Abstract:

A flexible pneumostoma management device maintains the patency of a pneumostoma while controlling the flow of material through the pneumostoma. The pneumostoma management device includes a pneumostoma vent having a tube which enters the pneumostoma to allow gases to escape the lung, a flange and a filter/valve to control flow of materials through the tube. The flange is a thin flexible patch which conforms and attaches to the chest of the patient. The flange secures the tube in position in the pneumostoma. In alternate embodiments the pneumostoma management device comprises a vent tube and chest mount.
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BACKGROUND OF THE INVENTION

[0001] In the United States alone, approximately 14 million people suffer from some form of Chronic Obstructive Pulmonary Disease (COPD). However, an additional ten million adults have evidence of impaired lung function indicating that COPD may be significantly underdiagnosed. The cost of COPD to the nation in 2002 was estimated to be $32.1 billion. Medicare expenses for COPD beneficiaries were nearly 2.5 times that of the expenditures for all other patients. Direct medical services accounted for $18.0 billion, and indirect cost of morbidity and premature mortality was $14.1 billion. COPD is the fourth leading cause of death in the U.S. and is projected to be the third leading cause of death for both males and females by the year 2020.

[0002] Chronic Obstructive Pulmonary Disease (COPD) is a progressive disease of the airways that is characterized by a gradual loss of lung function. In the United States, the term COPD includes chronic bronchitis, chronic obstructive bronchitis, and emphysema, or combinations of these conditions. In emphysema the alveoli walls of the lung tissue are progressively weakened and lose their elastic recoil. The breakdown of lung tissue causes progressive loss of elastic recoil and the loss of radial support of the airways which traps residual air in the lung. This increases the work of exhaling and leads to hyperinflation of the lung. When the lungs become hyperinflated, forced expiration cannot reduce the residual volume of the lungs because the force exerted to empty the lungs collapses the small airways and blocks air from being exhaled. As the disease progresses, the inspiratory capacity and air exchange surface area of the lungs is reduced until air exchange becomes seriously impaired and the individual can only take short shallow labored breaths (dyspnea).

[0003] The symptoms of COPD can range from the chronic cough and sputum production of chronic bronchitis to the severe disabling shortness of breath of emphysema. In some individuals, chronic cough and sputum production are the first signs that they are at risk for developing the airflow obstruction and shortness of breath characteristic of COPD. With continued exposure to cigarettes or noxious particles, the disease progresses and individuals with COPD increasingly lose their ability to breathe. Acute infections or certain weather conditions may temporarily worsen symptoms (exacerbations), occasionally where hospitalization may be required. In others, shortness of breath may be the first indication of the disease. The diagnosis of COPD is confirmed by the presence of airway obstruction on testing with spirometry. Ultimately, severe emphysema may lead to severe dyspnea, severe limitation of daily activities, illness and death.

[0004] There is no cure for COPD or pulmonary emphysema, only various treatments, for ameliorating the symptoms. The goal of current treatments is to help people live with the disease more comfortably and to prevent the progression of the disease. The current options include: self-care (e.g.,
quitting smoking), medications (such as bronchodilators which do not address emphysema physiology), long-term oxygen therapy, and surgery (lung transplantation and lung volume reduction surgery). Lung Volume Reduction Surgery (LVRS) is an invasive procedure primarily for patients who have a localized (heterogeneous) version of emphysema; in which, the most diseased area of the lung is surgically removed to allow the remaining tissue to work more efficiently. Patients with diffuse emphysema cannot be treated with LVRS, and typically only have lung transplantation as an end-stage option. However, many patients are not candidates for such a taxing procedure.

A number of less-invasive surgical methods have been proposed for ameliorating the symptoms of COPD. In one approach, new windows are opened inside the lung to allow air to more easily escape from the diseased tissue into the natural airways. These windows are kept open with permanently implanted stents. Other approaches attempt to seal off and shrink portions of the hyperinflated lung using chemical treatments and/or implantable plugs. However, these proposals remain significantly invasive and are still in clinical trials. None of the surgical approaches to treatment of COPD has been widely adopted. Therefore, a large unmet need remains for a medical procedure that can sufficiently alleviate the debilitating effects of COPD and emphysema.

**SUMMARY OF THE INVENTION**

In view of the disadvantages of the state of the art, Applicants have developed devices and methods for treating COPD in which an artificial passageway is made through the chest wall into the lung. An anastomosis is formed between the artificial passageway and the lung by creating a pleurodesis between the visceral and parietal membranes surrounding the passageway as it enters the lung. The pleurodesis prevents air from entering the pleural cavity and causing a pneumothorax (deflation of the lung due to air pressure in the pleural cavity). The pleurodesis is stabilized by a fibrotic healing response between the membranes. The artificial passageway through the chest wall also becomes epithelialized. The result is a stable artificial aperture through the chest wall which communicates with the parenchymal tissue of the lung.

The aperture into the lung through the chest wall is referred to herein as a pneumostoma. A pneumostoma provides an extra pathway that allows air to exit the lung while bypassing the natural airways which have been impaired by COPD and emphysema. By providing this ventilation bypass, the pneumostoma allows the stale air trapped in the lung to escape from the lung thereby shrinking the lung (reducing hyperinflation). By shrinking the lung, the ventilation bypass reduces breathing effort (reducing dyspnea), allows more fresh air to be drawn in through the natural airways and increases the effectiveness of all of the tissues of the lung for gas exchange. Increasing the effectiveness of gas exchange allows for increased absorption of oxygen into the bloodstream and also increased removal of carbon dioxide. Reducing the amount of carbon dioxide retained in the lung reduces hypercapnia which also reduces dyspnea. The pneumostoma thereby achieves the advantages of lung volume
reduction surgery without surgically removing a portion of the lung or sealing off a portion of the lung.

[0008] Procedures, techniques and tools for creating a pneumostoma are described in applicants' copending application entitled "Surgical Procedure And Instrument To Create A Pneumostoma And Treat Chronic Obstructive Pulmonary Disease" to Tanaka (Provisional Serial No. 61/038371 Filed March 20, 2008). Additional devices for managing a pneumostoma are described in applicants' copending patent application titled "Pneumostoma Management System And Methods For Treatment Of Chronic Obstructive Pulmonary Disease" to Tanaka (Provisional Serial No. 61/032877 filed February 29, 2008). These patent applications, and all other patents and patent applications referred to herein, are incorporated by reference in their entirety.

[0009] In accordance with one embodiment, the present invention provides a pneumostoma management system which includes a pneumostoma management device having a temporarily implantable pneumostoma vent. The temporarily implantable pneumostoma vent is placed into a pneumostoma to maintain the patency of the pneumostoma, prevent the entry of foreign substances into the lung, control air flow through the pneumostoma and collect any materials that may exit the lung.

[0010] In accordance with one embodiment, the present invention provides a two-piece pneumostoma management system which includes a partially-implantable pneumostoma vent and a chest mount. The partially-implantable pneumostoma vent is placed into a pneumostoma through an aperture in the chest mount. The partially-implantable pneumostoma management device is designed such that every component is larger than the aperture in the chest mount and thus cannot enter the pneumostoma.

[0011] In accordance with one embodiment, the present invention provides a two piece pneumostoma management system which includes two component pneumostoma management device having a partially-implantable pneumostoma vent and a chest mount. The partially-implantable pneumostoma vent is placed into a pneumostoma through the chest mount to maintain the patency of the pneumostoma, prevent the entry of foreign substances into the lung, control air flow through the pneumostoma and collect any materials that may exit the lung.

[0012] In accordance with one embodiment, the present invention provides a two piece pneumostoma management system which includes a partially-implantable pneumostoma vent and a chest mount. The partially-implantable pneumostoma vent is placed into a pneumostoma through an aperture in the chest mount. The partially-implantable pneumostoma management device is designed such that every component is larger than the aperture and thus cannot enter the pneumostoma.

[0013] In accordance with one embodiment, the present invention provides a two piece pneumostoma management system which includes a partially-implantable pneumostoma vent and a chest mount. The partially-implantable pneumostoma vent is placed into a pneumostoma through an
aperture in the chest mount. Insertion and removal tools are provided for inserting the partially-
implantable pneumostoma vent into the chest mount and removing it from the chest mount.

[0014] In accordance with one embodiment, the present invention provides a two piece
pneumostoma management system which includes a partially-implantable pneumostoma vent and a
chest mount. An insertion tool is used to position the partially-implantable pneumostoma vent into a
pneumostoma through an aperture in the chest mount. The removal tool is designed such that it does
not release the pneumostoma management device after extraction thereby protecting the non-sterile
device from reuse.

[0015] In accordance with one embodiment, the present invention provides a two piece
pneumostoma management system which includes a partially-implantable pneumostoma vent and a
chest mount. The partially-implantable pneumostoma vent is placed into a pneumostoma through an
aperture in the chest mount. The chest mount is secured to the skin of the patient and is replaced every
two days to one week. The pneumostoma vent is replaced daily or when necessary.

[0016] In accordance with particular embodiments, the present invention provides a flexible
pneumostoma management system for maintaining the patency of a pneumostoma while controlling
the flow of material through the pneumostoma. The pneumostoma management system includes a
pneumostoma vent having a thin flexible flange which attaches to the chest and conforms to the skin
of the patient. The pneumostoma vent includes a filter. In some embodiments a thin flexible chest
mount is positioned between the flange and the chest of the patient.

[0017] In accordance with a specific embodiment, the present invention provides a pneumostoma
management system having: a tube adapted for insertion into the chest through the pneumostoma, the
tube having a lumen, a proximal end and a distal end, the distal end of the tube having an atraumatic
tip, the distal end of the tube having at least one opening adapted to admit gases from the lung; and a
flange connected to the proximal end of the tube such that an opening in the flange connects to the
lumen of the tube, the flange projecting a sufficient distance from the tube to preclude passage of
flange into the pneumostoma, the flange being sufficiently thin and flexible to conform to the chest of
the patient, the flange having an adhesive coating for releasably securing the flange to the chest of the
patient; and a filter disposed over the opening in the flange and secured to one of the flange and tube
such that gases passing into and out of the lumen of the tube pass through the filter.

[0018] In accordance with one embodiment, the present invention provides a pneumostoma
management system comprising a cover and a pneumostoma management device. The pneumostoma
management device comprises a tube for insertion in a pneumostoma connected to an external section
for securing the pneumostoma management device to the chest of a patient. The cover is configured to
attach to the pneumostoma management device such that it presents an outward surface which
substantially obscures the external section of the pneumostoma management device from view. The
outward surface of the cover is designed to have a preferred visual appearance compared to the
external section of the pneumostoma management device.
[0019]

Thus, various systems, components and methods are provided for managing a pneumostoma and thereby treating COPD. Other objects, features and advantages of the invention will be apparent from drawings and detailed description to follow.

5

**BRIEF DESCRIPTION OF THE DRAWINGS**

[0021] The above and further features, advantages and benefits of the present invention will be apparent upon consideration of the present description taken in conjunction with the accompanying drawings.

10 [0022] FIG. 1A shows the chest of a patient indicating alternative locations for a pneumostoma that may be managed using the device and methods of the present invention.

[0023] FIG. 1B shows a sectional view of the chest illustrating the relationship between the pneumostoma, lung and natural airways.

[0024] FIG. 1C shows a detailed sectional view of a pneumostoma.

15 [0025] FIG. 2A shows a perspective view of components of a pneumostoma management system according to an embodiment of the present invention.

[0026] FIG. 2B shows a sectional view of the components of FIG 2A.

[0027] FIG. 2C shows an alternative pneumostoma vent.

[0028] FIGS. 3A-3C show an alternative pneumostoma management device according to an embodiment of the present invention.

[0029] FIGS. 4A-4F show alternative pneumostoma management devices according to embodiments of the present invention.

[0030] FIGS. 5A-5C show alternative pneumostoma management devices according to embodiments of the present invention.

25 [0031] FIGS. 6A-6F show alternative pneumostoma management devices according to embodiments of the present invention.

[0032] FIGS. 6G-6J show alternative filter arrangements for pneumostoma management devices according to embodiments of the invention.

[0033] FIGS. 7A and 7B show instructions for using a pneumostoma management system in accordance with an embodiment of the present invention.

[0034] FIGS. 8A-8D show plugs for pneumostoma management devices according to embodiments of the present invention.

[0035] FIGS. 9A-9H show alternative pneumostoma vent and chest mount configurations for pneumostoma management systems according to embodiments of the present invention.

35 [0036] FIGS. 10A-10D show alternative adhesive patterns for attachment of pneumostoma vents according to embodiments of the present invention.
[0037] FIGS. 10E-10G show views of an alternative pneumostoma vent according to and embodiment of the present invention.

[0038] FIGS. 10H-10J show views of alternative pneumostoma vents according to embodiments of the present invention.

[0039] FIGS. 11A-I1D show views alternative pneumostoma vents according to a preferred embodiments of the present invention.

[0040] FIGS. 11E-I1H show steps in the manufacture of a pneumostoma vent tube according to an embodiment of the present invention.

[0041] FIGS. 11I and I1U show packaging options for a preferred pneumostoma vent system according to an embodiment of the present invention.

[0042] FIGS. 11K-I1M show steps in the deployment of a preferred pneumostoma vent system as packaged in FIG. 11J according to an embodiment of the present invention.

[0043] FIG. 11N shows a preferred embodiment of a pneumostoma vent tube for a pneumostoma vent.

[0044] FIG. 12A shows a perspective view of components of a pneumostoma management system according to an embodiment of the present invention.

[0045] FIG. 12B shows a section view of the components of FIG 12A.

[0046] FIG. 12C shows a perspective view of the mounting flange of FIG 12A.

[0047] FIG. 12D shows a perspective view of the aperture plate of the flange of FIG 12C.

[0048] FIG. 12E shows a perspective view of the pneumostoma vent of FIG. 12A.

[0049] FIG. 12F shows an exploded perspective view of the pneumostoma vent of FIG. 12E.

[0050] FIG. 13A shows an insertion tool of a pneumostoma management system according to an embodiment of the present invention.

[0051] FIGS. 13B-13F show aspects of the components and operation of the insertion tool of FIG. 13A.

[0052] FIG. 14A shows a removal tool of a pneumostoma management system according to an embodiment of the present invention.

[0053] FIGS. 14B-14F show aspects of the components and operation of the removal tool of FIG. 14A.

[0054] FIGS. 15A-15D show steps and tools for applying a chest mount according to embodiments of the present invention.

[0055] FIGS. 16A-16I show steps and tools for inserting a pneumostoma vent and removing a pneumostoma vent according to embodiments of the present invention.

[0056] FIGS. 17A and 17B show instruction for using a pneumostoma management system in accordance with an embodiment of the present invention.
[0057] FIGS. 18A and 18B show sterile packaging for components of the pneumostoma management system in accordance with an embodiment of the present invention.

[0058] FIGS. 19A-19D show alternative pneumostoma vent configurations for pneumostoma management systems according to embodiments of the present invention.

[0059] FIGS. 19E-19H show pneumostoma plugs according to embodiments of the present invention.

[0060] FIGS. 20A-20E show alternative chest mount configurations for pneumostoma management systems according to embodiments of the present invention.

[0061] FIG. 21A shows a perspective cutaway view of a pneumostoma management system according to an embodiment of the present invention.

[0062] FIG. 21B shows a sectional view of the pneumostoma management system of FIG 2A.

[0063] FIG. 21C shows a perspective view of the cover of FIG 2A.

[0064] FIG. 22A shows the chest of a patient showing the positioning of the pneumostoma management system of the present invention.

[0065] FIG. 22B shows an alternative cover according to an embodiment of the present invention.

[0066] FIG. 22C shows an alternative cover according to an embodiment of the present invention.

[0067] FIG. 23A shows a perspective cutaway view of an alternative pneumostoma management system having a cover according to an embodiment of the present invention.

[0068] FIG. 23B shows a sectional view of the pneumostoma management system of FIG. 23A having an alternative cover.

[0069] FIGS. 24A-24B show views of an alternative pneumostoma management system having a cover according to an embodiment of the present invention.

[0070] FIG. 24C shows an alternative cover for the pneumostoma management system of FIG. 24A.

[0071] FIGS. 25A-25B show views of an alternative pneumostoma management system having a cover according to an embodiment of the present invention.

[0072] FIGS. 26A-26B show views of an alternative pneumostoma management system having a cover according to an embodiment of the present invention.

**DETAILED DESCRIPTION OF THE INVENTION**

[0073] The following description is of the best modes presently contemplated for practicing various embodiments of the present invention. The description is not to be taken in a limiting sense but is made merely for the purpose of describing the general principles of the invention. It is to be understood that features described in reference to a particular embodiments may be combined with features of other particular embodiments. The scope of the invention should be ascertained with reference to the claims. In the description of the invention that follows, like numerals or reference designators will be used to refer to like parts or elements throughout. In addition, the first digit of a
reference number (or first two digits of a 4 digit reference number) identifies the drawing in which the reference number first appears.

**Pneumostoma Formation and Anatomy**

[0074] FIG. IA shows the chest of a patient indicating alternative locations for creating a pneumostoma that may be managed using the system and methods of the present invention. A first pneumostoma 110 is shown on the front of the chest 100 over the right lung 101 (shown in dashed lines). The pneumostoma is preferably positioned over the third intercostal space on the mid-clavicular line. Thus the pneumostoma 110 is located on the front of the chest between the third and fourth ribs. Although the pneumostoma 110 is preferably located between two ribs, in alternative procedures a pneumostoma can also be prepared using a minithoracotomy with a rib resection.

[0075] In FIG. IA, a second pneumostoma 112 is illustrated in a lateral position entering the left lung 103 (shown in dashed lines). The pneumostoma 112 is preferably positioned over the fourth or fifth intercostal space under the left arm 104. In general, one pneumostoma per lung is created; however, more or less than one pneumostoma per lung may be created depending upon the needs of the patient. In most humans, the lobes of the lung are not completely separate and air may pass between the lobes.

[0076] A pneumostoma is surgically created by forming an artificial channel through the chest wall and joining that channel with an opening through the visceral membrane of the lung into parenchymal tissue of the lung to form an anastomosis. The anastomosis is joined and sealed by sealing the channel from the pleural cavity using adhesives, mechanical sealing and/or pleurodesis. Methods for forming the channel, opening, anastomosis and pleurodesis are disclosed in applicant's pending and issued patents and applications including U.S. Patent Application Serial No. 10/881,408 entitled "Methods and Devices to Accelerate Wound Healing in Thoracic Anastomosis Applications" and U.S. Patent Application Serial No. 12/030,006 entitled "Variable Parietal/Visceral Pleural Coupling" which are incorporated herein by reference in their entirety.

