, the device may include a snap-on or adhesive cover for covering one or more leak pathways. In some variations, the cover is adjustable so it only partially occludes the leak pathway. An example of an adhesive plug or cover may be a piece of tape or adhesive strip that can be used to cover the leak pathway. In some variations the cover or plug is attached (e.g., by a tether, hinge, etc.) to the nasal device. In some variations the plug is integral to the device and may be pushed (e.g., by a finger) to activate and increase the resistance (and pulled to decrease the resistance).

[0043] In general, in any of the variations described herein, the resistance (e.g., to expiration) may be modulated by controlling the amount of a leak pathway occluded/opened, or the number of leak pathways opened or occluded. If a device has multiple leak pathways, the resistance may be stepped up by blocking increasing numbers of the leak pathways. In any of these variations, the nasal devices may include adjustable controls that are calibrated as to the resistance (e.g., expiratory resistance). For example, a snap-fit cover to increase resistance may be labeled or otherwise marked to indicate the resistance (or range of resistances) that the nasal device will have after applying the cover. This general principle may be applied to any of the nasal devices or components used to modulate the resistance described herein. For example, a control for continuously or discretely adjusting the resistance may include markings or settings to indicate the resistance.

[0044] In some variations, an adjustable resistance nasal device may include a leak pathway that is directly adjustable by changing the size or shape of the leak pathway opening. For example the leak pathway may be adapted to constrict (e.g., by including an inflatable or swellable material). In some variations the leak pathway may include a shutter or cover that may be used to close it off, or partially close it off. For example, the leak pathway may include a louver-type cover or shutter that can be moved to partially or completely occlude the opening of one or more leak pathways. In some variations the leak pathway includes an iris (e.g., a dilating iris) that can be used to cover or open the leak pathway. In any of these embodiments, the device may include one more handles/controls for manually operating the closing and/or opening of the leak pathway or may include electronic means of closing and/or opening the leak pathway, especially from a remote location (for example in the control room of a sleep laboratory).

[0045] Also described herein are nasal devices in which the position of all or a part of the airflow resistor may be adjusted to modify the resistance. For example, the position of the

airflow resistor may be modified relative to a passageway through the device. In some variations the registration of the airflow resistor relative to the passageway may be changed, to increase/decrease the size of a leak pathway at least partially around the airflow resistor. For example, the airflow resistor may include a flap valve that can be rotated slightly relative to the passageway. In some variations the airflow resistor is a flap valve that can be shifted with respect to the flap valve limiter (e.g., supports or struts) across a passageway, so that the flap valve can be seated in different positions that allow more or less air to pass through the passageway (leak) when the valve is closed during expiration. In some variations the proximal/distal position of the airflow resistor may be changed. For example, the airflow resistor may be moved proximally or distally along the length of a tapered passageway. As the device moves in the direction of the narrowing of the tapered passageway (e.g., proximally) less air may pass around the device, thereby increasing the leak size and the thus the resistance to expiration. In some variations movement of the airflow resistor (or a portion of the airflow resistor) may be controlled by a control such as a knob. For example, a worm-screw type control may be used to move the airflow resistor proximally or distally in some variations. In some variations, the nasal device includes one or more leak pathways as part of the nasal device. For example, the airflow resistor may include a flap valve having one or more holes (leak pathways). The expiratory resistance may be adjustable by rotating the flap valve so that the holes on the flap valve are partially occluded (or un-occluded) when the flap valve is closed during expiration. For example, the holes may be aligned with a portion of the flap valve limiter (e.g., struts, mesh, etc.) that blocks the holes closed when the valve is closed.

[0046] Also described herein are adjustable resistance nasal devices in which the operation of the airflow resistor is modified. For example, device may be adapted so that the airflow resistor (e.g., flap valve) is prevented to a controllable degree from closing completely during expiration. In some variations the device includes one or more adjustable members that prevent the edge of the valve from fully closing during expiration by propping the valve open. In some variations the device includes an adjustable member that raises or lowers the hinge or pivot portion of the valve so that the valve cannot seat closed (completely) during expiration.

[0047] Also described herein are adjustable resistance nasal devices in which the length of the leak pathway is adjustable (e.g., can be increased and/or decreased). For example, the length of the leak pathway can be decreased by removing a section of the leak pathway to decrease the resistance during expiration. In some variations the leak pathway is a telescoping channel that can be elongated or shortened.

[0048] Methods of adjusting the resistance, and particularly the expiratory resistance, are also described. In general, any of the devices described herein, alone or in combination, can be

used to adjust or control (e.g., increase or decrease) the resistance to expiration through the devices. These devices may be used to optimize treatment of disorders such as sleeping disorders, as described briefly above.

[0049] Also described herein are systems for adjusting the resistance of a nasal device. In particular, a system may include any of the nasal devices described herein and any cover for altering the expiratory resistance (e.g., a snap-on cover or plug, etc.).

[0050] A system for optimizing the resistance to expiration may include a plurality of nasal devices having progressively increasing or decreasing resistances to expiration. Such a system may be used to determine a patient-specific resistance for expiration. In use, a subject may sequentially wear nasal devices having different expiratory resistance to determine comfort and/or efficacy of treatment.

[0051] In particular, described herein are systems or kits having a plurality of nasal devices each with increasing resistances to expiration (and/or inspiration). The kit may include instruction to the user indicating the order in which each of the nasal devices is to be worn for a particular number of nights. Such a systems or kits may be referred to as "ramp systems", "ramp kits," "acclimation systems " or "acclimation kits." For example, a system may include a first device or set of devices having a very low resistance to expiration (e.g., less than 20 cm H_2O/(L/sec)), a second device or set of devices having a resistance to expiration that is slightly higher (e.g., approximately 30 cm H_2O/(L/sec)), a third device or set of devices having a slightly higher yet resistance to expiration (e.g., approximately 40 cm H_2O/(L/sec)), a fourth device or set of devices having a slightly higher resistance to expiration than the third device or set of devices (e.g., approximately 50 cm H20/(L/sec)), a fifth device or set of devices having a slightly higher resistance to expiration than the fourth device or set of devices (e.g., approximately 60 cm H20/(L/sec)), etc. so that the resistance of the next device or set of devices in the series is slightly higher than the previous device or set of devices. These first, second, third, etc. devices or set of devices are marked to indicate their order in the sequence (or are packaged to indicate their order in the sequence). The first device or set of devices in the sequence may be a 'sham' device, which does not include a significant resistance to exhalation compared to inhalation. The instructions may indicate the number of nights (or days) that the user should wear a device (or devices) at each resistance level. In some variations, a single (e.g., disposable) device may be included for each night that that it should be worn. For example, the user may be instructed to wear the first device (or a device from the set of devices) and each subsequent set of devices for 3 days, in order for them to acclimate to the increasing expiratory resistance level. In another example, the system or kit may just include a series of sequentially labeled devices (or pairs of device if packaged as single-nostril devices) that indicate for each consecutive night which

device should be worn; sequentially numbered device may have the same expiratory resistance or the expiratory resistance may increase slightly.

[0052] Thus, described herein are systems for acclimating a subject to a nasal device having a greater expiratory resistance than inspiratory resistance comprising a plurality of nasal devices having increasing resistances to exhalation, wherein most (if not all) of the devices have a resistance to exhalation that is greater than the resistance to inhalation. The plurality of devices are either marked or arranged to indicate the increasing resistance to exhalation corresponding to the order in which the devices are to be used by a subject. These nasal devices typically include an airflow resistor and holdfast, as described herein.

[0053] The general principles, and at least some of the variations described above are illustrated in greater detail and described briefly below.

INCORPORATION BY REFERENCE

[0054] All publications and patent applications mentioned in this specification are herein incorporated by reference in their entirety, as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference in its entirety.

BRIEF DESCRIPTION OF THE DRAWINGS

[0055] FIGS. 1A and 1B are bottom and top perspective views, respectively, of one variation of a nasal device.

[0056] FIGS. 2A and 2B show one variation of a layered nasal device in a top view and an exploded perspective view, respectively.

[0057] FIGS. 3A to 3C illustrate operation of flap valves having four, six and eight flaps, respectively, during simulated inspiratory flow.

[0058] FIGS. 4A to 4C show various dome-shaped noise-reduction elements.

[0059] FIGS. 5A to 5D show noise-reduction elements configured as projections.

[0060] FIGS. 6A to 6C show conical noise-reduction elements.

[0061] FIGS. 7A to 7C show perspective, top and side cross-sectional views, respectively of one variation of a noise-reduction element configured as a cone.

[0062] FIGS. 8A to 8F show perspective views of variations of cone-type noise-reduction elements.

[0063] FIG. 9A shows a conical noise-reduction element having a low height, and FIG. 9B shows a portion of a nasal device including a conical noise-reduction element having a low height.

[0064] FIG. 10 is another variation of a noise-reduction element configured as a cone.

[0065] FIG. 11 illustrates variations of flaps which may be used as flap valves.

[0066] FIG. 12A is a butterfly-type noise-reduction flap. FIG. 12B illustrates the operation of the noise-reduction flap of FIG. 12A during a simulated inspiratory flow.

[0067] FIG. 13A is another variation of a noise-reduction flap. FIG. 13B illustrates the operation of the noise-reduction flap of FIG. 13A during a simulated inspiratory flow.

[0068] FIG. 14A is another variation of a noise-reduction flap. FIG. 14B illustrates the operation of the noise-reduction flap of FIG. 14A during a simulated inspiratory flow.

[0069] FIG. 15A is another variation of a noise-reduction flap. FIG. 15B illustrates the operation of the noise-reduction flap of FIG. 15A during a simulated inspiratory flow.

[0070] FIG. 16A shows a noise-reduction element. FIG. 16B shows a flap valve that may be used with the nose-reduction element shown in FIG. 16A, and FIG. 16C shows a nasal device including the noise-reduction element of FIG. 16A and the flap of FIG. 16B.

[0071] FIG. 17 is a cross-section though a noise-reduced nasal device having both a noise-reduction cone and a noise-reduction flap.

[0072] FIG. 18 is an exploded view of a noise-reduced nasal device including a noise-reduction element.

[0073] FIGS. 19A to 19C are three variations of noise-reduction elements.

[0074] FIG. 20 is an exploded view of a noise-reduced nasal device including a noise-reduction flap.

[0075] FIGS. 21A-21G show variations of nasal devices or portions of nasal devices which may be adapted to be adjustable resistance nasal devices. In particular, FIG. 21A show a whole-nose nasal device that includes conformable holdfasts for insertion into a subject's nostrils. FIG. 21B shows the airflow resistor portion of a nasal device including a relatively stiff flap valve including a central leak pathway. FIG. 21C shows another variation of the airflow

resistor including a leak pathway. FIG. 21D illustrates a layered-type nasal device including a flap valve layer, an adhesive holdfast layer, and a protective backing. FIGS. 21E and 21F shows whole-nose nasal devices. FIG. 21G is an adhesive nasal device configured to communicate with a single nostril.

[0076] FIG. 22A shows a portion of a nasal device, including four leak pathways, and FIG. 22B is a snap-on resistance modifying member.

[0077] FIG. 23 is a whole-nose nasal device including removable adhesive covers for adjusting the resistance.

[0078] FIG. 24 illustrates a constrictable leak pathway that may be included as part of a nasal device for adjusting the resistance.

[0079] FIG. 25 is one variation of an adjustable resistance nasal device in which the airflow resistor is movable to adjust the resistance.

[0080] FIGS. 26A and 26B show another variation of an adjustable resistance nasal device in which the airflow resistor is movable to adjust the resistance.

[0081] FIG. 27 is a variation of an adjustable resistance nasal device including a movable flap valve and configured so that moving the flap valve alters the resistance.

[0082] FIG. 28A shows one variation of an adjustable resistance nasal device in which the valve body is rotatable to adjust the resistance.

[0083] FIG. 28B is another variation of an adjustable resistance nasal device in which the flap valve is rotatable relative to the rest of the nasal device to adjust the resistance.

[0084] FIG. 29 shows a cross-section through another variation of a nasal device having an adjustable resistance in which the flap valve may be displaced to regulate the expiatory resistance.

[0085] FIG. 30A and 30B show top and side views of one variation of a snap-on device for adjusting the resistance of a nasal device by partially displacing the airflow resistor of the nasal device.

[0086] FIG. 30C illustrates operation of device such as that shown in FIGS. 30A and 30B.

[0087] FIGS. 31A and 31B illustrate a partial view of another variation of an adjustable resistance nasal device.

[0088] FIG. 32 is a partial cross-section though another variation of an adjustable resistance nasal device, in which the length of the leak pathway may be regulated.

[0089] FIG. 33 is a bottom view (showing the non-adhesive side facing away from the patient) of an adjustable resistance variation of a nasal device.

DETAILED DESCRIPTION OF THE INVENTION

Noise Reduced Nasal Devices

[0090] Described herein are noise-reduced nasal devices. Noise-reduced nasal devices typically include a noise-reduced feature such as a noise-reduction flap for a flap valve, a noise-reduction element, or both. The noise-reducing features described are configured as part of the nasal device so that the resistance to exhalation and inspiration of the nasal devices is typically between about 0.01 and about 0.25 cm H_2O/(ml/sec) for exhalation and between about 0.0001 and about 0.02 cm H_2O/(ml/sec) for inspiration when resistance is measured at 100 ml/sec. Inspiratory resistance or resistance to inhalation, refers to the resistance to airflow moving though the device in the direction of inhalation when the device is oriented as it would be when worn by a user. Likewise, expiratory resistance or resistance to exhalation refers to the resistance to airflow through the device in the direction of exhalation when the device is oriented as it would be when worn by a user.

[0091] As used herein, the term noise-reduced nasal device or noise-reduction nasal device refers to any nasal device that includes one or more noise-reduction features, such as a noise-reduction flap valve as described and exemplified herein, or a noise-reduction element as described herein. Noise reduction typically refers to the reduction or elimination of noise such as buzzing, whistling, hissing or other vibratory or airflow noise which may be heard or sensed by a subject wearing a nasal device. These noises typically arise from the undesirable and unnecessary oscillation of the flap valve forming the airflow resistor in the nasal device.

[0092] As used herein, the singular forms "a," "an," and "the" include plural reference unless the context clearly dictates otherwise.

[0093] The noise-reduction features described herein may be used with any appropriate nasal devices, particularly those having a flap valve. Before describing the noise-reduction features, examples of nasal devices that may be used with these noise-reduction features are first described.

Nasal Devices

[0094] Any appropriate nasal device may be configured as a noise-reduction nasal device, including the adhesive nasal devices described in more detail in FIGS. 1A to 2B, below. The noise-reduction nasal devices described herein typically include a passageway configured to

communicate with a subject's nasal passage (or cavity), a flap valveairflow resistor in communication with the passageway, and a noise-reduction feature.

[0095] The nasal devices described herein may be secured in communication with a subject's nose, and specifically with one or both of the subject's nasal cavities. A typical nasal device includes an airflow resistor that is configured to resist airflow in a first direction more than airflow in a second direction, and may also include a holdfast configured to secure the airflow resistor at least partially over, in, and/or across the subject's nose or nostril. The holdfast may include a biocompatible adhesive and a flexible region configured to conform to at least a portion of a subject's nose. The nasal devices described herein are predominantly adhesive nasal devices, however the noise-reducing features described may be used with nasal devices that are not adhesive nasal devices, including nasal devices having compressible or expandable holdfasts. Other embodiments include nasal devices in which the holdfast is mask that fits over the nose, the mouth or both the nose and mouth.

[0096] Nasal devices may be worn by a subject to modify the airflow thorough one or (more typically) both nostrils. Nasal devices may be secured over both of a subject's nostrils so that airflow through the nostrils passes primarily or exclusively through the nasal device(s). Adhesive nasal devices are removably secured over, partly over, and/or at least partly within the subject's nostrils by an adhesive. The nasal devices described herein may be completely flexible, or partially rigid, or completely rigid. For example, the devices described herein may include an adhesive holdfast region that is at least partially flexible, and an airflow resistor. The airflow resistor may be flexible, or rigid. In some variations, the devices described herein also include one or more alignment guides for helping a subject to orient the device when securing it over the subject's nose. The alignment guide may also include or be configured as a noise-reduction element, as described in greater detail below. The adhesive nasal devices described herein may be composed of layers. Nasal devices composed of layers, which may also be referred to as layered nasal devices, may be completely or partially flexible, as previously mentioned. For example, a layered nasal device may include an airflow resistor configured to resist airflow in a first direction more than airflow in a second direction and an adhesive holdfast layer. In some variations, the airflow resistor may be a flap valve layer adjacent to a flap valve limiting layer, and may include an adhesive holdfast layer comprising an opening across which the airflow resistor is operably secured. The airflow resistor may be disposed substantially in the plane of the adhesive holdfast layer. The adhesive holdfast layer may be made of a flexible substrate that includes an additional layer of biocompatible adhesive.

[0097] The nasal devices described herein may be considered as passive nasal devices, because the flap valve may operate to passively regulate a subject's respiration. For example, a nasal device may create positive end expiratory pressure ("PEEP") or expiratory positive airway pressure ("EPAP") during respiration in a subject wearing the device. In contrast to active nasal devices, such as CPAP machines that apply positive pressure to the subject, the passive devices described herein do not require the addition of pressurized respiratory gas.

[0098] The noise-reduced nasal devices and methods described herein may be useful to treat a variety of medical conditions, and may also be useful for non-therapeutic purposes. For example, a nasal respiratory device may be used to treat sleep disordered breathing or snoring. The systems, devices and methods described herein are not limited to the particular nasal device embodiments described. Variations of the embodiments described may be made and still fall within the scope of the disclosure.

[0099] As used herein, a nasal device may be configured to fit across, partly across, at least partly within, in, over and/or around a single nostril (e.g., a "single-nostril nasal device"), or across, in, over, and/or around both nostrils ("whole-nose nasal device"). Any of the features described for single-nostril nasal devices may be used with whole-nose nasal devices, and vice-versa. In some variations, a nasal device is formed from two single-nostril nasal devices that are connected to form a unitary adhesive nasal device that can be applied to the subject's nose. Single-nostril nasal devices may be connected by a bridge (or bridge region, which may also be referred to as a connector). The bridge may be movable (e.g., flexible), so that the adhesive nasal device may be adjusted to fit a variety of physiognomies. The bridge may be integral to the nasal devices. In some variations, single-nostril nasal devices are used that are not connected by a bridge, but each include an adhesive region, so that (when worn by a user) the adhesive holdfast regions may overlap on the subject's nose.

[00100] One variation of a nasal device that may include a noise-reduction feature (e.g., a noise-reduction flap or noise-reduction element) is a layered nasal device, formed of two or more layers. For example, a layered nasal device may include an adhesive holdfast layer and an airflow resistor layer. These layers may themselves be composed of separate layers, and these layers may be separated by other layers, or they may be adjacent. For example, the adhesive holdfast layer may be formed of layers (optionally: a substrate layer, a protective covering layer, an adhesive layer, etc), and thus may be referred to as a layered adhesive holdfast. Similarly, the airflow resistor may be formed of multiple layers (optionally: a flap valve layer, a valve limiter layer, etc.), and thus may be referred to as a layered airflow resistor. In some variations, the

layered adhesive holdfast and the layered airflow resistor share one or more layers. For example, the flap valves layer and the adhesive substrate layer may be the same layer, in which the leaflets of the flap valve layer are cut from the substrate layer material. As used herein, a "layer" may be a structure having a generally planar geometry (e.g., flat), although it may have a thickness, which may be uniform or non-uniform in section. As mentioned briefly above, the support backing may be formed of one of the layers of a layered nasal device, such as the adhesive substrate layer.

[00101] In some variations, a nasal device has a body region including a passageway configured to be placed in communication with a subject's nasal passage. The body region may be a stiff or flexible body region, and may secure an airflow resistor therein. In some variations, the body region is at least partially surrounded by a holdfast (i.e., a planar adhesive holdfast). The body region may be modular, meaning that it is formed of two or more component sections that are joined together. Examples of such nasal devices can be found in US Patent No. 7,506,649, filed on 6/7/07, and previously incorporated by reference in its entirety. As described therein, the body region may be configured so that it does not irritate a subject wearing the nasal device. For example, the body region may be slightly undersized compared to the size of the average user's nostrils. Thus the body region may fit into the subject's nose, and the seal with the subject's nose is formed by the adhesive holdfast region, rather than the body region. In some variations the body region does not substantially contact the inner walls of the subject's nose. Furthermore, the body region may extend only slightly into the subject's nose.

[00102] In some variations, the adhesive nasal device includes a support frame. The support frame may provide structural support to all or a portion of the nasal device, such as the flexible adhesive portion. For example, the support frame may support the adhesive holdfast portion of the device and be completely or partially removable after the device has been applied to the subject. In some variations, the support frame remains on the nasal device after application. In some variations, the support frame is a support frame layer.

[00103] An adhesive nasal device may also include a tab or handle configured to be grasped by a subject applying the device. In some variations, this tab or handle is formed of a region of the layered adhesive holdfast.

[00104] The various components of the device may be made of any appropriate materials, as described in greater detail below. For example, some device components (e.g., an alignment guide, a body region, noise-reduction element) may be made of medical grade plastic, such as Acrylonitrile Butadiene Styrene (ABS), polypropylene, polyethylene, polycarbonate,

polyurethane or polyetheretherketone. The airflow resistor may be a flap valve and the flap may be made of silicone or thermoplastic urethane. The adhesive holdfast may include an adhesive substrate made of silicone, polyurethane or polyethylene. Examples of biocompatible adhesive on the adhesive holdfast may include hydrocolloids or acrylics. These lists of materials are not exclusive, and other (or alternative) materials may be used.

