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(54) Title: NASAL DEVICES APPLICATORS

(57) Abstract: Described herein are applicator systems and applicators for nasal devices, and methods of applying nasal devices. In general, an applicator system includes a nasal device and one or more of: an inserter from which the nasal device is released, a handle that is releasably connected to the nasal device, or an applicator liner that can be removed after positioning the device relative to the nasal cavity.
NASAL DEVICES APPLICATORS

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of US Provisional Patent Application 60/859,715 (titled "Nasal Devices"), filed 11/16/2006. This provisional patent application is herein incorporated by reference in its entirety.

BACKGROUND OF THE INVENTION

[0002] The devices, methods, and kits described herein relate generally to applicators for nasal devices. These nasal devices may be therapeutically used to treat medical disorders, particularly in the fields of cardiovascular medicine, sleep medicine, pulmonology, gastroenterology, and internal medicine.


[0004] These patent applications describe nasal respiratory devices, including devices configured to be applied in, over, or across a subject’s nose to treat a variety of medical diseases or conditions. Examples of medical conditions that may be treated include but are not limited to snoring, sleep apnea (obstructive, central and mixed), Cheyne Stokes breathing, UARS, COPD, hypertension, asthma, GERD, heart failure, and other respiratory and sleep conditions. Nasal devices of particular interest are those that inhibit expiration more than inspiration. These devices may be placed in communication with a subject's nasal passage(s) without effecting respiration through the subject's mouth. One variation of these nasal devices are nasal respiratory devices configured to induce positive end-expiratory pressure ("PEEP") or expiratory positive
airway pressure ("EPAP"), that are adapted to be removably secured in communication with a nasal cavity.

[0005] Exemplary nasal devices are described herein, and may include one or more airflow resistors that inhibit expiration more than inhalation. These devices may include a passageway with an opening at a proximal end, and an opening at a distal end, where the airflow resistor is in communication with the passageway. The devices typically also include a holdfast that is configured to removably secure the respiratory device within (or over, or around) the nasal passage or cavity.

[0006] The previously described nasal devices may be applied manually by the subject (self-application), or they may be applied by a medical professional. Self-application of the devices typically requires using a mirror as a guide, and practice may be necessary to readily orient the device properly. Proper application may be critical to securing the nasal device in communication with the subject's nasal passageway and ensuring proper function. Thus, it is desirable to provide devices and/or methods that allow simple and accurate application of nasal devices. Described herein are applicators, systems including applicators for nasal devices, and methods of applying nasal devices that may address these issues.

SUMMARY OF THE INVENTION

[0007] Systems, devices and methods for applying nasal devices are provided. A system for applying nasal devices generally includes a nasal device and an applicator. In particular, the applicator may be an inserter from which the nasal device is released, a handle that is connected (e.g., releasably connected) to the nasal device, or an applicator liner that can be removed after positioning the device relative to the nasal cavity. The system for applying nasal devices may be used to apply the nasal device around or over a nasal passage (or nasal passages), within a nasal passage or nasal passages, or some combination of around, over and/or within a subject's nasal passage or nasal passages, depending on the configuration of the nasal device and applicator.

[0008] For example, a system for applying a nasal device in communication with a subject's nasal passage may include a nasal device and an applicator configured as an inserter for inserting a nasal device at least partially within the subject's nasal passage, where the inserter includes a handle having a grip region configured to be grasped, and a
nasal device engagement portion having at least one surface configured to engage a nasal device thereagainst, wherein the engagement portion comprises a cavity configured to hold the nasal device. Any appropriate nasal device may be used, particularly a nasal device including a passageway, an airflow resistor in communication with the passageway (wherein the airflow resistor is configured to inhibit expiration through the passageway more than inspiration through the passageway, and a holdfast region at least partially surrounding the passageway.

The inserter may also include an ejector configured to eject the nasal device from the nasal device engagement. In addition, the inserter may include a trigger that is operably connected to an ejector for triggering ejection of the nasal device. The trigger may be any control, including a button, plunger, knob, switch, etc.

Also described herein are systems for applying a nasal device in communication with a subject’s nasal passage that include a nasal device and a handle that is releasably connected to the first body of the nasal device, wherein the handle comprises a grip surface for holding the nasal device. A handle that is releasably connected to a nasal device may be frangibly (e.g., breakably) connected, screwed on, friction fit, snap fit, or the like. Any appropriate nasal device may be included as part of the system, such as a nasal device having a passageway through a first body, wherein the passageway is configured to fluidly connect with a subject’s nasal passage, an airflow resistor in communication with the passageway, and a holdfast configured to removably secure the nasal device in communication with the subject’s nasal passage.

The handle may be an elongate member that projects from the device. For example, the handle may project from the device by about half an inch or more (e.g., one inch, two inches, etc.), allowing the handle to be readily grasped. The handle may be stiff. In some variations the handle includes an engagement surface for engaging at least a portion of the nasal device. For example, the handle may include an engagement surface that engages at least a portion of the passageway of the nasal device, and/or the holdfast region of the nasal device.

Also described herein are systems for applying a nasal device in communication with a subject’s nasal passage that include a nasal device and an applicator liner, wherein the applicator liner comprises a grip region configured to be grasped by the subject, a flexible adhesive backing region releasably secured to the nasal device, and a folded bend region connecting the grip region and the adhesive backing.
region. The applicator liner may be removed from the nasal device to at least partially engage the holdfast. The nasal device typically includes a passageway through a first body, wherein the passageway is configured to fluidly connect with a subject's nasal passage, an airflow resistor in communication with the passageway, and a holdfast configured to removably secure the nasal device in communication with the subject's nasal passage.

[0013] In some variations, the applicator liner further comprises an aligner configured to align the passageway of the nasal device with the subject's nasal passage. For example, the applicator liner may include a pop-up aligner that can be transitioned from a first configuration (e.g., a 'flat' or substantially 'flat' collapsed configuration) into a second configuration that can be inserted into the nose to align the nasal device (e.g., an expanded configuration). The aligner may be a foam aligner.

[0014] The system may also include a second applicator liner that has a grip region configured to be grasped by the subject. The second aligner may also include an adhesive backing region releasably secured to the nasal device, and a bend region connecting the grip region and the adhesive backing region. The grip regions of these applicator liners (e.g., the first and second applicator liners) may extend in opposite directions from the passageway of the nasal device. In some variations, the grip regions of the applicator liners extend in the same direction from the passageway of the nasal device.

[0015] The applicator aligner may be any appropriate material or materials, such as paper, fabric, polymer, or the like. In general, the grip region, bend region and adhesive backing region of the applicator aligner may be formed from a flat or planar material (e.g., a layer, strip, membrane, etc.). In some variations the three regions are made of the same material. In some variations, at least some of the regions are made of different materials. For example, all three regions may be formed of paper. The adhesive backing region may be coated with an adhesive, or an adhesive release material. For example, the adhesive backing region may include a wax coating.

[0016] Also described herein are systems for applying a nasal device in communication with a subject's nasal passage that include a nasal device having an airflow resistor configured to be placed in communication with the subject's nasal passageway and inhibit expiration more than inspiration, and an applicator liner having a grip region configured to be grasped by the subject, an adhesive backing region
releasably secured to the nasal device, a folded bend region connecting the grip region and the adhesive backing region; and an aligner attached to the applicator liner, wherein the aligner is convertible between a collapsed position and an extended position, and wherein the extended position is configured to align the passageway of the nasal device with the subject's nasal passage.

[0017] This applicator system may also include a second (or more) applicator liner that also includes a grip region, an adhesive backing region and a folded bend region, as mentioned above. The aligner may be positioned between two or more applicator liners, or attached to only one applicator liner.