[0077] FIG. IB shows a sectional view of chest 100 illustrating the position of the pneumostoma 110. The parenchymal tissue 132 of the lung 130 is comprised principally of alveoli 134. The alveoli 134 are the thin walled air-filled sacs in which gas exchange takes place. Air flows into the lungs through the natural airways including the trachea 136, carina 137, and bronchi 138. Inside the lungs, the bronchi branch into a multiplicity of smaller vessels referred to as bronchioles (not shown). Typically, there are more than one million bronchioles in each lung. Each bronchiole connects a cluster of alveoli to the natural airways. As illustrated in FIG. IB, pneumostoma 110 comprises a channel through the thoracic wall 106 of the chest 100 between two ribs 107. Pneumostoma 110 opens at an aperture 126 through the skin 114 of chest 100.

[0078] FIG. 1C shows a detailed sectional view of the pneumostoma 110. As illustrated in FIG. 1C, pneumostoma 110 comprises a channel 120 through the thoracic wall 106 of the chest 100.
between the ribs 107. The channel 120 is joined to cavity 122 in the parenchymal tissue 132 of lung 130. Although shown having a particular shape, the channel 120 and cavity 122 will typically conform to the shape of a device inserted into the pneumostoma 110. An adhesion or pleurodesis 124 surrounds the channel 120 where it enters the lung 130. The thoracic wall 106 is lined with the parietal membrane 108. The surface of the lung 130 is covered with a continuous sac called the visceral membrane 138. The parietal membrane 108 and visceral membrane 138 are often referred to collectively as the pleural membranes. Between the parietal membrane 108 and visceral membrane 138 is the pleural cavity (pleural space) 140. The pleural cavity usually only contains a thin film of fluid that serves as a lubricant between the lungs and the chest wall. In pleurodesis 124 the pleural membranes are fused and/or adhered to one another eliminating the space between the pleural membranes in that region.

[0079] An important feature of the pneumostoma is the seal or adhesion surrounding the channel 120 where it enters the lung 130 which may comprise a pleurodesis 124. A pleurodesis 124 is the fusion or adhesion of the parietal membrane 108 and visceral membrane 138. A pleurodesis may be a complete pleurodesis in which the entire pleural cavity 140 is removed by fusion of the visceral membrane 138 with the parietal membrane 108 over the entire surface of the lung 130. However, as shown in FIG. 1C, the pleurodesis is preferably localized to the region surrounding the channel 120. The pleurodesis 124 surrounding the channel 120 prevents air from entering the pleural cavity 140. If air is permitted to enter pleural cavity 140, a pneumothorax will result and the lung may collapse.

[0080] Pleurodesis 124 can be created between the visceral pleura of the lung and the inner wall of the thoracic cavity using chemical methods including introducing into the pleural space irritants such as antibiotics (e.g. Doxycycline or Quinacrine), antibiotics (e.g. iodoacetate or silver nitrate), anticancer drugs (e.g. Bleomycin, Mitoxantrone or Cisplatin), cytokines (e.g. interferon alpha-2 and Transforming growth factor-β); pyrogens (e.g. Corynebacterium parvum, Staphylococcus aureus superantigen or OK432); connective tissue proteins (e.g. fibrin or collagen) and minerals (e.g. talc slurry). A pleurodesis can also be created using surgical methods including pleurectomy. For example, the pleural space may be mechanically abraded during thoracoscopy or thoracotomy. This procedure is called dry abrasion pleurodesis. A pleurodesis may also be created using radiotherapy methods, including radioactive gold or external radiation. These methods cause an inflammatory response and or fibrosis, healing, and fusion of the pleural membranes. Alternatively, a seal can be created in an acute manner between the pleural membranes using biocompatible glues, meshes or mechanical means such as clamps, staples, clips and/or sutures. The adhesive or mechanical seal may develop into pleurodesis over time. A range of biocompatible glues are available that may be used on the lung, including light-activatable glues, fibrin glues, cyanoacrylates and two part polymerizing glues.
a channel through the chest wall to the inner volume of the lung without causing a pneumothorax and is incorporated herein by reference for all purposes.

[0081] When formed, pneumostoma 110 provides an extra pathway for exhaled air to exit the lung 130 reducing residual volume and intra-thoracic pressure without the air passing through the major natural airways such as the bronchi 138 and trachea 136. Collateral ventilation is particularly prevalent in an emphysemous lung because of the deterioration of lung tissue caused by COPD. Collateral ventilation is the term given to leakage of air through the connective tissue between the alveoli 134. Collateral ventilation may include leakage of air through pathways that include the interalveolar pores of Kohn, bronchiole-alveolar communications of Lambert, and interbronchiolar pathways of Martin. This air typically becomes trapped in the lung and contributes to hyperinflation. In lungs that have been damaged by COPD and emphysema, the resistance to flow in collateral channels (not shown) of the parenchymal tissue 132 is reduced allowing collateral ventilation to increase. Air from alveoli 134 of parenchymal tissue 132 that passes into collateral pathways of lung 130 is collected in cavity 122 of pneumostoma 110. Pneumostoma 110 thus makes use of collateral ventilation to collect air in cavity 122 and vent the air outside the body via channel 120 reducing residual volume and intra-thoracic pressure and bypassing the natural airways which have been impaired by COPD and emphysema.

[0082] By providing this ventilation bypass, the pneumostoma allows stale air trapped in the parenchymal tissue 132 to escape from the lung 130. This reduces the residual volume and intra-thoracic pressure. The lower intra-thoracic pressure reduces the dynamic collapse of airways during exhalation. By allowing the airways to remain patent during exhalation, labored breathing (dyspnea) and residual volume (hyperinflation) are both reduced. Pneumostoma 110 not only provides an extra pathway that allows air to exit the lung 130 but also allows more fresh air to be drawn in through the natural airways. This increases the effectiveness of all of the tissues of the lung 130 and improves gas exchange. Increasing the effectiveness of gas exchange allows for increased absorption of oxygen into the bloodstream and also increased removal of carbon dioxide. Reducing the amount of carbon dioxide retained in the lung reduces hypercapnia which also reduces dyspnea. Pneumostoma 110 thus achieves many of the advantages sought by lung volume reduction surgery without surgically removing a portion of the lung or sealing off a portion of the lung.

[0083] Applicants have found that pneumostoma management devices in accordance with embodiments of the present invention are desirable to maintain the patency of the pneumostoma and control flow of materials between the exterior of the patient and the parenchymal tissue of the lung via the pneumostoma. The pneumostoma management devices include a pneumostoma vent to enter the pneumostoma and allow gases to exit the lung and may also include a chest mount, and/or one or more of the tools, packaging, auxiliary device and methods described herein. In general terms a pneumostoma management device ("PMD") or pneumostoma vent comprises a tube which is inserted into the pneumostoma and an external component which is secured to the skin of the patient to keep
the tube in place. Gasses escape from the lung through the tube and are vented external to the patient. The pneumostoma management device may, in some, but not all cases, include a filter which only permits gases to enter or exit the tube. The pneumostoma management device may, in some, but not all cases, include a one-way valve which allows gases to exit the lung but not enter the lung through the tube.

**Pneumostoma Management Devices**

[0084] FIGS. 2A and 2B illustrate views of a pneumostoma management device ("PMD") 200 in accordance with an embodiment of the present invention. PMD 200 is designed so as not to interfere with the range of motion or clothing of the patient. This is of importance for a device such as PMD 200 which must be used continuously to be effective. Comfort and ease of use are important if patient compliance with treatment protocols is to be achieved. The low profile of PMD 200 allows it to be inconspicuously positioned on the chest 100 of a patient in either the frontal 110 or lateral 112 locations (See FIG 1A).

[0085] PMD 200 includes a pneumostoma vent 204 which is inserted in a pneumostoma and secured to the chest of the patient. In some embodiments, the PMD is a single piece device in which a pneumostoma vent has a flange which secures the pneumostoma vent directly to the skin of the patient. However, PMD optionally includes a chest mount 202 which may be mounted to the skin of the patient and through which the chest vent 204 may be inserted into the pneumostoma. Where an optional chest mount 202 is utilized, pneumostoma vent 204 is mounted through an aperture 224 in chest mount 202. As will be further described below, the connection between the chest mount 202 and pneumostoma vent 204 may be engineered so as to ensure that pneumostoma vent 204 cannot be over-inserted into the lung.

[0086] A patient will typically wear a PMD at all times and thus the materials should meet high standards for biocompatibility. In preferred embodiments, pneumostoma vent 204 is formed from biocompatible/implantable polymers or biocompatible/implantable metals. In preferred embodiments, chest mount 202 is also formed from biocompatible polymers or biocompatible metals. Further description of suitable materials for manufacturing a PMD are provided in the Materials section below.

[0087] FIGS. 2A and 2B shows a perspective view of a two-component pneumostoma management device 200 which includes a pneumostoma vent 204 and an optional chest mount 202. Chest mount 202 is mounted to the skin of the patient and pneumostoma vent 204 is fitted to the chest mount 202. Pneumostoma vent 204 is mounted through an aperture 224 in chest mount 202. The chest mount is configured so that pneumostoma vent 204 cannot be over-inserted into the lung and to protect the skin of the chest from irritation. PMD 200 is preferably disposable. Pneumostoma vent 204 will be replaced periodically, such as daily, or when necessary. Chest mount 202 will also be replaced periodically, such as weekly, or when necessary. The patient will also be provided with a supply of
chest mounts 202 and pneumostoma vents 204 by a medical practitioner or by prescription. A one
week supply of pneumostoma vent 204 (such as seven pneumostoma vents 204) may be conveniently
packaged together with one chest mount 202.

[0088] Pneumostoma vent 204 includes a tube 240 sized and configured to fit within the channel
of a pneumostoma and a flange 242. The aperture 224 in the chest mount is adapted and configured to
receive the tube 240 of pneumostoma vent 204. A flange 242 is formed in one piece with, or
permanently connected to, the proximal end of tube 240. Flange 242 is sufficiently thin and flexible
that it can conform to the surface of the chest mount 202. In typical embodiments, flange 242 is less
than about 3mm in thickness, and in preferred embodiments, disc 222 is less than about 2mm in
thickness. Flange 242 is, however, too large to fit through aperture 224, and thus acts as an insertion
stop. Flange 242 is shown as a circular disc with a plurality of tabs 244. The distal surface of flange
242 may be covered in whole or in part with a releasable adhesive 246 adapted to temporarily fix
flange 242 to the skin of the patient or to the optional chest mount 202.

[0089] Tube 240 is stiff enough that it may be inserted into a pneumostoma without collapsing.
Over time, a pneumostoma may constrict and it is one function of PMD 200 to preserve the patency
of the channel of the pneumostoma by resisting the natural tendency of the pneumostoma to constrict. A
 crush recoverable material may be incorporated into tube 240 in order to make it crush recoverable.
 Tube 240 of pneumostoma vent 204 is sufficiently long that it can pass through the thoracic wall and
into the cavity of a pneumostoma inside the lung. The length of tube 240 required for a pneumostoma
vent 204 varies significantly between different pneumostomas. Because of the variation in
 pneumostomas, pneumostoma vents 204 are manufactured having tubes 240 in a range of sizes and a
patient is provided with a pneumostoma vent 204 having a tube 240 of appropriate length for the
patient's pneumostoma. The material and thickness of tube 240 of pneumostoma vent 204 is
preferably selected such that tube 240 is soft enough that it will deform rather than cause injury to the
 pneumostoma or lung.

[0090] Tube 240 of pneumostoma vent 204 preferably comprises an atraumatic tip 252 at the
distal end as shown in FIGS. 2A and 2B. Tip 252 may be rounded, beveled or curved in order to
reduce irritation or damage to the tissues of the pneumostoma or lung during insertion or while in
position. Pneumostoma vent 204 has an opening 254 in tip 252 of tube 240. Opening 254 allows the
entry of gases from the cavity of the pneumostoma into lumen 258 of tube 240. Tube 240 is optionally
provided with one or more side openings (not shown) positioned near tip 252 and/or along the length
of tube 240 to facilitate the flow of gas and/or mucous/discharge into lumen 258.

[0091] Pneumostoma vent 204 includes a hydrophobic filter 248 over the proximal end of tube
240. Hydrophobic filter 248 is positioned and mounted such that material moving between lumen 258
and the exterior of pneumostoma vent 204 passes through hydrophobic filter 248. Hydrophobic filter
248 may also be selected to prevent the entry of microbes, pollen and other allergens and pathogens
into the lumen 258. Hydrophobic filter 248 also prevents the exit of liquid and particulate discharge
from lumen 258 to the exterior of pneumostoma vent 204. Hydrophobic filter 248 is preferably
designed such that it fits into a recess in flange 242. However, hydrophobic filter 248 is thin and
flexible and thus will not protrude far if affixed to the surface of flange 242. Hydrophobic filter 248
may be permanently attached to flange 242, as shown in FIG. 2B. Hydrophobic filter 248 may be
permanently attached to flange 242 using a press fitting, permanent adhesive, welding or other
bonding technology. Flange 242 of pneumostoma vent 204 is releasably connected to chest mount 202
during use. Hydrophobic filter 248 may be made from a material such as medical grade GOR-TEX
(W. L. Gore & Associates, Inc., Flagstaff, AZ) or a reticulated polyurethane-based open cell foam.

Hydrophobic filter 248 serves several purposes. In general, hydrophobic filter 248
controls the passage of solid or liquid material between the lumen 258 and the exterior of cap 242. For
example, hydrophobic filter 248 prevents the flow of water into the lumen 258 through proximal
opening 255. Thus, a patient using PMD 200 may shower without water entering the lung through the
pneumostoma. Hydrophobic filter 248 may also be selected so as to prevent the entry of microbes,
pollen and other allergens and pathogens into the lumen 258. Hydrophobic filter 248 also prevents the
exit of liquid and particulate discharge from lumen 258 to the exterior of pneumostoma vent 204. This
is desirable to prevent contact between liquid and particulate discharge and clothing for example.

Pneumostoma vent 204 may mount directly to the skin of the chest or to an optional chest
mount 202 which is secured to the chest of the patient. In one embodiment, illustrated in FIGS. 2A and
2B, chest mount 202 comprises a flange 222 and an aperture 224. Chest mount 202 includes a thin and
flexible disc 222 designed to conform to the chest of the subject. Disc 222 is generally circular but is
provided with one or more tabs 236 to facilitate application and removal of disc 222 from the skin of
the patient. In typical embodiments, disc 222 is less than about 3mm in thickness, and in preferred
embodiments, disc 222 is less than about 2mm in thickness. However, the disc may be thicker if
absorbing requirements of the discharge around the tube is high. Additionally a thicker disk may
provide a forgiving surface to apply the flange to a rough or highly contoured skin surface. Disc 222 is
thus sufficiently flexible that it can conform to the surface of the chest but is relatively inelastic so that
the size and shape of aperture 224 is relatively stable. Disc 222 has a contact surface 232 which
contacts the skin of the patient surrounding the pneumostoma and positions the aperture 224 over the
opening of the pneumostoma. Contact surface 232 of disc 222 is provided with a biocompatible
adhesive 234, such as a hydrocolloid adhesive, for securing disc 222 to the skin of the patient. The
adhesive 234 may be protected by a protector sheet that is removed prior to use of disc 222. Adhesive
234 should be selected so as to secure disc 222 to the chest of the patient in the correct position
relative to the pneumostoma without causing undue irritation to the skin of the patient. The adhesive
need not create an air tight seal between disc 222 and the skin of the patient indeed, as described
above, it may be desirable to allow air to circulate behind disc 222 so that moisture does not
accumulate. Moisture may also be allowed to escape by making disc 222 from a porous material or
creating pores in the material of disc 222.
The aperture 224 is adapted and configured to receive the pneumostoma vent 204. In a preferred embodiment, the dimensions of aperture 224 are tightly controlled and the size and shape of aperture 224 remains stable even under any reasonably possible application of force to chest mount 202. The size of the aperture limits what components of the system may enter the pneumostoma and prevents components from passing completely into the pneumostoma. All the components of the pneumostoma vent 204 (other than the distal end of tube 240) and chest mount 202 or other tools designed for use by the patient are preferably larger than the aperture 224 thus precluding passage of any component from passing completely through the aperture even in the unlikely event of device failure. These safety features prevent unsafe entry of any of the components of pneumostoma vent 204 into pneumostoma even in the unlikely event of device failure.

In an alternative embodiment shown in FIG. 2C, hydrophobic filter 248 is releasably attached to flange 242 of a pneumostoma vent 260. Hydrophobic filter 248 may, for example, be releasably attached to flange 242 using a joint such as a threaded coupling or snap fitting. As shown in FIG. 2C, a ring 263 surrounding hydrophobic filter 248 snaps into place in a receiver 268 in flange 242. Hydrophobic filter 248 may be removed by pulling on tab 264. Removal of hydrophobic filter 248 allows access to lumen 258 while pneumostoma vent 260 is still positioned in the pneumostoma. This also allows access to the pneumostoma via the tube 240 of pneumostoma vent 260. Access to the pneumostoma may be useful, for example, for suction, irrigation and/or drug delivery. The pneumostoma vent 260 of FIG. 2C may be used with or without the chest mount 202 of FIGS. 2A and 2B.

It is not necessary that a flow-control device be used in a pneumostoma vent to form an airtight seal against the entry of air into the lung through the pneumostoma. Indeed, air may enter the lung through the pneumostoma between removal and reinsertion of the pneumostoma vent 204. The pleurodesis of the pneumostoma prevents the entry of air into the pleural cavity which would otherwise cause pneumothorax. However, it is sometimes desirable to restrict flow of air in through the pneumostoma so as to encourage a reduction in hyperinflation and to preclude the aspiration of solid, liquid or gas into the lung through the pneumostoma. Thus, in alternative embodiments a pneumostoma vent may be provided with a flow control device instead of, or in addition to, the hydrophobic filter 248. The flow-control device may comprise a one-way valve assembly such as a flapper valve, Heimlich valve, reed valve or the like for allowing air to be exhaled with very low resistance through the pneumostoma while restricting the flow of air or other matter into the pneumostoma from outside the body. A suitable flow-control device preferably includes only a small number of components for ease of manufacturing and reliability and should be designed such that it has no small parts which might be aspirated through the pneumostoma.

FIGS. 3A-C illustrate an alternative pneumostoma management device 300 having a combination hydrophobic filter and one-way valve. PMD 300 includes a pneumostoma vent 304. Pneumostoma vent 304 includes a tube 340 formed in one piece with a flange 342. Flange 342 is also
thin and flexible so that it may conform to the chest of the patient. In typical embodiments, flange 342 is less than about 3mm in thickness, and in preferred embodiments, flange 342 is less than about 2mm in thickness. Flange 342 has one or more tabs 344 to facilitate insertion and removal. The distal surface of flange 342 may be covered in whole or in part with a releasable adhesive 346 adapted to temporarily fix flange 342 to the chest of the patient. PMD 300 may optionally include a chest mount such as chest mount 202 of FIG. 2A (not shown in FIG. 3A).