[00105] In some versions, the nasal device further comprises an active agent. In some versions, this active agent is a drug (e.g., a medicament). In some versions, this active agent comprises an odorant, such as a fragrance. In some versions, the active agent comprises menthol, eucalyptus oil, and/or phenol. In other versions, the nasal device may be used with other pulmonary or medical devices that can administer medication or other medical treatment, including, but not limited to, inhalers and nebulizers.

[00106] A nasal device may include a filter. This filter may be a movable filter, such as a filter that filters air flowing through the passageway in one direction more than another direction (e.g., the device may filter during inhalation but not exhalation).

[00107] As mentioned, the adhesive nasal devices described herein typically include a holdfast region (or layer) and at least one airflow resistor. As will be apparent from the figures, many of these nasal devices may be removable and insertable by a user without special tools. In some variations, a subject may use an applicator to apply the device (e.g., to help align it). FIGS. 1A through 2B illustrate different exemplary nasal devices.

[00108] FIGS. 1A and 1B show perspective views of one exemplary variation of an adhesive nasal device that may be configured as a noise-reduced nasal device and may include a noise-reducing feature (not apparent in these figures). FIG. 1A shows a front perspective view of an adhesive nasal device, looking at the "outer" side of the device, which is the side facing away from the subject's nose when the device is worn. The device shown in FIG. 1A includes two single-nostril rim bodies 101 and a single adhesive holdfast 104. A nasal device may be configured to communicate with a single nostril (a single-nostril nasal device), or it may be configured to communicate with both of a subject's nostrils (a double-nostril nasal device as shown here).

[00109] The holdfast 104 (which adhesively secures the device to the subject) is shown as a layered structure including a backing or adhesive substrate 105. This backing may act as a substrate for an adhesive material, or it may itself be adhesive. The holdfast 104 may have different regions, including two peri-nasal regions surrounding the rim bodies 101. Each rim

body has at least one passageway 108 for airflow therethrough. The adhesive holdfast also includes two tabs or grip regions 110 that may make the device easier to grasp, apply, and remove. A bridge region 112 is also shown. In this example, the bridge region is part of the adhesive holdfast (e.g., is formed by the same substrate of the adhesive holdfast) and connects the peri-nasal regions. Although the tab and bridge regions are shown as being formed as part of (integral with) the holdfast material, these regions may also be formed separately, and may be made of different materials.

[00110] The rim body regions 101 shown in the exemplary device of FIG. 1A include outer rim body regions which each encompass a passageway 108. These first (e.g., outer) rim body regions may mate with second (e.g., inner) rim body regions to form the rim body region(s) of the device that each include a passageway 108. This passageway is interrupted by crossing support members 114 (e.g., cross-beams or cross-struts) that may partly support or restrict movement of the airflow restrictor. In addition, each rim body region 101 includes two leak pathways 116, through which air may pass even when the passageway through the device is otherwise blocked by the airflow resistors. The leak pathways 116 are shown here as small openings at the narrow ends of the oval-shaped outer rim body region. The rim body region may also be referred to as 'rim' or 'scaffold' regions of the device.

[00111] FIG. 1B shows a back perspective view of the opposite side of the adhesive nasal device shown in FIG. 1A, the "inner side" of the device. The inner side of the device faces the subject, and a portion of this side of the device may contact the subject. This side of the device, and particularly the adhesive holdfast of the device, includes an adhesive (which may be covered by a protective cover 107) forming part of the holdfast 104. In some variations, the entire skin-facing side of the holdfast 104 includes an adhesive on the surface, although in some variations, only a portion of this region includes adhesive. The adhesive may be a distinct layer of the holdfast (e.g., it may be layered on top of an adhesive substrate), or it may be an integral part of the holdfast (e.g., the adhesive substrate may be made of an adhesive material). In some variations an adhesive may be separately added to the device (e.g., the holdfast region) before use. The adhesive material may be covered by a removable protective cover or liner 107, to prevent the adhesive from sticking to surfaces until after the liner is removed. In FIG. 1B, the protective cover 107 covers the entire skin-facing surface of the holdfast. The device may be applied by first removing the liner. For example, the liner may be peeled off, to expose the adhesive. In some variations, the liner protecting the adhesive may be partially removed. For example, the tab region 121 of the device may include a separate (or additional) liner that remains over the tab region when other liner regions are removed. This may allow the device to

be held by the tab region without having it adhere to the skin. After removing the cover, or a part of the cover, the device may be positioned and adhered to the subject's skin around the nasal cavity, so that the passageways through the rim body are aligned with the openings of the subject's nasal cavities. In some variations, an additional adhesive cover region (e.g., the protective cover region over the tabs 121) can then be removed to secure the device to the rest of the subject's nose. The adhesive cover may include a fold (or crimp, crease, lip, or the like) that helps to remove the protective cover from the adhesive.

[00112] The second, or inner, rim body region 103 shown in the exemplary device of Fig. 1B is shaped with an inwardly-tapering edge, so that it may fit at least slightly within the opening of the subject's nostril when a subject wears the device. The inner rim body includes one or more passageways 108 that correspond with the passageways 108 shown in FIG. 1A. Similarly, the leak pathways pass completely through the rim body (both inner and outer bodies). The tapering external walls of the inner rim body region(s) shown in FIG. 1B are shown as smooth, and may also include an additional material (e.g., an auxiliary holdfast material) for securing them in the subject's nostrils, or for cushioning them to prevent injury or discomfort. These surfaces may also be more or less angled, in order to facilitate comfort when the adhesive nasal device is worn in the subject's nose. A cross bar (hinge region 115) may also be provided as part of the inner rim body. The inner rim body 103 may extend some distance above the peri-nasal annular region of the holdfast, as shown in FIG. 1B. This distance may be sufficient to prevent any portion of the airflow resistor (e.g., a flap portion of a flap valve) from extending out of the device and into the nasal cavity where it might contact body tissues. In some variations, the inner body region includes one or more noise-reduction elements, such as a projection at least partially into the passageway that prevents an edge region of the flap face of the flap valve from orienting in parallel with the direction of airflow during inhalation.

[00113] All of the nasal devices described herein also include an airflow resistor, which is located in one or more passageways formed through the device. In FIGS. 1A and 1B, the airflow resistor is a flap valve, and includes cross bars that support the flap valve (and can prevent it from opening during exhalation). In general, the airflow resistor opens in one direction (during inhalation) and is closed during exhalation. The flap may be made of silicone. In the device shown in FIGS. 1A and 1B, the flap can be secured between the inner and outer rim bodies. The flap valve may also be configured so that the flap is a noise-reduction flap, as described in greater detail below.

[00114] FIG. 2A is a top view of another example of a nasal device. The nasal device shown in FIGS. 2A-2B is a layered nasal device that includes a holdfast layer 201 and an airflow resistor 203. The reverse side of the device shown in FIG. 2A includes an adhesive material (not shown) that may be covered by a protective covering. The protective covering (which may also be referred to as a protective liner) can be removed to expose the adhesive before application of the device. Thus, the holdfast layer of the device secures it to the subject. This holdfast layer may itself be layered, and may include an adhesive substrate (e.g., a backing layer). For example, the adhesive substrate may be a foam backing. This backing may act as a substrate for an adhesive material. In some variations, the adhesive substrate is itself adhesive. The holdfast layer 201 may have different regions, including a peri-nasal regions surrounding a passageway (though which air may flow), and a tab 205 or grip region forming a tab that may make the device easier to grasp, apply and remove. Other regions may include regions of more aggressive and less aggressive adhesive (e.g., more or less adhesive material), or regions of hydrogel material (including adhesive hydrogels) to help prevent irritation from repeated or extended use. Although the tab is shown as part of (integral with) the holdfast material, this region may also be formed separately, and may be made of different materials.

[00115] FIG. 2B shows an exploded view of the device of FIG. 2A. This exploded perspective view illustrates the layers of the device, including the adhesive holdfast 201 (which may itself be layered), two layers forming the airflow resistor, including the flap valve 207 and flap valve limiter 209, and an adhesive ring 211 that may help attach the flap valve and flap valve limiter to the adhesive holdfast.

[00116] An adhesive holdfast for a nasal device may comprise any appropriate material. For example, the adhesive substrate may be a biocompatible material such as silicone, polyethylene, or polyethylene foam. Other appropriate biocompatible materials may include some of the materials previously described, such as biocompatible polymers and/or elastomers. Suitable biocompatible polymers may include materials such as: a homopolymer and copolymers of vinyl acetate (such as ethylene vinyl acetate copolymer and polyvinylchloride copolymers), a homopolymer and copolymers of acrylates (such as polypropylene, polymethylmethacrylate, polyethylmethacrylate, polymethacrylate, ethylene glycol dimethacrylate, ethylene dimethacrylate and hydroxymethyl methacrylate, and the like), polyvinylpyrrolidone, 2-pyrrolidone, polyacrylonitrile butadiene, polyamides, fluoropolymers (such as polytetrafluoroethylene and polyvinyl fluoride), a homopolymer and copolymers of styrene acrylonitrile, cellulose acetate, a homopolymer and copolymers of acrylonitrile butadiene styrene, polymethylpentene, polysulfones polyimides, polyisobutylene, polymethylstyrene and

other similar compounds known to those skilled in the art. Structurally, the substrate may be a film, foil, woven, non-woven, foam, or tissue material (e.g., poluelofin non-woven materials, polyurethane woven materials, polyethylene foams, polyurethane foams, polyurethane film, etc.).

[00117] In variations in which an adhesive is applied to the substrate, the adhesive may comprise a medical grade adhesive such as a hydrocolloid or an acrylic. Medical grade adhesives may include foamed adhesives, acrylic co-polymer adhesives, porous acrylics, synthetic rubber-based adhesives, silicone adhesive formulations (e.g., silicone gel adhesive), and absorbent hydrocolloids and hydrogels.

Noise-Reduced Nasal Devices

[00118] As mentioned above, nasal devices including those illustrated in FIGS. 1A-2B may produce undesirable noises when worn, particularly during inhalation, when the rate of airflow through the device is greatest. An analysis of these devices has identified oscillation of the flap portion of the valve during inspiratory airflow as one possible source of noise. In particular, the edge portion of a flap may vibrate or oscillate during the inspiratory phase of respiration causing an audible buzzing noise, particularly at relatively high flow rates during inhalation.

[00119] Any of the noise-reduced nasal respiratory devices described herein may be configured so that the flap valve does not produce nose from oscillation during operation of the device in a range of normal inhalation and/or exhalation flow rates. Typical flow rates for operation during inhalation may be between about 20 and about 750 ml/sec, or between about 20 and about 500 ml/sec, or between about 10 and about 800 ml/sec, etc.). The flow rate typically refers to the flow rate through the device during inhalation (or in some variations, exhalation).

[00120] For example, FIGS. 3A-3C show different flap valve variations during a simulated inhalational air flow. These figures capture the oscillation of the flaps of the flap valves which may produce an audible buzzing sound. For example, FIG. 3A illustrates a flap valve comprising four valve leaflets (flaps), formed as a four-piece pie-shaped valve having a central opening or leak pathway. During inhalation, the four flaps bend upwards, opening the valve. As shown in the photograph, the upper (tip) regions of the valves in this figure are blurred, because they are oscillating a relatively high frequency in the simulated inspiratory airflow. The flap on the right side of the figure shows a tracing indicating the angle formed by the valve as it oscillates. In this example, the valve was measured to oscillate through an approximately 35 degree angle of arc. The rate at which the valve oscillates may depend on the

airflow, the material properties of the valve (including the stiffness), and the shape of the valve. The rate of oscillation may also determine the frequency or pitch of the resulting noise. In some devices, buzzing was not in the audible range until one or more flaps was constrained; preventing or limiting flow through one flap effectively increased the rate of flow through the other flaps, increasing the rate of oscillation.

[00121] FIGS. 3B and 3C are similar examples showing six-leaflet (FIG.3B) and eight-leaflet (FIG. 3C) valves during a simulated inspiratory airflow. In all of these examples, the unconstrained ends or edge of the flaps are oscillating within the inspiratory airflow. "Buzzing" may result when a flap is allowed to open vertically aligning with the airflow and vibrate in the passing airstream.

[00122] In theory, the flap oscillates and produces noise when the force of air pressure on opposite sides of the flap becomes dynamically unstable, resulting in the back and forth (oscillatory) motion of the flap as the unstable forces acting on either side of the flap push on the flap. This phenomenon may be similar to the motion that the sail of a sailboat undergoes when the sail "luffs". Based on an analysis of the flaps of flap valve nasal devices during simulated inspiratory airflow, it appears that oscillation occurs when the flap valve luffs when an edge face region of the flap becomes aligned in parallel with the airflow through the device. When this occurs, the air pressure on either side of the flap pushes the flap back and forth, oscillating it. This oscillation may produce a buzzing noise.

[00123] Constraining the oscillation of the flap may reduce or eliminate noise. For example, a flap may be constrained by limiting the ability of the edge (particularly the distal tip region) to oscillate. Alternatively, or in addition, a flap, and particularly the edge region of the flap, may be dampened to reduce or eliminate the oscillation. Finally, the flap may be prevented from oscillating by preventing an edge region of the flap face of the flap from aligning with the inspiratory airstream.

[00124] Noise-reduction features therefore include elements for constraining the oscillation of the edge region of a flap. Buzzing, apparently a result of the oscillations, may be reduced or prevented by including a noise-reduction feature that prevents the flaps forming the flap valve from opening so that an edge region of the flap face of the flap is essentially parallel with the direction of airflow through the device. Any appropriate structure for constraining the oscillation may be used as a noise-reduction element, including cages, spacers, cones, or tethers. Examples of these noise-reduction elements are given below.

[00125] Noise-reduction elements may be attached to the nasal device on the proximal side of the device (e.g., the side facing the subject, in the direction of inspiratory airflow. For example, a noise-reduction element may be a cone or cage (e.g., dome) that is placed over or partially across the passageway of the device so that it may control the edge or tip of the flap. In some variations the nose-reducing element may also act as an alignment guide, and may protect the valve or flap valve from interference. The noise-reduction element may also prevent the flaps from contacting a subject's nose, which would interfere with their operation and could irritate the subject's nose or causing a tickling sensation.

[00126] In general, noise-reduction elements limit the oscillation of the flap. FIGS. 4A to 4C illustrate noise-reduction elements configured as domes or cages that extend over the proximal side of the passageway and limit the motion of the flap valves to prevent them from buzzing. For example, FIG. 4A is a wire dome 401 that surrounds the flaps 405 of the flap valves. The dome has large openings, but the wires forming the dome prevent the flaps of the valve from opening completely. In particular, they prevent an edge region of the flap face from opening in parallel with the direction of airflow through the valve. The arrow 408 indicates the net direction of airflow during inhalation. In this example, the walls forming the dome curve inward slightly, preventing the flap(s) from opening fully during inhalation. In some variations, the dome or cage has a height that is less than the full extension of the flaps if they were to open in parallel with the direction of airflow. An example of this is shown in FIG. 4B.

[00127] In FIG. 4B the noise-reduction element is configured as a dome formed of a plastic mesh. In this example, the 'wires' forming the dome are thicker than those shown in FIG. 4A, and the openings in the noise-reduction element are smaller than those in the noise-reduction element of FIG. 4A. The resistance through the dome (during both inspiration and exhalation), may therefore be slightly higher than the resistance without the dome, or compared to the device shown in FIG. 4A. The example of a noise-reduction element shown in FIG. 4C may have an even greater effect on the resistance to airflow through the nasal device. In this example the dome is formed of a plastic (e.g., shaped or molded plastic) cut to provide openings (circular openings in this example). These openings may be larger and/or more numerous, in order to adjust the effect on the resistance to inspiration. In this way the resistance to inspiration (and exhalation) can be adjusted so that it is within a desired range.

[00128] FIGS. 5A-5D show variations of nasal devices including noise-reduction elements configured as spacers that are formed as part of a body region as described above for FIGS. 1A and 1B. For example, in FIG. 5A the inner body region includes a cross-beam with

two projections or spacers 503, 503' extending into the passageway to contact the distal tips of the flaps during inhalation, and prevent them from oscillating. In this example, the edge region of the flap face is prevented from aligning with the direction of airflow (perpendicular to the opening in FIG. 5A). As discussed above, this may prevent the flaps from oscillating. In FIG. 5A these projections 503, 503' extend downwards toward the flap valve. Any projection that prevents the edge region of the flap valve from oscillating (e.g., that prevents the edge region of the flap face from aligning parallel to the direction of airflow) may work. The noise-reduced nasal device shown in FIG. 5B is similar to the device shown in FIG. 5A, except that the noise-reduction elements (projections 503, 503') are longer, and therefore extend further in the passageway(s). FIGS. 5C and 5D illustrate another variation of a nasal device including noise-reduction elements that are configured as projections.

[00129] For example, in FIG. 5C, the noise-reduction element is a pair of spaced projections 505,505' and 507, 507' arranged so that each of the pair of flaps valves (not visible in the figure) will contact both of them when opening during inspiration. The spacing between the two projections may also help control the air pressure on one side of the flap, since the space formed between the two projections on each side will allow a gap preventing pressure to build up between a face of the flap and the cross-beam or projection spanning the passageway. This may help further prevent oscillation of the flap by maintaining the pressure differential with respect to the opposite face of the flap. The noise-reduced nasal device shown in FIG. 5D is similar to that shown in FIG. 5C, except that the projections are smaller (e.g., don't extend as far across the passageway(s) formed through the device). The size and/or number of the projections used to reduce or eliminate noise may depend on the material properties (such as stiffness) of the flap valve and the velocity of the expected airflow. For example, more projections that may be used with larger flap valves.

[00130] Other configurations of noise-reduction projections may include ribs or arcs that extend at least partially across the opening or passageway. These projections do not need to be part of a cone (e.g., an alignment cone or other structure) as illustrated in FIGS. 5A-5C, but may project from the side of the device near the flap valve (or from the holdfast region). In some variations a noise-reduction element is a cone (which may also be an alignment guide) that controls the edge regions of a flap to prevent it from oscillating and thereby reduce or eliminate noise such as buzzing.

[00131] For example, FIGS. 6A-6C illustrate three variations of noise-reduction elements configured as cones. Other examples of conical noise-reduction elements are shown in FIGS. 7A-10.

[00132] In FIG. 6A the cone extends up from the valve so that the top of the cone is as high as, or slightly higher than, the tip of the flap valves. In this example, the inner walls of the cone are slightly angled inward, so that the distal edge region of the flap face (the edge region of the flap face facing away from the subject when the device is worn) cannot move out of the path of the inspiratory airflow. Put another way, the distal edge regions of the flap face cannot become parallel with the net direction of air flow through the passageway of the device. The cone includes openings (cutout regions) 605 near each flap that may also prevent pressure from building up behind the flap as it nears the wall, potentially introducing instability. The openings may also (or alternatively) provide another path for airflow, helping to compensate for the size of the opening at the top of the cone, and keep inspiratory resistance low. FIGS. 6B and 6C illustrate different variations of cones that may also be used.

[00133] For example, FIG. 6B shows a simple formed cone that does not include any cutout regions. FIG. 6C shows a similar cone having a castle-topped (or crenellated) form in which cutouts have been made along the sides. In variations including cutouts or crenellations, the number of side cutouts is generally equal to at least the number of flaps. For example, in FIG. 6C there are eight flaps (cut to form a flap valve having eight "pie slices") and eight cuts forming eight crenellations. As mentioned, the cut out regions 607 may unexpectedly improve the noise-reducing capability compared to the simple formed cone of FIG. 6B. When tested at high flow rates (simulating a high inspiratory flow rate), the castle-topped variation shown in FIG. 6C produced less noise compared to the simple cone shown in FIG. 6C.

[00134] FIGS. 7A-7C illustrate another variation of a noise-reduction element configured as a simple formed cone, showing exemplary dimensions. For example, FIG. 7A shows a side perspective view of a conical noise-reduction element similar to that shown in FIG. 6B. FIG. 7B shows a top view of the same conical noise-reduction element. FIG. 7C is a side view indicating relative thicknesses and angles for the same noise-reduction cone. This basic noise-reduction cone may be cut to create the castle-topped variation or any other conical noise-reduction element. Examples of additional variations of conical noise-reduction elements are shown in FIGS. 8A-8F.

[00135] FIGS. 8A through 8C show cones designed to prevent flap vibration having one or more projection into the passageway region. For example, FIG. 8A is configured to be used

with a flap valve having six flaps (cut from a circular flap disk). There are three corresponding projections 803 that are configured to prevent an edge region of the flap face from orienting parallel to the direction of fluid flow. FIG. 8B is a similar conical noise-reduction element having four projections 805 rather than three, and may be used with an eight-flap variation. FIG. 8C is another variation having a ring-shaped projection to prevent flap buzz. The cone having a ring-shaped projection has the advantage that it can be used any flap valves regardless of the number of flaps, and further, the projections do not need to be aligned with the flaps, as may need to be done with the conical noise-reduction elements shown in FIGS. 8A and 8B. In the examples shown in FIGS. 8A-8C the walls of the cones may be relatively flat or parallel to the direction of airflow. Thus, although these are referred to as "cones" or conical noise-reduction elements, the walls don't angle substantially into the passageway, although the projections may. These variations may also include cutouts in the sides of the device, which may lower the inspiratory resistance, and also help prevent oscillation of the flap.