[0018] In some variations, the aligner is a perforated aligner, a foam aligner, or a folded aligner. For example, an aligner may be a pop-up aligner as previously mentioned. In general, the aligner is configured so that is can be removed when the applicator liner is removed. Thus, the aligner is connected to an applicator liner (typically on the grip region, though it may be part of any region of the applicator liner), and may be pulled from the nose while the nasal device is held closely adjacent to the nose. For example, the aligner may be compressible or collapsible so that it can slide between the aligner and the nose to remove it after the aligner system is positioned against the subject.

[0019] Also described herein are methods of applying a nasal device in communication with a nasal passage. For example, the method may include the steps of: placing a nasal device applicator system adjacent to the nose (wherein the nasal device applicator system comprises a nasal device having an airflow resistor and an applicator liner having a grip region, a flexible adhesive backing region releasably secured to the nasal device, and a folded bend region connecting the grip region and the adhesive backing region); and removing the adhesive backing region from the nasal device to expose an adhesive holdfast by pulling the grip region. The step of removing the adhesive backing region from the nasal device may include the step of sliding the grip region over the adhesive backing region as the grip region is pulled.

[0020] The method may also include the step of placing an aligner attached to the applicator liner at least partially in the nose. In some variations, the aligner is part of the applicator liner (or is connected to the applicator liner). In other variations, the aligner is part of the nasal device.
Additionally or optionally, the method may also include the step of removing a second adhesive backing region from the nasal device by pulling a second grip region.

INCORPORATION BY REFERENCE
All publications and patent applications mentioned in this specification are herein incorporated by reference in their entirety to the same extent as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference.

BRIEF DESCRIPTION OF THE DRAWINGS
FIGS. 1A and 1B show front and exploded views, respectively, of an exemplary nasal device.
FIG. 2A is another exemplary nasal device.
FIGS. 2B-2D illustrate the manual application of the nasal device of FIG. 2A.
FIG. 3A is an applicator system for applying a nasal device including an inserter.
FIGS. 3B-3E illustrate application of a nasal device using the applicator system of FIG. 3A.
FIG. 4A is an applicator system for a nasal device.
FIGS. 4B-4D illustrates application of a nasal device using the applicator system of FIG. 4A.
FIG. 5A is an applicator system for a nasal device including a handle configured to engage the nasal device.
FIGS. 5B-5D illustrate application of a nasal device using the applicator system of FIG. 5A.
FIG. 6A is another applicator system for a nasal device including handle.
FIGS. 6B-6D illustrate application of a nasal device using the applicator system of FIG. 6A.
FIG. 7A is another applicator system for a nasal device including a handle configured to engage the nasal device.
FIGS. 7B-7E illustrate application of a nasal device using the applicator system of FIG. 7A.

FIG. 8A is a side perspective view of an applicator having a handle for applying a nasal device. FIG. 8B is a side perspective view of the applicator of FIG. 8A as part of an applicator system including a nasal device.

FIGS. 8C-8E illustrate application of a nasal device using the applicator system of FIG. 8B.

FIGS. 9A and 9B are side and top views of one variation of an applicator system for applying a nasal device including an applicator liner.

FIG. 9C is a top perspective view of a system for applying nasal devices similar to the system of FIGS. 9A and 9B.

FIGS. 10A and 10B are side and top views of one variation of an applicator system for applying a nasal device including an applicator liner.

FIG. 10C is a top perspective view of a system for applying nasal devices similar to the system of FIGS. 10A and 10B.

FIGS. 11A and 11B are side and top views of one variation of an applicator system for applying a nasal device including an applicator liner.

FIG. 11C is a top perspective view of a system for applying nasal devices similar to the system of FIGS. 11A and 11B.

FIGS. 12A and 12B are side and top views of one variation of an applicator system for applying a nasal device including an applicator liner.

FIG. 12C is a top perspective view of a system for applying nasal devices similar to the system of FIGS. 12A and 12B.

FIG. 13 is an exploded view of one variation of an applicator system including an applicator liner.

FIG. 14A is an applicator system including an applicator liner.

FIG. 14B-14F illustrates application of a nasal device using the applicator system of FIG. 14A.

FIG. 15A is an applicator system including an applicator liner.

FIG. 15B-15F illustrates application of a nasal device using the applicator system of FIG. 15A.

FIG. 16A is an applicator system including an applicator liner and a removable aligner.
FIGS. 16B-16C illustrate retraction and extension of the aligner from the applicator system of FIG. 16A.

FIGS. 16D-16E illustrate application of a nasal device using the applicator system of FIG. 16A.

FIGS. 17A-17D illustrate operation of another variation of an applicator system including an applicator liner and a removable aligner.

FIGS. 18A-18D show variations of applicator systems including applicator liners and removable aligners.

FIGS. 19A-19C illustrate operation of another variation of an applicator system including an applicator liner and a removable aligner.

FIGS. 20A-20C illustrate operation of another variation of an applicator system including an applicator liner and a removable aligner.

FIGS. 21A-21C illustrate operation of another variation of an applicator system including an applicator liner and a removable aligner.

FIG. 22A is a top perspective view of an applicator system including an applicator liner.

FIGS. 22B-22F are top perspective views of applicator systems including applicator liners and removable aligners.

FIG. 23A and 23B are perspective views of another variation of an applicator system including an applicator liner having a removable aligner.

**DETAILED DESCRIPTION OF THE INVENTION**

Described herein are applicator systems and applicators for nasal devices, and methods of applying nasal devices. In general, an applicator system includes a nasal device and one or more of: an inserter from which the nasal device is released, a handle that isfraigibly connected to the nasal device, or an applicator liner that can be removed after positioning the device against the subject. These variations are described in sections II through IV, respectively.

The nasal devices described herein typically refer to nasal devices having an airflow resistor that is configured to inhibit expiration through the nose more than it inhibits inspiration through the nose. Examples of nasal devices that may be used with the applicators described herein are provided in section I, below. However, the applicator systems and methods for applying nasal devices described herein may be used
with virtually any nasal device that is configured to be worn in, on, or over a subject's nostril(s) (nasal passage(s)) without covering the subject's mouth.

[0064] The nasal devices referred to herein may be equivalently called nasal respiratory devices, respiratory devices, or simply "devices." A nasal device may be configured to fit in, over and/or around a single nostril (e.g., a "single-nostril nasal device"), or in, over and/or around both nostrils ("whole-nose nasal device"). Both single-nostril nasal devices and whole-nose nasal devices may be referred to herein as "nasal devices," and (unless the context indicates otherwise), any of the features described for single-nostril nasal devices may be used with whole-nose nasal devices, and vice-versa.

[0065] The systems, devices and methods for applying nasal devices described herein are not limited to the particular embodiments described. Variations of the particular embodiments described may be made and still fall within the scope of the disclosure. As used in this specification, the singular forms "a," "an," and "the" include plural reference unless the context clearly dictates otherwise.

I. Nasal Devices

[0066] Any appropriate nasal device may be used with the applicators and systems described herein, particularly adhesive nasal devices, including those described in more detail in FIGS. IA and IB, below.

[0067] A typical nasal device as referred to herein includes: one or more passageways through which air may pass to enter or exit a respiratory orifice, an airflow resistor in communication with the passageway, and a holdfast (e.g., an adhesive holdfast or a compressible holdfast). The holdfast secures devices to the subject so that the passageway(s) of the device is in communication with a subject's nasal passage, and may include a contact surface (e.g., an adhesive surface) or pressure-exerting surface (e.g., a foam or elastomeric surface), or both. Nasal devices having flap valve airflow resistors may be particularly useful.