[0098] A combination hydrophobic filter and one-way valve 347 is attached to flange 342 over the proximal end of tube 340. Valve 347 includes an annular region 348 of porous hydrophobic material and a central non-porous region 349. Valve 347 is attached to the flange at the circumference.

As shown in FIG. 3B, when the pressure outside the pneumostoma is larger than the pressure inside the pneumostoma, valve 347 is pushed against flange 342 and non-porous region 349 blocks the proximal end of tube 340. This prevents entry of gases through the pneumostoma during inhalation or in the event of sudden pressure increases in the environment. As shown in FIG. 3C, when the patient exhales, the increased pressure inside tube 340 pushes valve 347 away from the proximal end 352 of tube 340. Gases can then pass radially out of tube 340 and escape through the porous annular region 348 as shown by arrows 350. Thus valve 347 provides a simple way to provide one-way valve and filter functionality to pneumostoma vent 304. Other arrangements of valves and/or filters may be used in alternative embodiments.

[0099] The pneumostoma vents of FIGS. 2A-2C and 3A-3C are designed to be inserted into a pneumostoma and removed from a pneumostoma without the need for special tools. A releasable adhesive or releasable coupling temporarily secures the pneumostoma vent to the chest of the patient (or optional chest mount). One or more tabs allow the pneumostoma vent to be peeled away from the chest of the patient (or optional chest mount) and removed. The tabs should be made sufficiently large that they can be used by the patients. It may additionally be useful to provide an alignment tool for aligning the aperture of the chest mount with the pneumostoma during application of the chest mount to the skin of the chest. It may also be useful to provide a plug which may be used to protect the pneumostoma from the entry of foreign material during times of activities when a pneumostoma vent is not present in chest mount. The alignment tool and/or pneumostoma plug are designed to engage the chest mount in the same way as the pneumostoma vent, for example, by using a releasable adhesive or other releasable coupling.

[00100] FIGS. 4A-4F show views of alternative designs of pneumostoma vent. As shown in FIG. 4A, pneumostoma vent 400 includes a tube 404 and a flange 402. Flange 402 is thin and flexible so that it may conform to the chest of the patient or an optional chest mount (such as chest mount 202 of FIG. 2A). In typical embodiments, flange 402 is less than about 3mm in thickness, and in preferred embodiments, flange 402 is less than about 2mm in thickness. Flange 402 may be provided with one or more tabs (not shown) to facilitate insertion and removal. The distal surface of flange 402 is covered in whole or in part with a releasable adhesive (see FIG 4C). The adhesive is adapted to
temporarily secure flange 402 to the chest of the patient (or chest mount if used). The size, shape and thickness of the flange 402 are selected to facilitate installation and enhance the comfort of the patient during use while maintaining the correct placement of tube 404 in the pneumostoma. Tube 404 has an atraumatic tip 405 and an aperture 407 at the distal end. Flange 402 may be generally circular as shown in FIG. 4A. In the alternative embodiment of FIG. 4B flange 412 of pneumostoma vent 410 is generally strip-shaped or rectangular. A hydrophobic filter 408 is mounted to the flange 402 or 412 over the proximal opening of tube 404. In the embodiments of FIGS. 4A-4C, hydrophobic filter 408 is a thin disc of hydrophobic material which is press fit into a raised region 406 of the flange 402 or 412. The sectional view of the pneumostoma vent 400 of FIG. 4A shown in FIG 4C illustrates one way in which interference between hydrophobic filter 408 and raised region 406 can secure hydrophobic filter 408. In alternative embodiments, a hydrophobic filter may be secured to the flange using adhesive or other bonding methods. Other arrangements of valves and/or filters may be used instead of or in addition to the hydrophobic filter shown.

[00101] As previously discussed, the length of tube 440 required for a pneumostoma vent 404 varies significantly between different pneumostomas. Because of the variation in pneumostomas, pneumostoma vents 404 should be manufactured having tubes 440 in a range of sizes and a patient should be provided with a pneumostoma vent 404 having a tube 440 of appropriate length for the patient's pneumostoma. Pneumostoma vents 404 having different lengths of tube 440 may be manufactured in a number of different ways. FIGS. 4C-4F and 5A-5C illustrate designs which facilitate the manufacture of pneumostoma vents having a range of different lengths.

[00102] FIG. 4C is a sectional view of pneumostoma vent 400 of FIG. 4A made according to one alternative embodiment. As shown in FIG. 4C, tube 404 is formed as a separate piece from flange 402. Tube 404 is connected at a butt joint 420 to a tubular extension 422 of flange 402. Butt joint 420 may be adhesively bonded, welded or otherwise secured. A single shape of mold/tooling can be used to make all of the flanges 402 for all lengths of pneumostoma vent 400. Tube 404 can be advantageously formed using an extrusion process. The extruded tube can be cut to any desired length and then tipped to create atraumatic tip 405 around distal aperture 407. Different lengths of tube 404 can be bonded to flange 402 to create a range of different lengths of pneumostoma vent 400 without requiring different tooling for each size of pneumostoma vent. Additionally, a different material may be used to make flange 402 than tube 404. For example, a softer more conformable material may be used for flange 402 to allow it to conform to the chest of the patient. A harder material may be used for tube 404 to allow it to resist crushing while having a thin wall thickness and consequently a large inner diameter for the passage of air. An adhesive 403 is placed on the distal surface of flange 402 to releasably secure the flange to the chest of the patient (or a chest mount if present).

[00103] FIG. 4D is a sectional view of pneumostoma vent 440 made according to another alternative embodiment. As shown in FIG. 4D, tube 444 is again formed as a separate piece from flange 442. A single shape of mold/tooling can again be used to make all of the flanges 442 for all
lengths of pneumostoma vent 440. Also tube 444 can be advantageously formed using an extrusion process. As before, the extruded tube can be cut to any desired length and then tipped to create atraumatic tip 405 around distal aperture 407. Different lengths of tube 444 can be bonded to flange 442 to create a range of different lengths of pneumostoma vent 440 without requiring different tooling for each size of pneumostoma vent 440. Additionally, a different material may be used to make flange 442 than tube 444. For example a softer more conformable material may be used for flange 442 to allow it to conform to the chest of the patient. A harder material may be used for tube 444 to allow it to resist crushing while having a thin wall thickness and consequently a large inner diameter for the passage of air. In the embodiment of FIG. 4D, a flare 449 is formed at the proximal end of tube 444. Tube 444 is received through aperture 447 in flange 442. However flare 449 is too large to pass through aperture 447 and therefore engages the rim 441 around aperture 447. Flare 449 is securely connected to rim 441 of flange 442. Flare 449 may be adhesively bonded, sealed, welded or otherwise secured to rim 441. This design is advantageous in that flare 449 is too large to fit through aperture 447 even if the joint fails between the flare 449 and rim 441. As before, the extruded tube 444 can be cut to any desired length and then tipped to create atraumatic tip 405 around distal aperture 407.

Different lengths of tube 444 can be bonded to flange 442 to create a range of different lengths of pneumostoma vent 404 without requiring different tooling for each size of pneumostoma vent. A hydrophobic filter 448 is secured within raised region 446 of flange 442 and an adhesive 443 is applied to the distal surface of flange 442 as in previous embodiments.

FIG. 4E is a sectional view of pneumostoma vent 450 made according to another alternative embodiment. As shown in FIG. 4E, tube 454 is again formed as a separate piece from flange 452 for the same advantages previously discussed with respect to FIGS. 4C and 4D. In the embodiment of FIG. 4E, flange 452 is formed with tubular extension 451 having a plurality of ridges 457. Tubular extension 451 functions like a hose barb. The proximal end 459 of tube 454 is pushed over tubular extension 451 and is deformed by ridges 457. The ridges 457 are designed to secure tube 454 to flange 452 without adhesive. However an adhesive or other bonding technology may be used in addition to the mechanical connection afforded by tubular extension 451. As before, the extruded tube 454 can be cut to any desired length and then tipped to create atraumatic tip 405 around distal aperture 407. Different lengths of tube 454 can be bonded to flange 452 to create a range of different lengths of pneumostoma vent 450 without requiring different tooling for each size of pneumostoma vent 450. A hydrophobic filter 458 is secured within raised region 456 of flange 452 and an adhesive 453 is applied to the distal surface of flange 452 as in previous embodiments.

FIG. 4F is a sectional view of a pneumostoma vent 460 made according to another alternative embodiment. As shown in FIG. 4F, tube 464 is again formed as a separate piece from a flange 462 for the same advantages previously discussed with respect to FIGS. 4C and 4D. In the embodiment of FIG. 4D, flange 462 is a small disc with a raised region 466 for receiving hydrophobic filter disc 468. Flange 462 has a small extension 461 which extends into tube 464. Tube 464 is formed
integral with two arms 467, 469 which extend perpendicular to tube 464. The arms 467, 469 are formed by splitting tube 464 in half along a length equal to the length of arms 467, 469. The two parts of tube 464 are then bent perpendicular to tube 464, hot pressed and trimmed to make arms 467, 469. Flange 462 is then bonded to the proximal opening of tube 464 and to arms 467, 469 and serves to hold filter 468 and also to keep arms 467, 469 perpendicular to tube 464. An adhesive or other bonding technology may be used in addition to the mechanical connection afforded by the extension.

As before, the extruded tube 464 can be cut to any desired length and then tipped to create atraumatic tip 405 around distal aperture 407. Different lengths of tube 464 can be bonded to flange 462 to create a range of different lengths of pneumostoma vent 460 without requiring different tooling for each size of pneumostoma vent. A hydrophobic filter 468 is secured within raised region 466 of flange 462 and an adhesive 463 is applied to the distal surface of flange 462 as in previous embodiments. Although two arms 467, 469 are shown in FIG. 4F, in alternative embodiments, tube 464 can be split into three, four or more sections to make three, four or more arms. See FIG. 6E for an example with ten arms.

[00106] In alternative embodiments, as illustrated in FIGS. 5A-5C, the flange and tube can be formed in one piece. However, it is still advantageous to use a minimum of tooling to make the pneumostoma vent of various sizes. One way to avoid having different molds/tooling for each size of pneumostoma vent is to make all of the pneumostoma vents with the same length of tube. If the tube length is selected to be longer than the longest tube needed for a pneumostoma, then the tube can be trimmed to the desired size and tipped to form the atraumatic tip 405 at the distal end.

[00107] FIG. 5A shows one design with an integrated flange 502 and tube 504. Note that the inside diameter 570 of tube 504 reduces in size towards the open distal tip 571. It is desirable to have this draft in the inside diameter 570 of tube 504 to enable the tube 504 to be removed from the pin of the tooling/mold. Thus tube 504 can be reduced in exterior diameter along its length, or the exterior diameter can be preserved the same and the inner diameter 570 can be reduced as shown. One disadvantage of this design is that the inner diameter 570 may be significantly reduced for long lengths of tube 504. It is preferred, where possible, that the inner diameter 570 be as large as possible, especially for longer tubes 504 so that air and discharge may more easily pass along the tube 504.

[00108] After the integrated flange 502 and tube 504 has been removed from the tooling/mold, the tube 504 can be trimmed to the desired length. The cut end of tube 504 can then be tipped to form the atraumatic tip 505 around the aperture 507 at the distal end of the finished tube 504. The pneumostoma vent 500 may be completed by adding the other components, for example a hydrocolloid adhesive and hydrophobic filter.

[00109] FIGS. 5B and 5C show an alternative design of pneumostoma vent featuring an integrated flange 512 and tube 514. Note that in this design, tube 514 is initially closed at the distal end 572. Because tube 514 is closed when molded it may be blown off the pin of the mold/tooling occupying the interior of tube 514 using compressed air. This design allows tube 513 to be removed from the tooling/mold without any draft (reduction in inner diameter 580). This design is advantageous as it
allows the inner diameter 580 of tube 514 to be kept constant along the length of tube 514. After the integrated flange 512 and tube 514 have been removed from the tooling/mold, the tube 514 can be trimmed to the desired length for example along line C-C. The cut end of tube 514 can then be tipped to form the atraumatic tip 505 around the aperture 507 at the distal end of the finished tube 514 as shown in FIG 5C. FIG. 5C shows tube 514 cut to length and tipped. The closed portion 586 of tube 514 has been cut off and may now be recycled or discarded. The pneumostoma vent 510 may be completed by adding the other components, for example, a hydrocolloid adhesive and hydrophobic filter.

[00110] FIGS. 6A-6C shows different views of a pneumostoma vent system 600. Pneumostoma vent system 600 is designed for use without a chest mount although it could be adapted for use with a chest mount. FIG. 6A shows an exploded view of the four main components of pneumostoma vent system. From right to left these components are annular adhesive cover 602, filter 604, pneumostoma vent 606 and hydrocolloid ring 608.

[00111] Annular adhesive cover 602 is a thin porous biocompatible membrane which is adhesive on the surface facing the pneumostoma (the inner surface see 622 in FIG. 6C) and non-adhesive on the outer surface 620. A suitable material for annular adhesive cover 602 is a CHG Chlorhexidine Gluconate IV Securement Dressing available under the Tradename TEGADERM™ from 3M of St. Paul, MN. TEGADERM™ is thin layer of polyurethane bonded to a thin hydrocolloid adhesive layer. The film is biocompatible as well as thin, strong, and breathable. Other thin biocompatible dressings and adhesive films may be used as an alternative to TEGADERM™. Annular cover 602 has an aperture 624 large enough to allow air to exit through filter 604. Aperture 624 may however be slightly smaller than filter 604 so that annular cover can be used to secure filter 604 to pneumostoma vent 606. Exposed portions of annular adhesive cover 602 are provided with a paper cover to protect the adhesive ring prior to use.

[00112] Filter 604 is a circular disc of filter material. Filter 604 is preferably a hydrophobic filter material, for example GORETEX. Filter 604 is larger than the proximal aperture in pneumostoma vent 606 and is positioned over the proximal aperture to filter material moving in and out of the pneumostoma vent 606. Filter 604 may be secured to pneumostoma vent 606 by and adhesive, welding, or other bonding technology. Filter 604 may also be secured to pneumostoma vent 606 by annular adhesive cover 602 instead of or in addition to other bonding techniques.

[00113] Pneumostoma vent 606 comprises a tube 660 for entering the pneumostoma. As previously discussed, tube 660 has an atraumatic tip 665 and one or more apertures 667 in the distal end to allows gases and discharge to enter tube 660 from the pneumostoma. Tube 660 is connected to a flange 662 at the proximal end. Flange 662 may be formed in one piece with tube 660 or formed separately and joined to tube 662 as previously described with respect to other embodiments. Filter 604 is secured over proximal opening 663 as described in the previous paragraph. The proximal opening 663 of pneumostoma vent is sized so that filter 604 covers proximal opening 663.
Hydrocolloid ring 608 is a biocompatible hydrocolloid material which is naturally sticky like an adhesive on both sides. Hydrocolloid ring may be provided with a film coating and a transitional adhesive on the side facing flange 662 and annular cover 602 in order to better secure hydrocolloid ring 608 to the flange and annular cover. Hydrocolloid ring 608 is preferably less than 3mm thick and is more preferably, approximately 1 mm in thickness. However, the hydrocolloid ring may be thicker if absorbing requirements of the discharge around the tube is high. Additionally a thicker ring of hydrocolloid may provide a forgiving surface to secure pneumostoma vent system 600 to a rough or highly contoured skin surface. Exposed portions of hydrocolloid ring 608 are provided with a paper cover to protect the adhesive ring prior to use.

Pneumostoma vent system 600 may be provided as a kit of separate components or one or more of the components may be preassembled when provided to the patient. FIG. 6B shows an assembly of all four main components including annular adhesive cover 602, filter 604, pneumostoma vent 606 and hydrocolloid ring 608. Note that tube 660 fits through the middle of hydrocolloid ring 608. Note also that flange 662 is trapped between annular adhesive cover 602 and hydrocolloid ring 608. In this embodiment, filter 604 is also secured to pneumostoma vent 606 by annular adhesive cover 602. Exposed adhesive regions of annular adhesive ring 602 and hydrocolloid ring 608 on the patient side of the pneumostoma vent system assembly are provided with protective covers (for example paper covers) to protect the adhesive during shipping and prior to use. The completed or partially completed assembly is provided as a sterile product to the patient or caregiver who inserts the pneumostoma vent into a pneumostoma as part of a pneumostoma care program.

FIG. 6C shows the pneumostoma vent system 600 in position within a pneumostoma 110. As shown in FIG. 6C, tube 660 is inserted into the pneumostoma and passes through the chest wall into the lung. Aperture 667 in the distal end of tube 660 is positioned inside the lung so that gases and discharge may enter the tube 660 of the pneumostoma vent system. Flange 662 of pneumostoma vent 606 is secured to the skin of the patient by hydrocolloid ring 608 and annular adhesive cover 602. Flange 662 secures the position of tube 660 within pneumostoma 110. Flange 662 secures the position of aperture 663 on the chest of the patient such that gases from the lung may vent through tube 660 and filter 604. Both hydrocolloid ring 608 and annular adhesive cover 602 contact the skin 114 of the patient to secure the pneumostoma vent system. In some cases a barrier film may be applied by the patient prior to securing the pneumostoma vent system to reduce skin irritation caused by application and removal of the system. An additional ring of absorbent material (not shown), for example, gauze or another absorbent fabric may be positioned around tube 660 between hydrocolloid ring 608 and the skin 114 of the patient for absorbing any discharge from pneumostoma 110 which escapes around tube 660.

As shown in FIG. 6D a pneumostoma vent system 620 may be provided in a number of shapes and sizes to suit the needs and anatomy or different patients. In pneumostoma vent system 620, adhesive cover 622 is generally rectangular or strip-like in shape with an aperture 623 through which
filter 624 is exposed. Hydrocolloid ring 628 is oval in shape so that it fits within the coverage of adhesive cover 622. Assembly of pneumostoma vent system is essentially as described with respect to pneumostoma vent system 600. Filter 624 is sandwiched between pneumostoma vent 626 and adhesive cover 622. Tube 625 of pneumostoma vent 626 passes through the middle of hydrocolloid ring 628. Flange 627 of pneumostoma vent 626 is sandwiched between hydrocolloid ring 628 and adhesive cover 622. A protective backing is added to protect the exposed adhesive surfaces prior to application to the patient.

[00118] In the alternative embodiment of FIG. 6E, pneumostoma vent 636 has a flange which comprises ten arms 637. The arms 637 may be made, for example by splitting the proximal end of tube 635 into slices which are then bent perpendicular to tube 635. The arms 637 may be sandwiched between hydrocolloid ring 638 and adhesive cover 632 as before. Alternatively, the arms 637 may be distributed and embedded within a hydrocolloid layer. As before, adhesive cover 632 secures filter 634 over the proximal opening in tube 635.