[00136] FIGS. 8D to 8F illustrate conical noise-reduction elements having internal walls that angle inward to prevent the oscillation of the flap. FIG. 8D is similar to the example of FIG. 6A, having angled sides and cutouts. FIGS. 8E and 8F are different variations of castle-topped or crenellated cones having cutout regions that extend to the upper edge of the device. The method of making these two similar cones may be quite different. For example, the cone forming the noise-reduction element in FIG., 8E may be formed by molding a simple formed cone similar to the formed cone shown in FIG. 7A. The noise-reduction element of FIG. 8F can be formed by cutting a disk of material and bending or folding it up so that it forms the cone structure shown.

[00137] A conical noise-reduction cone should be sufficiently tall so that the entire flap, including the tip region is controlled. Preventing the edge region of the flap face, including the tip region of the flap, from aligning with the direction of inspiratory airflow should prevent the flap from oscillating. FIGS. 9A and 9B illustrate one variation of a cone that only minimally inhibits noise due to buzzing or oscillation of the flaps. For example, FIG. 9A shows a short cone. When connected to a nasal device, this short cone may not project proximally sufficiently far to prevent an edge region of the flap face from oscillating, since the tips (the proximal ends of the movable flaps) may extend beyond the cone, as shown in the example of FIG. 9B. Thus, the height of the cone or other noise-reduction element should extend far enough to limit or prevent oscillation of the tip regions of the flap. FIG. 10 illustrates a taller variation of the cone that may be sufficiently tall compared to the element shown in FIG. 9A.

[00138] FIGS. 16A shows another example of a noise-reducing cone having a noise-reducing element 1601 that projects into the passageway and prevents the flap valve 1603, an example of which is provided in FIG. 16B, from orienting in parallel with the direction of airflow. The projection 1601contacts the distal tip region of the flap valve 1603, constraining it from orienting in parallel with the direction of airflow. FIG. 16C illustrates a nasal device, shown as an adhesive nasal device, that may be applied to the subject's nose.

Noise-Reduction Flap Valves

[00139] Noise-reduction flap valves typically include one or more flaps whose shapes and/or composition limit or prevent oscillation of the flap. For example a noise-reduction flap may constrain or limit an edge region of the flap face from aligning in parallel with the direction of airflow. Noise-reduction flap designs may provide flaps whose edges are either tethered, and therefore prevented from extending in the direction of airflow, or include one or more cuts which cause the flap to assume a three-dimensional configuration when the airflow through the valve is within the normal inspiratory range wherein the edge region of the flap faces are not able to align with the direction of airflow or otherwise oscillate.

[00140] FIG. 11 illustrates examples of a number of flap valves, some of which are noise-reduction flap valves. Although these flaps are formed from a circular layer, any appropriate flap design may be used. For example, a flap (including a noise-reduced flap) may be oval or may be pinned or otherwise attached to the nasal device, rather than being partially cut out of a substrate. FIGS. 12A-15B show specific examples of noise-reduced flaps and illustrate principles that may help design them.

[00141] FIG. 12A is a butterfly noise-reduction flap valve. FIG. 12B shows the butterfly noise-reduction flap valve (which may also be referred to as a double-butterfly flap valve) in an open configuration, when inspiratory airflow is flowing through the flap valve. As seen in FIG. 12B, the flaps open in two opposing directions; the outer flaps formed by the two outer cuts 1201, bend upwards, but are prevented from folding upwards and aligning with the direction of airflow in the valve by the flaps formed by the inner H-shaped cut 1203. These flaps also open upward, but push against the other flaps, preventing them from aligning with the direction of airflow, as shown. The additional cuts also shorten the effective bendable length of the flap, making the flap stiffer, and requiring greater inspiratory force in order to fully align a face of the flap with the direction of airflow. Thus, this butterfly flap is one variation of a noise-reduction flap valve.

[00142] FIG. 13A is another variation of a noise-reduction flap valve also having outer cuts and inner cuts which form flaps that may oppose each other and form a three-dimensional shape in the inspiratory airflow pathway. FIG. 13B shows this flap valve in the open position in an exemplary inspiratory airflow. In this example, as in the butterfly-type flap valve, the open flaps are constrained (at normal inspiratory flow rates) from opening so that one or more edge face regions are aligned in parallel with the direction of inspiratory airflow and therefore they are constrained from oscillating.

[00143] Two other variations of noise-reduction flap valves are illustrated in FIGS. 14A-15B. For example, in FIG. 14A, the clover-leaf pattern of internal flaps cut into each of the four larger flaps results in opposing pairs of flaps (e.g., each inner flap is opposed by an outer flap) that open in opposite directions, similar to the butterfly flap valve of FIGS. 12A-12B.

[00144] In all of these flap valve designs shown in FIGS. 12A-15B the opening of the outer flaps is opposed by the opening of an inner flap that is typically cut into the outer flap. As a result of the opposing flap openings, neither inner or outer flaps may open so that an edge region of the flap face is fully parallel with the direction of current flow, at least within the range of normal inspiratory airflows. At extremely high flow rates this may not hold, particularly at non-physiological flow rates.

[00145] In FIGS. 15A and 15B, a four-flap (a four-pie) valve example has been modified by including an additional "T" shaped cut along the center of the valve. As a result, these "T" cut regions will form adjacent flaps that open slightly to stiffen the larger flap region (the quarter pie-shaped region), preventing it from aligning an edge region of the flap face with the direction of airflow. This is illustrated in FIG. 15B. The noise-reduction performance for this type of valve may be improved by locating the slit forming the top of the "T" further than halfway up the flap from the attachment site of the quarter pie-shaped flap. In general, the further up the flap this cross-slit is located, the greater the stiffness preventing the quarter pie-shaped flap from opening so that an end face is aligned with the direction of airflow.

[00146] In some variations, the noise-reduction flap valve comprises a flexible flap having a durometer (or a durometer and thickness) that is high enough to reduce noise during the range of air flow past the flap that is experienced during inhalation through the device. The durometer of a material is a measure of the 'hardness' or 'stiffness' of the material. In general, higher durometer materials (e.g., higher than about 40 Shore A, higher than about 45 Shore A, higher than about 50 Shore A, etc.) were believed to increase the noise of operation of the device, and in particular, higher durometer (stiffer) materials were expected to make noises upon closing.

Surprisingly, experiments examining the noise resulting from similarly structured flaps with different thicknesses and durometer revealed that higher durometer materials were more noise-reducing than lower durometer materials. In particular, the combination of thickness and durometer of the materials was found to contribute to noise-reduction in these experiments. In general, flaps within the range of 2 mil to 5 mil having a higher durometer (greater than 40, e.g., 50) were quieter than flaps having a lower durometer. For example, flaps having a thickness of greater than about 2 mil (e.g., 2 mil, 3 mil, 4 mil) and flaps having a durometer of greater than 40 (e.g., greater than 45, greater than 50) were more noise-reducing. In particular, flaps having a thickness of between about 3 mil to 5 mil and a durometer of about 50 or higher were surprisingly less noisy than flaps having a lower durometer. In addition to helping reduce the sound of closing of the flap valve (which may produce a 'clicking' noise upon switching between inhalation and exhalation), the higher durometer flaps described herein may also reduce noise due to oscillation. Thus flaps within the above-described range of durometers and thicknesses may be considered noise-reduced flap valves.

[00147] The noise-reduction flap valves described herein may also be used in conjunction with the noise-reduction elements described herein. For example, a conical noise-reduction element may be used with a noise-reduction flap valve, as illustrated in FIG. 17. FIG. 17 shows a cross-section through a noise-reduced device including a noise-reduction flap valve 1703 that is similar to the butterfly flap valve illustrated in FIGS. 12A and 12B, above. A noise-reducing cone 1707 is also included, which can help prevent the edge of the flap(s) from oscillating. Airflow through the device is indicated by arrows 1705.

[00148] In addition to the noise-reduction elements and noise-reducing valves shown and described above, a noise-reducing feature may also dampen the oscillation of the edge of the flap. For example, the edge of the flap may be thickened or stiffened compared to other regions of the flap. An increased stiffness in the flap, and particularly the edge region, may dampen the oscillation of the flap without substantially changing the airflow through the device. For example, a device in which the edge portion of the flap is thicker than other portions of the flap may dampen oscillations. In another variation, the edge portion may be lined with a material having a different stiffness (e.g., a different modulus of elasticity).

[00149] FIGS. 18 and 20 illustrate proposed methods for assembling noise-reduced nasal devices. For example, FIG. 18 shows an exploded view of a noise-reduced nasal device including a noise-reduction element 1801. In this example, the noise-reduction element may be any of the elements described herein, including those shown in FIGS. 19A-19C. FIGS.19A-19C

shows three exemplary noise-reduction elements, including a cage 1901, a ribbed cone 1905, and a protrusion that is configured as two ribs 1903. In FIG. 18, the noise-reduction element 1801 may be attached on the proximal side of the device (the side to be inserted into the nostril in this example). The noise-reduction element 1801 may be attached by any appropriate method. For example, the noise-reduction element 1801 may be attached with an adhesive to a portion of the adhesive holdfast 1803, 1811 which includes an opening or passageway in which the airflow resistor is attached. The airflow resistor in this example is formed from a flap valve 1805 and a flap valve limiter 1807. An annular attachment ring or substrate 1811 is also used to attach to (and/or partially form) the adhesive holdfast which may secure the airflow resistor in place. The airflow resistor may include a noise-reduction flap valve as the flap valve 1805.

[00150] FIG. 20 shows an exploded view of another variation of a nose-reduced nasal device including a noise-reduction flap valve 2007. This figure is very similar to FIG. 2B except that the flap layer 207 of FIG. 2B has been replaced with the noise-reduction flap valve 2007. As mentioned above with reference to FIG., 17, additional noise-reduction elements may also be included. The devices may be assembled in any appropriate order, using appropriate manufacture techniques, to form the nasal devices. For example, the devices may be manually or automatically assembled.

[00151] Noise-reduced nasal devices may be worn to treat any disorder that would benefit from the use of a nasal device, including but not limited to respiratory or sleeping disorders, such as snoring, sleep apnea (obstructive, central, mixed and complex), COPD, cystic fibrosis and the like. Noise-reduced nasal device may be particularly beneficial for treatments in which the subject is encouraged or permitted to sleep while wearing the device, because they may prevent potentially disrupting noise. The noise-reducing features of these nasal devices may decrease the noise of operation of the nasal device by preventing the flap valve from oscillating during operation of the device (particularly during inhalation). To use the noise-reduced nasal device, it is first placed in communication with the subject's nasal cavity so that airflow from the subject's nose passes through the device as it is worn. The noise-reducing feature (e.g., a noise-reduction flap valve and/or a noise-reduction element) may then prevent or eliminate noise by limiting oscillation of the flap during inhalation and/or exhalation through the device. The nasal device may be placed in communication with the nasal passageway by placing it into or at least partially over or around the subject's nasal cavity. For example, an adhesive holdfast attached to the nasal device may be used to secure the device in position.

[00152] In addition to the elimination of buzzing due to oscillation of the flap, noise-reduced nasal devices may also include features or elements to help reduce whistling or other noise arising independently of the oscillation of the flap valve. In some variations, "whistling" noise may be reduced by minimizing or limiting the creation of turbulence as air flows through the device. For example, the surfaces of the device across which air flows (e.g., the passageway, rim body, etc.) may be smoothed or buffered to prevent whistling. The surfaces may be oriented to limit whistling by reducing air turbulence. The sizes of openings such as the leak pathway(s) and central passageways may also be configured to prevent whistling through the device. In some variations, opening of the leak pathway (or other surfaces) is oriented in parallel with the direction of airflow to reduce whistling by reducing the turbulent flow of air across the device. In some variations, edges exposed to airflow are smoothed or rounded to minimize turbulence. Whistling may also be minimized by reducing the perimeter length of an opening or openings through which air must pass. For example, in general, air flowing through a hole of a given frontal area will make less noise than air flowing through 10 holes each with 1/10 of the area of the single hole, but having a cumulative perimeter of over 3 times the circumference of the larger hole.

[00153] Many other materials and structures may be used to achieve the noise-reducing features described. This description is not intended to be limited to the structures and materials mentioned, but is intended to also encompass many other materials and structures having similar properties. Appendix A, attached below, suggests a number of modifications and variations of the devices and methods already described.

[00154] In contrast to the noise-reduced nasal devices, fluttering or vibrating nasal devices (which may or may not produce noise) may also be used. In particular, such devices may be configured to promote a vibration or fluttering sensation when worn, by promoting oscillation of the edge region of the flap face and/or tip of the flap during inhalation and or exhalation. The turbulence created by nasal devices and the resulting pressure waves may be useful for those patients requiring pulmonary therapy or rehabilitation. For example, a nasal device that caused oscillation during exhalation (and subsequent creation of oscillatory pressure waves that may be transmitted to the smaller airways) could be helpful in the treatment of cystic fibrosis or other diseases in which mucous clearance is important. These devices may also utilize any of the previously described device features which may be used to prevent oscillation and noise in one direction of airflow while promoting oscillation and/or pressure waves in another direction of airflow.

[00155] For example, a method of treating a disorder (e.g., cystic fibrosis) may include placing a passive-resistance nasal device in communication with a subject's nasal cavity, and oscillating the flap valve to produce vibrations. For example, the device may be configured so that the flap valve oscillates during inhalation through the nasal device. The nasal devices described herein may also be referred to as "passive-resistance" nasal devices because they do not require the active application of air pressure (e.g., blowing or pumping air or suctioning or removing air) from the subject. In some variations the devices are configured to oscillate during inhalation by orienting a flap (e.g., the flap valve) in parallel with the direction of airflow during inhalation. The devices may be configured to include a vibratable member (e.g., a membrane) in addition to the flap valve that is oriented so that an edge region is approximately parallel to the direction of airflow through the device. In some variations, the devices may be configured to oscillate or vibrate during exhalation as well as, or instead of, during inhalation.

Adjustable-Resistance Nasal Devices

[00156] FIGS. 22A through 33 illustrate different variations of adjustable-resistance nasal devices and method of using them, as well as resistance modifying members that may be used with nasal devices to form adjustable-resistance nasal devices. A resistance-modifying nasal device may include, for example: a resistance modifying member such as a plug or cover that blocks one or more leak pathways; a leak pathway with an adjustable cover (such as a cover including louvers/sliders to cover all or a portion of the leak pathway); an adjustable flap valve to increase/decrease the size of the leak pathway; an adjustable airflow resistor that may be adjusted to prevent a complete seal by the edges and/or the center of the airflow resistor when the device is worn; one or more constrictable holes; and one or more leak pathways whose length can be changed to increase/decrease the resistance.

[00157] For example, in some variations, a nasal device may be adjustable by covering or blocking a leak pathway. The leak pathway (typically a pre-formed leak pathway on any appropriate portion of the nasal device) may be completely or partially covered in a controllable fashion. For example a nasal device may be used with a resistance-modifying member such as that shown in FIG. 22B. FIG. 22A shows a portion of a nasal device 2201 including four leak pathways 2203 which are openings around the perimeter of a valved passageway 2205 (the valve is not shown in FIG. 22A). These leak pathways may be open during both inspiration and exhalation. The expiratory resistance may be modified by plugging any of these leak pathways, thereby increasing expiratory resistance, or by unplugging them, thereby decreasing expiratory

resistance. For example, FIG 22B illustrates one variation of a resistance-modifying member that includes plugs 2211 that may be used to block these leak pathways. In this variations, the resistance-modifying member is a snap-on device that may be attached (e.g., friction fit) to the nasal device to block one or more of the leak pathways. The device shown in FIG. 22B includes four plugs, however variations in having more or fewer plugs may be used. The plugs may be partial plugs, so that the diameter of the leak pathway may be reduced by some percentage (e.g., 10%, 20%, 25%, 50%, 75%, etc.) to increase resistance. In some variations, the 'plug' portions of the snap-on device are removable or adjustable. For example, the "plug" may be a slider or shutter that can be moved across the leak pathway(s) to partially occlude them. Thus, virtually any nasal device may be adapted to be a variable-resistance nasal device by including an attachable resistance-modifying member. In some variations the resistance-modifying member does not occlude or otherwise block the valved central opening, and therefore it does not modify inspiratory resistance. Although the resistance-modifying member shown in FIG. 22B is a snap-on resistance-modifying member, a resistance-modifying member may be attached to the nasal device in other ways as well. For example, the resistance-modifying member may be adhesively secured to the nasal device, magnetically secured to the nasal device, etc.

[00158] FIG. 23 illustrates another variation of an adjustable-resistance nasal device including a plug or cover which may occlude or partially occlude one or more of the leak pathways in the nasal device. In this example, the nasal device 2300 is a whole-nose nasal device that may fit over the subject's nose, and includes an airflow resistor (e.g., flap valve) 2301, and a plurality of openings (leak pathways) 2303 that may be covered with an adhesive tape or plug. This device may be adhesively secured to a subject's nose by an adhesive holdfast 2305 or other holdfast. Alternatively, the holdfast may not comprise adhesive. In some embodiments, the whole-nose nasal device will be a nose mask that is roughly the shape of a user's nose (whether customized or not) and may be held in place using straps, tethers or the like. The mask is designed to create a complete or partial seal with the user's nose or face. A soft interface material (eg silicone or foam for example) may be used to promote a seal and provide user comfort. The mask may be reusable to single-use. In some embodiments, the whole-nose nasal device can be configured for use with active positive airway pressure devices including CPAP, Bi-level PAP, VPAP and the like.

[00159] In some variations of the adjustable-resistance nasal devices described herein, the plugs or covers may be integrated into the nasal device, without the need for a separate resistance-modifying member. For example, a nasal device may include a cover or plug that integral with the nasal device or linked to the nasal device (e.g., by a hinge or tether).

[00160] Other variations of adjustable-resistance nasal devices may include adjustable leak pathways. For example, a leak pathway may be constrictable, so that the cross-sectional diameter of the leak pathway may be decreased or increased. In some variations, the leak pathway includes a diaphragm, shutter or other member that may be used to expand or constrict the opening of the leak pathway. For example, the leak pathway may include a louver-type cover which can be opened or closed to various degrees. A leak pathway may include a dilating iris-type shutter which can be closed to increase resistance. In some variations the leak pathway includes an inflatable or swellable material to reduce the diameter of the leak pathway. A control that may be used to open/close the constrictable leak pathway may also be included on the nasal device. For example, the control may be a dial, button, slider, or the like.

[00161] In some embodiments, a porous material including but not limited to some formulations of polyethylene or polypropylene (such as Porex® brand products) may find use. These porous plastics have pores that can become filled with condensed water vapor. When such porous materials are used in any of the components of the devices described herein (including the holdfast or rim), the resistance through the device will adjust or increase as the user breathes through the device, as the pores are plugged or filled and therefore resistance will increase in time. For example, FIG. 24 shows one variation of a constrictable leak pathway 2405, in which the diameter of the leak pathway may be increased or decreased. FIG. 24 shows a magnified view of a single leak pathway which may be part of a nasal device 2401. In some variations, an adjustable nasal device includes a leak pathway 2405 having the wall (or a portion of the wall) 2403 that is inflatable (e.g., an inflatable bladder or plug) that can be inflated to occlude the leak pathway. As mentioned, the leak pathway may include a swellable material that can be swollen to at least partially occlude the leak pathway. The resistance may be adjusted by adding fluid to cause the material to swell and occlude one or more leak pathways.

[00162] An adjustable-resistance nasal device may also include an adjustable airflow resistor that may be manipulated to adjust the expiratory (and/or inspiratory) resistance. For example, an adjustable airflow resistor may be moved to modify one or more leak pathways through the device. For example, a nasal device may include an airflow resistor that can be rotated to enlarge or reduce a leak pathway. In some variations the airflow resistor is in communication with a central passageway through the device, and the airflow resistor may be moved in or out of register with the central passageway, creating or eliminating a leak pathway adjacent to the airflow resistor. In some variations, moving the airflow resistor may enlarge or contract a leak pathway formed between the nasal device and the subject wearing the device.

[00163] FIG. 25 illustrates one variation of an adjustable-resistance nasal device in which a leak pathway 2509 is formed around the airflow resistor 2501, 2503 as the airflow resistor is moved proximally or distally within a tapered central passageway 2511. The device includes a control knob 2505 that can be turned to move the airflow resistor proximally or distally, to increase or decrease the size of the leak around the device (and thus modify the expiratory resistance when the airflow resistor is otherwise closed). In this example, the airflow resistor includes a flap/diaphragm 2501 and a flap limiter 2503.

[00164] FIGS. 26A and 26B illustrate an alternative variation of an adjustable-resistance nasal device, in which the internal surface of the central passageway 2603 is threaded 2605, and the airflow resistor 2601 may be moved (e.g., by rotating) proximally or distally, causing the airflow resistor to flex. This flexing of the airflow resistor 2601 (and particularly the seating portion for the flap valve) may prevent the valve from closing during expiration, decreasing the resistance. This embodiment may also provide feedback to the user as the resistance is decreased, since it may become progressively more difficult to advance the airflow resistor proximally (to the right in FIGS. 26A and 26B).