[0068] In general, a nasal device may be secured in communication with a subject's nose, and specifically with one or both of the subject's nasal cavities. As mentioned, 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 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.

For example, a nasal device may be worn by a subject to modify the airflow thorough one or (more typically) both nostrils. One or more nasal devices may be secured over, across, and/or within both of the subject's nostrils so that airflow through the nostrils passes primarily or exclusively through the nasal device(s). A nasal device, particularly an adhesive nasal device, 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.

A nasal device may be composed of layers, and may therefore be referred to as a layered nasal device. In one example, a layered nasal device includes 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 is 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 a biocompatible adhesive.

A layered nasal device may be composed of separate layers, and these layers may be separated by other layers, or they may be adjacent. For example, an adhesive holdfast layer may be itself 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.

In some variations, a nasal device (including an adhesive nasal device) has a body 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.

In some variations, the adhesive nasal device may further include 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.

An adhesive nasal device may also include a tab or handle as part of the holdfast or body (e.g., rim body region) of the nasal device. In some variations, this tab or handle is formed of a region of the layered adhesive holdfast. This tab or handle is different than the applicator liners and applicators described in greater detail below, and cannot be used to precisely position the nasal device relative to the nose after aligning the nasal device with the nose, as described for many of the applicator systems herein.

The various components of the nasal devices described herein may be made of any appropriate materials, as described in greater detail below. For example, some device components (e.g., a body region of a nasal device, portions of the airflow resistor, etc.) 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 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.

FIGS. IA and IB show one example of a nasal device configured as a layered nasal device. FIG. IA is a top view of a layered nasal device that includes a holdfast layer 101 and an airflow resistor 103. The reverse side of the device shown in FIG. IA includes an adhesive material (not shown) that may be covered by a protective covering. In some variations, this protective covering is (or is connected to) an applicator liner that may be removed once the device has been positioned, as described
below. In general, 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. The adhesive holdfast layer may include an adhesive substrate that may be, for example, 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 101 may have different regions, including a peri-nasal regions surrounding an opening (though which air may flow), and a tab 105 or grip region forming a tab that may make the device easier to grasp and remove. Other regions may include regions of more aggressive and less aggressive adhesive (e.g., more or less adhesive material), regions of hydrogel material (including adhesive hydrogels) to help prevent irritation from repeated or extended use, etc.

[0077] FIG. 1B shows an exploded view of the device of FIG. 1A. This exploded perspective view illustrates the layers of the device, including the adhesive holdfast 101 (which may itself be layered), two layers of airflow resistor, including the flap valve 107 and flap valve limiter 109, and an adhesive ring 111 that may help attach the flap valve and flap valve limiter to the adhesive holdfast.

[0078] 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 polyvinyl chloride copolymers), a homopolymer and copolymers of acrylates (such as polypropylene, polymethylmethacrylate, polyethylenmethacrylate, 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.).

[0079] In variations in which an adhesive is used (e.g., as part of the holdfast and/or as part of the applicator liner), 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.

II. Inserters

[0080] In some nasal device variations, the nasal device is inserted completely or partially in one or both of the subject's nostrils. For example, FIGS. 2A-2D illustrates manual insertion of one variation of a nasal device into a subject's nose. The outer surface of this nasal device 201 is substantially surrounded by a holdfast region. The holdfast is made of a memory material (e.g., a foam) that maybe compressed, and thereafter expand back toward its original shape. To insert the device, the subject (or a physician or other assistant) may compress the holdfast region by rolling it between the fingers to decrease the diameter of the device. The compressed holdfast region allows the device to more easily fit into the subject's nostril, so that it can be inserted as shown. Once inserted into the nostril, the device (e.g., the holdfast region) expands back outwards until it contacts the walls of the nostril, so that it is held snugly in position. An airflow resistor (e.g., a flap valve) resides in a passageway through the body of the device (not visible).

[0081] Nasal device insertion may be simplified or improved by the use of an applicator. For example, an inserter may be used, as illustrated in FIGS. 3A-3E. The applicator shown in FIG. 3A is configured as an inserter 301. In general, an inserter includes a nasal device engagement portion that releasably engages with the nasal device. For example, a nasal device engagement portion may be a cavity, opening or channel into which the nasal device fits, so that it can be placed at least partially in the subject's nose. In general, and inserter may include an ejector that pushes or otherwise ejects the nasal device from the inserter and into the subject's nose. The ejector may include an ejector control (e.g., a switch, button, knob, etc.) for triggering ejection.
For example, in FIG. 3A, the inserter 301 includes a channel 305 into which at least one nasal device 201 fits. The nasal device 201 may be ejected from the distal end of the inserter and into a subject's nose, as illustrated in FIG. 3D. An inserter may include a tubular body having a passage or cavity into which one or more nasal device may be held (e.g., and compressed before insertion), as shown in FIG. 3B. In some variations the inserter comes pre-loaded with the nasal device. Thus, the distal end of the inserter may be open. In the example shown in FIG. 3A, the proximal end includes a plunger 310 (the ejector control) that may be pushed to eject the nasal device from the inserter. The plunger shown is slideably disposed within the inserter 301 so that it (piston-like) can push a nasal device out of the cavity or passage holding the nasal device. The opening into the inserter (e.g. the passageway the opens distally) may be smaller in diameter than the relaxed diameter of the nasal device. Thus, the nasal device may be compressed to fit within the inserter, and the nasal device can expand to fit a nostril into which it has been inserted.

The inserter variation 301 shown in FIG. 3A also includes a grip (configured as two finger grips 309, 309') which allows the device to be more easily held so that the plunger at the distal end can be pushed to eject the nasal device into the subject's nose. In some variations the device may also include a bias for returning the plunger (or pusher) distally, allowing another nasal device to be loaded into to the inserter. In some variations, more than one nasal device can be loaded (or pre-loaded) and ejected from the device (allowing the separate release of more than one nasal device from the inserter). An inserter may be part of a system or kit. For example, an inserter may be provided pre-loaded with one or more nasal devices, or it may be manually loaded by a subject, as shown in FIG. 3B.

FIGS. 4A-4D shows another variation of an inserter 402 with a nasal device. In FIG. 4A the inserter is pre-loaded with a device 401. The proximal end of the inserter is configured as a grip (handle 403) that can be held by the subject. The handle 403 in FIG. 4A is a tapered grip, however any appropriately shaped handle (fluted, looped, etc.) may be used.

As mentioned, inserters for inserting a nasal device (either a whole-nose or single-nostril nasal device) generally include one or more engagement regions for releasably securing the nasal device. An engagement region typically has one or more surfaces that engage a nasal device. Thus, a nasal device may be friction fit to an

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inserter. For example, an inserter may include an engagement region configured as a cavity or channel (as shown in FIG. 3A) into which a nasal device is placed until it is ejected for insertion into a subject's nose. In some variations, the inserter includes an engagement configured as a post; the walls of the post may engage with an opening or passage on the nasal device.

Although the inserters illustrated above are single-nostril nasal device inserters, an inserter may be configured as a whole-nose nasal device inserter that may inserts a whole-nose nasal device into, over, or around both of a subject's nostrils. For example, an inserter may have multiple channels or chambers for parallel delivery of two single-nostril nasal devices into both nostrils.

FIG. 4A also illustrates a protective cap or cover 405 that covers at least a portion of the nasal device. In particular, the cap 405 may cover at least a portion of the device that is to be inserted into the subject's nose (e.g., the distal end of the nasal device). In general, the cap may cover any appropriate portion of the nasal device (e.g., the entire device, including the holdfast region, or just a portion of the device). In some variations, the cap prevents contamination of the device prior to use.