[00119] FIG. 6F shows an alternative kit 680 in which a smaller cover 682, filter 604, pneumostoma vent 606 and hydrocolloid ring 608 are preassembled and provided together with a secondary cover 690. In this embodiment, cover 682 is approximately the same size as hydrocolloid ring 608 and thus does not contact the skin of the patient but serves only to secure filter 604 and flange 662. Note that tube 660 extends through hydrocolloid ring 608. Flange 662 and filter 604 are trapped and secured between smaller cover 682 and hydrocolloid ring 608. Exposed adhesive regions of hydrocolloid ring 608 on the patient side of the pneumostoma vent system 600 are provided with protective covers (for example paper covers) to protect the adhesive during shipping and prior to use. The two components are provided as a sterile kit to the patient or caregiver. The pneumostoma vent is first secured in the pneumostoma. The secondary cover is applied over the top of the pneumostoma vent. The secondary cover 690 is designed not to block the flow of air through filter 604. Secondary cover 690 is either sufficiently porous to allow air to pass or is provided with one or more openings to allow air to pass.

[00120] In order to increase air flow through the filter a filter material with low to extremely low resistance to air flow is preferred. The resistance of the filter to air flow may be reduced by increasing the area of the air filter through which air may pass. The surface area of the filter may be increased in several ways. First the filter area may be increased by flaring out the proximal aperture in the pneumostoma vent and consequently a larger filter 604. Second the filter can be folded, shaped or pleated to increasing the area of filter material for a given aperture. Third, as shown in FIG. 3C, the filter can be arranged such that a filter larger than the aperture may be utilized. FIG. 6G shows an alternate pneumostoma vent system 600g having a flare 640 in the proximal end of pneumostoma vent 606g. As shown in FIG. 6G, the flare 640 increases the diameter of the proximal opening 663 of pneumostoma vent 606g by approximately 50%. As a consequence, the area of proximal opening 663
and filter 604g through which gases may escape is approximately doubled compared to the pneumostoma vent system 600 with a non-flared pneumostoma vent 606 (see FIG 6C).

[00121] FIG. 6H shows an alternate pneumostoma vent system 600h having a conical filter 604h received within pneumostoma vent 606. Conical filter 604h presents approximately four times the surface area for air flow as compared to the flat circular filter 604 of pneumostoma vent system 600 with the same diameter of proximal opening 663 (see FIG 6C). FIG. 6I shows a perspective view of conical filter 604h. As shown in FIG. 6J, the surface area of filter 604j is increased even further by inclusion of numerous folds/pleats 650 in the material of filter 604j. These techniques for increasing the area of the filter may be used alone or in combination in any of the pneumostoma management devices disclosed herein.

[00122] The components of the pneumostoma management system are preferably supplied to the patient in sterile packaging. In preferred embodiments, the components are supplied in packaging that assists the patient in utilizing the components of the system in the correct sequence. The packaging should include instructions for use. The packaging may also be printed with material that assists the patient in the appropriate sequence of the steps for using the enclosed components. The package may also be designed to provide the components to the patient in the order required for use and maintain sterility during use. For example, the package may be designed so that, upon opening the package, the components are physically arranged in a tray in the order in which they are to be used by the patient. Alternatively, the components may be provided as individual components separately packaged. For example, cleaning and moisturizing swabs and barrier spray/cream may alternatively or additionally be packaged separately and provided to patient. The insertion tool, removal tool and pneumostoma vent may also be separately packaged.

Use Of Pneumostoma Management Devices

[00123] The pneumostoma management system is designed such that the system may be used by a patient in a sterile manner. After creating and healing of the pneumostoma the patient will be responsible for applying and removing the PMD and components thereof such as the pneumostoma vent 204 and chest mount 202 (if used). The patient will typically exchange one pneumostoma vent 204 for another and dispose of the used pneumostoma vent 204. Pneumostoma vent 204 will be replaced periodically, such as daily, or when necessary. The patient will be provided with a supply of pneumostoma vents 204 by a medical practitioner or by prescription. To avoid irritation to the chest, it is preferable that the chest mount, if provided, be changed less frequently than the pneumostoma vent. In a preferred embodiment, the chest mount remains attached for up to a week thereby avoiding irritation of the skin caused by daily attachment and removal of a mount. Chest mount 202 will be replaced periodically, such as weekly, or when necessary. The patient will also be provided with a supply of chest mount 202 by a medical practitioner or by prescription. A one week supply of pneumostoma vent 204 (such as seven pneumostoma vents 204) may be conveniently packaged.
together with one chest mount 202. Where a chest mount is not used, a barrier cream or spray may be used to protect the skin of the chest from irritation.

[00124] To use PMD 200, chest mount 202 is first positioned over a pneumostoma and secured with adhesive to the skin of the patient. Chest mount may be positioned by the patient by manual alignment of the aperture 224 of chest mount 202 with the aperture of the pneumostoma. In one embodiment, the chest mount 202 may be aligned with the pneumostoma 110 using a pneumostoma vent 204 assembled with the chest mount 202. The chest mount 202 may be provided to the patient with the pneumostoma vent 204 as one assembly. Alternatively, the patient may insert the pneumostoma vent 204 into the chest mount 202 prior to applying chest mount 202 to the chest. The patient then manipulates the chest mount by the tabs 236. The patient places the tip 252 of pneumostoma vent 204 into the aperture 126 of the pneumostoma 110 and pushes the pneumostoma vent 204 gently and slowly into the pneumostoma 110. During insertion the patient lets the pneumostoma vent 204 align itself with the channel 120 of the pneumostoma 110 such that when the chest mount 202 contacts and adheres to the skin 114 of the chest 100, the aperture 224 of the chest mount 202 is perfectly aligned with the aperture 126 of the pneumostoma 110. A pneumostoma vent 204 may be inserted in the same way without a chest mount 202 if the particular PMD used does not come with a chest mount 202.

[00125] FIG. 7A provides a set of instructions for use (IFU) 720 for replacement of a chest mount according to an embodiment of the invention. At step 722, the patient obtains the replacement chest mount and verifies that it is the correct size for his/her pneumostoma. At step 724, the patient removes the prior chest mount and disposes of it as appropriate. At step 726, the patient removes a sterile cleaning swab from the chest mount package. At step 728, the patient cleans the area of the skin around the pneumostoma. The patient cleans in a direction radially out from the pneumostoma. At step 730, the patient inspects the tissue around the pneumostoma and the pneumostoma for inflammation or injury. If injury or inflammation is observed the patient should seek medical advice.

[00126] At step 732, the patient removes a new disposable (or sterilized reusable) chest mount from its packaging. At step 734, the patient removes the backing from the adhesive pad of the chest mount. Care is taken during steps 732 and 734 to handle the chest mount only by the tabs and not to touch the surface which will be in contact with the pneumostoma. At step 736, the patient applies the chest mount to the pneumostoma aligning the aperture of the chest mount with the aperture of the pneumostoma. Chest mount may be packaged with an alignment tool or assembled with a pneumostoma vent to assist in positioning chest mount correctly. If pain or injury is perceived during application the patient should seek medical advice. The steps of IFU 720 may also be performed by a caregiver or medical practitioner.

[00127] FIG. 7B provides a set of instructions for use (IFU) 740 for replacement of a pneumostoma vent according to an embodiment of the invention. At step 742, the patient obtains the replacement pneumostoma vent and verifies that it is the correct size for his/her pneumostoma. The
packaging of the pneumostoma vent is clearly marked with the length of the pneumostoma vent. In addition, the pneumostoma vent can be color coded either on the cap or tube such that a particular color indicates a particular length of pneumostoma vent. At step 744, the patient removes the used pneumostoma vent by pulling on the flange or tabs. The patient cleans or disposes of the used pneumostoma vent as appropriate. At step 746, the patient removes a sterile cleaning swab from the chest mount package and cleans the chest mount or the area of the skin around the pneumostoma if no chest mount is used. The patient cleans in a direction radially out from the pneumostoma. At step 748 the patient inspects the tissue around the pneumostoma and the pneumostoma for inflammation or injury. If injury or inflammation is observed the patient should seek medical advice.

At step 750, the patient removes a new pneumostoma vent from the packaging. The patient does not directly touch the tube of the pneumostoma vent. Patient grips the flange or tabs of the new pneumostoma vent. At step 752, the patient removes the protective covering on the back of the pneumostoma vent exposing the adhesive. At step 754, the patient aligns the tip of the tube of the new pneumostoma vent with the pneumostoma and inserts the tube until the flange is in contact with the chest of the patient or the chest mount. Care is taken during steps 750, 752 and 754 to handle the pneumostoma vent only by the tabs and/or flange and not to touch the sterile tube of the pneumostoma vent. If pain or injury is perceived during insertion of pneumostoma vent the patient should seek medical advice. The steps of IFU 740 may also be performed by a caregiver or medical practitioner.

Accessories For Pneumostoma Management Devices

FIGS. 8A and 8B shows views of a pneumostoma plug 840 which may be used to protect the pneumostoma from the entry of foreign material during times or activities when a pneumostoma vent is not present in the pneumostoma or when it is necessary or desirable to close the pneumostoma for activities such as, for example, spirometry testing of lung function or swimming. As shown in FIG. 8A, pneumostoma plug 840 includes a cover 842 for covering the external aperture in the chest or chest mount 202. The cover 242 preferably conforms to the outside surface 235 of chest mount 202 or chest to form a functional seal of the aperture. If the exterior surface of cover 842 is subjected to increased pressure such as by water pressure when swimming, cover 842 is pushed into better contact with surface 235 making a better seal and precluding the entry of water. Pneumostoma plug 840 has a recessed handle 846 or similar gripping mechanism to allow plug 240 to be grasped by the patient and removed when necessary. One or more tabs 848 may be provided on the periphery of cover 842 to allow the cover to be grasped by the patient to remove pneumostoma plug 840. Tabs 848 may be provided instead of or addition to handle 846. Plug 840 is however preferably low profile so as to avoid being caught and removed accidentally during an activity. Cover 842 is coated on one side with a releasable adhesive 850 (shown in FIG. 8B) to secure the cover to the chest mount or chest of the patient. Adhesive 850 ensures that pneumostoma plug 840 stays in place and remains there until
removed by the patient. Note that cover 842 and chest mount engagement section 850 are large enough to preclude pneumostoma plug 840 from passing through the pneumostoma.

[00130] Referring again to FIGS. 8A and 8B, pneumostoma plug 840 includes a stopple 852 sized and configured to pass into the pneumostoma (and pass through the aperture of the chest mount if present) into the pneumostoma and to fill the pneumostoma tightly so as to prevent the entry or exit of material through the pneumostoma. Stopple 852 preferably has an atraumatic tip 854 which is soft, and or curved to facilitate insertion of stopple 852 and reduce irritation to the pneumostoma. Note that stopple 852 may be relatively short compared to a pneumostoma vent such that stopple 852 preferably does not penetrate beyond the end of the channel of pneumostoma. Stopple 852 may, alternatively, be as long as the pneumostoma vent the patient typically uses. Stopple 852 is preferably designed so as to preclude contact of stopple 852 with lung parenchymal tissue during vigorous activity. The surface of stopple 852 may also be provided with surface features such as ridges (not shown) to make a better seal of the pneumostoma. Pneumostoma plug 840 may be designed for use with or without a chest mount 202.

[00131] FIGS. 8C and 8D illustrate an alternative pneumostoma plug 860 designed to operate in conjunction with a pneumostoma vent 204. Pneumostoma plug 860 comprises a cover 862 designed to engage the flange 242 of pneumostoma vent 203 (it may also engage chest mount 202 if present). Note that pneumostoma plug 860 is designed such that it will not fit through the aperture of chest mount 202, if present, and will not fit entirely into the pneumostoma. Pneumostoma plug 860 is provided with a ring of releasable adhesive 864 to secure it to the top of pneumostoma vent 204. Adhesive 864 is preferably positioned so as not to contact filter 248. Pneumostoma plug 860 is also provided with a handle 866 and/or tab 868 to facilitate application and removal of pneumostoma plug 860. Pneumostoma plug 860 is designed to cover, obstruct and protect hydrophobic filter 248 to prevent material entering or exiting tube 240 during use. Unlike the pneumostoma plug 840 of FIGS. 8A-8B, pneumostoma plug 860 does not include a stopple 852. During use of plug 860 of FIGS. 8C and 8D, the channel of a pneumostoma 110 will contain the tube 240 of pneumostoma vent 204 as shown in FIG 8D. Pneumostoma plug 860 is non-porous and may be used to temporarily cover and/or seal a pneumostoma vent 204 during brief activities such as e.g. spirometry testing, showering or working in a dirty environment to prevent entry of material into the pneumostoma or exit of material from the pneumostoma. Note the pneumostoma plug 860 may be used with a pneumostoma vent 204 even where no chest mount 202 is used.

**Alternative Features And Embodiments**

[00132] FIGS. 9A-9H show views of alternative designs of pneumostoma vent. FIG. 9A shows an alternative pneumostoma vent 900 which has features within tube 904 designed to encourage migration of discharge (for example mucus and sputum) out of the lung and prevent it from re-entering the lung. These features may include baffles that preferentially allow discharge to travel along and out
of the inner lumen of the tube. As shown in FIG. 9A the interior surface of tube 904 is covered with an array of baffles 905 which point away from the aperture 906 in the distal end of tube 904. Discharge that enters tube 904 through aperture 905 is pushed towards filter 908 by air flow during exhalation. When the patient inhales, some air may enter through cap 908, however, the discharge is inhibited from traveling back towards aperture 905 by the shape of the baffles 905. Thus, discharge is collected in tube 904. The discharge is removed and disposed of when pneumostoma vent 900 is replaced.

[00133] FIG. 9B shows a pneumostoma vent 910 having external features on the surface of tube 914. External features such as rings or ridges may be utilized on a pneumostoma vent to make a better seal between the exterior of the pneumostoma vent and the interior of the channel of the pneumostoma. FIG. 9B shows a sectional view through two rings 915, 917 around the exterior surface of tube 914. These rings engage the channel of the pneumostoma to make a better seal. The rings 915, 917 serve to prevent leakage of mucus and discharge around tube 904. The rings 915, 917 also reduce the possibility of the entry of any materials into the pneumostoma other than through filter 918 and aperture 916.

[00134] FIG 9C shows an alternative pneumostoma vent 920 which has a plurality of side apertures 925 in order to facilitate entry of gases and/or discharge from a pneumostoma into the lumen of tube 924. Gases may leave tube 924 through filter 928 while discharge is retained within tube 924. One or more side openings 925 may be provided along tube 924 and/or close to the distal opening 926. The side openings 925 may be provided instead of, or in addition to, the opening 926 in the end of distal tip of tube 925. The side openings 925 permit gases and/or discharge to enter tube 924 even if one or more openings is occluded by tissue or other matter. Side openings may be provided in any of the pneumostoma vent tubes discussed in this application. The tube of a pneumostoma vent such as tube 924 may also be created from a porous material such that air may enter the lumen of the tube through the wall of the tube 924. The porous tube wall may be provided in addition to or instead of the presence of distal opening 926 or side openings 925. The tube of pneumostoma vent such as tube 932 may also be provided with features for maintaining the patency of the pneumostoma as shown in U.S. Patent Application Serial No. 12/030,006 entitled "Variable Parietal/Visceral Pleural Coupling" which is incorporated herein by reference.

[00135] FIG. 9D shows an alternative pneumostoma vent 930 which has features within tube 934 designed to absorb discharge and prevent it from re-entering the lung. As shown in FIG. 9D, tube 934 includes a layer of absorbent material 935 within the wall of tube 934. The absorbent material 935 is exposed where the tube 934 is penetrated by side openings 937 Discharge that enters tube 934 through side openings 937 is absorbed by absorbent material 935. Any discharge that enters tube 934 though side openings 937 and end opening 936 is retained within tube 934 by filter 938 which is mounted flush with flange 932. Thus, discharge is collected in tube 934. The discharge is removed and disposed of when pneumostoma vent 930 is replaced.
FIG. 9E shows an alternative pneumostoma vent 940 which has features within tube 944 designed to absorb discharge and prevent it from re-entering the lung. As shown in FIG. 9E, tube 944 includes a layer of absorbent material 945 coated on the inside of tube 944. The absorbent material 945 is exposed on the inside of tube 944 such that discharge that enters tube 944 through opening 946 is absorbed by absorbent material 945. Any excess discharge that enters tube 944 is retained within tube 944 by filter 948 which is interference fit within flange 942. Thus, discharge is collected in tube 944. The discharge is removed and disposed of when pneumostoma vent 940 is replaced.

FIG. 9F shows an alternative pneumostoma vent 950 which has features external to tube 954 designed to absorb discharge and prevent it from re-entering the lung. As shown in FIG. 9F, a ring of absorbent material 955 is positioned around the proximal end of tube 954 where it meets flange 952. During use, the absorbent material 955 is trapped between flange 952 and the skin of the patient surrounding the pneumostoma. Discharge that leaks from the pneumostoma around the tube 954 is absorbed by absorbent material 955. Any discharge that enters tube 954 is retained within tube 954 by filter 958 which is bonded to the surface of flange 952. Thus, discharge is collected in tube 954. The discharge is removed and disposed of when pneumostoma vent 950 is replaced.

FIG. 9G shows an alternative pneumostoma vent 960 which has features incorporated in flange 962 to absorb discharge and prevent it from re-entering the lung. As shown in FIG. 9G, disc of absorbent material 965 is laminated within a flexible flange 962. The flange 962 may be a laminate of polymers with an absorbent material in the middle which is flexible enough to conform to the chest of a patient. The flange 962 may be 3mm or less in thickness and more preferably approximately 1mm or less in thickness. The disc of absorbent material 965 is exposed around the proximal end of tube 964 where it meets flange 962. During use, the absorbent material 965 is exposed to the opening of the pneumostoma. Discharge that leaks from the pneumostoma around the tube 964 is absorbed by absorbent material 965. Any discharge that enters tube 964 is retained within tube 964 by filter 968. Filter 968 is attached to the proximal end of tube 964 by a plug 969. Plug 969 may be welded, bonded with adhesive or otherwise secured to tube 964 and/or flange 962 and operates in combination with flexible flange 962 to limit insertion of tube 964 into a pneumostoma. Thus, discharge is collected in tube 964 and flange 962. The discharge is removed and disposed of when pneumostoma vent 960 is replaced.