[00165] FIG. 27 illustrates another variation of an adjustable-resistance nasal device, in which the flap valve portion 2701 of the airflow resistor may be moved off-center from the central passageway 2703 by turning the knob 2709, rotating the flap of the airflow resistor around a pivot axis 2707, so that a leak pathway may be formed around the flap 2701. Displacing an entire airflow resistor or a portion of an airflow resistor (e.g., the flap portion) may be particularly useful to open and close leak pathways that are not pre-formed but form as the airflow resistor is displaced. In one variation of this concept, the knob may rotate the airflow resistor or a portion of the airflow resistor (e.g., the flap of a flap valve airflow resistor) around a central axis but the airflow resistor or flap of the airflow resistor is moved out of register with the opening or passageway that is regulated by the airflow resistor. For example, if the airflow resistor and passageway are non-circular (e.g., oval).

[00166] In one alternative embodiment, an example of which is illustrated in FIGS. 28A and 28B, rotation of all or a part of the airflow resistor with respect to the body of the nasal device results in blocking or unblocking pre-formed leak pathways. For example, in FIG. 28A, the flap of the flap valve 2811 is rotatable around the central axis. The edge of the flap 2801 includes projection regions 2817 (which may be different sizes) that may be rotated to cover one or more of the leak pathways (openings 2815) in the region surrounding the central passageway.

The flap is shown as transparent in this example, so that the supporting cross-beams 2807 forming the flap valve limiter may be seen.

[00167] In FIG. 28B the leak nasal device include six leak pathways 2805 on the surface of the flap valve. The flap valve is supported by two cross-beams forming a "+" pattern on which the flap may sit. These cross-beams are one variation of a flap valve limiter that limits the valve from opening during expiration. In this example, the flap valve limiter may also block the leak pathway openings through the flap valve when the openings are aligned with the cross-beams 2807. Thus rotation of the flap valve with respect to the cross-beams may expose or cover the leak pathways on the flap valve 2811. In FIG. 28B, the valve is oriented so that four of the leak pathways on the flap (holes 2805) are opened; by rotating the flap 2811, two or four of the holes may be partially or completely blocked when the valve is closed (e.g., during exhalation). Thus, the resistance to exhalation may be adjusted in discrete steps (leak paths unblocked, two leak paths blocked, four blocked, etc.).

[00168] The resistance of an adjustable resistance nasal device may also be adjusted by deflecting all or a portion of the airflow resistor distally or laterally with respect to the passageway through the nasal device, as illustrated in FIGS. 29-33. For example, in FIG. 29, the airflow resistor 2091 of the nasal device 2900 (shown in cross-section) may be displaced up (proximally) so that the flap valve cannot seat on the flap valve limiter (e.g., cross beams), preventing the edges of the flap valve 2901 from sealing and may allow leak flow around the flap, decreasing resistance. The more the flap valve is displaced, the less the resistance. A handle or knob 2905 may be used to displace the flap. In this example, knob is threaded 2909 so that as it is rotated, the flap valve is raised or lowered to increase or decrease the leak pathway and thereby decrease or increase the resistance to exhalation.

[00169] FIGS. 30A and 30B illustrate another variation, in which a resistance-modifying member may be used with a nasal device to displace a portion of the airflow resistor. FIG. 30A shows a bottom view of a nasal device, showing the flap valve 3001 resting against the valve limiting layer (shown as cross-hair beams 3003). The valve limiting layer includes openings 3005, into which a flap valve displacing member 3009 (shown in profile in FIG. 30B) may be inserted. In this example, the resistance-modifying member is the displacing member 3009which includes four displacing elements 3011 that project from the resistance-modifying member through the openings in the valve limiting layer 3003 to prop open the edges of the flap valve 3001, preventing the flap from closing completely during expiration, as illustrated in FIG. 30C in partial cross-section.

[00170] FIGS 31A and 31B shows another variation of an adjustable-resistance nasal device, in which the nasal device includes a flap valve limiter (cross bars 3101) which may be deflected up or down from the plane of the airflow resistor (when in the 'closed' position). For example, the valve limiting member (cross-hairs) may be hinged or bendable so that it can be moved to prevent the nasal device from closing completely, forming a leak pathway around the flap and decreasing expiratory resistance.

[00171] In addition to modifying the position or structure of the airflow resistor to modify resistance, and/or changing the opening size of a leak pathway to modify the resistance, the length of the leak pathway may also be modified to change the resistance. For example, FIG. 32 illustrates one variation in which the length of the leak pathway 3201 may be decreased to decrease the resistance. In this example, the leak pathway is formed by segments that may be removed (or added) to modify the resistance through the leak pathway, and therefore the resistance to expiration. In some variations the leak pathway may be telescoping in length, so that it can be shortened or lengthened without removing segments.

[00172] FIG. 33 shows another variation of an adjustable resistance nasal device that includes two adhesively removable resistance modifying members 3301, 3303. In FIG. 33, these resistance modifying members are initially (in this variation) attached to the nasal device so that the central leak pathway through the nasal device is partially occluded. The two separate modifying members 3301, 3303 are layered over the leak pathway, and each other so that the outermost resistance modifying member (removable tab 3303) has a small diameter opening that restricts the leak pathway to this small diameter size. The second resistance modifying member (removable tab 3301) has a slightly larger opening than that of removable tab 3303, but is still slightly smaller than the leak pathway opening of the nasal device. In operation, the first and the second (or both the first and second) resistance modifying members may be removed to progressively decrease the resistance to expiration. Similarly, adhesive resistance modifying members may be added to partially obstruct the leak pathway, and thereby increase the resistance to expiration. In this example, the resistance modifying members may include tabs or grasping regions that may be gripped and removed to pull off the adhesive resistance modifying member.

[00173] Adjustable resistance nasal devices such as those described herein may be adapted so that they may be readily adjusted by a third party who is not the subject or patient wearing the device. For example, the adjustable nasal device (or a nasal device that is adjustable by adding or removing a resistance modifying member) may be adjusted by a doctor, nurse or technician (e.g., sleep technician) without disturbing a sleeping subject wearing the device. This may be

particularly useful in adjusting a device worn or operated as part of a sleep study. However, this adjustability may also be useful or significant to other third parties (e.g., sleeping partners, spouses, etc.). In addition, the subject himself or herself may also adjust the resistance, which may be helpful in optimizing the comfort or operation of the nasal device.

Ramp Kits or Systems

[00174] In addition to the adjustable resistance devices described herein, systems or kits including a plurality of nasal devices having fixed expiratory resistances but which increase in resistance relative to each other may also be used. The individual nasal devices may be organized and/or marked in order of increasing expiratory resistance. Such systems or kits may permit a subject to grow accustomed to the increasing expiratory resistance over time by gradually increasing the resistance to exhalation over one or more nights wearing the devices, for some span of time (an acclimation period). The resistance may be increased by any desired amount from a negligible resistance (e.g., a 'sham' device) to the final desired expiratory resistance. For example, the resistance of each step may increase by 10% (or 5%, 15%, 20%, 25%, etc.) until the final target expiratory resistance is achieved. This final target expiratory resistance may be approximately 30 cm H_2O/(L/sec), approximately 35 cm H_2O/(L/sec), approximately 40 cm H_2O/(L/sec), approximately 45 cm H_2O/(L/sec), approximately 50 cm H_2O/(L/sec), approximately 55 cm H_2O/(L/sec), approximately 60 cm H_2O/(L/sec), approximately 65 cm H_2O/(L/sec), approximately 70 cm H_2O/(L/sec), approximately 75 cm H_2O/(L/sec), approximately 80 cm H_2O/(L/sec), approximately 85 cm H_2O/(L/sec), approximately 90 cm H_2O/(L/sec), approximately 95 cm H_2O/(L/sec), approximately 100 cm H_2O/(L/sec), approximately 105 cm H_2O/(L/sec), approximately 110 cm H_2O/(L/sec), approximately 115 cm H_2O/(L/sec), although other levels are possible. In one example, the resistance is increased in even steps (e.g., increasing by equivalent amounts between each step), while in some variations the expiratory resistance increases by different amounts between each step, as some increases in expiratory resistance may feel more drastic than others.

[00175] Any number of steps of increasing resistance may be used. For example, the number of steps (e.g., the number of different expiratory resistance levels) may depend on the target expiratory resistance, or the period of acclimation. In some variations, two, three, four, five, six, seven, eight, etc. steps may be used. Any number of devices may be used at each step (e.g., any number of devices having the same expiratory resistance) as part of the system or kit. In some variations, each step is 'held' for between 1-7 nights. For example, the kit may include three 'sham' devices having negligible expiratory resistance, three devices having low expiratory resistance (e.g., 20 cm H_2O/(L/sec)), three devices having a resistance to expiration that is

slightly higher (e.g., approximately 40 cm H_2O/(L/sec)), three devices having a still slightly higher resistance to expiration (e.g., approximately 60 cm H_2O/(L/sec)), and four devices having an even higher resistance to expiration (e.g., approximately 80 cm H20/(L/sec)). In some variations some 'steps' may include more than three or less than three devices. In this example, each device is intended to be worn for one night, with devices being worn on consecutive nights. After completing the series of devices, the user may be acclimated to the final resistance and may thereafter use devices having this final (target) resistance.

[00176] As mentioned, any of these systems or kits may include instructions for use, indicating that the subject should use the devices in an indicated order which corresponds to an increasing expiratory resistance. The instructions may be included with the devices. In some variations the devices in the kit or system are numbered or otherwise marked to indicate the order to be used. In other variation, the devices are packaged in such a way that they are dispensed or provided in the desired order.

[00177] In some variations, there may be excess devices at each step, and the subject may be instructed to remain at a particular step (level of expiratory resistance) until they are comfortable with that level of expiratory resistance, and then proceed to the next higher level. Thus, in any of these variations, the devices corresponding to each step may be labeled sequentially, or marked sequentially via the packaging or dispensing. For example, the devices or set of devices are marked to indicate their order in the sequence (or are packaged to indicate their order in the sequence).

[00178] Although the examples of adjustable-resistance nasal devices described above and shown in the figures provided are exemplify the principles taught herein. These same principles may be applied or adapted for use in other nasal device variations. For example, the nasal devices described herein are primarily mostly device for altering the expiratory resistance of a nasal device. Adjustable nasal devices in which the inspiratory resistance is adjustable (in addition to the expiratory resistance or instead of adjusting the expiratory resistance) are also contemplated as part of this invention. In addition, although the noise-reduced and adjustable-resistance nasal devices are separately described and illustrated, a nasal device may include both features, which may be combined. For example, a noise-reducing element may also provide an adjustable leak pathway.

[00179] Furthermore, although the nasal devices described herein are configured so that (in normal operation) the resistance through the device is greater during exhalation than during inhalation, other configurations may also be used with the noise-reduced devices or features

described herein. For example, a nasal device may be configured with an airflow resistor that inhibits inhalation more than exhalation, which may be used with a noise-reduction element or flap valve configured to inhibit oscillation of the flap (or flaps) during exhalation instead (or in addition to) inhalation. In general a noise-reduced nasal device may limit the oscillation of the flap during both inhalation and exhalation. While the methods and devices have been described in some detail here by way of illustration and example, such illustration and example is for purposes of clarity of understanding only. It will be readily apparent to those of ordinary skill in the art in light of the teachings herein that certain changes and modifications may be made thereto without departing from the spirit and scope of the invention.

CLAIMS

WHAT IS CLAIMED IS:

1. A noise-reduced nasal respiratory device comprising:

a noise-reduced airflow resistor comprising a flap valve, wherein the noise-reduced airflow resistor is configured to inhibit exhalation more than inhalation and to inhibit oscillation of a free edge of the flap valve during inhalation when the flow rate is between about 20 and 750 ml/sec; and

a holdfast configured to secure the noise-reduced nasal respiratory device in communication with the subject's nasal cavity.

2. A noise-reduced nasal respiratory device comprising:

a noise-reduced airflow resistor comprising a noise-reduction flap valve that is configured to inhibit exhalation more than inhalation, wherein the noise-reduction flap valve is further configured so that a free edge of the flap valve does not orient in parallel with the direction of airflow through the nasal device during inhalation; and

a holdfast configured to secure the device in communication with the subject's nasal cavity.

3. A noise-reduced nasal respiratory device comprising:

an opening configured to communicate with the nasal cavity;

a noise-reduced airflow resistor comprising a flap valve in communication with the opening and a noise-reduction element configured to limit oscillation of the flap valve, wherein the noise-reduced airflow resistor is configured to increase the resistance to air exhaled through the opening more than the resistance to air inhaled through the opening; and

a holdfast configured to secure the opening in communication with the subject's nasal cavity.

4. A noise-reduced nasal respiratory device comprising:

an opening configured to communicate with the nasal cavity;

a noise-reduced airflow resistor comprising a flap valve in communication with the opening and a noise-reduction element configured to prevent an edge region of a flap face of the flap valve from becoming oriented substantially in parallel with the direction of airflow through the opening during inhalation, wherein the noise-reduced airflow resistor is configured to increase the resistance to air exhaled through the opening more than the resistance to air inhaled through the opening; and

a holdfast configured to secure the opening in communication with the subject's nasal cavity.

5. The device of claim 1, wherein the noise-reduced airflow resistor comprises a noise-reduction flap valve.

6. The device of claim 1, wherein the noise-reduced airflow resistor comprises a noise-reduction element configured to limit oscillation of the flap valve.

7. The device of claims 2 or 5, wherein the noise-reduction flap valve comprises a butterfly-type flap valve.

8. The device of claims 2 or 5, wherein the noise-reduction flap valve comprises a plurality of cuts arranged so that the edge of the flap valve does not orient substantially in parallel with the direction of airflow through the nasal device during inhalation.

9. The device of claims 2 or 5, wherein the noise-reduction flap valve comprises a first flap and a second flap wherein the first and second flaps are configured to open during inhalation so that the opening of the second flap inhibits the first flap from opening substantially in parallel with the direction of airflow through the nasal device during inhalation.

10. The device of claims 2 or 5, wherein the noise-reduction flap comprises a dampened edge.

11. The device of claims 2 or 5, wherein the flap of the noise-reduction flap valve comprises a material having a durometer that is greater than 40 Shore A.

12. The device of claims 2 or 5, wherein the flap of the noise-reduction flap valve comprises a material having a durometer that is greater than 40 Shore A and a thickness between about 2 mil and about 5 mil.

13. The device of claims 3, 4 or 6, wherein the noise-reduction element comprises a projecting surface that communicates with the flap valve to prevent an edge of the flap valve from orienting substantially in parallel with the direction of airflow through the nasal device during inhalation.

14. The device of claim 13, wherein the projecting surface comprises a rib extending at least partially across an opening through the nasal device, wherein the noise-reduced airflow resistor communicates with the opening through the nasal device to increase the resistance to air exhaled through the opening more than the resistance to air inhaled through the opening.

15. The device of claims 3, 4 or 6, wherein the noise-reduction element comprises a cone.

16. The device of claims 3, 4 or 6, wherein the noise-reduction element comprises a cone having at least one cut-out region for air passage along the perimeter.

17. The device of claims 3, 4 or 6, wherein the noise-reduction element comprises a castle-topped cone.

18. The device of claims 3, 4 or 6, wherein the noise-reduction element comprises a cage.

19. The device of claims 3, 4 or 6, wherein the noise-reduction element comprises a spacer configured to prevent the edge of the flap valve from opening substantially in parallel with the direction of airflow during inhalation.

20. The device of claims 3, 4 or 6, wherein the noise-reduction element does not substantially increase the inspiratory resistance.

21. The device of claims 1, 2, 3 or 4 further comprising a leak pathway configured to remain open during both inhalation and exhalation.

22. The device of claims 1, 2, 3 or 4, wherein the holdfast comprises a compressible holdfast

23. The device of claims 1, 2, 3 or 4, wherein the holdfast comprises an adhesive holdfast.

24. The device of claims 1, 2, 3 or 4, wherein the nasal respiratory device has a resistance to exhalation that is between about 0.01 and about 0.25 cm H_2O/(ml/sec) when resistance is measured at 100 ml/sec.

25. A method of decreasing the noise of operation of a nasal device having a flap valve airflow resistor, the method comprising:

placing a nasal device in communication with a subject's nasal cavity, wherein the device includes a flap valve airflow resistor configured to inhibit exhalation more than inhalation; and

limiting the oscillation of the flap valve during inhalation through the nasal device.

26. The method of claim 25, wherein the step of limiting the oscillation of the flap valve comprises preventing an edge of the flap valve from orienting substantially in parallel with the direction of inspiratory airflow through the nasal device.

27. The method of claim 25, further comprising preventing the flap valve from oscillating by limiting the motion of the free end of the flap valve.

28. The method of claim 25, further comprising adhesively securing the nasal device at least partly over or at least partly within the subject's nasal cavity.

29. A method of decreasing the noise of operation of a nasal device, the method comprising:

placing a nasal device in communication with a subject's nasal cavity, wherein the device includes an opening, a flap valve airflow resistor in communication with the opening, and a noise-reduction element, wherein the flap valve airflow resistor is configured to inhibit exhalation more than inhalation; and

inhibiting the oscillation of the flap valve during inhalation through the nasal device by contacting at least a portion of a free edge of the flap valve to the noise-reduction element during inhalation.

30. An adjustable resistance nasal device comprising:

an airflow resistor configured to inhibit exhalation more than inhalation;

a holdfast configured to secure the nasal device in communication a subject's nasal cavity;

a leak pathway through the nasal device configured to be open during both exhalation and inhalation; and

an adjustable shutter configured to at least partially occlude the leak pathway.

31. The device of claim 30, wherein the adjustable shutter comprises a control configured to allow manual adjustment of the shutter.

32. An adjustable resistance nasal device comprising:

an airflow resistor configured to inhibit exhalation more than inhalation;

a holdfast configured to secure the nasal device in communication a subject's nasal cavity;

a leak pathway through the nasal device configured to be open during both exhalation and inhalation; and

a removable and replaceable cover configured to occlude the leak pathway.

33. An adjustable resistance nasal device system comprising:

a nasal device comprising

an airflow resistor configured to inhibit exhalation more than inhalation;

a holdfast configured to secure the nasal device in communication a subject's nasal cavity;

a leak pathway through the nasal device configured to be open during both exhalation and inhalation; and

a resistance-modifying member configured to secure to the nasal device and at least partially occlude the leak pathway.

34. The system of claim 33, wherein the resistance modifying member is a snap-on resistance modifying member configured to mechanically secure to the nasal device.

35. The system of claim 33, wherein the resistance modifying member is an adhesive resistance modifying member configured to adhesively secure to the nasal device.

36. An adjustable resistance nasal device comprising:

a passageway through the nasal device;

an airflow resistor in communication with the passageway and configured to inhibit exhalation more than inhalation; and

a holdfast configured to secure the nasal device in communication a subject's nasal cavity;

a control connected to the airflow resistor wherein the airflow resistor is configured to be moved within the passageway by adjusting the control so that a leak pathway is created at least partially around the airflow resistor.

37. An adjustable resistance nasal device comprising:

an airflow resistor configured to inhibit exhalation more than inhalation;

a holdfast configured to secure the nasal device in communication a subject's nasal cavity; and

a constrictable leak pathway through the nasal device configured to be open during both exhalation and inhalation.

38. The device of claim 37, wherein the constrictable leak pathway comprises an inflatable bladder.

39. The device of claim 37, wherein the constrictable leak pathway comprises a swellable material.

40. A method of controllably adjusting the resistance of a nasal device, wherein the nasal device comprises an airflow resistor configured to have a greater resistance to exhalation than inhalation, a holdfast for securing the nasal device in communication with a subject's nasal cavity and a leak pathway configured to be open during both exhalation and inhalation, the method comprising at least partially occluding a leak pathway of a nasal device.