The cap 405 shown in FIG. 4A is initially attached to (or formed from) the distal end of the inserter 402. Thus, the cap is removed to reveal the end of the nasal device 401 (this end of the nasal device will be inserted into the subject's nostril). In some variations, the cap 405 is removably secured onto the device, rather than onto (or as part of) an inserter, as shown in FIG. 4A. In FIG. 4A, a pull-tab 407 is used to removably secure the cap 405 over the distal end of the device 401. Before inserting the device into the nostril, a subject first removes the cap by pulling the pull-tab 407, as shown. In some variations, the cap may help keep the device sterile or otherwise fresh.

III. Handles

In some variations, the applicator system includes an applicator configured to include a handle that is releasably (e.g., frictionally) connected to the nasal device so that it can be removed after applying the device. Handle variations may be particularly useful with devices that are at least partially inserted into a subject's nostril(s).

For example, FIGS. 5A-5D illustrates one variation of an applicator system including a nasal device and an inserter configured as a removable handle. In
FIG. 5A, the nasal device 503 is adapted to be held on the distal end of inserter 500. In the example shown, the nasal device has an opening (e.g., opening into the passageway of the device) into which a post on the inserter 500 fits. The inserter includes a grip region 501 that can readily be grasped by the subject's fingers, allowing the subject to manipulate the nasal device and position it within the nostril. Once the device is in position, the inserter can be removed, leaving the device in position. In some variation, the nasal device is first compressed (e.g., as shown in FIG. 2B), so that it fits and then expands into position in the subject's nostril. In some variations, the inserter is frangibly connected to the device, so that it can be broken off of the device after being positioned within the subject's nostril.

[0091] A nasal device may include a handle or positioner that can be used to help insert or position the device. FIGS. 6A-6D illustrate a device 601 having a handle frangibly attached at the proximal end. In FIG. 6A the handle is an elongate projection 603 that is frangibly attached to the proximal end of the device. This handle can be disconnected (e.g., by breaking it off) once the device is inserted, for example, by twisting and pulling it, as shown in FIG. 6C. In some variations, the handle is a stiff member. The handle may be formed so that it is easy to grasp. For example, the handle may be curved, flattened, textured, or otherwise shaped to enhance grasping. In some variations, the handle is made of the same material as a portion of the nasal device (e.g., the same material as the walls of the passageway, etc.).

[0092] An applicator configured as a handle may also be used with a layered nasal device, as illustrated in FIG. 7A-E. In this example, the applicator is configured as a handle 701 that includes a seat 707 onto which the nasal device (the layered nasal device 703) may sit and/or attach. The distal end of the applicator is configured as an aligner 711 that can insert into the subject's nostril. The aligner passes through the passageway of the nasal device, as shown in FIGS. 7B and 7C. In this variation, the aligner region 711 is substantially flat, so that it may pass through the central passageway of the nasal device. The nasal device includes a flap valve and flap valve support 722. The aligner 711 passes through the flap valve and flap valve support 722 without substantially disrupting them, as shown most clearly in FIG. 7C.

[0093] A nasal device 703 may be releasably held on the handle by any appropriate releasable fashion. For example, the nasal device may be held onto the applicator by a weak adhesive. In some variations, the nasal device is held onto the seat
707 region by an adhesive that secures to the outer face of the nasal device (e.g., the back side of the holdfast). In some variations, the nasal device is held to the seat 707 region by a mechanical retainer such as a clasp or other fastener. The connection between the seat region of the applicator and the nasal device may be relatively weak, particularly in comparison to the adhesive connection between the nasal device and the subject's nose.

In some variations, the nasal device is releasably held onto the handle by the connection between the passageway and the distal end of the handle. In FIG. 7A-7E, the nasal device is at least partly held onto the applicator by friction between the aligner 711 at the distal end of the applicator and the central passageway (including the airflow resistor) in the nasal device. Thus, the nasal device is friction fit onto the applicator when the aligner is pushed through the device.

The seat region 707 of the applicator handle 701 in FIGS. 7A-7E also includes two leafs or wings 715, 715' that may be retracted (pulling the adhesive holdfast away from the distal end of the nasal device) or extended (to push the a nasal device seated thereon against the nose during application). This is shown in FIG. 7D. Before applying the nasal device against the nose, the seat region of the applicator may be at least partially retracted 707 by pulling down on the arms connected to the seat region 715, 715', casing the seat region to partially collapse, and folding the nasal device (adhesive holdfast region) away from the distal end of the applicator 711. Retracting moving at least part of the adhesive portion of the nasal device away from the distal end of the applicator forming the aligner 711 may make it easier to apply the device without interfering with the adhesive holdfast until the subject is ready to position the nasal device in or over the nose and secure the adhesive holdfast.

In operation, the nasal device applicator system shown in FIG.7A-7E may be used to apply one or more nasal devices to a subject's nose. For example, this nasal device applicator may be re-used. For example, a nasal device may be first mounted on an applicator having a handle, as shown in FIG. 7A. In this example, the holdfast of the nasal device 703 is releasably attached to the seat 707, e.g., by a weak adhesive. The adhesive holdfast region may include a protective liner 709 that can be removed by peeling it off, as indicated in FIGS. 7B. In FIG. 7C the liner has been removed, exposing the adhesive holdfast 713.

Once the adhesive layer is exposed, the aligner may be at least partially inserted into the nostril, as shown in FIG. 7D. The handle allows the nasal device to be
oriented as necessary before it is secured to the nose. In the applicator variation illustrated in FIGS. 7A-7E, four hinged arms form the wings of the seat region 715 and also slideably connect to the handle, so that pushing distally on the hinged arms causes the seat region to expand distally, helping to secure the device against the subject's nose. The adhesive holdfast helps secure it against the nose. Finally, as shown in FIG. 7E, the applicator may be removed by pulling the handle away from the nose. The releasable connection between the nasal device and the applicator releases, leaving the nasal device attached to the subject's nose. The user may then help further seal the device manually if necessary.

FIGS. 8A-8E illustrate another variation of an applicator that may be used with an adhesive (e.g., layered) nasal device. FIG. 8A shows a perspective view of the applicator 801 without a nasal device attached. In FIG 8A, the applicator includes a handle region 803 that can be grasped. The handle is folded to present a nasal device seating surface having two parts 805, 805', corresponding to the two leafs or wings in the variation shown in FIGS 7A-7E. An elongate central shaft 807 passes through the handle region 803, and ends distally in an aligner region 809. FIG. 8B shows the inserter of FIG. 8A with a nasal device attached. The nasal device is a layered nasal device that is flexible. The aligner is again inserted through the passageway and airflow resistor (e.g., flap valve and flap valve limiter), and the nasal device is also releasably secured to the seat region 805, 805' of the handle of the inserter. The handle of the inserter may then be flattened (bending the nasal device), as shown in FIG. 8B, leaving the aligner 809 projecting distally. The handle region 803 slides over the central shaft 807. Thus, a system including the applicator and the nasal device may be packaged together flat, similar to the system shown in FIG. 8B.

In some variations, the applicator can be expanded to flatten the nasal device (and spread the seating surface 805, 805') by sliding the handle region up against the central shaft, as illustrated from FIGS. 8C to 8D.

In operation, a nasal device applicator system including a nasal device and an applicator 801, such as the device shown in FIG. 8A, may be used to apply a nasal device by first grasping the handle region 803, as shown in FIG. 8B, then positioning the nasal device with respect to the nose, as shown in FIG. 8C. Positioning may be aided by inserting the aligner region 809 of the inserter into the nose. Once the device is aligned, the seating surfaces of the device may be expanded by pushing up on
the handle region, as shown in FIG. 8D. Finally, the applicator may be withdrawn, releasing the nasal device, as shown in FIG. 8E.