FIG. 9H shows an alternative pneumostoma management system 970 which has features incorporated in a chest mount 972 to absorb discharge and prevent it from re-entering the lung. As shown in FIG. 9H, a disc of absorbent material 975 is laminated within a flexible chest mount 972. The chest mount 972 may be a laminate of polymers with an absorbent material in the middle which is flexible enough to conform to the chest of a patient. The chest mount 972 may be 3mm or less in thickness and more preferably approximately 1mm or less in thickness. The disc of absorbent material 975 is exposed around the proximal end of tube 974 of pneumostoma vent 971 where it passes through chest mount 972. During use, the absorbent material 975 is exposed to the opening of the
pneumostoma. Discharge that leaks from the pneumostoma around the tube 974 is absorbed by absorbent material 975. Any discharge that enters tube 974 is retained within tube 974 by filter 978. Filter 978 is attached to the proximal end of tube 974 as described elsewhere. Thus, discharge is collected in tube 974 and chest mount 972. The discharge is removed and disposed of when pneumostoma vent 971 and chest mount 972 is replaced. One or more features to control and/or absorb discharge emanating from the pneumostoma, for example those features shown in FIGS. 9A-9F may be incorporated into pneumostoma vents and chest mounts of different design - for example those other pneumostoma vent designs described elsewhere in this application.

[00140] FIGS. 10A-D illustrate alternative configurations of adhesive on the distal surface 1032 of a pneumostoma vent 1000. Flange 1002 of pneumostoma vent 1000 has an adhesive material distributed thereon. In the absence of a chest mount, this adhesive is used to temporarily secure the flange 1002 of the pneumostoma vent 1000 to the chest of the patient. Adhesive materials may be hydrocolloid adhesives which absorb moisture while retaining good adhesiveness. However, even the best adhesives may cause irritation of the skin during prolonged exposure. Tissue irritation may result from merely from build up of moisture on the skin behind the pneumostoma vent 1000 regardless of the presence of any particular adhesive. However, the distribution of adhesive may be controlled so as to help reduce irritation to the skin of the patient.

[00141] One way to reduce the potential for irritation is by reducing the amount of time any particular portion of skin is in contact with adhesive and/or allowing the skin in regions behind pneumostoma vent 1000 to "breathe" when not in contact with adhesive. Thus, in some embodiments the adhesive may be provided in stripes or patches and absent in other stripes or patches. The adhesive areas may also be elevated slightly above the surface of flange 1002 such that non adhesive areas of flange 1002 do not contact the skin but leave a slight air gap through which air may circulate and/or moisture may escape. The adhesive patches themselves may comprise a breathable laminate and adhesive so that the prolonged attachment of the PMD does not irritate the skin. The adhesive patches may be arranged differently on different chest mounts so as to contact different regions of skin surrounding a pneumostoma. Alternatively the arrangement of adhesive patches may be the same on each chest mount but the registration of the patches may be changed by chance or deliberately each time a chest mount is replaced so that the adhesive patches contact different regions of skin surrounding a pneumostoma.

[00142] Referring now to FIG. 10A where the contact surface 1032 of a flange 1002 of a pneumostoma vent 1020 is shown. Adhesive pads 1034, 1035 are located on contact surface 1032 around tube 1004. The adhesive is selected so as to help maintain the correct position of pneumostoma vent 1020 without causing undue irritation to the skin of the patient. As shown in FIG. 10A, adhesive pads 1034, 1035 are provided in two discrete spaced-apart regions. Each adhesive pad 1034, 1035 preferably comprises a laminate structure with an inner plastic, paper or foam layer (e.g., closed-cell polyethylene foam) sandwiched between layers of adhesive. The adhesive pads 1034, 1035 are
elevated above contact surface 1032 by the thickness of the inner layer. Thus, only some portions of skin around a pneumostoma will be in contact with adhesive each time pneumostoma vent 1000 is changed. Different pneumostoma vents may be provided with different arrangements of adhesive patches. For example a second pneumostoma vent may have adhesive patches located in the empty areas 1036, 1037 of contact surface 1032 such that it will contact different areas of skin.

[00143] FIG. 10B shows a sectional view of pneumostoma vent 1020 along line B-B. FIG. 10B shows that contact surface 1032 is spaced apart from the skin of the patient when pneumostoma vent 1000 is applied. Air can circulate between the adhesive pads 1034, 1035. As previously described, the adhesive pads may be protected by a protector sheet that is removed prior to use of PMD 200. The pneumostoma vent 1000 is also provided with one or more tabs 1016 which are free of adhesive. These tabs 1016 allow a patient to grip the flange 1002 to gently peel the chest mount off the skin when it needs replacement.

[00144] Adhesive pads 1034, 1035 may alternatively be rings of hydrocolloid adhesive of approximately a millimeter in thickness and secured to flange 1002 with a transfer adhesive. Any medically approved water resistant pressure sensitive adhesive may be used to attach the pneumostoma vent to the skin of the patient, such as hydrocolloid adhesives, zinc oxide adhesives and hydrogel adhesives. Particularly effective adhesives in providing the desired adhesive properties to secure the pneumostoma vent to the skin of the wearer without irritation are formed from cross-linking polymers with a plasticizer to form a 3-dimensional matrix. Some useful adhesives are disclosed in WO 00/07637, WO 00/45866 WO 00/45766 and U.S. Pat. No. 5,543,151 which are incorporated herein by reference. The adhesive can be applied to the contact surface 1032 of flange 1002 by any means known in the art, for example slot coating, spiral, or bead application or printing.

[00145] Referring now to FIG. 10C where a different distribution of adhesive on contact surface 1042 of flange 1041 of a pneumostoma vent 1040 is shown. As shown in FIG. 10C, adhesive pads may be distributed in small patches 1042. The adhesive patches 1044 may cover a less than 100% of the contact area 1042. As shown in FIG. 10C, adhesive patches 1044 cover approximately half of the contact surface 1042 of pneumostoma vent 1040. Adhesive patches 1044 preferably cover from 10% to 50% of contact surface 1042. With the distribution pattern of FIG. 10C all pneumostoma vents may have the same distribution of adhesive. Because patches 1044 are small and evenly distributed, variations of the orientation of placement of pneumostoma vent 1040 will randomize the location of the patches 1044 relative to the skin of the patient such that a particular region of skin is only in contact with adhesive for a percentage of time similar to the percentage of coverage.

[00146] FIG. 10D illustrates an alternative method for rotating the portions of skin around a pneumostoma that are in contact with adhesive. As shown in FIG. 10D, pneumostoma vent 1050 has eight radial adhesive patches 1052. The patches are arranged in a regular pattern around tube 1058 such that the patches are interspersed with non-adhesive areas 1056. As shown in FIG. 10D, adhesive patches 1054 cover approximately half of the contact surface 1052 of pneumostoma vent 1050.
Adhesive patches 1054 preferably cover from 10% to 50% of contact surface 1052. A tab 1057 is aligned with one of the adhesive patches 1054. With the pneumostoma vent 1050 of FIG. 10D, the patient deliberately changes the orientation of tab 1057 relative to the pneumostoma each time a pneumostoma vent 1050 is changed. By changing the rotation of the pneumostoma vent 1050 the patient can change which portions of skin are in contact with adhesive patches 1054. The adhesive distribution pattern of FIG. 10D is also advantageous because air can circulate between adhesive patches 1054. The circulation of air allows moist air to exit from between the skin of the patient and flange 1051.

[00147] FIGS. 10E-10G illustrate an alternate pneumostoma vent 1060. As shown in FIG. 10E, pneumostoma vent 1060 has a flexible connector 1061 connecting flange 1062 and tube 1064. As illustrated in FIG. 10E, flexible connector 1061 may be formed in one piece with flange 1062 and tube 1061. An accordion or bellows-like flexible connector 1061 is shown. In alternative embodiments connector 1061 may be a separate joint/coupling/component or a region of flexible material. For example, a lower durometer material having more flexibility to allow bending but also having a wire reinforcement to prevent radial tube collapse. Flexible connector should be flexible enough to allow relative movement of flange 1062 and tube 1064 while providing sufficient stability to allow insertion of tube 1064 into a pneumostoma. Additionally, the connector should be selected so as not to prevent gases from escaping through the lumen of tube 1064. In alternative embodiments the flexible connector 1061 may form part of flange 1062 instead of tube 1064.

[00148] As shown in FIG. 10F, in some embodiments, flexible connector 1061 may be sufficiently flexible to allow flange 1062 to fold parallel to tube 1064. This is advantageous in that it reduces the size of packaging required to contain pneumostoma vent 1060. In many cases, a patient will change their pneumostoma vent daily. Thus, the space occupied by one month's supply of pneumostoma vents becomes considerable. By folding the flange 1062 parallel with the tube 1064, the overall packaging volume (height*length*width) for the pneumostoma vent 1060 can be significantly reduced. The reduction in volume weight and amount of packing increases the convenience to the patient. Additionally, the reduction in volume and packing materials required reduces associated shipping costs and expense.

[00149] As shown in FIG. 10G, a flexible connector 1061 may also be useful to facilitate insertion of tube 1064 into a pneumostoma 1068 which is oriented at an angle relative to the skin 114 of the patient. A pneumostoma 1068 may be formed at an angle during the pneumostomy procedure or may migrate slightly over time. The angle formed between the skin 114 of the chest 100 and the pneumostoma 1068 will depend not only upon the pneumostomy procedure but also the location of the pneumostoma and the patient's anatomy in the region of the pneumostoma 1068. If the flange 1062 is inflexibly mounted to the tube 1064, it will tend to pull up on one side of the pneumostoma and "dig in" on the other side of the pneumostoma - destabilizing the pneumostoma vent and causing the patient discomfort.
As shown in FIG. 10G, flexible connector 1061 is advantageous in that it allows flange 1062 to lay flat against the skin 114 of chest 100 while allowing tube 1064 to follow the channel of pneumostoma 1068. The flexible connector 1061 allows the pneumostoma vent 1060 to conform to the pneumostomas of a wide range of patients. Note that flexible connector is designed so as to allow variation in the relative angle of flange 1062 and tube 1064 without greatly impinging upon the lumen of tube 1064. However, for this application it is not essential that flexible connector permit flange 1062 and tube 1064 to be parallel to one another as the pneumostoma will more typically be oriented within forty-five degrees of perpendicular to the skin 114 of chest 100.

FIG. 10H illustrates an alternate pneumostoma vent 1070. As shown in FIG. 10H, pneumostoma vent 1070 has a flexible connector 1071 connecting flange 1072 and tube 1074. An accordion or bellows-like flexible connector 1071 is shown. As illustrated in FIG. 10H, flexible connector 1071 may be formed in one piece with flange 1072 and/or tube 1071. Flexible may alternatively be formed separately from flange 1072 and/or tube 1071 and securely attached to flange 1072 and/or tube 1071. Flexible connector 1071 may expand or contract in length thereby allowing adjustment to the length of pneumostoma vent 1070. The length of pneumostoma vent 1070 may be manually adjusted by stretching or compressing flexible connector 1071. The length of pneumostoma vent 1070 may be manually adjusted to suit a particular patient prior to insertion of tube 1074 into a pneumostoma. Additionally flexible connector 1071 may bend during insertion to facilitate insertion of tube 1074 into a pneumostoma which is oriented at an angle relative to the skin 114 of the patient. Additionally flexible connector 1071 may expand or contract in vivo thereby allowing the length of pneumostoma vent 1070 to adjust and accommodate movement of the pneumostoma as the patient moves. Additionally, flexible connector 1071 may be sufficiently flexible to allow flange 1072 to fold parallel to tube 1074 prior to use for reduced packaging volume.

FIG. 101 illustrates an alternate pneumostoma vent 1080. As shown in FIG. 101, pneumostoma vent 1080 has a spring 1081 an inner tube 1085 and outer tube 1084. Inner tube 1085 is connected to flange 1082. Spring 1081 is a polymer or metal spring and is preferably bonded at the proximal end inner tube 1085 and at the distal end to outer tube 1084. Spring 1081 may be a coil spring as shown or a leaf spring, or other elastic element. As shown outer tube 1084 is received over inner tube 1085 and can slide so that the overall length of pneumostoma vent 1080 may increase or decrease by compressing or stretching spring 1081. Spring 1081 may expand or contract in length thereby allowing adjustment to the length of pneumostoma vent 1080. The length of pneumostoma vent 1080 may be manually adjusted by stretching or compressing spring 1081. The length of pneumostoma vent 1080 may be manually adjusted to suit a particular patient prior to insertion of tube 1084 into a pneumostoma. Additionally spring 1081 may expand or contract in vivo thereby allowing the length of pneumostoma vent 1080 to adjust and accommodate movement of the pneumostoma as the patient moves.
FIG. 1OJ illustrates an alternate pneumostoma vent 1090. As shown in FIG. 1OJ, pneumostoma vent 1090 has a flexible connector 1091 formed at the end of an inner tube 1095. Inner tube 1095 is connected at the other end to flange 1092. Flexible connector 1091 is preferably formed in one piece with inner tube 1095 and then bonded at the distal end to outer tube 1094. As shown in FIG. 1OJ, outer tube 1094 is received over inner tube 1095 and can slide so that the overall length of pneumostoma vent 1090 may increase or decrease by compressing or stretching flexible connector 1091. Flexible connector 1091 may expand or contract in length thereby allowing adjustment to the length of pneumostoma vent 1090. The length of pneumostoma vent 1090 may be manually adjusted by stretching or compressing flexible connector 1091. The length of pneumostoma vent 1090 may be manually adjusted to suit a particular patient prior to insertion of tube 1094 into a pneumostoma. Additionally, flexible connector 1091 may expand or contract in vivo thereby allowing the length of pneumostoma vent 1090 to adjust and accommodate movement of the pneumostoma as the patient moves.

FIGS. 11A-B show exploded and sectional views of a pneumostoma management device comprising pneumostoma vent system 1100. Pneumostoma vent system 1100 is designed to be secured directly to the chest of the patient. FIG. 11A shows an exploded view of the main components of pneumostoma vent system. From left to right these components are carrier sheet 1101, adhesive cover 1102, filter 1104, vent 1106, and adhesive patch 1109 and washer 1110.

Adhesive cover 1102 is a thin porous biocompatible membrane which is adhesive on the surface facing the pneumostoma (the inner surface see 1126 in FIG. 6B) and non-adhesive on the outer surface 1120. A suitable material for adhesive cover 1102 is a thin polyurethane film bearing an acrylic adhesive - such materials are available from 3M of St. Paul, MN. The film is biocompatible as well as thin, strong, and breathable. Adhesive cover 1102 has an aperture 1103 large enough to allow air to exit through filter 1104. Aperture 1103 is preferably slightly smaller than filter 1104 so that annular cover can be used to secure filter 1104 to vent 1106. Exposed portions of annular adhesive cover 1102 are provided with a paper cover to protect the adhesive prior to use. Adhesive cover is releasably secured to a carrier liner 1101 for ease of handling during manufacture and application of the finished pneumostoma vent system 1100. Carrier liner 1101 is removed after the pneumostoma vent system 1100 has been correctly positioned in the pneumostoma. The carrier liner 1101 need not cover the entire adhesive cover 1102, but may be star-shaped or another shape different than the adhesive cover. This allows for ease of handling and placing the adhesive cover with reduced likelihood of creating bubbles and wrinkles in the adhesive cover during placement. The carrier liner may be arranged, for example, in a window configuration.

Filter 1104 is a circular disc of filter material. Filter 1104 is preferably a hydrophobic filter material. In a preferred embodiment, filter 1104 is a reticulated open cell polyurethane foam or an open cell polyurethane or polyester foam or melt blown polyethylene. Exemplary filter materials include Delpore® DP2001-10P, Delpore® DP2001-20P, and Delpore® DP2001-30P available from
Delstar Technologies, Inc. (Middletown, Delaware). Filter 1104 is larger than the proximal aperture 1123 in vent 1106 and is positioned over the proximal aperture 1123 to filter gases moving in and out of the vent 1106. Filter 1104 may be secured to vent 1106 by an adhesive, welding, or other bonding technology. In a preferred embodiment, filter 1104 is secured to vent 1104 with a ring of pressure sensitive adhesive. Filter 1104 is also secured to vent 1106 by adhesive cover 1102 instead of or in addition to other bonding techniques.

[00156] Vent 1106 comprises a tube 1120 for entering the pneumostoma. As previously discussed, tube 1120 has an atraumatic tip 1121 and one or more apertures 1122 in the distal end to allows gases and discharge to enter tube 1120 from a pneumostoma. Tube 1120 has a flange 1124 at the proximal end. Flange 1124 is formed in one piece with tube 1120. Filter 1104 is secured over proximal opening 1123 of vent 1106 as described in the previous paragraph. Vent 1106 may be made of a suitable plastic/thermoplastic polymer/thermoplastic elastomer. For example in one preferred embodiment vent 1106 is made of Pebax® a block copolymer with suitable mechanical and chemical properties available from Arkema (Colombes, France).

[00157] An efficient way to make tube 1120 and flange 1124 is illustrated in FIGS. 11E-I 11G. The process begins with extruded tube stock. The tube stock is cut to the approximate length required as shown in FIG. 11E which shows a length of extruded tube 1160. Vents may be readily manufactured in a range of lengths according to this method. Next, the proximal end of the tube 1160 is cut in half parallel to the long axis of the tube to a depth of 20 mm or so. The proximal end of tube 1160 is thus in two sections 1162, 1164. The proximal end of tube 1160 is then placed in a heated fixture to form the two wings 1166, 1168 of flange 1124. Any excess material is trimmed and the flange 1124 is finished as shown in FIG. 11G. In a preferred embodiment, wings 1166, 1168 extend at least 0.125 to 0.25 inches from the outer diameter of tube 1160 in order to secure tube 1160 to the remainder of pneumostoma vent system 1100. Tube 1160 may then be trimmed at the distal end to the exact length required. The distal end is then tipped using a heated fixture to form the distal end into the rounded distal tip 1121 of the finished vent 1106 as shown in FIG. 11H.

[00158] Another way to make vent 2006 is illustrated by pneumostoma vent 1190 of FIG. UN. Pneumostoma vent 1190 is made from two pieces. A washer-shaped flange 1192 and a tube 1194. The flange 1192 preferably has an outer diameter approximately twice the diameter of tube 1194. The aperture 1193 of flange 1192 is approximately the same size as the inner diameter of the proximal opening 1195 in tube 1194. Flange 1192 is preferably heat set to the proximal end of tube 1194 but may also be bonded to tube 1194 using adhesive, ultrasonic welding and/or other reliable methods of securing the components. As before, tube 1194 may be cut to length from extruded stock and then tipped at the distal end 1196 in a heated fixture either before or after attaching flange 1192 to the proximal end.