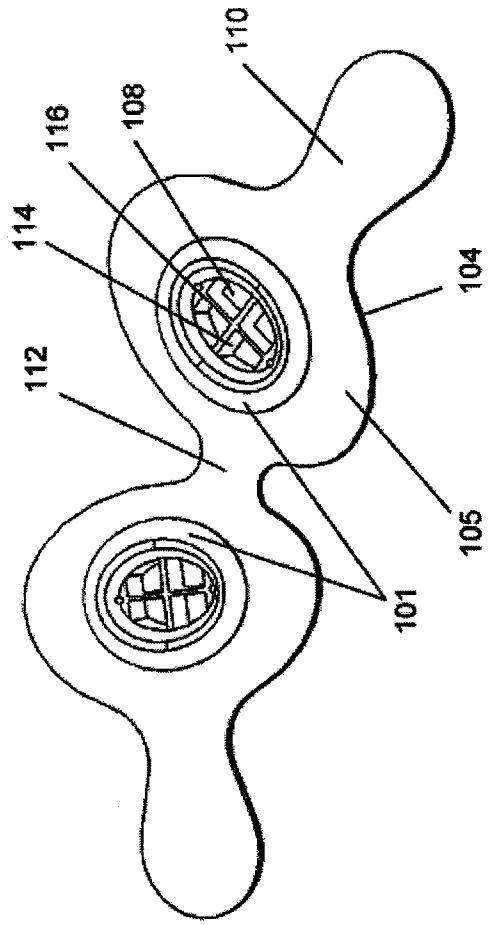

FIG.1A

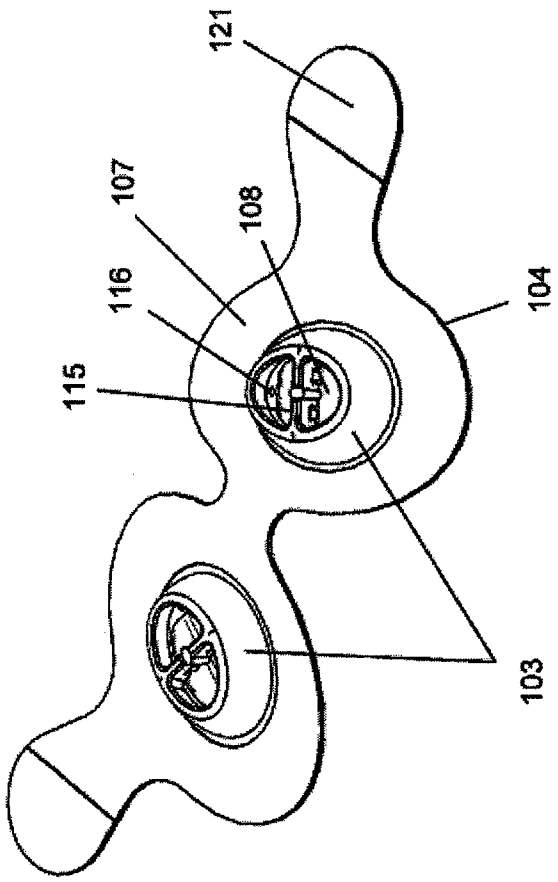

FIG. 1B

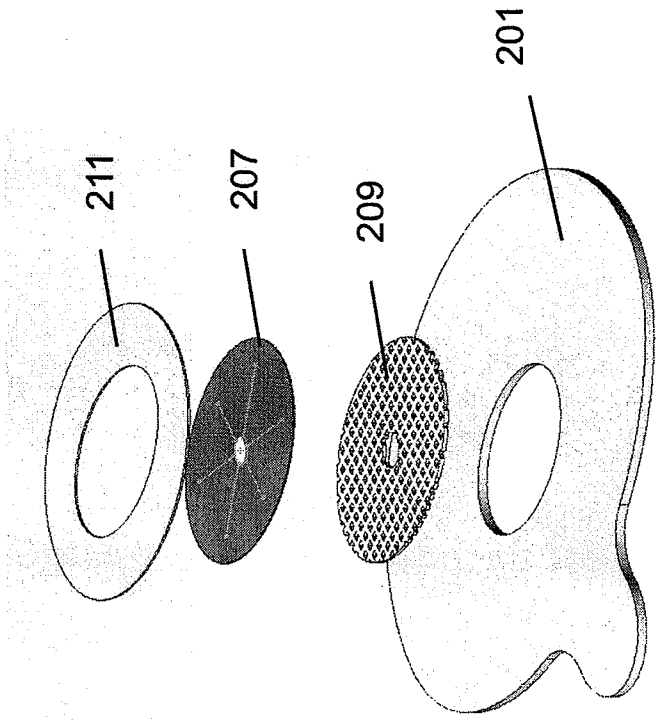

FIG. 2B

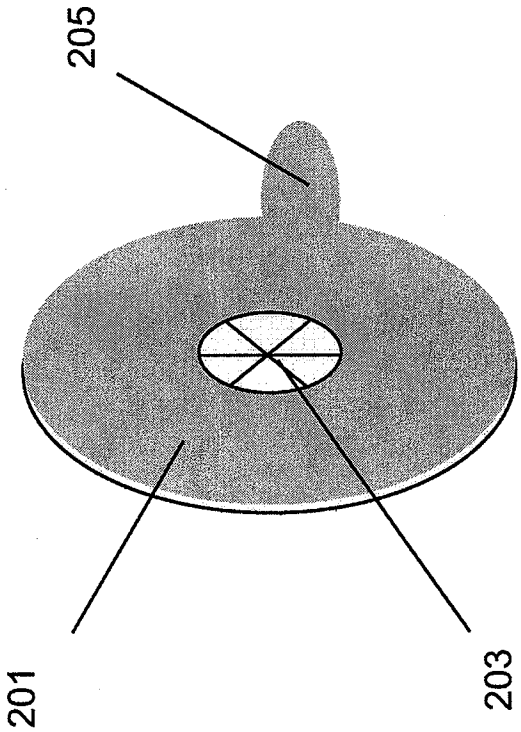

FIG. 2A

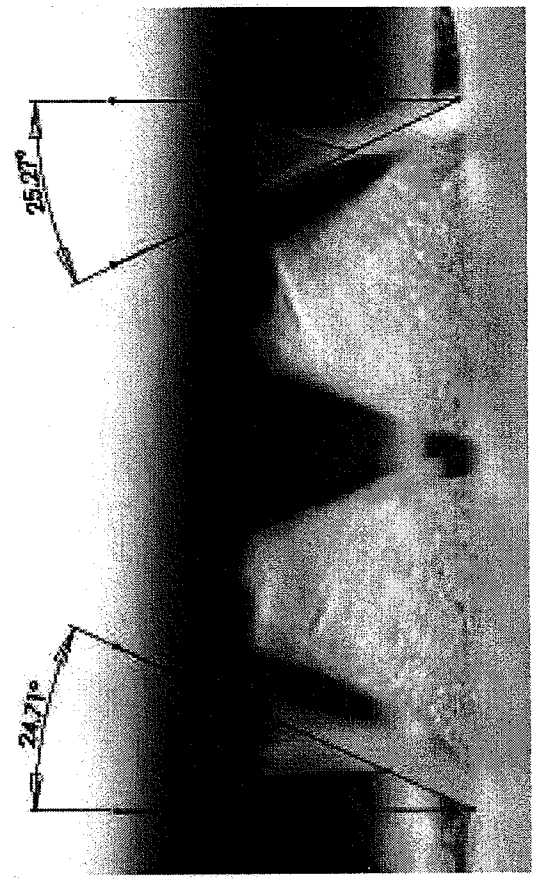

FIG. 3B

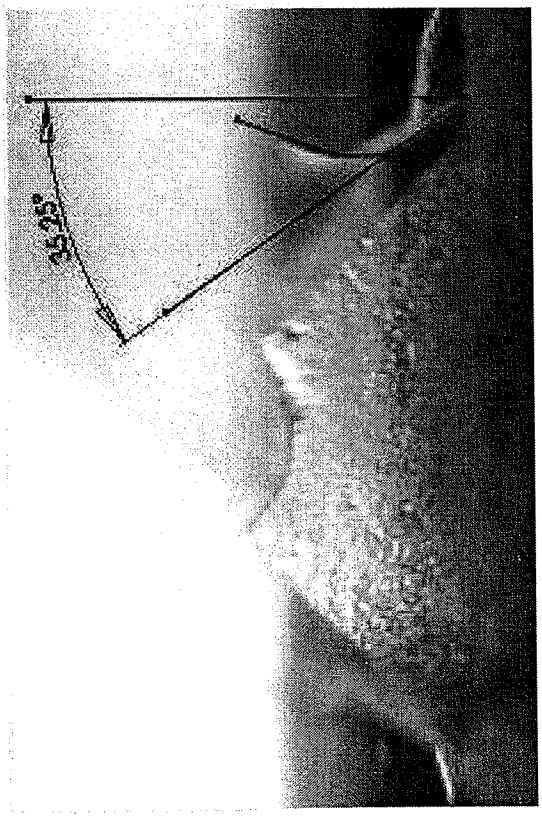

FIG. 3A

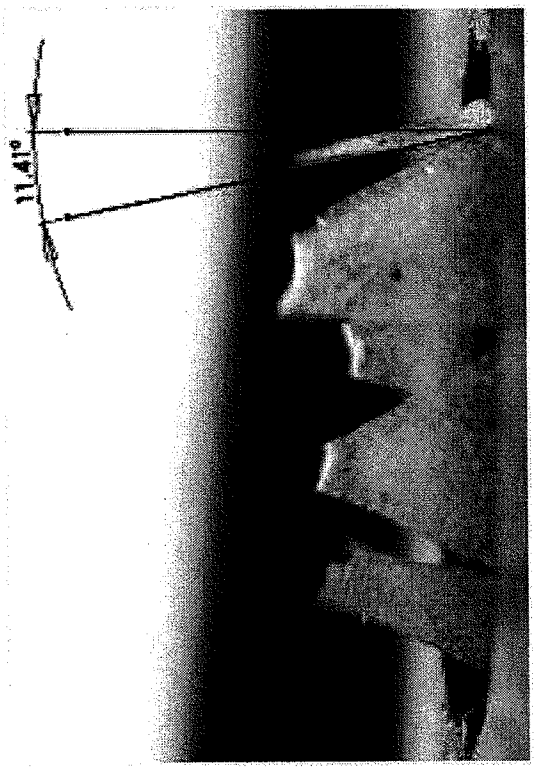

FIG. 3C

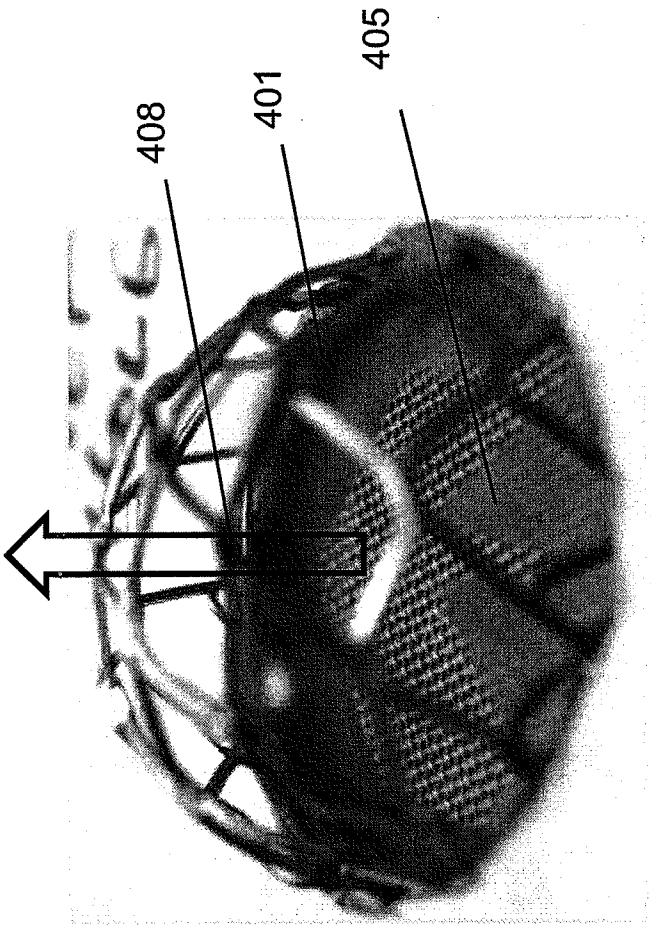

FIG. 4A

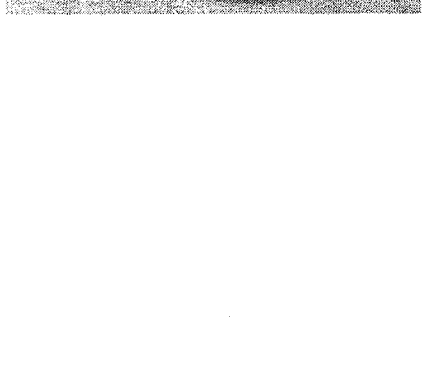

FIG. 4B

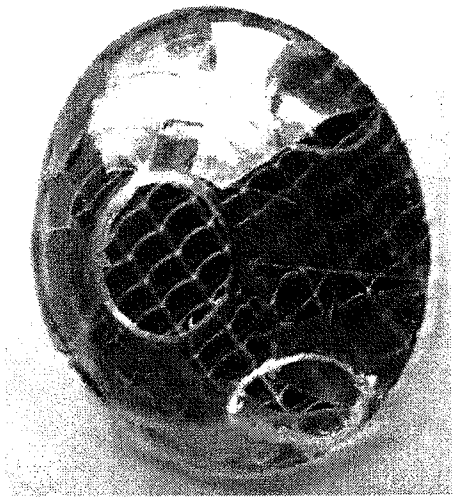

FIG. 4C

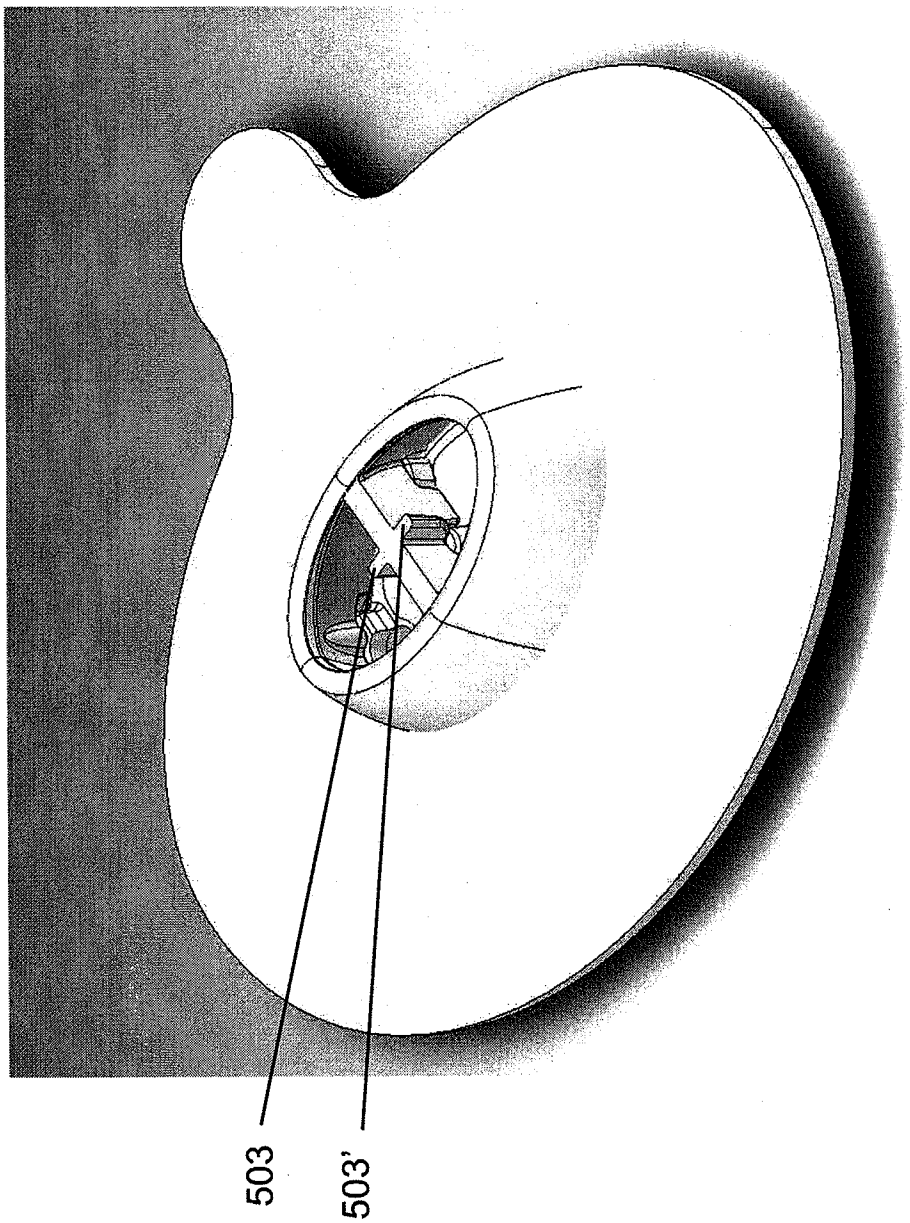

FIG. 5A

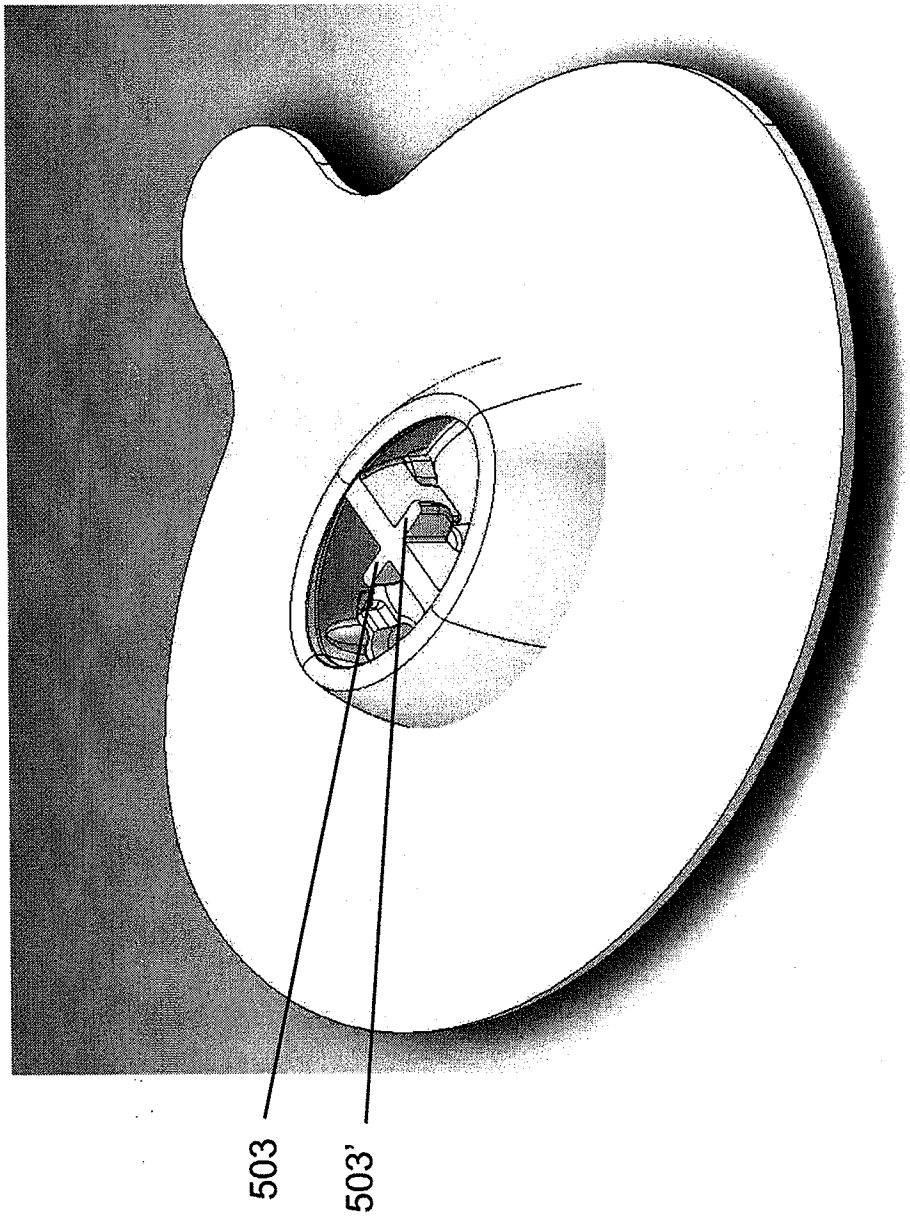

FIG. 5B

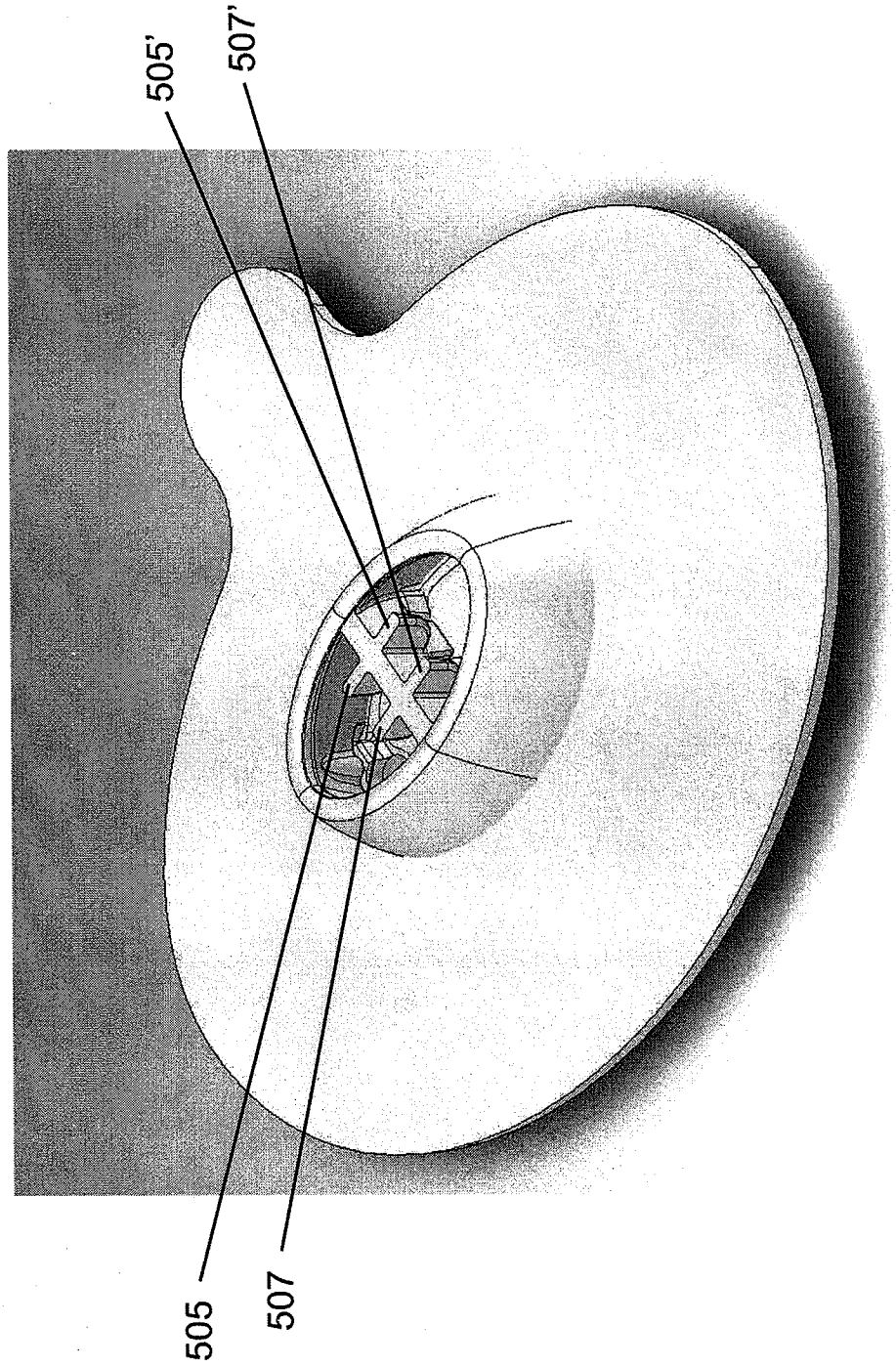

FIG. 5C

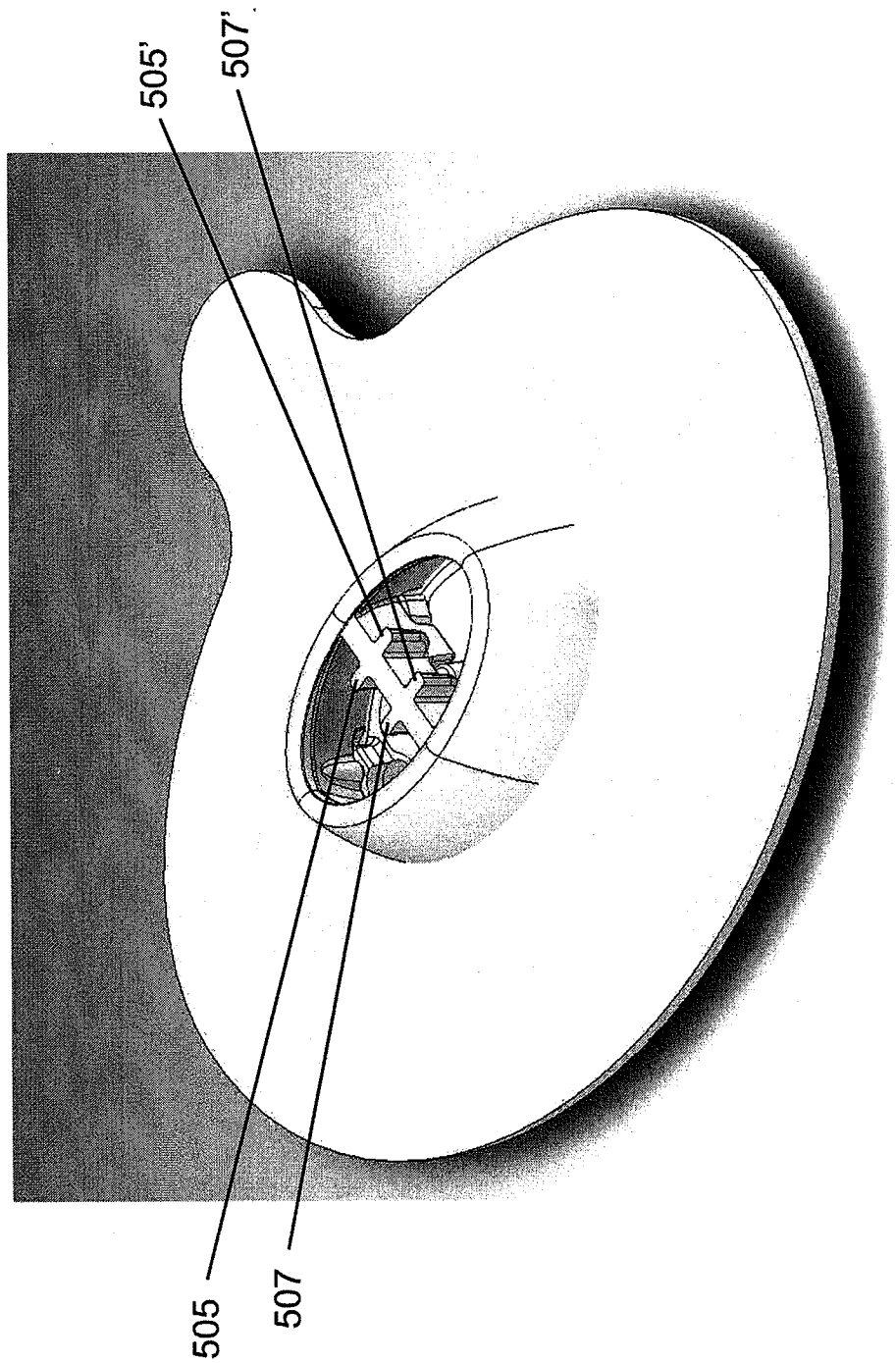

FIG. 5D

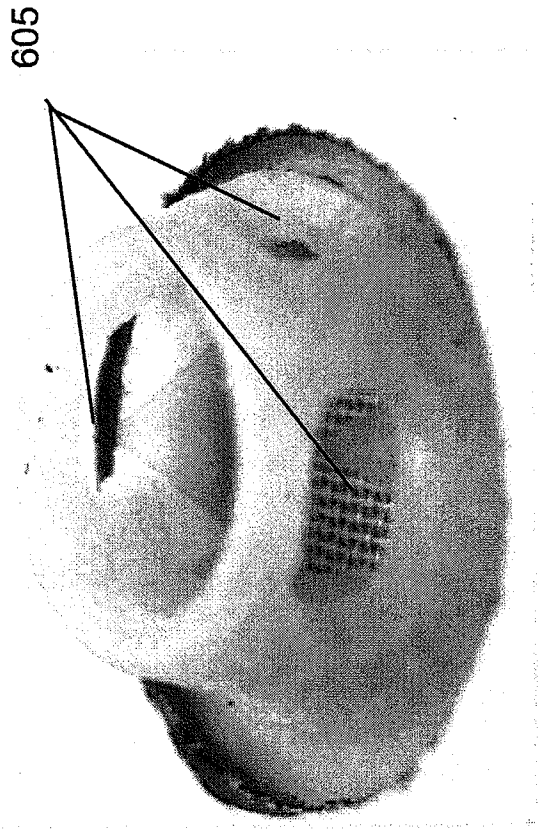

FIG. 6A

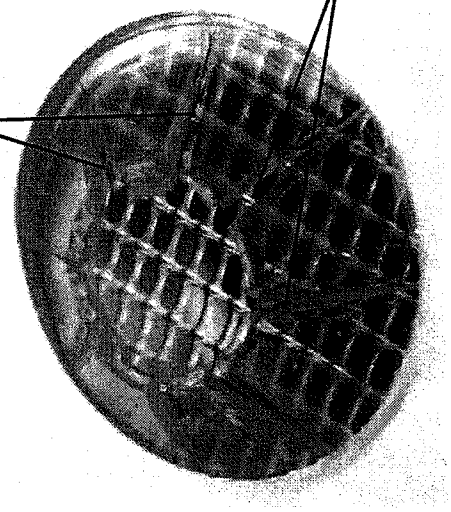

FIG. 6C

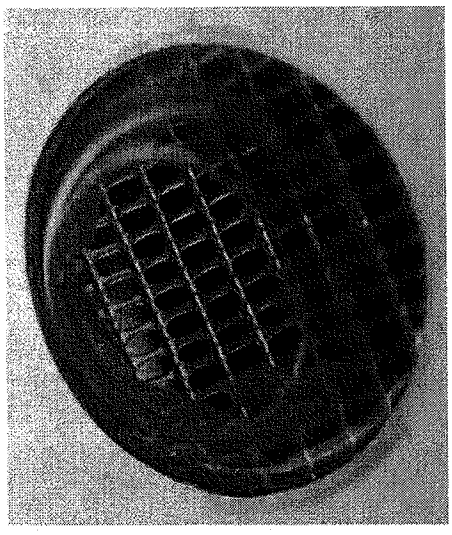

FIG. 6B