IV. Applicator Liners

[00101] A nasal device applicator may also be configured as an applicator liner. An applicator liner may be used in conjunction with an adhesive nasal device as part of a system for applying a nasal device. This system typically includes a nasal device having an adhesive layer or surface for securing the device to the subject's nose, and the applicator liner may protect the adhesive layer. Thus, the applicator liner may be connected to the adhesive layer of the nasal device, or it may be connected to another protective liner covering the adhesive layer. The applicator liner is removed to attach the nasal device in, over, or around the subject's nasal passage. An applicator liner may allow the nasal device to be positioned against the subject before removal of the protective liner, which could not be done otherwise (for example, with other protective liners covering the adhesive device, as in FIG. 7B).

[00102] An applicator liner typically includes an adhesive backing region, a grip region and a bend or hinge region. The grip region is connected to the adhesive backing region by the bend or hinge region. All three regions may be made of the same material, or they may be made of different material. The three regions typically form a continuous layer that is folded, bent or configured to be folded or bent when applied. In particular, the bend or hinge region is configured to be bent when applied to the subject, so that the adhesive backing layer is folded over the grip region through a fold in the bend region, and at least a portion of the grip region is layered over the adhesive backing region when the adhesive backing region is covering the adhesive holdfast portion of the nasal device.

[00103] In operation, a nasal device may be applied using an applicator liner by first orienting the nasal device and placing it against the nose or nostril, so that the applicator liner contacts the face, and then pulling the grip region of the applicator liner, causing removal of the adhesive backing layer, exposing the adhesive holdfast directly against the skin. Thus, the adhesive backing layer (and any protective backing layer, if present) is removed while the device is properly positioned, without requiring further positioning.
As mentioned, the protective backing region of the applicator liner may at least partially cover the adhesive layer of the adhesive holdfast. The protective backing liner may protect the adhesive surface. In this variation, the adhesive backing layer is configured to be removed from the adhesive holdfast without damaging the adhesive. For example, the adhesive backing region may be made of a material that is readily releasable from the adhesive used by the adhesive holdfast (e.g., a silicone coating, a wax coating, or other low-friction/non-stick coating). In some variations, the adhesive backing region of the applicator liner is attached to the protective liner. In this variation, the adhesive backing region is configured to securely adhere to the protective liner, so that it is removed with the adhesive backing region. The adhesive backing region is made of a flexible material.

The grip region is configured to be grasped and pulled, slid or otherwise manipulated. Thus, the grip region may extend beyond the profile of the nasal device (and beyond the adhesive backing region), so that it can be readily grasped. In some variations, the grip region is larger than the adhesive backing region. The grip region may also include holes, handles, or textured regions to facilitate gripping. In some variations the grip region comprises a stiff, or relatively inflexible material.

The bend or hinge region between the protective backing region and the grip is typically pre-bent. The bend region may have a scored surface, or may be creased. In some variations, the bend region is a hinge. The bend region may be reinforced (e.g., to prevent tearing when the grip region is pulled. As the protective backing region is removed from the nasal device by pulling the grip region, the hinge region straightens, and the bend propagates through the adhesive backing region. Thus, the adhesive backing region bends back upon itself.

In some variations the applicator liner includes an aligner configured to fit at least partially in the subject's nose and thereby align the nasal device with the subject's nostril(s). The aligner may be referred to as a removable aligner. In particular, the applicator liner may include a collapsible aligner that can be converted between an expanded configuration, in which it projects from the applicator liner and can insert into the subject's nostril, and a collapsed configuration, in which it can be removed from the nostril when the adhesive backing is removed by pulling on the grip region. A collapsible aligner may allow the nasal device to be packaged flat or substantially flat. The aligner may be attached to the applicator liner, or it may be formed from the same
layer of material as all or a part of the applicator liner. Generally, an aligner is a protrusion that projects perpendicular to planar axis of a layered nasal device and is configured to fit at least partially into a subject's nostril. The aligner may be conical, round, cylindrical, pyramidal, flat, or any other shape that may be dimensioned to fit at least partially into a subject's nostril. In some variations the aligner has a cross-section (e.g., parallel to the planar axis of the nasal device) that permits it to further orient the device with respect to the non-circular shape of the nostril opening. For example, the aligner may have an oval cross-section, a teardrop shaped cross-section or an asymmetric cross-section.

[00108] An aligner included as part of an applicator aligner is typically a removable aligner, a property which distinguishes it from aligners included as part of a nasal device (including layered nasal devices). Removable aligners may also be referred to as collapsible aligners or 'pop-up' aligners.

[00109] In some variations, the applicator system includes two or more applicator liners connected to the same nasal device. For example, one applicator liner may be attached to half of the adhesive layer of the nasal device, and a second applicator liner may be attached to the other half. When multiple applicator liners are used with the same nasal device, the applicator liners may be identical, or they may be different. For example in some variations, a first applicator liner includes an aligner, and the second applicator liner does not. In some variations, an aligner is secured between two (or more) applicator liners.

[00110] FIGS. 9A-12C illustrate different variations of applicator systems including applicator liners. For example, FIG. 9A shows a side view of an applicator system having two applicator liners 901, 901'. The first applicator liner 901 includes an adhesive backing region 903 covering (and removably secured over) the adhesive holdfast 922 of a layered nasal device 920. The applicator liner in this example may be made of a paper, polymer, fabric, etc. The surface of the adhesive backing region contacting the adhesive surface of nasal device holdfast maybe a non-stick surface (e.g., a silicone surface) that is matched to the adhesive used, so that the adhesive backing region may be unpeeled from the adhesive without compromising the adhesive. The non-stick surface typically requires only a small amount of force to separate from the adhesive backing region. The adhesive backing region 903 is connected to the grip region 907 through bend region 905. In particular, the grip region is oriented
substantially parallel to the adhesive backing region, and the two regions are connected through the bend region. The grip region and the adhesive backing region are further configured so that the pulling the grip region (e.g., away from the nasal device) causes the adhesive backing region to unpeel from the nasal device’s adhesive holdfast. The adhesive backing region unpeels by progressively bending, starting from the bend region 905, so that the adhesive backing region doubles back over itself. This configuration allows the nasal device to be held in position (aligned) against the nose before exposing the adhesive, greatly simplifying the application of the nasal device and reducing misalignment.

[00111] FIG. 9B is a bottom view of the nasal device applicator system of FIG. 9A, showing the first and second applicator liners 901, 901’ and the outside surface of the nasal device 920 (that will face away from the nostril when the device is applied). The adhesive backing region is not visible in FIG. 9B. In general, the grip region of the applicator liner 907 is larger than the adhesive backing layer, as is apparent in FIG. 9A. Thus, the grip region of the applicator liner 907 extends beyond the edges of the adhesive backing layer and the nasal device, providing better leverage and a larger area to grasp when pulling on the grip region to apply the nasal device.

[00112] FIG. 9C is a three-dimensional view of an applicator liner without a nasal device. Each applicator liner may be fabricated from a single piece of material (e.g., coated paper) and applied to a nasal device either before or during fabrication of the nasal device. The applicator liner may be formed by folding and/or cutting to shape the grip region, adhesive backing region and bend region. In FIG. 9C, the grip region of each applicator liner 901, 901’ includes a cut-out region 909 that may facilitate gripping and pulling the grip region.