[00159] Referring again to FIGS. 11A and 11B, adhesive patch 1109 is preferably a biocompatible hydrocolloid material. Adhesive patch 1109 has a central aperture 1109 which is sized to fit vent 1106.
The hydrocolloid material is provided with a polymer layer and a transitional adhesive on the side facing flange 1124 in order to better secure adhesive patch 1109 to the flange and annular cover. Flange 1124 is too large to fit through aperture 1109. The polymer layer prevents aperture 1109 from deforming sufficiently for the flange 1124 to pass through aperture 1109. During assembly, the distal side of flange 1124 may also be bonded to the polymer layer of adhesive patch 1109 using, for example, pressure sensitive adhesive, UV-cured adhesive or ultrasonic welding. Adhesive patch 1109 is preferably less than 3mm thick and is more preferably, approximately 1 mm in thickness. Exposed portions of adhesive patch 1109 are provided with a paper cover to protect the hydrocolloid adhesive prior to use. Washer 1110 slides over vent 1106 and is bonded to adhesive patch 1109 and vent 1106. Adhesive patch 1109 is sandwiched between washer 1110 and flange 1124 thereby firmly securing adhesive patch 1109 to vent 1106.

[00160] Pneumostoma vent system 1100 is preferably preassembled when provided to the patient. FIG. H B shows a sectional view of pneumostoma vent system 1100 as assembled. Note that tube 1120 fits through the middle of adhesive patch 1109. Note also that flange 1124 is trapped between adhesive cover 1102 and adhesive patch 1109. In this embodiment, filter 1104 is also secured to vent 1106 by adhesive cover 1102. Exposed adhesive regions of adhesive cover 1102 and adhesive patch 1109 on the patient side of the pneumostoma vent system 1100 assembly are provided with protective covers 1105 (for example paper covers) to protect the adhesive during shipping and prior to use. The completed or partially completed pneumostoma vent system 1100 is provided as a sterile product to the patient or caregiver. The protective covers 1105 are peeled off prior to application of the pneumostoma vent system 1100 to the pneumostoma. After the pneumostoma vent is correctly positioned in the pneumostoma, the carrier liner 1101 is also removed.

[00161] FIGS. 11C and 11D show exploded and sectional views of an alternate pneumostoma vent system 1130. Pneumostoma vent system 1130 is designed for use without a chest mount although it could be adapted for use with a chest mount. FIG. 11C shows an exploded view of the main components of pneumostoma vent system 1130. From right to left these components are carrier sheet 1131, adhesive cover 1132, filter 1134, vent 1136, adhesive patch 1138 and protective cover 1135. No washer is present in this embodiment.

[00162] Adhesive cover 1132 is a thin porous biocompatible membrane which is adhesive on the surface facing the pneumostoma (the distal surface) and non-adhesive on the outer surface 1150 (the proximal surface). Adhesive cover 1132 has an aperture 1133 large enough to allow air to exit through filter 1134. Aperture 1133 is slightly smaller than filter 1134 so that adhesive cover 1132 can be used to secure filter 1134 to vent 1136. Cover 1135 protects the exposed adhesive areas of adhesive cover 1132 prior to use. Adhesive cover 1132 is releasably secured to a carrier liner 1131 for ease of handling during manufacture and application of the finished pneumostoma vent system 1130. Carrier liner 1131 is removed after the pneumostoma vent system 1130 has been correctly positioned in the pneumostoma.
[00163] Vent 1136 comprises a tube 1150 for entering the pneumostoma. As previously discussed, tube 1150 has an atraumatic tip 1151 and one or more apertures 1152 in the distal end to allow gases and discharge to enter tube 1150 from a pneumostoma. Tube 1150 has a flange 1154 at the proximal end. Flange 1154 is formed in one piece with tube 1150 for example by using the process described with respect to FIGS. 11E-I1H. Filter 1134 is a circular disc of filter material. Filter 1134 is preferably a hydrophobic filter material. Filter 1134 is larger than the proximal aperture 1153 in pneumostoma vent 1136 and is positioned over the proximal aperture 1153 of vent 1136 to filter gases moving in and out of the vent 1136 as shown in FIG 11D. In a preferred embodiment, filter 1134 is secured to vent 1136 with a ring of pressure sensitive adhesive (not shown). Filter 1134 is also secured to vent 1136 by adhesive cover 1132.

[00164] Adhesive patch 1138 is preferably a biocompatible hydrocolloid material. Adhesive patch 1138 has a central aperture 1139 which is sized to fit vent 1136. The hydrocolloid material is provided with a polymer layer and a transitional adhesive on the side facing flange 1154 in order to better secure adhesive patch 1138 to the flange and adhesive cover. Flange 1154 is too large to fit through aperture 1139. The polymer layer prevents aperture 1139 from deforming sufficiently for the flange 1154 to pass through aperture 1139.

[00165] Pneumostoma vent system 1100 is preferably preassembled when provided to the patient. FIG. 11D shows a sectional view of pneumostoma vent system 1130 as assembled. Note that tube 1150 fits through the middle of adhesive patch 1138. Note also that flange 1154 is trapped between adhesive cover 1132 and adhesive patch 1138. In this embodiment, filter 1134 is also secured to vent 1136 by adhesive cover 1132. Exposed adhesive regions of adhesive cover 1132 and adhesive patch 1138 on the patient side of the pneumostoma vent system 1130 assembly are provided with protective cover 1135 (for example a paper cover which may be in one or more parts) to protect the adhesive during shipping and prior to use. The protective covers 1135 are peeled off prior to application of the pneumostoma vent system 1130 to the pneumostoma. After the pneumostoma vent 1136 is correctly positioned in the pneumostoma, the carrier liner 1131 is also removed.

[00166] Pneumostoma vent system 1100 and alternate pneumostoma vent system 1130 may be applied to a pneumostoma in the same ways previously described. See, e.g., FIGS. 6C, 7A, 7B and accompanying text. The vent is inserted into the pneumostoma and the tube of the vent passes through the chest wall into the lung. Gases and discharge may enter the vent of the pneumostoma vent system through the distal aperture. The flange is secured to the skin of the patient by the adhesive patch and adhesive cover. The flange, patch and cover cooperate to secure the vent in position within the pneumostoma. Discharge may accumulate in the tube of the vent during use. Periodically or as needed, the pneumostoma vent system is removed, disposed of and replaced. Typically the pneumostoma vent system will be replaced daily.

[00167] The completed pneumostoma vent system 1100 or 1130 is typically provided as an assembled and sterilized product to the patient or caregiver. The adhesive patch 1109, 1138 adhesive
cover 1102, 1132, carrier liner 1101, 1131 and protective cover 1105, 1135 are thin and flexible and thus may be folded along side the tube 1120, 1150 of vent 1106, 1136 for packaging and transport. This is advantageous in that it reduces the size of packaging required to contain pneumostoma vent system 1100, 1130. In many cases, a patient will change their pneumostoma vent daily. Thus, the space occupied by one month’s supply of pneumostoma vents becomes considerable. By folding the outer portion of the pneumostoma vent system 1100, 1130 parallel with the tube 1120, 1150, the overall packaging volume (height*length*width) for the pneumostoma vent 1130 can be significantly reduced. The reduction in volume weight and amount of packing increases the convenience to the patient. Additionally, the reduction in volume and packing required reduces associated shipping costs and expense.

[00168] FIG. 11I shows an example of a pneumostoma vent system 1130 in a folded configuration for shipping and storage. As shown in FIG. 11I, the carrier liner 1131, adhesive cover 1132, adhesive patch 1138 and protective cover 1135 are all folded alongside tube 1150 of vent 1136. The pneumostoma a vent system 1130 is unfolded prior to removal of protective cover 1135 and application to the patient.

[00169] FIG. 11U shows an alternate packaging of pneumostoma vent system 1130. As shown in FIG. 11J, pneumostoma vent system 1130 is packaged with a mandrel 1180 and cover 1182. Mandrel 1180 is a disposable structural element made of plastic or foam. Mandrel 1180 is positioned in line with tube 1150 of vent 1136. The carrier liner 1131, adhesive cover 1132, adhesive patch 1138 and protective cover 1135 are all folded alongside mandrel 1180. Mandrel 1180 provides support for the components and a gripping point for insertion of tube 1150 into a pneumostoma. Protective cover 1135 holds the remaining components against mandrel 1180 until removed. Cover 1182 is a test-tube shaped plastic molding which protects tube 1150 up until insertion in the pneumostoma thereby helping to keep the tube 1150 free from contaminants.

[00170] To use the pneumostoma vent system 1130 as packaged in FIG. 11U, the patient grips mandrel 1180 with one hand and removes and discards cover 1182 with the other hand exposing tube 1150. This arrangement keeps tube 1150 free of contaminants and helps avoid handling of tube 1150 by the patient/caregiver. The patient then inserts tube 1150 into the pneumostoma 110 as shown in FIG 11K. The patient then peels of protective cover 1135, exposing the adhesive surfaces of adhesive cover 1132 and adhesive patch 1138 and releasing them from mandrel 1180 as shown in FIG 11L. The patient then pushes the adhesive surfaces of adhesive cover 1132 and adhesive patch 1138 against the skin 114 adjacent the pneumostoma 110 and applies pressure to carrier liner 1131 to smooth them down. Mandrel 1180 may be removed and discarded at this time. Carrier liner 1131 facilitates handling of adhesive cover 1132 which is designed to be flexible and breathable so as not to irritate the skin surrounding the pneumostoma. Carrier liner 1131 may now be peeled away and discarded as shown in FIG. 11M, leaving pneumostoma vent system 1130 correctly positioned and deployed with filter 1134 exposed. Tube 1150 is secured by adhesive patch 1138 and adhesive cover 1132 which, by
sandwiching flange 1154 hold tube 1150 in the desired position. Gases may now escape from the pneumostoma via tube 1150 and filter 1134.

Alternate Pneumostoma Management Systems With Chest Mounts

[00171] FIGS. 12A and 12B illustrate views of a pneumostoma management device ("PMD") 1200 in accordance with an embodiment of the present invention. PMD 1200 includes a chest mount 1202 which may be mounted to the skin of the patient and a pneumostoma vent 1204 which is fitted to the chest mount 1202. In a preferred embodiment pneumostoma vent 1204 is mounted through an aperture 1224 in chest mount 1202. Chest mount 1202 has a first coupling that engages a second coupling of the pneumostoma vent to releasably secure the pneumostoma vent 1204 to the chest mount 1202. As will be further described below, the join between the two components is engineered so as to ensure that pneumostoma vent 1204 cannot be over-inserted into the lung if it separates from chest mount 1202. In preferred embodiments, pneumostoma vent 1204 is formed from biocompatible/implantable polymers or biocompatible/implantable metals. In preferred embodiments, chest mount 1202 is also formed from biocompatible polymers or biocompatible metals. A patient will typically wear a PMD at all times and thus the materials should meet high standards for biocompatibility. Further description of suitable materials for manufacturing a PMD are provided in the Materials section below.

[00172] Pneumostoma vent 1204 includes a tube 1240 sized and configured to fit within the channel of a pneumostoma. Tube 1240 is stiff enough that it may be inserted into a pneumostoma without collapsing. Over time, a pneumostoma may constrict and it is one function of PMD 1200 to preserve the patency of the channel of the pneumostoma by resisting the natural tendency of the pneumostoma to constrict. A crush recoverable material may be incorporated into tube 1240 in order to make it crush recoverable. In one example, Nitinol, or another superelastic material, incorporated into tube 1240 will give the tube collapse resistance and collapse recovery properties.

[00173] Tube 1240 of pneumostoma vent 1204 is sufficiently long that it can pass through the thoracic wall and into the cavity of a pneumostoma inside the lung. Pneumostoma vent 1204 is not however so long that it penetrates so far into the lung that it might interfere with a major blood vessel. Fortunately, the larger blood vessels of the lung are located centrally and associated with the bronchi. Thus, the pneumostoma will typically only be adjacent to smaller peripheral blood vessels and risk from injury by the pneumostoma vent is small.

[00174] The length of tube 1240 required for a pneumostoma vent 1204 varies significantly between different pneumostomases. A longer tube 1240 is usually required in patients with larger amounts of body fat on the chest. A longer tube 1240 is usually required where the pneumostoma is placed in the lateral position 112 rather than the frontal position 110. Because of the variation in pneumostomases, pneumostoma vents 1204 are manufactured having tubes 1240 in a range of sizes and a patient is provided with a pneumostoma vent 1204 having a tube 1240 of appropriate length for the patient's pneumostoma. Tube 1240 may be from 30 to 120 mm in length and from 5 mm to 20 mm in
diameter depending on the size of a pneumostoma. A typical tube 1240 may be between 40 mm and 80 mm in length and between 8 mm and 12 mm in diameter. In alternative embodiments, a pneumostoma vent 1204 is made with a single length (such as 120 mm) of tube 1240 and tube 1240 is then cut to the length appropriate for a particular patient.

[00175] Tube 1240 of pneumostoma vent 1204 preferably comprises an atraumatic tip 1252 at the distal end as shown in FIGS. 12A and 12B. (This application uses the terms proximal and distal regarding the components of the pneumostoma management system in the conventional manner. Thus, proximal refers to the end or side of a device closest to the hand operating the device, whereas distal refers to the end or side of a device furthest from the hand operating the device.) Tip 1252 may be rounded, beveled or curved in order to reduce irritation or damage to the tissues of the pneumostoma or lung during insertion or while in position. Where a single length tube 1240 is provided and subsequently cut to length it is desirable that the tube be shaped such that at each of a plurality of cut points cutting will generate an atraumatic tip. This can be achieved, for example, by including a series of rounded narrow points on tube 1240.

[00176] The material and thickness of tube 1240 of pneumostoma vent 1204 is selected such that tube 1240 is soft enough that it will deform rather than cause injury to the pneumostoma or lung. Pneumostoma vent 1204 has an opening 1254 in tip 1252 of tube 1240. Opening 1254 allows the entry of gases from the cavity of the pneumostoma into lumen 1258 of tube 1240. Tube 1240 is optionally provided with one or more side openings (not shown) positioned near tip 1252 and/or along the length of tube 1240 to facilitate the flow of gas and/or mucous/discharge into lumen 1258.

[00177] Pneumostoma vent 1204 includes a cap 1242 and a hydrophobic filter 1248 over the opening 1255 in the proximal end of tube 1240. Hydrophobic filter 1248 is positioned over the proximal opening 1255 into lumen 1258. Hydrophobic filter 1248 is positioned and mounted such that material moving between lumen 1258 and the exterior of pneumostoma vent 1204 must pass through hydrophobic filter 1248. Hydrophobic filter 1248 is preferably designed such that it may be fits into a recess in cap 1242. As shown in FIG. 12B, cap 1242 comprises a recess 1238 into which hydrophobic filter 1248 may be fit. Hydrophobic filter 1248 may alternatively be fitted into cap 1242 using a joint such as a threaded coupling or adhesive or, in some cases, formed integrally with cap 1242. Hydrophobic filter 1248 may be made from a material such as medical grade GOR-TEX (W. L. Gore & Associates, Inc., Flagstaff, AZ). As shown in FIG. 12B, a snap ring 1243 locks cap 1242 and hydrophobic filter 1248 onto the proximal end of tube 1240.

[00178] Hydrophobic filter 1248 serves several purposes. In general, hydrophobic filter 1248 controls the passage of solid or liquid material between the lumen 1258 and the exterior of cap 1242. For example, hydrophobic filter 1248 prevents the flow of water into the lumen 1258 through proximal opening 1255. Thus, a patient using PMD 1200 may shower without water entering the lung through the pneumostoma. Hydrophobic filter 1248 may also be selected so as to prevent the entry of microbes, pollen and other allergens and pathogens into the lumen 1258. Hydrophobic filter 1248 also
prevents the exit of liquid and particulate discharge from lumen 1258 to the exterior of pneumostoma vent 1204. This is desirable to prevent contact between liquid and particulate discharge and clothing for example.

[00179] Chest mount 1202 connects to the proximal end of pneumostoma vent 1204. In one embodiment, illustrated in FIGS. 12A and 12B, chest mount 1202 comprises a flange 1222 and an aperture 1224. The aperture 1224 is adapted and configured to receive the pneumostoma vent 1204. Chest mount 1202 is designed to have a smooth surface and a low profile so it is comfortable for the patient to wear. Chest mount 1202 should be designed so as not to snag on the patient's clothing or to restrict motion of the patient's arm (if placed in a lateral pneumostoma 112). Flange 1222 is significantly wider than pneumostoma vent 1204. Flange 1222 thus comprises a contact surface 1232 which contacts the skin of the patient surrounding the pneumostoma and positions the aperture 1224 over the opening of the pneumostoma. Flange 1222 is designed such that it is sufficiently flexible that it can conform to the surface of the chest. Contact surface 1232 is also provided with a pad of biocompatible adhesive 1234, such as a hydrocolloid adhesive, for securing flange 1222 to the skin of the patient. The adhesive 1234 may be protected by a protector sheet that is removed prior to use of flange 1222. Adhesive 1234 should be selected so as to secure flange 1222 to the chest of the patient in the correct position relative to the pneumostoma without causing undue irritation to the skin of the patient. The adhesive need not create an air tight seal between flange 1222 and the skin of the patient. Suitable adhesive pads are available commercially from Avery Dennison (Painesville, OH).

[00180] Referring now to FIG. 12C which shows a perspective view of chest mount 1202 without pneumostoma vent 1204. Flange 1222 is generally circular but is provided with one or more tabs 1236 to facilitate application and removal of flange 1222 from the skin of the patient. As shown in FIG. 12C, chest mount 1202 comprises an aperture 1224 through which tube 1240 of pneumostoma vent 1204 may be inserted. Flange 1222 is slightly convex on the upper surface 1235. Flange 1222 includes a recess 1226 into which cap 1242 of pneumostoma vent 1204 may be press fit. Flange 1222 is thick enough in the region of aperture 1224 to receive the cap 1242 of pneumostoma vent 1204 so that the cap of pneumostoma vent 1204 is flush with the upper surface 1235 of flange 1222. Recess 1226 forms a coupling adapted to releasably secure the cap 1242 of pneumostoma vent 1204 into flange 1222. As shown in FIGS. 12B and 12C, recess 1226 has a lip 1227 to releasably secure the cap 1242 of pneumostoma vent 1204 into flange 1222. However, other couplings may be used to releasably secure pneumostoma vent 1204 to chest mount 1202 including clips, pins, snaps, catches, threaded joints, temporary adhesive and the like.

[00181] In a preferred embodiment, an aperture plate 1228 is embedded in the conformable polymer of flange 1222. FIG. 12D shows a perspective view of an aperture plate 1228 that is embedded within flange 1222 of chest mount 1202. Note that aperture plate 1228 surrounds aperture 1224 of chest mount 1202. Aperture plate 1228 is made of a stiffer, less compliant material than flange 1222 in order that the dimensions of aperture 1224 are tightly controlled. Because aperture plate 1228
is stiff enough that the size and shape of aperture 1224 remains stable even under any reasonably possible application of force to chest mount 1202.