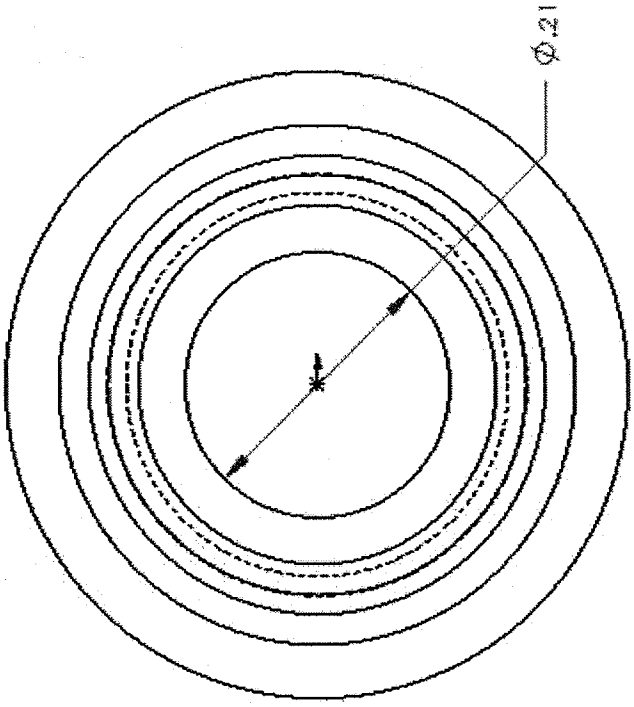

FIG. 7B

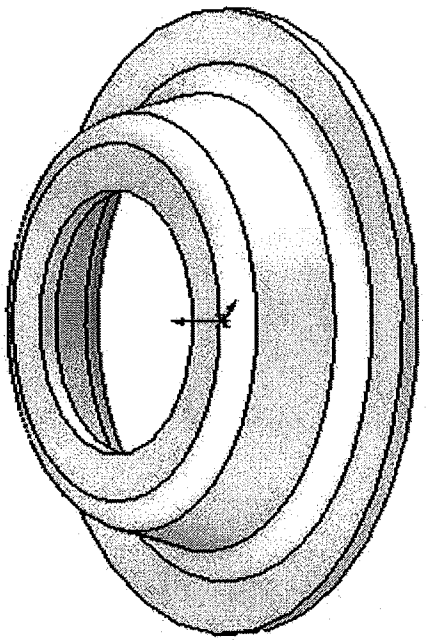

FIG. 7A

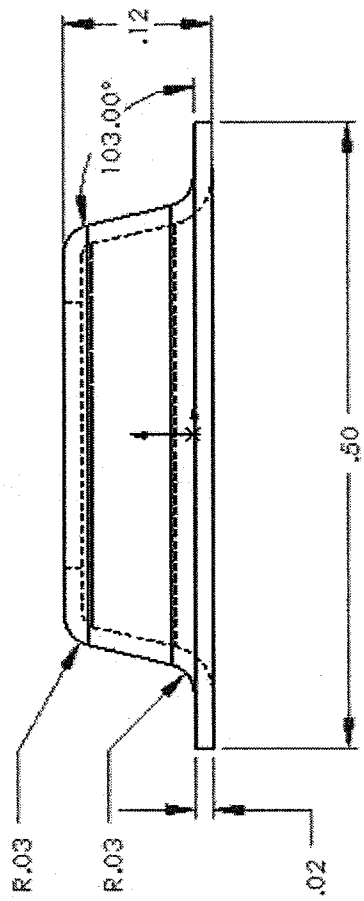

FIG. 7C

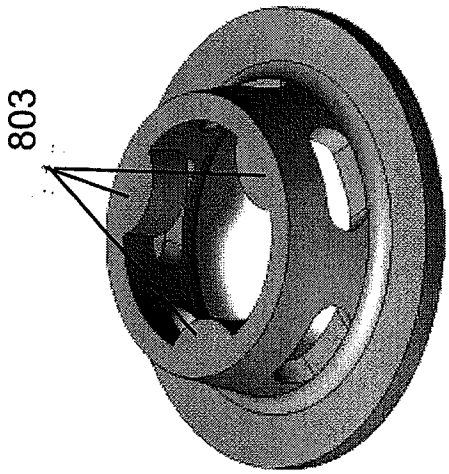

FIG. 8A

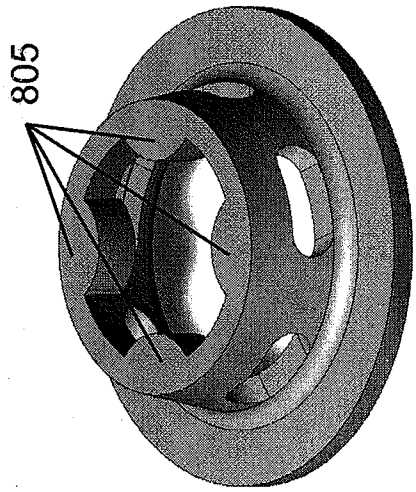

FIG. 8B

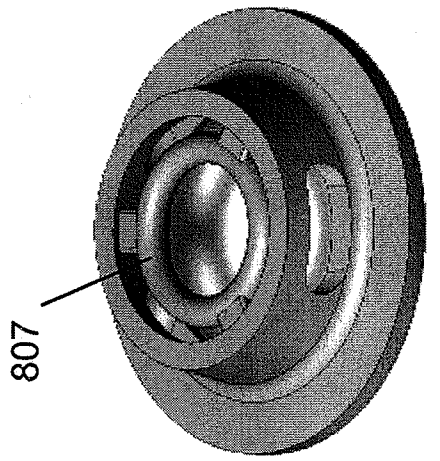

FIG. 8C

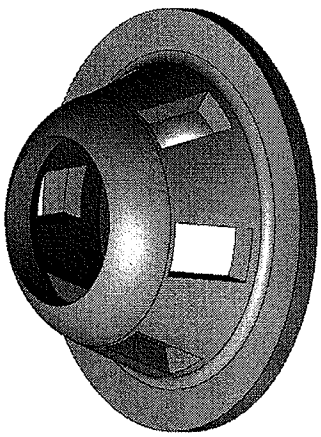

FIG. 8D

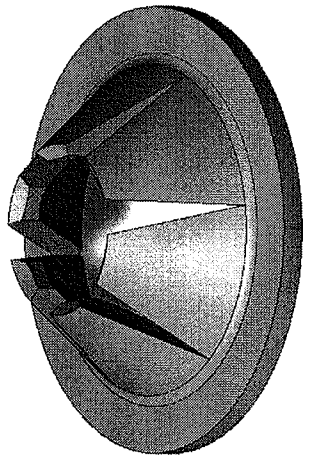

FIG. 8E

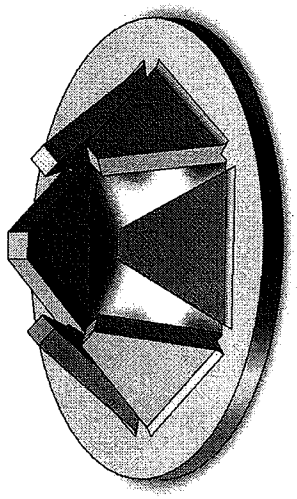

FIG. 8F

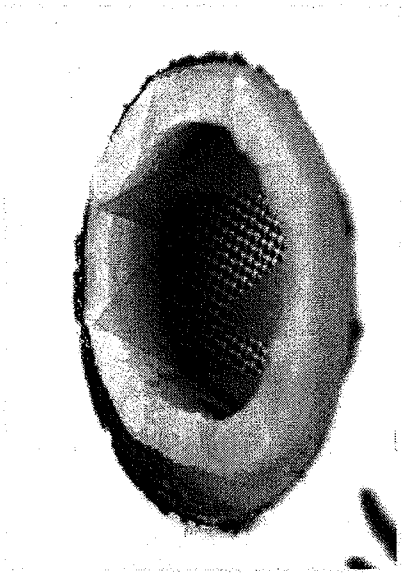

FIG. 9B

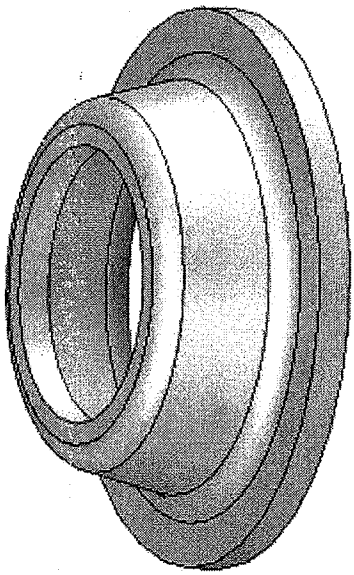

FIG. 9A

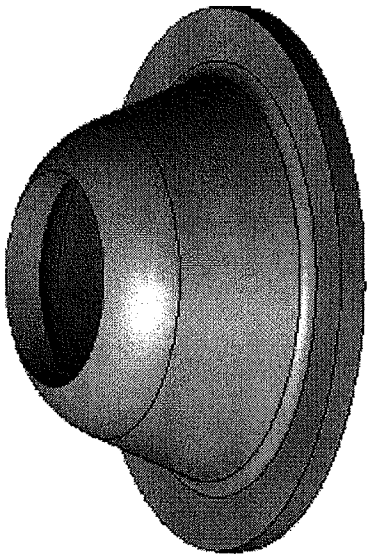

FIG. 10

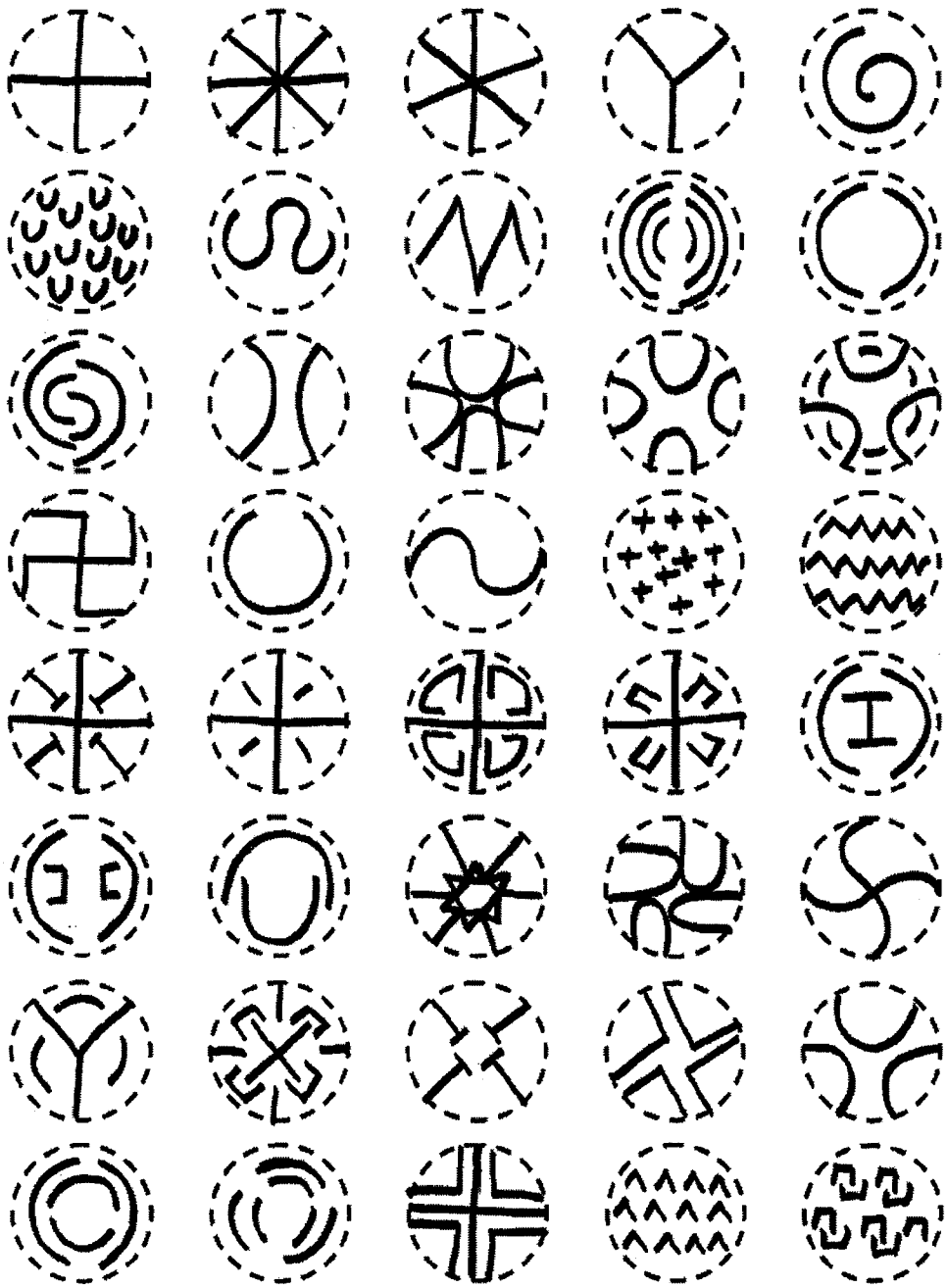

FIG. 11

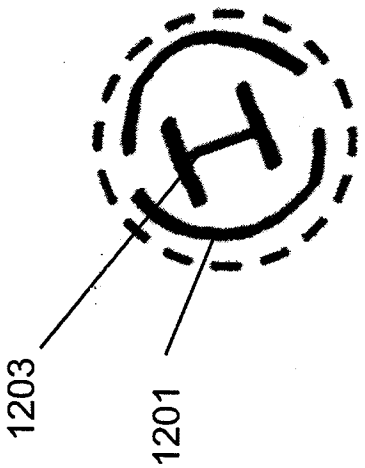

FIG. 12A

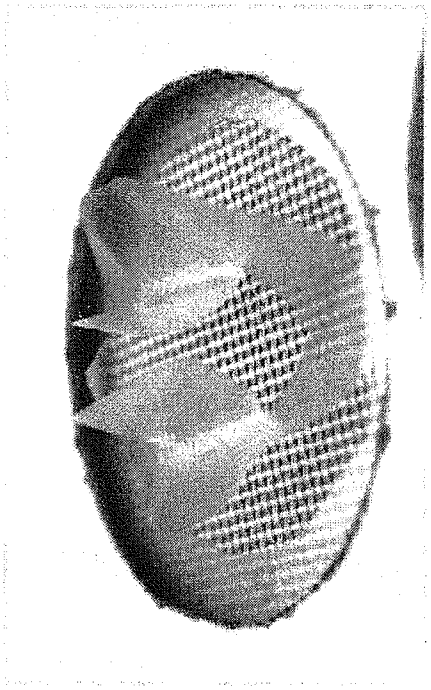

FIG. 12B

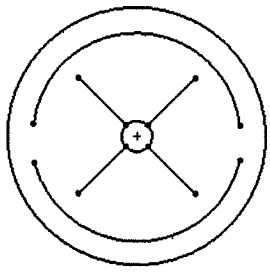

FIG. 13A

FIG. 13B

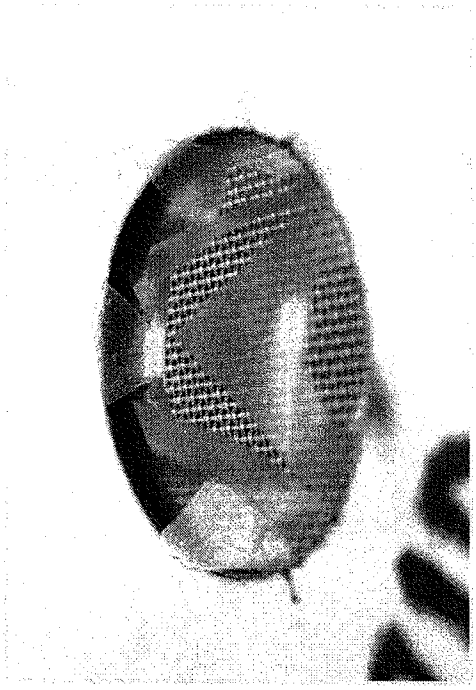

FIG. 14B