[00113] FIGS. 10A-10C illustrate another variation of an applicator system including an applicator liner. In this example, the applicator system has only a single applicator liner, and also includes an aligner. In FIG. 10A, the applicator liner includes an adhesive backing region 1003 connected to the adhesive holdfast 1022 (or connected to a protective liner on the adhesive holdfast), a bend region 1005 and a grip region 1007. The grip region 1007 passes around and through the nasal device 1020 and forms an aligner 1011. In this example, the aligner passes through the nasal device (e.g., through the passageway and through or around the airflow resistor). In some variations,
the aligner is located on the upper side of the system and does not pass through the passageway.

[00114] FIG. 10B shows a partially transparent top view of the applicator system of FIG. 10A. In this case, the top view shows the side of the applicator system that will be applied against the subject's nose. The grip region 1007 extends beyond the adhesive backing region (and the airflow resistor). To apply a nasal device using a system such as the system shown in FIG. 10A-10C, the system is first applied against the subject's nose, and the extended aligner is positioned in the subject's nostrils. The grip region is then pulled to remove the aligner and the adhesive backing region, and to expose the adhesive holdfast, allowing it to attach to the subject. In some variations, the aligner may be removed first (e.g., by pulling the grip region of the applicator liner from the region closer to the aligner). FIG. 10C shows a perspective view of a similar applicator liner without an airflow resistor.

[00115] FIGS. 11A-11C illustrate another variation of an applicator system having a single applicator liner. As shown in FIG. 11A, this variation of an applicator liner includes two adhesive backing regions 1103, 1103’, two bend regions 1105, 1105, and two grip regions 1107, 1107’. The two adhesive backing regions are connected (across the bottom of the nasal device in FIG. 11A) by a connector region 1113. An aligner (not shown) may also be connected to both (or either) of the grip regions 1107, 1107’ over the region spanning the passageway of the nasal device 1120.

[00116] FIG. 11B shows a bottom view of the system of FIG. 11A (facing outward when the system is applied to a subject's face), including the outline of the nasal device 1120. FIG. 11C shows a perspective view of an applicator liner similar to the applicator liner shown in FIGS. 11A and 11B.

[00117] FIGS. 12A-12C illustrate another variation of an applicator system having two applicator liners. FIG. 12A shows a side view of the applicator system. An adhesive backing region 1203 extends across the device (and may extend over the passageway of the nasal device or it may pass around it, as indicated by the dashed lines 1204), and is connected to the grip region 1207 through bend region 1205. The grip region of the second applicator liner 1207’ is visible in FIG. 12B, which is positioned parallel to the grip region of the first applicator liner 1207. In this variation, the two applicator liners extend in the same direction from the nasal device. Thus, the nasal device may be applied without switching hands, by pulling on both grip regions using the
same (e.g., right/left) hand, in contrast to the variations shown in FIGS. 9A-9C and 11A-11C, which may require switching hands to pull the two grip regions.

[00118] FIG. 12C shows a perspective view of an applicator liner similar to that shown in FIGS. 12A-12B.

[00119] FIG. 13 is an exploded view of one variation of a system including a nasal device and an applicator liner. FIG. 13 also illustrates one method in which an applicator system may be fabricated, by combining (e.g., serially) different layers forming the nasal device and applicator liner. In FIG. 13, the nasal device is a layered nasal device having an airflow resistor that is configured as a flap valve 1303 and a flap valve limiter 1305. The nasal device maybe assembled by layering the flap valve 1303 across a passageway formed in a substrate 1302 (shown as cut out region 1301). The substrate forms the substrate for the adhesive holdfast. For example, the substrate may be a thin layer of polyurethane coated with an acrylic adhesive on at least one side (e.g., the side facing away from the flap valve 1303). The flap valve 1303 layer may be secured to the substrate by an adhesive mount (double-sided adhesive ring 1307), and the flap valve limiter 1305 may be secured over the flap valve by securing the edge region of the limiter between the adhesive mount and a second adhesive mount (single-sided adhesive ring 1309). The adhesive mounts may also be formed of polyurethane coated with an acrylic adhesive. Two applicator liners 1313, 1313' may then be secured to the adhesive side of the substrate 1302. In this example the applicator liners, including a grip region 1315, bend region 1317 and adhesive backing region 1319, are formed from a single folded layer of material (e.g., coated paper). Other arrangements, including other nasal devices or other applicator liners, may be substituted, and additional components (e.g., aligners on either or both the nasal device and/or the applicator liner) may also be included.

[00120] Prior to assembly of the system, the component parts may be fabricated and at least partially pre-assembled. For example the applicator liner may be die-cut and folded into the appropriate configuration. Subassemblies of the nasal device may also be pre-assembled. For example, the flap valve 1303, mounts 1307, 1309 and flap valve limiter 1305 may be pre-assembled.

[00121] FIG. 14A is a bottom perspective view of another variation of an applicator system for a nasal device similar to that shown in FIG. 9B, above (showing the side of the applicator system that will face away from the subject when the system is
applied to the subject's nose. In FIG. 14A, the nasal device is a nasal device having a rim body (similar to those described in pending US patent application No. 11/81 1,339, titled "Nasal Devices", herein incorporated by reference in its entirety). Thus, the rim body of the nasal device may act as an aligner for this system. The 'bottom' of the device (visible in FIG. 14A) faces away from a subject when the nasal device is worn.

FIGS. 14B-14F illustrate application of a nasal aligner. In FIG. 14B, the nasal aligner is first placed near the subject's face, and aligned with the nasal passage. The nasal device (e.g., the bottom side of the nasal device) is held in position with one hand, while the second hand is used to pull the grip region of one of the applicator liners, as shown in FIG. 14C. The applicator liner allows the removal of the protective liner (in this case, the adhesive backing region of the applicator liner) to be removed while the device is positioned in the nose by pulling the grip region in the plane approximately parallel to the subject's face. In FIG. 14D, the applicator liner has been removed from half of the nasal device. The other half of the nasal device is applied by switching hands, holding the nasal device with the second hand and pulling on the grip region of the second applicator liner with the first hand, as shown in FIG. 14E. After both applicator liners have been removed, as shown in FIG. 14F, the adhesive holdfast is secured to the subject's nose, placing the nasal device in communication with the nasal passage. A second nasal device may be applied to the other nasal passage in the same manner.

FIG. 15A shows another system for applying a nasal device, and FIGS. 15B-15F illustrate application of a nasal device using this system. The applicator system shown in FIG. 15A includes two applicator liners and a removable aligner 1501 (shown as two prongs). This aligner is attached to only one of the applicator liners. The aligner is extended by folding the system up along the axis formed between the two applicator liners, as shown in FIG. 15B. After extending the aligner, the applicator system is placed near the nose, and the removable aligner is placed in the nostril, as shown in FIG. 15C. Once the device is positioned relative to the subject's nostril, one of the applicator liners can be removed with one hand, while the other hand maintains the position of the device in the nose, as shown in FIGS. 15D and 15E. Thereafter, the second applicator liner can be removed by again pulling on the grip region (in a plane parallel to the plane of the nostril opening), as shown in FIG. 15F.

The system for applying nasal devices described herein may also be applied using one hand. FIGS. 12A-12C, described above, illustrates one variation of a
system for delivering nasal devices including an applicator liner that may be applied to
the subject's nose without switching hands. Typically, systems including two or more
applicator liners in which the grip regions project from the device in a single direction
(e.g., to the right or to the left of the nasal device, as shown in FIG. 12A) may be
removed using one hand, usually while the other hand holds the nasal device in position
against the subject's nose. In contrast, systems including two or more applicator liners
that have grip regions project from the device in different directions (e.g., as shown in
FIG. 9A) may require switching hands to completely apply the nasal device.