[00182] Referring now to FIG. 12E which shows a perspective view of pneumostoma vent 1204 without chest mount 1202. Cap 1242 is attached to the proximal end of tube 1240. Hydrophobic filter 1248 is sandwiched between cap 1242 and tube 1240. An opening 1244 in cap 1242 communicates with the lumen 1258 of tube 1240 via hydrophobic filter 1248. As shown in FIGS. 12B and 12E, cap 1242 comprises a lip 1246 which releasably engages lip 1227 of recess 1226 of flange 1222 to secure pneumostoma vent 1204 within the recess 1226 of flange 1222. Lip 1246 forms a coupling element of pneumostoma vent 1204 that cooperates with recess 1226 to releasably secure pneumostoma vent 1204 into chest mount 1202 with tube 1240 positioned through aperture 1224.

[00183] FIG. 12F shows an exploded view of pneumostoma vent 1204 showing the individual components of pneumostoma vent 1204. Hydrophobic filter 1248 is sandwiched between tube 1240 and cap 1242. Tube 1240 has a flange 1241 at its proximal end. Snap ring 1243 slides over tube 1240. The inner diameter of snap ring 1243 is too small to pass over flange 1241 thus when snap ring 1243 is locked into cap 1242, tube 1240 is locked to cap 1242. It should be noted that the outer diameter of each of snap ring 1243, hydrophobic filter 1248, flange 1241 and cap 1242 is larger than the diameter of aperture 1224 of aperture plate 1228. Aperture plate 1228 is sufficiently stiff that the dimensions of aperture 1224 will not change even under loads significantly higher than would be expected during use of the device. Thus, snap ring 1243, hydrophobic filter 1248, flange 1241 and cap 1242 cannot pass through aperture 1224 into the pneumostoma. Distal tip 1252 of tube 1240 and the body of tube 1240 are small enough to pass through aperture 1224 however, flange 1241 and/or cap 1242 serve to limit the passage of tube 1240 through aperture 1224. These safety features prevent unsafe entry of any of the components of pneumostoma vent 1204 into pneumostoma even in the unlikely event of device failure. Likewise all the components of the chest mount 1202 such as flange 1222 and aperture plate 1224 are significantly larger than the aperture of a pneumostoma thus precluding passage of any component of the chest mount 1202 into a pneumostoma even in the unlikely event of device failure.

**Insertion Tool**

[00184] The pneumostoma management system may also include insertion and/or removal tools for use with pneumostoma vent 1204. The tools help control insertion and removal of pneumostoma vent 1204 and also help maintain sterility of pneumostoma vent 1204 before and during insertion into a pneumostoma. FIGS. 13A-13F show views of an insertion tool 1300 which forms part of the pneumostoma system according to one embodiment of the invention.

[00185] Referring now to FIG. 13A which shows an external view of insertion tool 1300. Insertion tool 1300 includes a casing 1340, having a handle 1360 at the proximal end and a grasper 1380 at the distal end. The tool also comprises an end cap 1320 at the distal end of casing 1340 (not shown in FIG 3A). When handle 1360 is pushed up against the distal end of casing 1340, grasper 1380 is configured
to lock to the cap of a pneumostoma vent. When handle 1360 is pulled away from casing 1340 in the
direction of arrow 1306, grasper 1380 is configured to release the cap of a pneumostoma vent.
Insertion tool 1300 includes an internal mechanism that allows handle 1360 to be moved away from
casing 1340 in the direction of arrow 1306 one time and then locks handle 1360 in place. Thus handle
1360 is a single use device. Handle 1360 is provided in sterile packaging, the one-time-use lock
protects the no-longer-sterile insertion tool from reuse.

[00186] FIG. 13B shows a sectional view of insertion tool 1300. Casing 1340 has a central lumen
1344 running from the proximal end to the distal end. End cap 1320 is designed such that it may be
snap fit into the proximal end of casing 1340 to lock together the components of insertion tool 1300
without the use of adhesive. End Cap 1320 has a step 1322 which is engaged by lip 1342 of casing
1340. End cap 1320 has an opening 1324 through which a portion of the handle 1360 is received. End
cap 1320 also has a tongue 1326 that protrudes into casing 1340.

[00187] Handle 1360 includes a mandrel 1362. In this embodiment the handle and mandrel are
formed in one piece. Mandrel 1362 comprises a square tab 1364 and a ramped tab 1366. Tabs 1364
and 1366 are on opposite sides of slot 1368 in mandrel 1362. Slot 1368 is sized and configured such
that mandrel 1362 is sufficiently flexible in the region of tabs 1364 and 1366 for the tabs to be pushed
towards each other slightly by compressing slot 1368. The portion of handle 1360 external to casing
1340 is too large to enter casing 1340 thus precluding over insertion.

[00188] Grasper 1380 comprises four arms 1382 attached to a tubular section 1381 (only two arms
shown in sectional view). Between the arms 1382 is a space 1384 for receiving mandrel 1362. The
space narrows slightly towards the distal end of the arms 1382 because arms 1382 ramp up slightly in
thickness towards the distal end. On the distal end of each of arm 1382 is a wedge 1390. In the tubular
section 1381 of grasper 1380 there is a proximal detent 1386 and a distal detent 1388 for receiving
ramped tab 1366 of mandrel 1362. In the tubular section 1381 of grasper 1380 there is also a slot 1392
opposite detents 1386 and 1388 for receiving square tab 1366 of mandrel 1362. The proximal end of
tubular section 1381 has a lip 1389 which engages a recess 1305 of the casing to fix the location of
grasper 1380 and preclude passage of grasper 1380 through casing 1340.

[00189] To assemble insertion tool 1300, mandrel 1362 is inserted through opening 1324 in end
cap 1320. Tabs 1364, 1366 are pushed towards one another compressing slot 1368 as the tabs pass
through opening 1324 which would otherwise be too narrow to allow tabs 1364, 1366 to pass. Mandrel
1362 is then inserted through the tubular section 1381 of grasper 1380 and between arms 1382 until
ramped tab 1366 is located in distal detent 1388 and square tab 1364 is located in slot 1392. Casing
1340 is then pushed over grasper 1380 until step 1322 of end cap 1320 engages lip 1312 at the
proximal end of casing 1340. Note that for ease of manufacturing, insertion tool comprises only four
components casing 1340, grasper 1380, handle 1360 and end cap 1320. Moreover, to ensure all failure
modes are as safe as possible, each of the grasper 1380, handle 1360 and end cap 1320 is too large to
pass through casing 1340 any further than is necessary for their function.
[00190] Insertion tool 1300 is assembled in its locked configuration as shown in FIGS. 13B and 13C. In this locked configuration of the insertion tool, as shown in FIG 3B, mandrel 1362 fills the space between 1384 between arms 1382 locking wedges 1390 outward as shown by arrows 1308. Ramped tab 1366 of mandrel 1362 is in distal detent 1386 of tubular section 1381. FIG. 13C shows a view of the distal end of insertion tool 1300 in the locked configuration note that each of arms 1382 has been forced to its outermost position by the presence of mandrel 1362 at the distal end of its travel in space 1384.

[00191] To release insertion tool 1300, handle 1360 is pulled in the direction shown by arrow 1306 relative to casing 1340. As shown in FIG. 13D, ramped tab 1366 is oriented such that the motion of handle 1360 in the direction 1306 compresses slot 1368 allowing ramped tab 1366 to pass out of distal detent 1386. Square tab 1364 rides in slot 1392 so that mandrel 1362 does not rotate relative to tubular section 1381. When ramped tab 1366 reaches proximal detent 1388, the slot 1368 is decompressed and ramped tab 1366 is pushed into proximal detent 1388. Note that ramped tab 1366 is oriented such that it is caught in proximal detent 1388 and cannot be returned from proximal detent 1388 to distal detent 1386. The travel of square tab 1364 is also limited by tongue 1326 of end cap 1320 so as to prevent removal of handle 1360 from casing 1340. Thus, handle 1360 is now fixed in the unlocked configuration.

[00192] In this unlocked configuration, shown in FIGS. 13D, 13E and 13F, the distal end of mandrel 1362 is retracted away from the distal end of casing 1340. Consequently space 1384 is vacant between arms 1382 of grasper 1380. As a consequence, wedges 1390 may move inward as shown by arrows 1310 because of the flexibility of arms 1382 no longer constrained by the presence of mandrel 1362. FIG. 13E shows a view of the distal end of insertion tool 1300 in the unlocked configuration note that each of arms 1382 has moved to an inner position because mandrel 1362 has been withdrawn from the distal end of space 1384. FIG. 13F shows a close-up of the distal end of insertion tool 1300 showing how inward displacement of arms 1382 because of retraction of mandrel 1362 allows wedges 1390 to disengage a cap 1242 of a pneumostoma vent 1204. Thus, in this unlocked configuration of the insertion tool 1300, insertion tool 1300 releases pneumostoma vent 1204 after insertion into a pneumostoma.

30 Removal Tool

[00193] The pneumostoma management system may also include insertion and/or removal tools for use with pneumostoma vent 1204. The tools help control insertion and removal of pneumostoma vent 1204 and also help maintain sterility of pneumostoma vent 1204 before and during insertion into a pneumostoma. FIGS. 14A-14F show views of a removal tool 1400 which forms part of the pneumostoma system according to one embodiment of the invention.

[00194] Referring now to FIG. 14A which shows an external view of removal tool 1400. Removal tool 1400, in this embodiment, comprises the same casing 1340, grasper 1380 and end cap 1320 as
insertion tool 1300. The structural difference between removal tool, 1400 and insertion tool 1300 is handle 1460. The starting position for handle 1460 is, as shown in FIG. 14A, spaced away from casing 1340. In this unlocked configuration grasper 1380 may be inserted into the cap of a pneumostoma vent. However when handle 1460 is pushed against casing 1340 as shown by arrow 1406, removal tool 1400 changes to the locked configuration and is secured to the cap of a pneumostoma vent allowing the pneumostoma vent to be removed from a chest mount. Removal tool 1400 includes an internal mechanism that only allows handle 1460 to be moved towards casing 1340 in the direction of arrow 1406 one time and then locks handle 1460 in place. Thus removal tool 1400 is a single use device. When removal tool 1400 is secured to a pneumostoma vent for removal, the removal tool and pneumostoma vent are locked to one another and are disposed of in that from. The one-time-use lock protects the no-longer-sterile removal tool and pneumostoma vent from reuse.

[00195] FIG. 14B shows a sectional view of removal tool 1400. The internal components of removal tool 1400 are the same as for insertion tool 1300 with the exception of handle 1460 and mandrel 1462. Handle 1460 and mandrel 1462 are formed in one piece. Note that mandrel 1462 comprises a square tab 1464 and a ramped tab 1466. Tabs 1464 and 1466 are on opposite sides of slot 1468 in mandrel 1462. Slot 1468 is sized and configured such that mandrel 1462 is sufficiently flexible in the region of tabs 1464 and 1466 for the tabs to be pushed towards each other slightly by compressing slot 1468. However, in mandrel 1462, ramped tab 1466 is ramped in the opposite direction to ramped tab 1366 of the insertion tool. Moreover, ramped tab 1466, square tab 1464 and slot 1468 are located such that in the unlocked configuration, ramped tab 1466 occupies proximal detent 1388 of grasper 1380 and square tab 1464 is at the proximal end of slot 1392. Note that for ease of manufacturing, removal tool 1400 and insertion tool 1300 share three out of four components. Thus, only five different components (casing 1340, grasper 1380, handle 1360, handle 1460 and end cap 1320) are required to make both the insertion tool 1300 and removal tool 1400. Moreover, to ensure all failure modes are as safe as possible, each of the grasper 1380, handle 1360, handle 1460 and end cap 1320 is too large to pass through casing 1340 any further than is necessary for their function.

[00196] Removal tool 1400 is assembled in the same way as insertion tool 1300; mandrel 1462 is first inserted through opening 1324 in end cap 1320. Tabs 1464, 1466 are pushed towards one another, compressing slot 1468 as the tabs pass through opening 1324, which would otherwise be too narrow to allow tabs 1464, 1466 to pass. Mandrel 1462 is then inserted through the tubular section 1381 of grasper 1380 and between arms 1382 until ramped tab 1466 is located in proximal detent 1388 and square tab 1464 is located in slot 1392. Casing 1340 is then pushed over grasper 1380 until step 1322 of end cap 1320 engages lip 1312 at the proximal end of casing 1340.

[00197] Removal tool 1400 is assembled in its unlocked configuration as shown in FIGS. 14B and 14C. In this unlocked configuration of the removal tool 1400, mandrel 1462 does not fill the space 1384 between arms 1382. Thus wedges 1390 can move inward as shown by arrows 1408. Ramped tab 1466 of mandrel 1462 is in proximal detent 1388 of tubular section 1381. FIG. 14C shows view of the
distal end of removal tool 1400 in the unlocked configuration. Note that each of arms 1382 can travel inwards because mandrel 1462 is not at the distal end of its travel in space 1384.

[00198] To secure removal tool 1400 to a pneumostoma tube, handle 1460 is pushed in the direction shown by arrow 1406 relative to casing 1340. As shown in FIG. 14D, ramped tab 1466 is oriented such that the motion of handle 1460 compresses slot 1468 allowing ramped tab 1466 to pass out of proximal detent 1388. Square tab 1464 rides in slot 1392 so that mandrel 1462 does not rotate relative to tubular section 1381. When ramped tab 1466 reaches distal detent 1386, the slot 1468 is decompressed and ramped tab 1466 is pushed into distal detent 1386. Note that ramped tab 1466 is oriented such that it is caught in distal detent 1386 and cannot be returned from distal detent 1388 to proximal detent 1388. Thus, handle 1460 is now fixed in the locked configuration. The travel of square tab 1464 is also limited by tongue 1326 of end cap 1320 so as to prevent removal of handle 1460 from casing 1340.

[00199] In the locked configuration of the removal tool shown in FIGS. 14D-14F, the distal end of mandrel 1462 is pushed into the distal end of casing 1340. Consequently mandrel 1462 fills space 1384 and pushes arms 1382 outward as shown by arrows 1410. FIG. 14E shows view of the distal end of removal tool 1400 in the locked configuration. Note that each of arms 1382 has moved to its outer position because mandrel 1462 has been pushed to the distal end of space 1384. FIG. 14F shows a close-up of the distal end of removal tool 1400 showing how outward displacement of arms 1382 by mandrel 1462 causes wedges 1390 to engage cap 1242 of a pneumostoma vent 1204. Thus, in this locked configuration of removal tool 1400, removal tool 1400 is secured to pneumostoma vent 1204 allowing it to be removed from the pneumostoma.

[00200] Insertion tool 1300 and removal tool 1400 do not contact the pneumostoma. Thus, the materials of insertion tool 1300 and removal tool 1400 do not have to be biocompatible and implantable materials. Suitable materials for making insertion tool 1300 and removal tool 1400 include medical grade metals, plastics, acrylics and resins. In a preferred embodiment, the insertion tool, removal tool and alignment tools may be made from ABS (Acrylonitrile-Butadiene-Styrene) plastic. In a preferred embodiment, the insertion and removal tool are made of the same material as aperture plate 1228 and cap 1242.

30 Use of The Pneumostoma Management System Having A Chest Mount

[00201] The pneumostoma management system is designed such that the system may be used by a patient in a sterile manner. After creating and healing of the pneumostoma the patient will be responsible for applying and removing the chest mount 1202 and the insertion, removal and disposal of pneumostoma vent 1204. The patient will exchange one pneumostoma vent 1204 for another and dispose of the used pneumostoma vent 1204. Pneumostoma vent 1204 will be replaced periodically, such as daily, or when necessary. The patient will be provided with a supply of pneumostoma vent 1204 by a medical practitioner or by prescription. Chest mount 1202 will also be replaced periodically,
such as weekly, or when necessary. The patient will also be provided with a supply of chest mount 1202 by a medical practitioner or by prescription. A one week supply of pneumostoma vent 1204 (such as seven pneumostoma vents 1204) may be conveniently packaged together with one chest mount 1202.

[00202] To use PMD 1200, chest mount 1202 is first positioned over a pneumostoma and secured with adhesive to the skin of the patient. In a preferred embodiment, the chest mount 1202 remains attached for up to a week thereby avoiding irritation of the skin caused by daily attachment and removal of a mount. FIG. 15A illustrates the positioning of chest mount 1202 over pneumostoma 110 and pneumostoma 112 of FIG. HA. As shown in FIG. 13A, the low profile of chest mount 1202 allows it to be inconspicuously positioned on the chest 100 of a patient in either the frontal 110 or lateral 112 locations. PMD 1200 is designed so as not to interfere with the range of motion or clothing of the patient. This is of importance for a device such as PMD 1200 which must be used continuously to be effective. Comfort and ease of use are important if patient compliance with treatment protocols is to be achieved. Chest mount may be positioned by the patient by manual alignment of the aperture 1224 of chest mount 1202 with the aperture of the pneumostoma. Alternatively, a pneumostoma vent or an alignment tool may be used to align the chest mount.

[00203] In one embodiment, the chest mount 1202 may be aligned with the pneumostoma 110 using a pneumostoma vent 1204 and optionally an insertion tool 1300. The chest mount 1202 may be provided to the patient with the pneumostoma vent 1204 and optional insertion tool as one assembly. Alternatively, the patient may insert the pneumostoma vent 1204 into the chest mount 1202 prior to applying chest mount 1202 to the chest. The patient then manipulates the chest mount 1202 by the tabs 1236 or insertion tool 1300. The patient places the tip of pneumostoma vent 1204 into the aperture 126 of the pneumostoma 110 and pushes the pneumostoma vent 1204 gently and slowly into the pneumostoma 110. During insertion the patient lets the pneumostoma vent 1204 align itself with the channel 120 of the pneumostoma 110 such that when the chest mount 1202 contacts and adheres to the skin 114 of the chest 100, the aperture 1224 of the chest mount 1202 is perfectly aligned with the aperture 126 of the pneumostoma 110. If an insertion tool 1300 was used, the patient then pulls gently on handle 1360 to detach the alignment tool 1300 from the pneumostoma vent 1204, leaving the chest mount 1202 and pneumostoma vent 1204 in place on the chest 100 of the patient.

[00204] Alternatively, an alignment tool may be used during positioning of chest mount 1202. FIGS. 15B and 15C show a chest mount alignment tool 1560 which aids positioning a chest mount 1202 and aligning the aperture 1224 of the chest mount 1202 with an aperture of a pneumostoma. The alignment tool 1560 comprises a handle section 1562 joined to a mount engagement section 1564 joined to a pneumostoma alignment probe 1566. The handle is designed to be gripped by the patient while applying the chest mount 1202. The handle 1562 allows the chest mount 1202 to be manipulated without direct handling of the chest mount 1202 by the patient. This reduces the risk of contaminating the chest mount 1202 and pneumostoma 110. Mount engagement section 1564 is shaped similarly to
the cap of a pneumostoma vent 1204 and is designed to fit into and engage the recess 1226 of a chest mount 1202. Like the cap of a pneumostoma vent, the mount engagement section 1564 is too large to pass through the aperture 1224 of an aperture plate 1228 and thus cannot be inserted too far through the chest mount 1202. However, the pneumostoma alignment probe 1566 fits through aperture 1224 and protrudes a short distance beyond the contact surface 1232 of the flange 1222. Pneumostoma alignment probe 1566 is preferably small enough that it will be suitable for use with all patients. Preferably the length of pneumostoma alignment probe 1566 is less than the length of the smallest available pneumostoma vent 1204. Alignment tool 1560 may be provided preassembled with a chest mount 1202 as shown in FIG 5B.