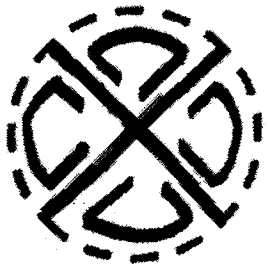

FIG. 14A

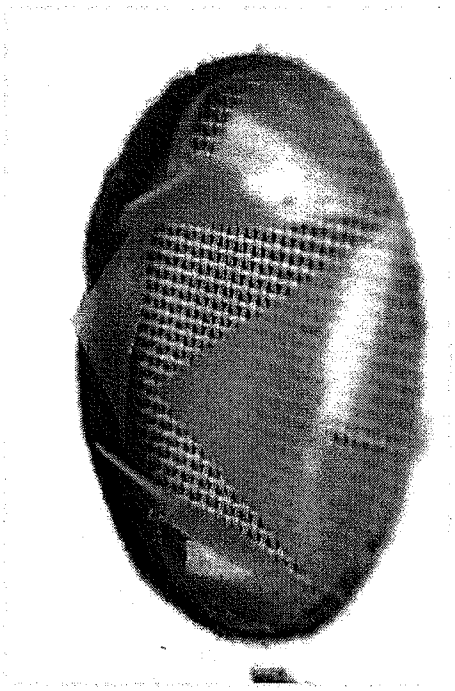

FIG. 15B

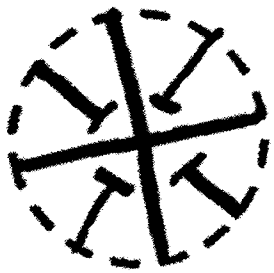

FIG. 15A

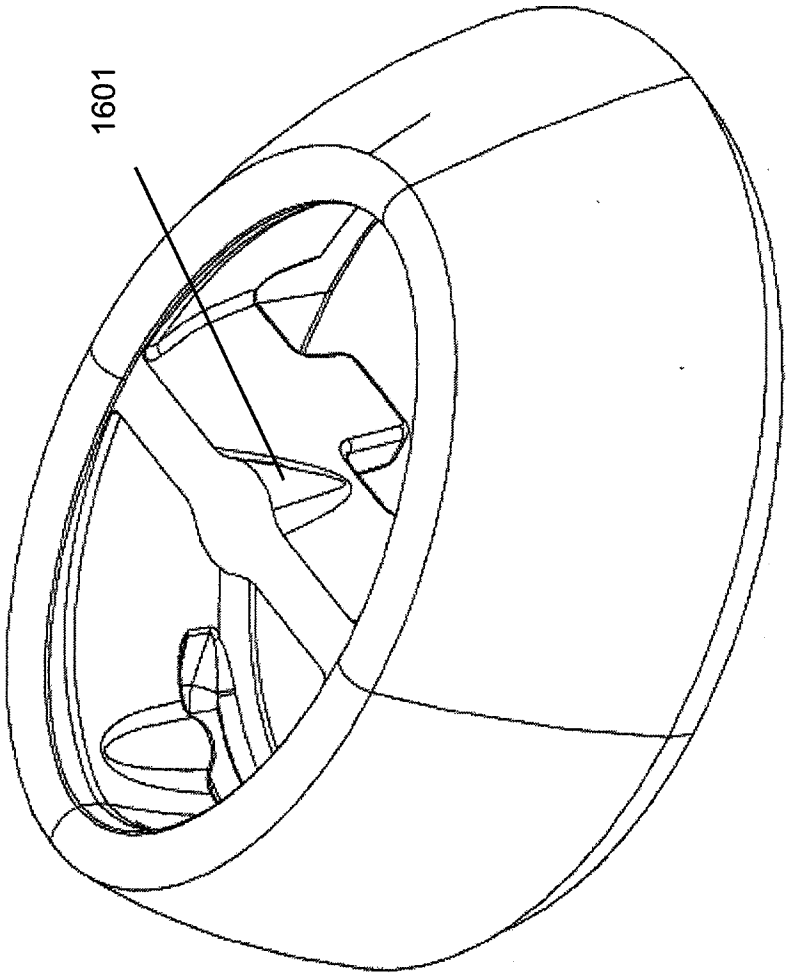

FIG. 16 A

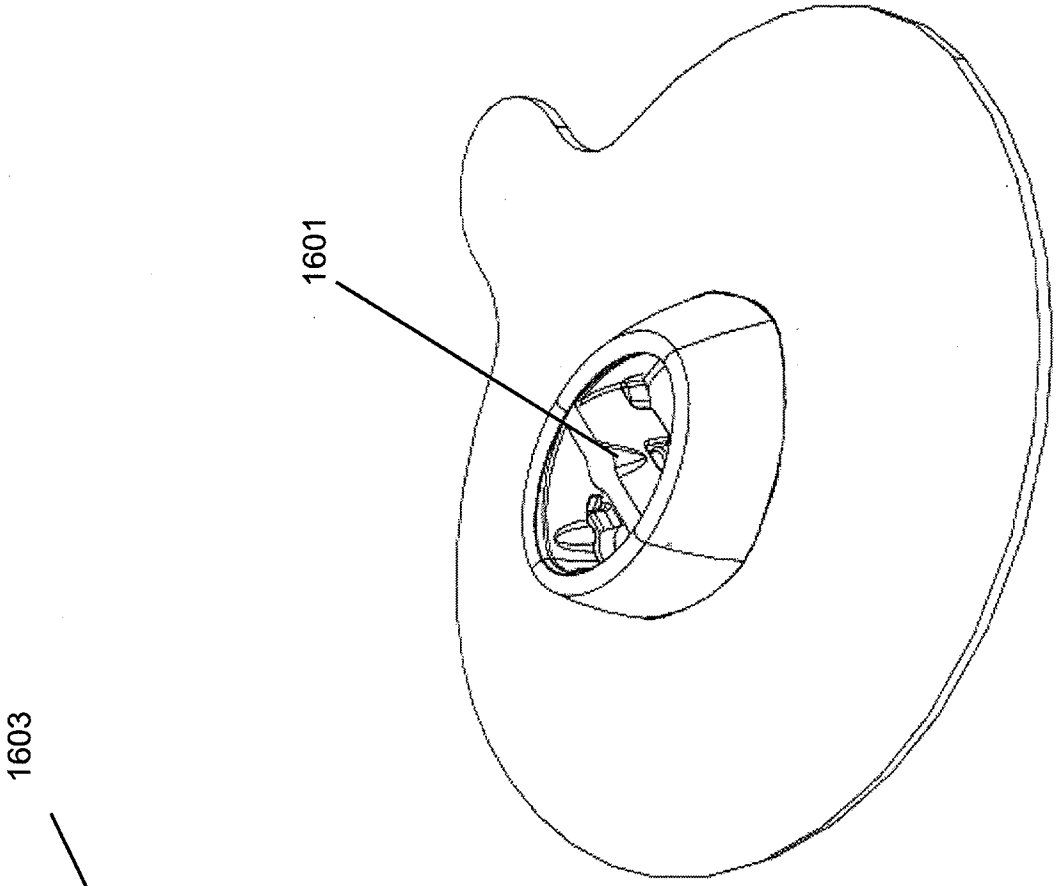

FIG. 16C

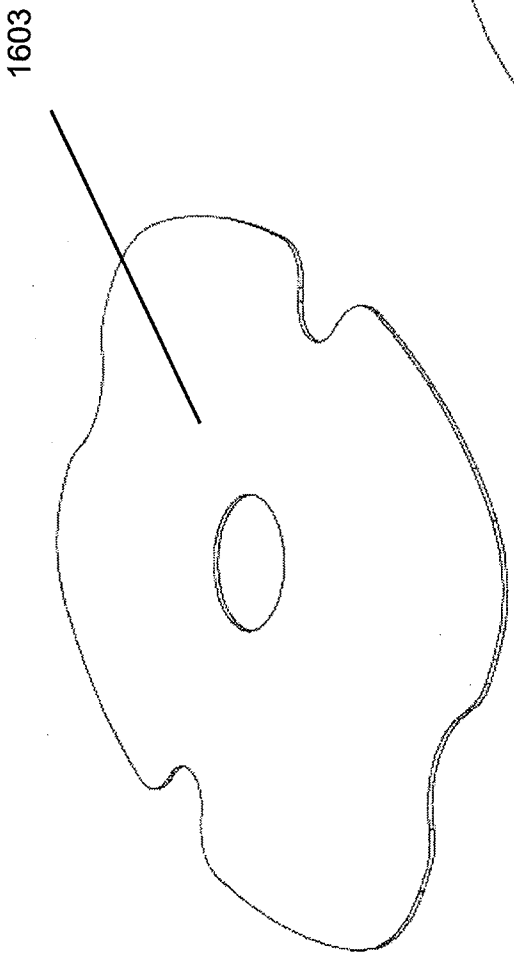

FIG. 16B

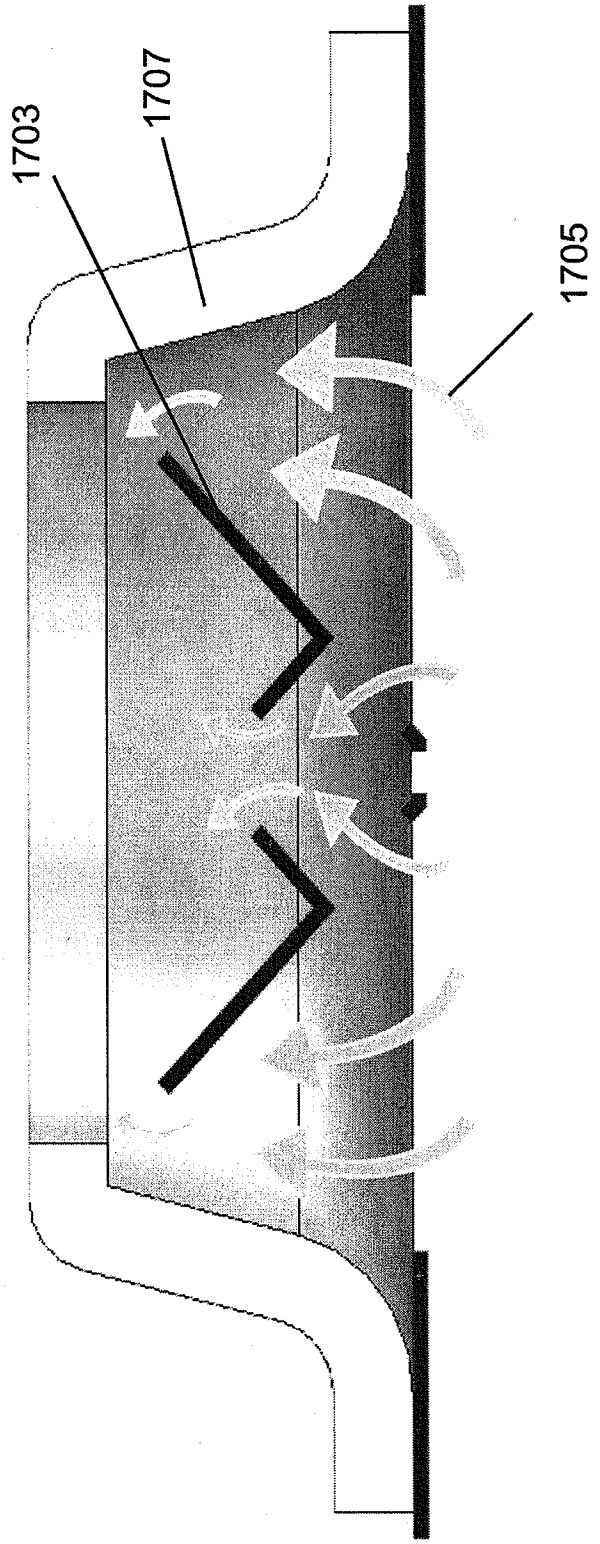

FIG. 17

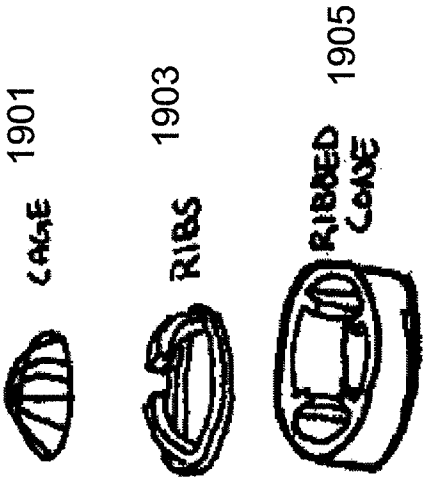

FIG. 19A FIG. 19B FIG. 19C

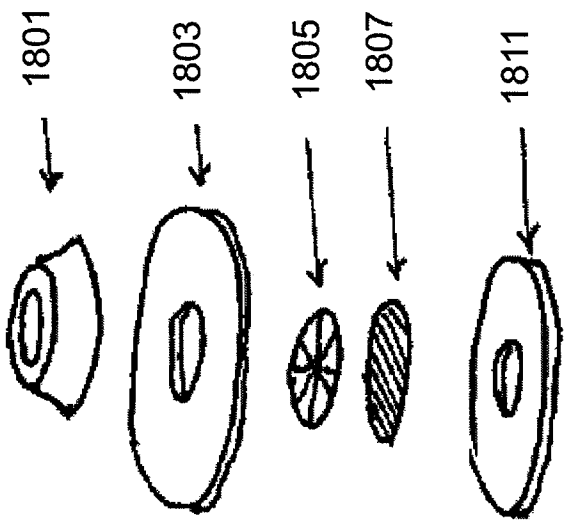

FIG. 18

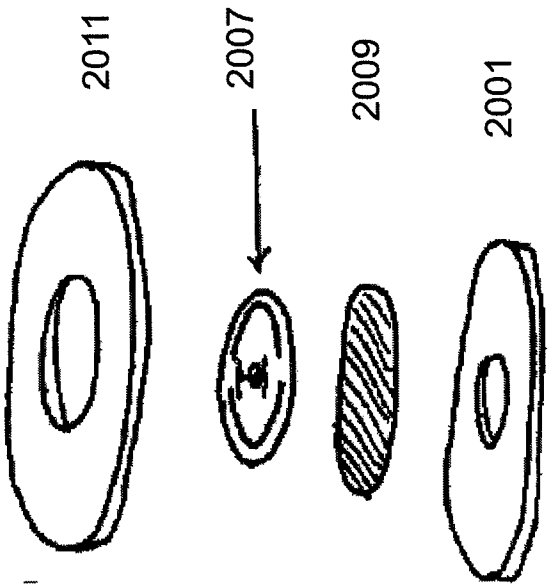

FIG. 20

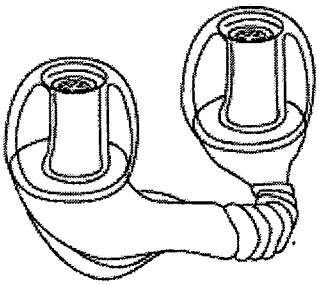

FIG. 21A

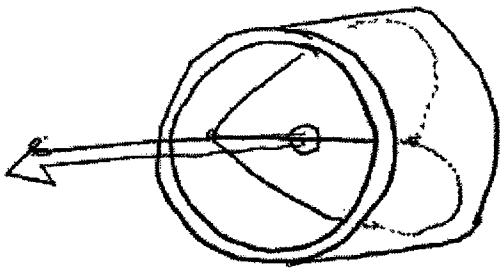

FIG. 21B

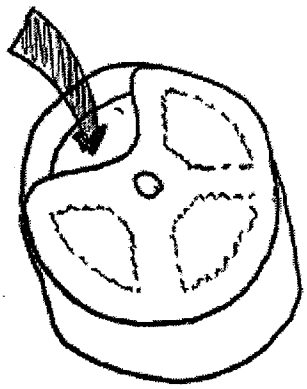

FIG. 21C

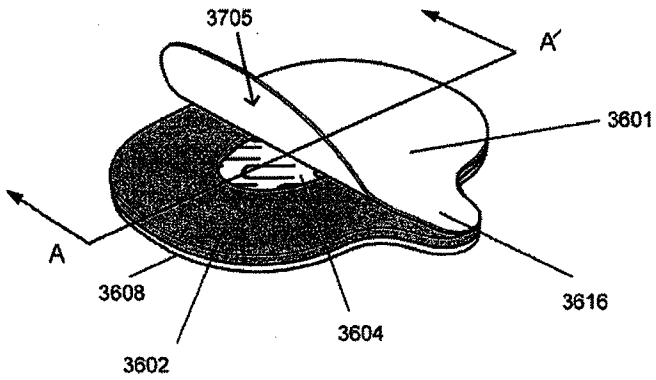

FIG. 21D

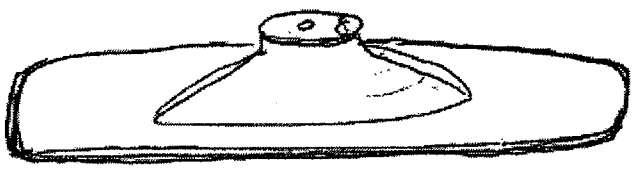

FIG. 21E

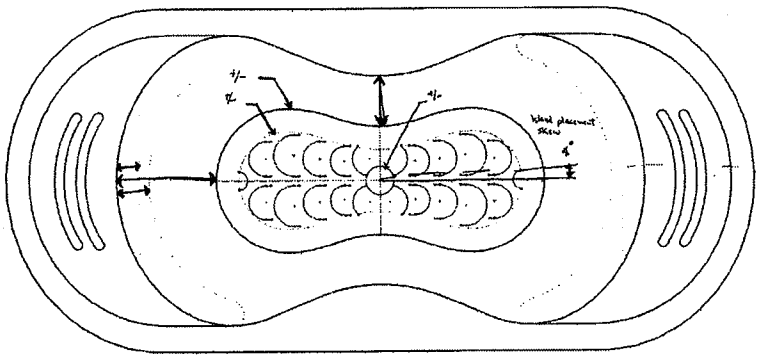

FIG. 21F

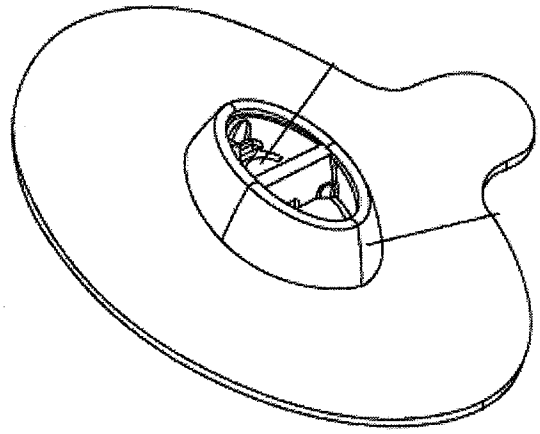

FIG. 21G