[00125] Another variation of a system for applying a nasal device including an
applicator liner is shown in FIG. 16A. In this variation, two applicator liners are
illustrated. One of the applicator liners (referred to as an adjustable applicator liner
1605) includes an aligner region 1603 that is configured to collapse or pop-up depending
on the position of the grip region of the aligner. This is illustrated in FIGS. 16B and
16C. Pulling the applicator liner 1605 to the right (away from the midline of the nasal
device), causes the aligner to first extend, as shown in FIG. 16B, and eventually collapse,
as shown in FIG. 16C. In this variation, the system for applying the nasal device may be
packaged flat, because the aligner may be collapsed flat by either pushing the adjustable
applicator liner 1605 in, or by pulling it out. FIGS. 16D and 16E illustrate application of
the nasal device. In virtually every other way, the basic steps for applying nasal device
with this applicator system (aligning the applicator system with the nasal cavity,
positioning against the face, pulling on the applicator liner) are identical to those
described above for the applicator systems shown in FIGS. 14A-15F.

[00126] FIGS. 17A-17D illustrate another nasal device applicator system having a
removable aligner that can be packaged flat, and expanded before applying the nasal
device. As shown in FIG. 17A, the device can be flattened for packaging, including the
removable aligner. Pulling the grip region of one of the applicator liners expands the
removable aligner, as shown in FIG. 17B. In some variation, the applicator liners are
pre-biased so that they open to expand the aligner when the system is removed from
packaging. For example, a spring may be used to pre-bias them, or the elastic properties
of the applicator liner may bias the liner. In this example the removable aligner is
connected to both the applicator liners, as shown in FIG. 17C. However, pulling on one
of the applicator liners during application (simulated in FIG. 17D) will release the
aligner from one of the applicator liners, allowing it to be removed even when positioned in a nostril.

[00127] Removable aligners may be configured in many different ways. A removable aligner may be attached to one or more applicator liners. Generally, a removable aligner is configured to switch between a collapsed and an expanded configuration. In the collapsed configuration, the aligner may be removed from the subject's nose without substantially disturbing the alignment. A system including a removable aligner may also be packaged with the aligner in the collapsed configuration. FIGS. 18A to 22D illustrate different variations of systems for applying nasal devices including applicator liners with removable aligners.

[00128] FIGS. 18A-18D illustrate variations of applicator liners having pop-up aligners. For example, FIG. 18A shows a nasal device applicator system having two applicator liners (a first liner and a second liner) and a removable aligner that is configured as a pop-up aligner. In this variation, the removable aligner is formed from the same material as the first applicator liner. A strip of material spanning the adhesive backing region, the bend region and a portion of the grip region is cut to form the removable aligner. The strip is essentially displaced towards the grip region to form the aligner, and one end of the strip 1801 forms a portion of the adhesive backing layer that is attached to the adhesive holdfast of the nasal device. The strip is folded in at least two places 1803, 1805 to form the pop-up, removable aligner.

[00129] The pop-up aligner in FIG. 18A is also configured to be stored flat. The grip region of the first applicator liner may fold over the second applicator liner, folding the pop-up aligner between them. The first applicator liner is folded along the bend region. During storage (e.g., when packaged), the grip region of the first applicator liner is folded, and the removable aligner is substantially flat. Before applying the device to the subject's nose, the grip region of the first applicator liner is folded (along the bend axis) back over the adhesive backing layer of the first applicator liner, expanding ('popping up') the aligner. The device may then be applied as described above (e.g., for FIGS. 14A-14F).

[00130] The systems for applying nasal devices shown in FIGS. 18B and 18C are also configured to be stored flat, by folding one of the grip regions of the applicator liner along the bend region to collapse the removable aligners. The system of FIG. 18B is very similar to FIG. 18A, except that the material forming the removable aligner is
frangibly connected to both the first and the second applicator liners. Thus, pulling one or the other applicator liners will tear or break the aligner (or the connection of the aligner to an applicator liner) as the applicator liner is removed. In FIG. 18C the removable aligner is formed by a strip of material that is attached to the grip region of the first applicator liner, is bent 1811 to form the distal (inserted) end of the aligner, and passes through a band cut in the second applicator liner that guides the strip. Pushing or pulling the strip forming the aligner can expand the aligner (as shown in FIG. 18C) or collapse it flat.

FIG. 18D illustrates another variation of a pop-up aligner that is formed by a separate folded material that is connected to both the first and second applicator liners. The removable aligner 1813 expands into a pyramidal shape, but can collapse flat between the grip regions of the first and second applicator liners when one is folded over the other.

FIGS. 19A-19C illustrate another variation of a removable pop-up aligner similar to the aligner in FIG. 18D. A folded strip of material is attached to the grip regions of both applicator liners. The aligner is collapsed by folding one of the grip regions over the other, as shown in FIG. 19A. The aligner can be expanded by separating the two grip regions, as shown in FIG. 19B. In the expanded configuration the removable aligner can be inserted into the nose to align the nasal device. The folded strip forming the aligner can be separated from one of the applicator liners when an applicator liner is removed from the system, as illustrated in FIG. 19C.

FIGS. 20A-20C are similar to 19A-19C, however in this example the aligner is perforated in its middle (along the fold) 2001. This forms a frangible connection that can be torn when one of the applicator liners is removed from the nasal device during application, as illustrated in FIG. 20C. Similarly, FIGS. 21A-21C illustrate a variation in which the aligner is formed by two pieces of material that are joined by a weak adhesive, as illustrated in FIG. 21B. Removing one or both applicator liners separates the two pieces, allowing the aligner to be removed as the nasal device is applied.

FIGS. 22A-22F illustrate other variations of systems for applying nasal devices including applicator liners. FIG. 22A is a system that does not include a removable aligner, but does include an aligner that is part of the nasal device (e.g., the body region of the nasal device). This aligner remains in the subject's nostril while the
device is worn. FIG. 22B-22F are all variations of systems for applying nasal devices having removable aligners that are attached to the applicator liner. For example, the removable aligner of FIG. 22C is a foam aligner that is compressible; the aligner is formed of two foam parts, each attached to an applicator liner. The aligner may be removed when the applicator liners are removed by compressing and collapsing the foam so that it can fit between the nasal device and the subject's nose or face. Another example of a foam aligner is shown in FIG. 23A and 23B. Other compressible materials may also be used as the aligner, in addition to foamed materials. The materials forming the removable aligner attached to applicator liner do not need to be compressible. For example, any low-profile aligner may be withdrawn by pulling the grip region of the applicator liner, so long a it is sufficiently thin (e.g., low-profile) so that it can be slid between the subject's face (nostril) and the nasal device when the applicator system is held against the subject's face over the subject's nostril.

Systems for applying nasal devices including removable aligners may be applied by the methods described above. If the removable aligner is a pop-up aligner, the aligner may be first expanded. The aligner may be expanded in some variations by separating the grip regions of the applicator liners. In other variations, the aligner may be expanded by pushing or pulling on a tab or strip connected to the aligner. Once the aligner is expanded, the assembly forming the applicator system is placed adjacent to the subject's face. The aligner is then placed at least partially in the subject's nose, and the nasal device applicator system is held in position. The one or more applicator liners can then be removed, removing the aligner. Removing an applicator liner may collapse the aligner. For example, in some variations, the aligner is frangible and is torn or otherwise removed from one or the other applicator liners as an applicator liner is pulled away from the nasal device.

As mentioned above, the various components of the applicator systems described herein (such as the applicator liner, aligner, and the nasal device), may be made of virtually any appropriate materials. Although specific exemplary materials have been provided in some examples, these devices are not limited to these materials unless the context indicates. For example, all or a portion of the applicator systems described herein may include a shape memory element or elements. For example, a holdfast, airflow resistor, body region forming the passageway, inserter, handle, or applicator liner or aligner may include a shape memory alloy. Any convenient shape
memory material that provides for flexibility and resumption of configuration following removal of applied force may be employed in these embodiments. For example, shape memory alloys may be used. A variety of shape memory alloys are known, including those described in U.S. Pat. Nos.: 5,876,434; 5,797,920; 5,782,896; 5,763,979; 5,562,641; 5,459,544; 5,415,660; 5,092,781; 4,984,581; the disclosures of which are herein incorporated by reference in their entirety. The shape memory alloy that is employed should generally be a biocompatible alloy. Biocompatible alloys may include nickel-titanium (NiTi) shape memory alloys sold under the Nitinol® name by Memry Corporation (Brookfield, Conn.). Also of interest are spring steel and shape memory polymeric or plastic materials, such as polypropylene, polyethylene, etc.

[00137] Rubber and polymeric materials may also be used as part (or all) of the nasal devices and/or applicators described herein. Injection moldable materials such as polyether block amide (e.g., PEBAX®), and the like may be used. Materials which may be used include: latex, polyethylene, polypropylene, polystyrene, polyvinyl chloride, polyvinylidene chloride, polyvinyl acetate, polyacrylate, styrene-butadiene copolymer, chlorinated polyethylene, polyvinylidene fluoride, ethylene-vinyl acetate copolymer, ethylene-vinyl acetate-vinyl chloride-acrylate copolymer, ethylene-vinyl acetate-acrylate copolymer, ethylene-vinyl acetate-vinyl chloride copolymer, nylon, acrylonitrile-butadiene copolymer, polycrylic acid, polyvinyl chloride, polyethylene, polybutadiene, thermoplastic polyimide, polyacetal, polyphenylene sulfide, polycarbonate, thermoplastic polyurethane, thermoplastic resins, elastomers, synthetic rubbers (such as a chloroprene rubber, styrene butadiene rubber, nitrile-butadiene rubber, and ethylene-propylene-diene terpolymer copolymer, silicone rubbers, fluoride rubbers, and acrylic rubbers), elastomers (such as a soft urethane, water-blown polyurethane), and thermosetting resins (such as a hard urethane, phenolic resins, and a melamine resins).

[00138] Biocompatible materials may be used, particularly for those portions of the system such as the nasal device holdfast, which may contact a user. In addition to some of the materials described above, the biocompatible materials may also include 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.

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. Further, the drawings and illustrations provided herein may not be to scale; in particular, certain features may be exaggerated or minimized.
CLAIMS

WHAT IS CLAIMED IS:

1. A nasal device applicator system for applying a nasal device in communication with a subject's nasal passage, the system comprising:
   a nasal device comprising:
   a passageway,
   an airflow resistor in communication with the passageway, wherein the airflow resistor is configured to inhibit expiration through the passageway more than inspiration through the passageway, and
   a holdfast region at least partially surrounding the passageway; and
   an inserter for inserting a nasal device, the inserter comprising:
   a handle having a grip region configured to be grasped;
   a nasal device engagement portion having at least one surface configured to engage a nasal device thereagainst, wherein the engagement portion comprises a cavity configured to hold the nasal device.

2. The system of claim 1, wherein the inserter comprises an ejector configured to eject the nasal device from the nasal device engagement.

3. The system of claim 1, wherein the inserter further comprises a trigger operably connected to an ejector for triggering ejection of the nasal device.

4. A nasal device applicator system for applying a nasal device in communication with a subject's nasal passage, comprising:
   a nasal device comprising:
   a passageway through a first body, wherein the passageway is configured to fluidly connect with a subject's nasal passage,
   an airflow resistor in communication with the passageway, and
   a holdfast configured to removably secure the nasal device in communication with the subject's nasal passage; and
a handle releasably connected to the first body of the nasal device, wherein the handle comprises a grip surface for holding the nasal device.

5. The device of claim 4, wherein the handle is frangibly connected to the first body of the nasal device.

6. A nasal device applicator system for applying a nasal device in communication with a subject's nasal passage comprising:
   a nasal device comprising:
   a passageway through a first body, wherein the passageway is configured to fluidly connect with a subject's nasal passage, an airflow resistor in communication with the passageway, and a holdfast configured to removably secure the nasal device in communication with the subject's nasal passage; and
   an applicator liner comprising:
   a grip region configured to be grasped by the subject, a flexible adhesive backing region releasably secured to the nasal device, and a folded bend region connecting the grip region and the adhesive backing region;
   wherein the applicator liner may be removed from the nasal device to at least partially engage the holdfast.

7. The system of claim 6, wherein the applicator liner further comprises an aligner configured to align the passageway of the nasal device with the subject's nasal passage.

8. The system of claim 7, wherein the aligner comprises a pop-up aligner.

9. The system of claim 7, wherein the aligner comprises a foam aligner.

10. The system of claim 6, further comprising a second applicator liner having:
a grip region configured to be grasped by the subject, 
an adhesive backing region releasably secured to the nasal device, and 
a bend region connecting the grip region and the adhesive backing region.

11. The system of claim 10, wherein the grip regions of the applicator liners extend in opposite directions from the passageway of the nasal device.

12. The system of claim 10, wherein the grip regions of the applicator liners extend in the same direction from the passageway of the nasal device.

13. The system of claim 6, wherein the applicator liner is a paper liner.

14. A nasal device applicator system for applying a nasal device in communication with a subject's nasal passage comprising: 
a nasal device having an airflow resistor configured to be placed in communication with the subject's nasal passageway and inhibit expiration more than inspiration; and 
an applicator liner comprising: 
a grip region configured to be grasped by the subject, 
an adhesive backing region releasably secured to the nasal device, 
a folded bend region connecting the grip region and the adhesive backing region; and 
an aligner attached to the applicator liner, wherein the aligner is convertible between a collapsed position and an extended position, wherein the extended position is configured to align the passageway of the nasal device with the subject's nasal passage.

15. The system of claim 14, comprising a second applicator liner including a grip region, an adhesive backing region and a folded bend region.

16. The system of claim 15, wherein the aligner is positioned between the applicator liner and the second applicator liner.
17. The system of claim 14, wherein the aligner is a perforated paper aligner, a foam aligner, or a folded paper aligner.

18. A method of applying a nasal device in communication with a nasal passage, the method comprising:
   placing a nasal device applicator system adjacent to the nose, wherein the nasal device applicator system comprises
   a nasal device having an airflow resistor, and
   an applicator liner having a grip region, a flexible adhesive backing region releasably secured to the nasal device, and
   a folded bend region connecting the grip region and the adhesive backing region; and
   removing the adhesive backing region from the nasal device to expose an adhesive holdfast by pulling the grip region.

19. The method of claim 18, further comprising placing an aligner attached to the applicator liner at least partially in the nose.

20. The method of claim 18, wherein the step of removing the adhesive backing region from the nasal device comprises sliding the grip region over the adhesive backing region as the grip region is pulled.

21. The method of claim 18, further comprising removing a second adhesive backing region from the nasal device by pulling a second grip region.
INTERNATIONAL SEARCH REPORT

INTERNATIONAL SEARCH REPORT

International application No
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A CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61 M 16/00 (2008.04)
USPC - 128/204.23
According to International Patent Classification (IPC) or to both national classification and IPC

B FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A61 M 16/00 (2008.04)
USPC - 128/204 23, 205 12 , 207 18

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
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C DOCUMENTS CONSIDERED TO BE RELEVANT

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<td>1, 4</td>
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<tr>
<td>Y</td>
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<td>2-3, 5-21</td>
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