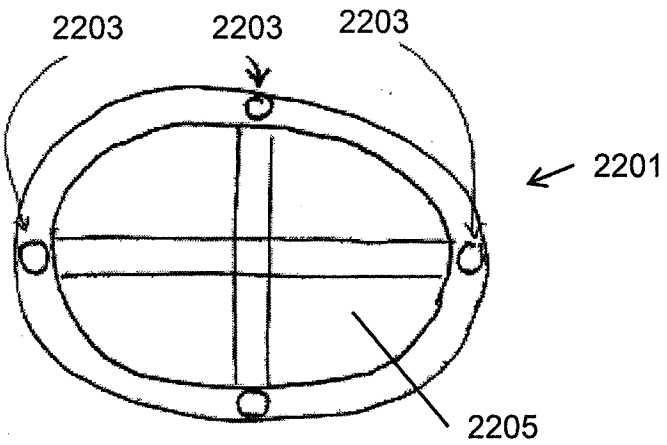

FIG. 22A

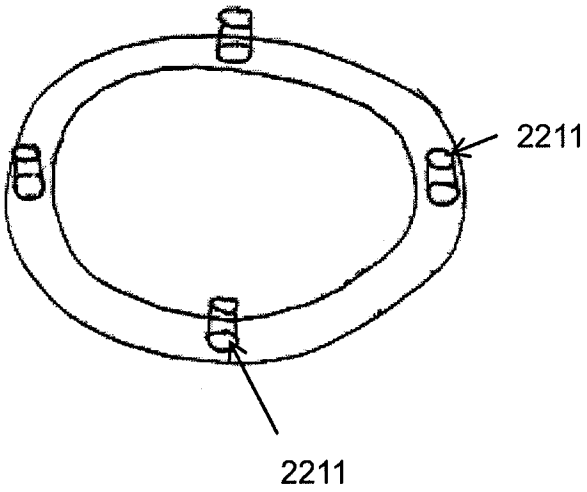

FIG. 22B

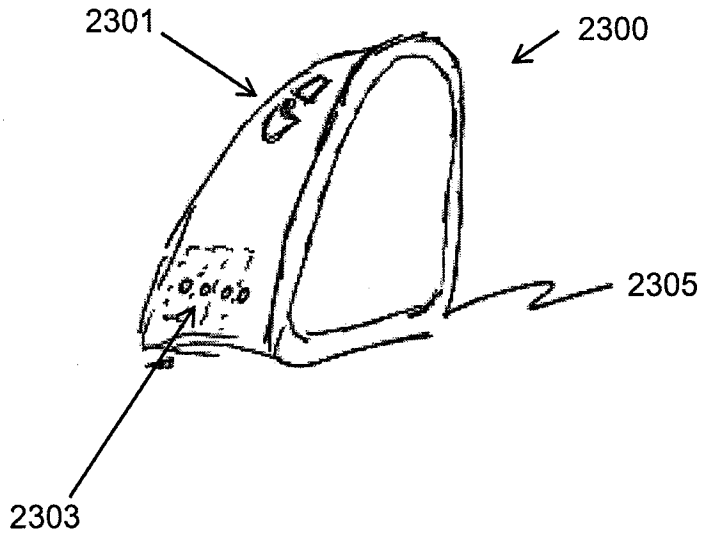

FIG. 23

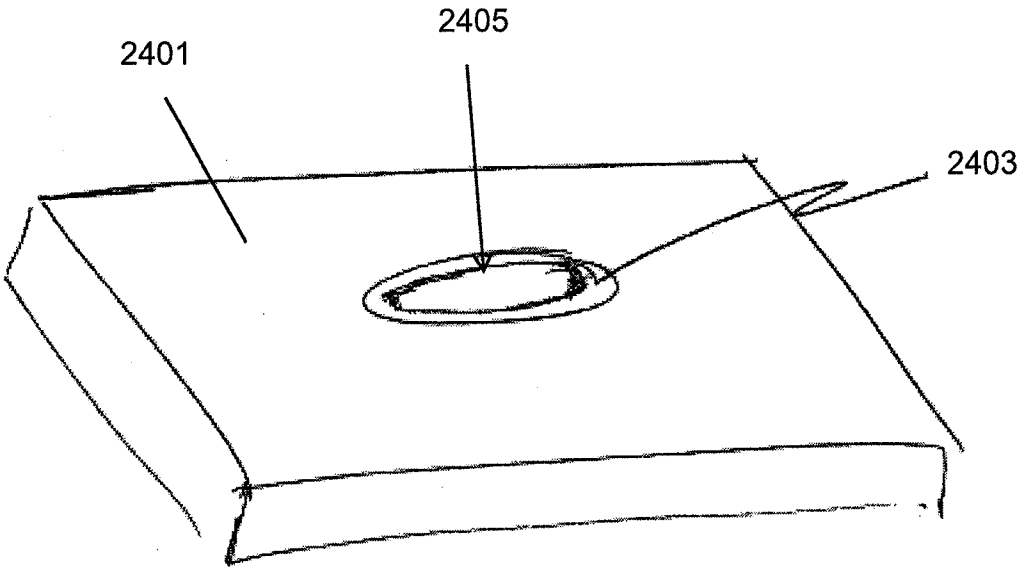

FIG. 24

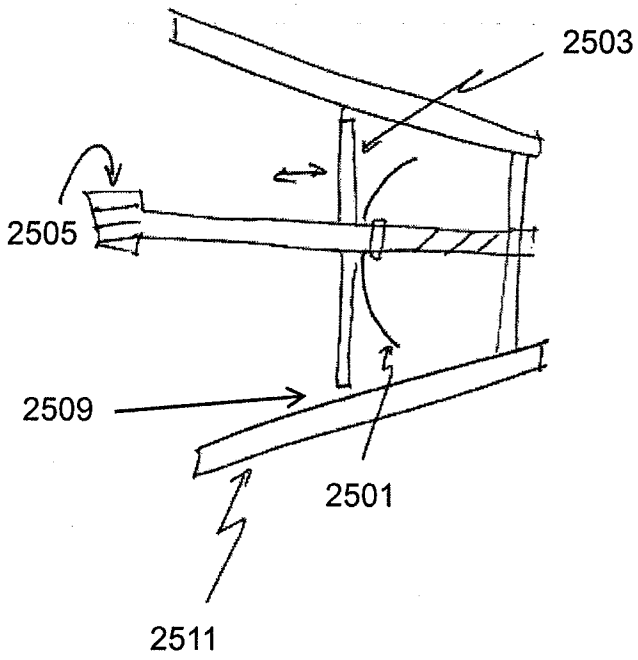

FIG. 25

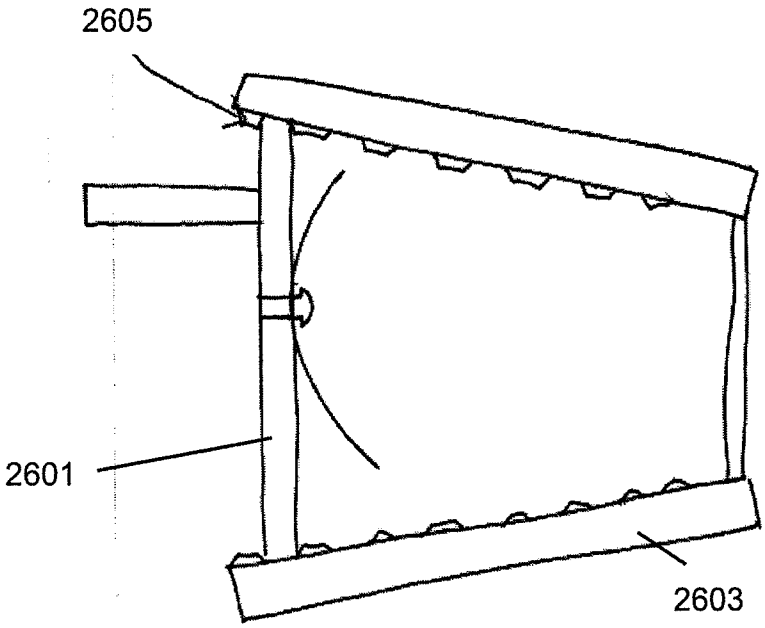

FIG. 26A

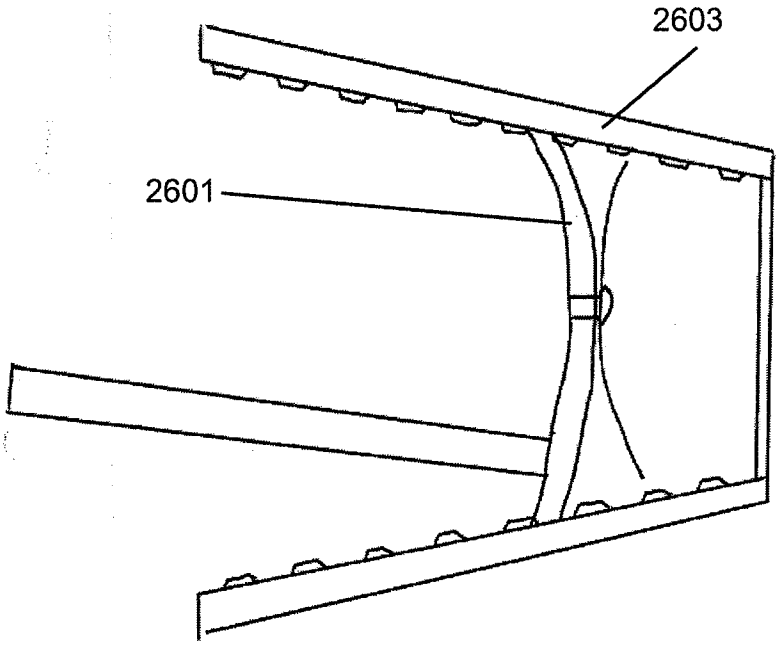

FIG. 26B

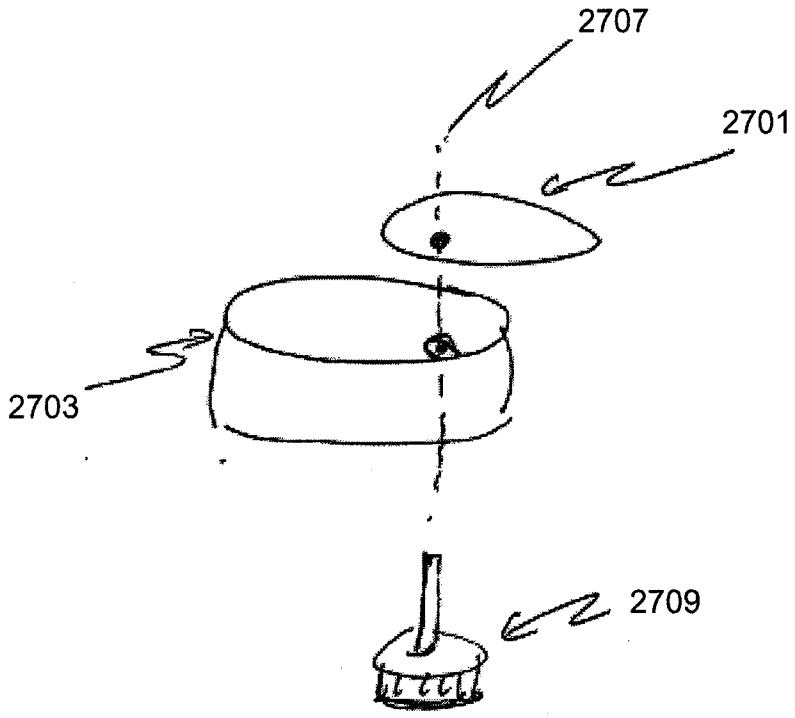

FIG. 27

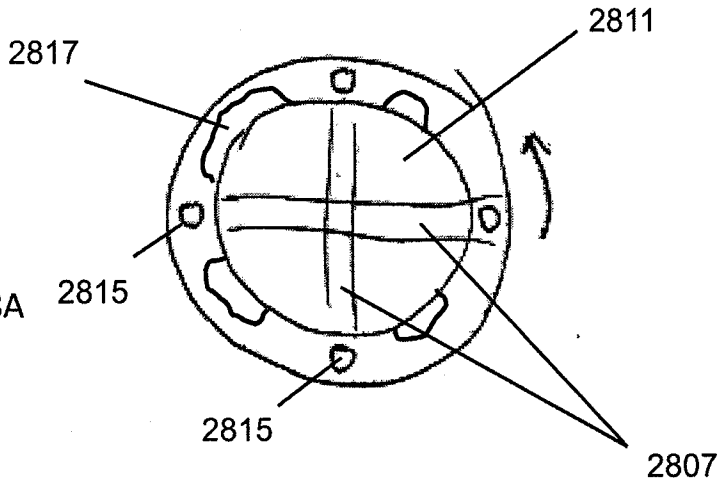

FIG. 28A

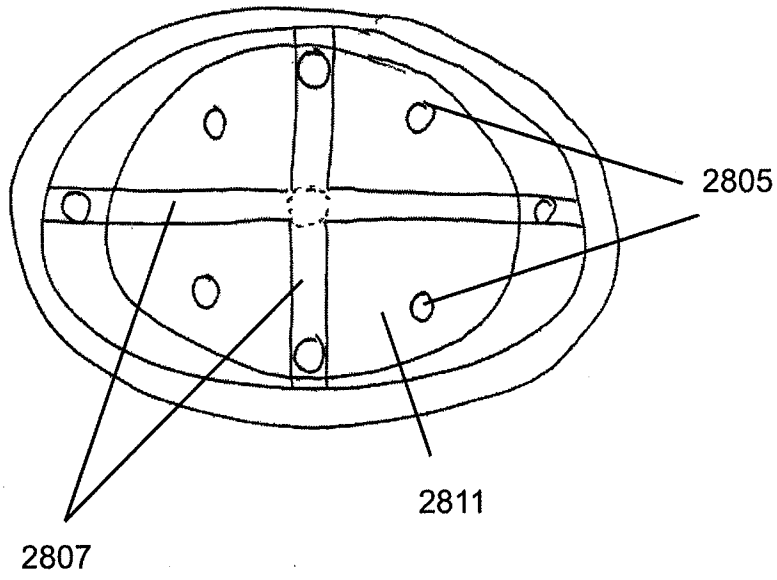

FIG. 28B

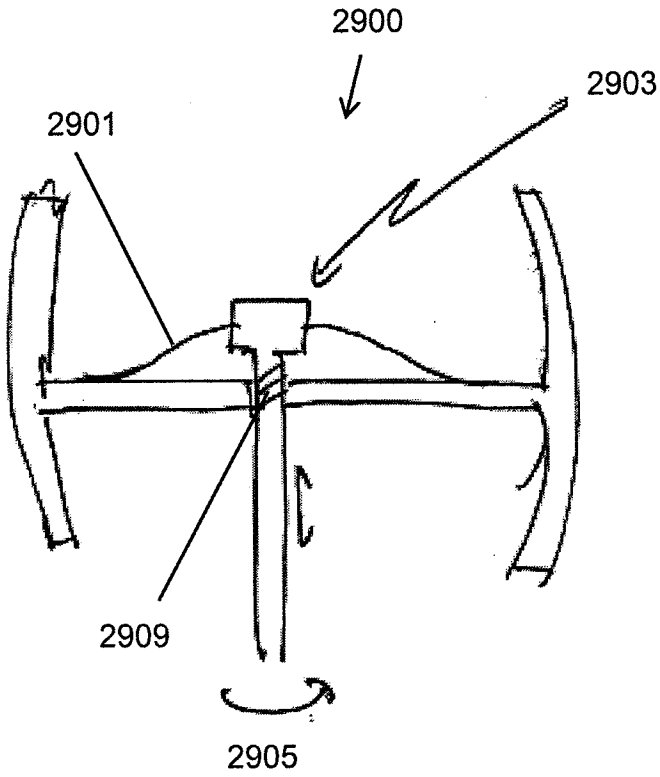

FIG. 29

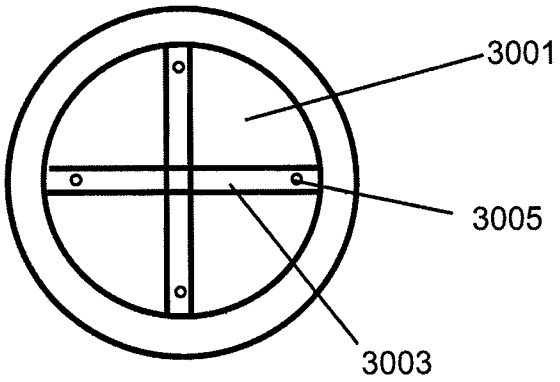

FIG. 30A

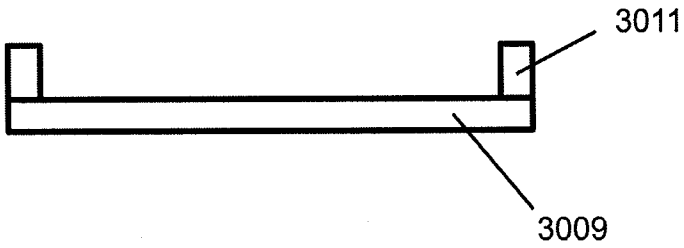

FIG. 30B

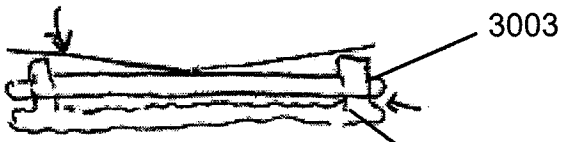

FIG. 30C

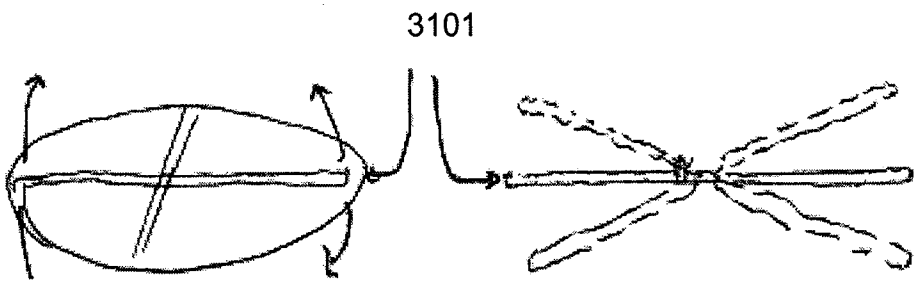

FIG. 31A

FIG. 31B

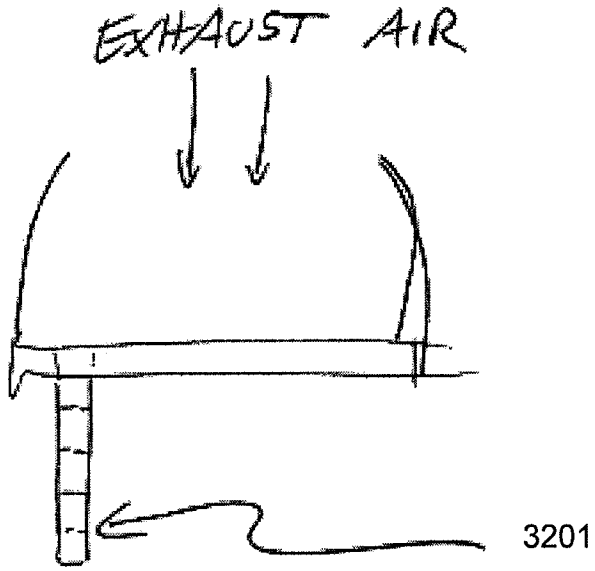

FIG. 32

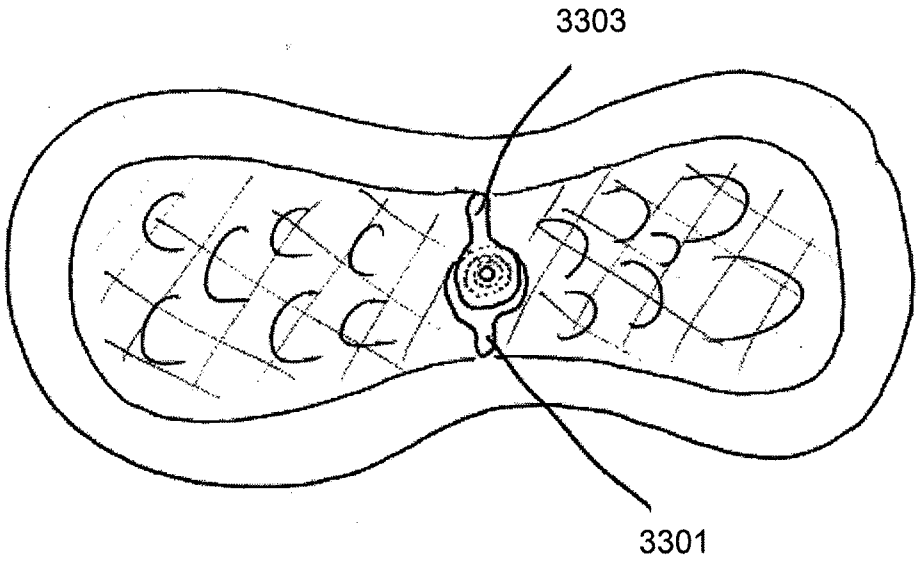

FIG. 33