[00205] As shown in FIG. 15C, to apply the chest mount 1202 the patient uses handle 1562 to remove the chest mount 1202 from its sterile packaging. The patient then removes any protective covering over the adhesive on the contact surface 1232 of the chest mount 1202. The patient then places the tip of pneumostoma alignment probe 1566 into the aperture 126 of the pneumostoma 110 and pushes the probe gently and slowly into the pneumostoma 110. During insertion the patient lets the probe 1566 align itself with the channel 120 of the pneumostoma 110 such that when the chest mount 1202 contacts and adheres to the skin 114 of the chest 100, the aperture 1224 of the chest mount 1202 is perfectly aligned with the aperture 126 of the pneumostoma 110. The patient then pulls gently on handle 1562 to remove the alignment tool 1500, leaving the chest mount 1202 in place on the chest 100 of the patient ready to receive a pneumostoma vent. The alignment tool 1500 is preferably formed in one piece for ease of manufacturing and safety. The pneumostoma alignment probe 1566 preferably has a atraumatic tip 1568 which may be soft, and or rounded so as to avoid causing injury or irritation to the pneumostoma during insertion of the probe.

[00206] In an alternative embodiment, illustrated in FIG. 15D, an alignment tool 1510 includes only the mount engagement section 1564 and pneumostoma alignment probe 1566. In this embodiment, the mount engagement section 1564 has a recess similar to the recess in the proximal end of a pneumostoma tube 1202 for engaging a removal tool 1400 as shown in FIG. 14F. The alignment tool is supplied preassembled to a chest mount 1202. To use this alignment tool 1510, the patient first secures the removal tool 1400 to the alignment tool 1510. The patient then uses casing 1340 or removal tool 1400 to remove the chest mount 1202 from its sterile packaging. The patient then removes any protective covering over the adhesive on the contact surface of the chest mount 1202. The patient then guides the pneumostoma alignment probe into the pneumostoma channel 120 as before. When the chest mount 1202 is positioned correctly and adhered to the skin of the chest, the patient removes the removal tool 1400 and pneumostoma alignment tool 1500 in one piece by pulling gently on the casing 1340 of the removal tool 1400 leaving the chest mount in position on the chest of the patient. The patient the discards the removal tool 1400 and pneumostoma alignment tool 1500 locked together as one unit.
[00207] FIG. 16A shows a pneumostoma vent 1204 secured to an insertion tool 1300. In a preferred embodiment, pneumostoma vents 1204 are supplied to a patient in the configuration shown in FIG. 16A. Thus when pneumostoma vent 1204 is removed from its sterile packaging by the patient, the patient only touches insertion tool 1300 and does not touch the pneumostoma vent 1204. Note that insertion tool 1300 is in the locked configuration and insertion tool 1300 is securely attached to cap 1242 of pneumostoma vent 1204 by the grasper 1380.

[00208] FIG. 16B shows insertion of a pneumostoma vent 1204 through a chest mount 1202 into a pneumostoma. The patient grips insertion tool 1300 and pushes tube 1240 of pneumostoma vent 1204 through the aperture in chest mount 1202 in the direction of arrow 1602 until the cap 1242 of pneumostoma vent 1204 engages the chest mount 1202 as shown in FIG 6C. In this position, cap 1242 is secured by chest mount 1202. The patient pulls handle 1360 in the direction of arrow 1604. This causes insertion tool 1300 to change to its unlocked configuration. In the unlocked configuration, grasper 1380 releases cap 1242 of pneumostoma vent 1204. (See FIGS. 13D-13F). This allows insertion tool 1300 to be removed leaving pneumostoma vent 1204 in the correct position as shown in FIG 6D. Insertion tool 1300 is now fixed in the unlocked position and may be discarded.

[00209] FIG 16D shows a sectional view through PMD 1200 and pneumostoma 110 showing the interaction of the PMD 1200 with the pneumostoma 110. Tube 1240 of pneumostoma vent 1204 fits snugly within channel 120 of pneumostoma 110. Pneumostoma vent 1204 thus maintains the patency of channel 120. Tube 1240 of pneumostoma vent 1204 is sized and configured such that it penetrates through channel 120 into cavity 122 in the parenchymal tissue 132 of lung 130. Chest mount 1202 is secured to the skin 114 of the patient. Aperture plate 1228 engages cap 1242 of pneumostoma vent 1204 to prevent over insertion of pneumostoma vent 1204 into the pneumostoma. Adhesive 1234 contacts skin 114 holding PMD 1200 in position on the chest 100 of the patient. Because of the snug fit of tube 1240 of pneumostoma vent 1204 within channel 120 and the contact between chest mount 1202 and skin 114, PMD 1200 effectively controls the movement of all material (including solids, liquids and gases) in and out of the pneumostoma. Air flows from cavity 122 of pneumostoma 110 into lumen 1258 of tube 1240 of pneumostoma vent 1204 as shown by arrow 1606. From lumen 1258, exhaled air flows through hydrophobic filter 1248 and vents to atmosphere as shown by arrow 1608.

[00210] The pneumostoma vent 1204 is left in position in chest mount 1202. After a day (or if otherwise necessary) pneumostoma vent 1204 may be removed from chest mount 1202 using a removal tool 1400. As shown in FIG. 16E, the patient inserts the grasper 1380 of a removal tool 1400 in the direction of arrow 1610 into the cap 1242 of the pneumostoma vent 1204. When removal tool 1400 is positioned as shown in FIG. 16F, the patient pushes in handle 1460 in the direction shown by arrow 1612. This causes removal tool 1400 to change to the locked configuration in which grasper 1380 is securely attached to the cap 1242 of pneumostoma vent 1204 as shown in FIG. 16G (see also FIGS. 14D-14F).
The patient may now pull casing 1340 of removal tool 1400 in the direction of arrow 1614 as shown in FIG. 6H. Because the grasper 1380 of removal tool 1400 is locked to the cap 1242 of pneumostoma vent 1204 the pneumostoma vent 1204 is removed from the chest mount 1202. Pneumostoma vent 1204 is removed completely from the pneumostoma and remains locked to removal tool 1400 as shown in FIG. 161. Removal tool 1400 and pneumostoma vent 1204 may be discarded as a single unit and a new pneumostoma vent 1204 may be inserted into the pneumostoma as shown beginning with FIG. 16A.

FIG. 17A provides a set of instructions for use (IFU) 1720 for replacement of a chest mount according to an embodiment of the invention. At step 1722, the patient obtains the replacement chest mount and verifies that it is the correct size for his/her pneumostoma. At step 1724, the patient removes the prior chest mount and disposes of it as appropriate. At step 1726 the patient removes a sterile cleaning swab from the chest mount package. At step 1728 the patient cleans the area of the skin around the pneumostoma. The patient cleans in a direction radially out from the pneumostoma. At step 1730 the patient inspects the tissue around the pneumostoma and the pneumostoma for inflammation or injury. If injury or inflammation is observed the patient should seek medical advice.

At step 1732 the patient removes a new disposable (or sterilized reusable) chest mount from its packaging. At step 1734 the patient removes the backing from the adhesive pad of the chest mount. Care is taken during steps 1732 and 1734 to handle the chest mount only by the tabs and not to touch the surface which will be in contact with the pneumostoma. In embodiments having a pneumostoma alignment tool, the patient can handle the chest mount using the alignment tool rather than using the tabs of the chest mount. At step 1736 the patient applies the chest mount to the pneumostoma aligning the aperture of the chest mount with the aperture of the pneumostoma. Chest mount may be packaged with an alignment tool to assist in positioning chest mount correctly. If pain or injury is perceived during application the patient should seek medical advice. The steps of IFU 1720 may also be performed by a caregiver or medical practitioner.

FIG. 17B provides a set of instruction for use (IFU) 1740 for replacement of a pneumostoma vent according to an embodiment of the invention. At step 1742, the patient obtains the replacement pneumostoma vent and verifies that it is the correct size for his/her pneumostoma. The packaging of the pneumostoma vent is clearly marked with the length of the pneumostoma vent. In addition the pneumostoma vent can be color coded either on the cap or tube such that a particular color indicates a particular length of pneumostoma vent. At step 1744, the patient takes a removal tool, inserts the grasper of the removal tool into the cap of the used pneumostoma vent 1204 and pushes in the handle to secure the removal tool to the used pneumostoma vent. At step 1746 the patient removes the used pneumostoma vent by pulling on the casing of the removal tool. At step 1748 the patient inspects the pneumostoma for inflammation or injury. The area around the pneumostoma and the aperture of the chest mount may be cleaned at this point if mucus or discharge is present. If injury or inflammation is observed the patient should seek medical advice.
At step 1750 the patient removes a new pneumostoma vent from the packaging. Pneumostoma vent 1204 is already attached to an insertion tool so patient does not directly touch the pneumostoma vent. Patient grips the casing of the insertion tool to install the new pneumostoma vent. At step 1752 the patient aligns the tube of the new pneumostoma vent with the opening in the chest mount 1202 and inserts the pneumostoma vent using the insertion tool until the cap snaps into place. Care is taken during steps 1750 and 1752 to handle the pneumostoma vent only by the insertion tool and not to touch the sterile pneumostoma tube. At step 1754 the patient releases the insertion tool by pulling back on the handle to cause it to enter the unlocked configuration. At step 1756 the patient removes the insertion tool and discards it. If pain or injury is perceived during insertion of pneumostoma vent the patient should seek medical advice. The steps of IFU 1740 may also be performed by a caregiver or medical practitioner.

Packaging For Pneumostoma Management Systems

The components of the pneumostoma management system are preferably supplied to the patient in sterile packaging. In preferred embodiments the components are supplied in packaging that assists the patient in utilizing the components of the system in the correct sequence. FIGS. 18A and 18B show an example of packaging for a chest mount 1202 and a pneumostoma vent 1204 respectively.

Referring now to FIG. 18A which shows package 1800 for chest mount 1202. Package 1800 comprises a tray 1810 and a top cover 1820. Tray 1810 comprises a plurality of dimples 1812, 1814, 1816 sized and configured to fit the components provided in the package. In this example, dimple 1812 contains a first sterile cleaning swab 1832, dimple 1814 contains a second sterile cleaning swab 1834, and dimple 1816 contains the chest mount 1202. The top cover 1820 is secured to the surface of tray 1810 with an adhesive seal that can be broken by a patient peeling the adhesive from the opening tabs 1822, 1824. The top cover may be printed with material that assists the patient in the appropriate sequence of the steps for using the enclosed components. For example, a patient opening the package shown in FIG. 18A in peeling top cover 1820 from package 1800 first exposes first sterile cleaning swab 1832 for cleaning the pneumostoma, then second sterile cleaning swab 1834 for cleaning the pneumostoma, and finally and chest mount 1202 for application to the cleaned pneumostoma. Thus the package provides the components to the patient in the order required for use.

Referring now to FIG. 18B which shows package 1850 for pneumostoma vent 1204. Package 1850 comprises a tray 1860 and a top cover 1880. Tray 1860 comprises a plurality of dimples 1862, 1864 sized and configured to fit the components provided in the package. In this example, dimple 1862 contains a removal tool 1400, dimple 1864 contains an insertion tool 1300 assembled to a 65 mm pneumostoma vent 1204. The top cover 1870 is secured to the surface of tray 1860 with an adhesive seal that can be broken by a patient peeling the adhesive from the opening tab 1872. The top cover may be printed with material that assists the patient in the appropriate sequence of the steps for
using the enclosed components. For example, a patient opening the package shown in FIG. 18A in peeling top cover 1870 from package 1800 first exposes removal tool 1400 for removing the pneumostoma vent 1204 to be replaced. The patient then exposes the insertion tool 1300 and pneumostoma vent 1204. Thus the package provides the components to the patient in the order required for use. Additionally, the insertion tool 1300 is made accessible to the patient so that the patient does not handle pneumostoma vent 1204 directly. Note that the top cover is clearly marked with a size indicator 1874 so that patient may confirm that pneumostoma vent 1204 is the correct size for their pneumostoma prior to commencing the replacement procedure.

[00219] As previously noted, it may be desirable to replace the chest mount 1202 only every few days so as to avoid unnecessary irritation to the skin surrounding the pneumostoma. It may be desirable to replace the pneumostoma vent 1204 every day. Thus, chest mount 1204 is preferably provided in a separate sterile tray from the chest mount 1202. In preferred embodiments, a weekly kit may be provided having one chest mount 1204 and seven pneumostoma vents 1204. Thus, a weekly kit may be a single package including one of package 1800 of FIG. 18A and seven of package 1850 of FIG. 18B. Alternatively, the components may be provided as individual components separately packaged. For example, cleaning and moisturizing swabs may alternatively or additionally be packaged separately and provided to patient. The insertion tool, removal tool and pneumostoma vent may also be separately packaged.

Additional and Alternative Pneumostoma Management Device Features

[00220] It is not necessary that a flow-control device be used in a pneumostoma vent to form an airtight seal against the entry of air into the lung through the pneumostoma. Indeed, air may enter the lung through the pneumostoma between removal and reinsertion of the pneumostoma vent 1204. The pleurodesis of the pneumostoma prevents the entry of air into the pleural cavity which would otherwise cause pneumothorax. However, it is sometimes desirable to restrict flow of air in through the pneumostoma so as to encourage a reduction in hyperinflation and to preclude the aspiration of solid, liquid or gas into the lung through the pneumostoma. Thus, in alternative embodiments a pneumostoma vent may be provided with a flow control device instead of, or in addition to, the hydrophobic filter 1248. The flow-control device may comprise a one-way valve assembly such as a flapper valve, Heimlich valve, reed valve or the like for allowing air to be exhaled with very low resistance through the pneumostoma while restricting the flow of air or other matter into the pneumostoma from outside the body. A suitable flow-control device preferably includes only a small number of components for ease of manufacturing and reliability and should be designed such that it has no small parts which might be aspirated through the pneumostoma.

[00221] FIGS. 19A and 19B show the cap of a pneumostoma vent 1910 which includes an integrated flow control device and hydrophobic filter. Pneumostoma vent 1910 includes tube 1912, cap 1914, snap ring 1916 and filter/valve plate 1918. Tube 1912 has an aperture 1913 which is aligned
with a non-porous region 1917 of the filter/valve plate 1918. Filter valve plate 1918 is free to move slightly within the cap 1914 in response to air pressure. As shown in FIG. 19A, when the air pressure in tube 1912 is higher than the air pressure outside of cap 1914 the filter/valve plate 1918 moves away from tube 1912 and aperture 1913 thus allowing air to pass out of tube 1912 and through the porous hydrophobic filter region 1919 of filter/valve plate 1918 along path 1908. As shown in FIG. 19B, when the air pressure outside cap 1914 is higher than the air pressure inside tube 1912 the filter/valve plate 1918 moves towards tube 1912 and aperture 1913 thus blocking aperture 1913 with non-porous region 1917 of the filter/valve plate 1918 and preventing air from entering tube 1913 through the cap. Thus, the integrated flow control device and hydrophobic filter allows air to exit pneumostoma vent 1910 via the filter but operates as a one-way valve to prevent entry of air through the pneumostoma vent 1910. Note also that, as before, all parts of the cap and integrated valve/hydrophobic filter are too large to fit though the aperture of a chest mount to be used with the pneumostoma vent 1910 thereby precluding any failure mode in which a part of the pneumostoma vent is aspirated into the lung.

Optionally the filter/valve plate 1918 if FIGS. 19A and 19B may be biased closed with a light spring force that pushes the late into the closed position of FIG. 19B. The spring force is selected so that it is readily overcome by the exhalation air pressure allowing the filter/valve plate 1918 to move to the position shown in FIG 9A during exhalation. In an alternative embodiment, filter/valve plate 1918 may be a flexible disc that is fixed at the edges. During exhalation, the center of filter/valve plate 1918 bows outwards away from aperture 1913 allowing the escape of air. During inhalation, the external air pressure pushes filter/valve plate 1918 flat against aperture 1913 thus blocking aperture 1913 with non-porous region 1917 of the filter/valve plate 1918 and preventing air from entering tube 1913 through the cap.

FIG. 19C shows an alternative pneumostoma vent 1920 which has features within tube 1922 designed to encourage migration of discharge such as mucus and sputum out of the lung and prevent it from re-entering the lung. These features may include barbs/fins that preferentially allow discharge to travel along and out of the inner lumen of the tube. As shown in FIG. 19C, the interior surface of tube 1922 is covered with an array of barbs 1925 which point away from the aperture 1923 in the tube 1922. Mucus and sputum that enters tube 1922 through aperture 1923 is pushed towards cap 1924 by air flow during exhalation. When the patient inhales, some air may enter through cap 1924, however, the mucus and sputum is inhibited from traveling back towards aperture 1923 by the shape of the barbs. Thus discharge is collected in tube 1922. The discharge is removed and disposed of when pneumostoma vent 1920 is replaced. Also shown in FIG. 19C are external feature 1927 such as rings or ridges which may be utilized on a pneumostoma vent to make a better seal between the exterior of the pneumostoma vent and the interior of the channel of the pneumostoma.

FIG 9D shows an alternative pneumostoma vent 1930 which has a plurality of side apertures 1935 in order to facilitate entry of gases and/or discharge from a pneumostoma into the lumen 1938 of tube 1932. One or more side openings 1935 may be provided along tube 1940 and/or
close to the distal tip 1934. The side openings 1935 may be provided instead of, or in addition to, the opening 1933 in the end of distal tip 1934. The side openings 1935 permit gases and/or discharge to enter lumen 1938 even if one or more openings is occluded by tissue or other matter.

[00225] The tube of a pneumostoma vent such as tube 1932 may be created from a porous material such that air may enter the lumen of the tube through the wall of the tube. The porous tube wall may be provided in addition to or instead of the presence of distal opening 1933 or side opening 1935. The tube of pneumostoma vent such as tube 1932 may also be provided with features for maintaining the patency of the pneumostoma as shown in U.S. Patent Application Serial No. 12/030,006 entitled "Variable Parietal/Visceral Pleural Coupling" which is incorporated herein by reference.

[00226] FIGS. 19E and 19F shows views of a pneumostoma plug 1940 which may be used to protect the pneumostoma from the entry of foreign material during times or activities when a pneumostoma vent is not present in chest mount 1202. Or when it is necessary or desirable to close the pneumostoma for activities such as, for example, spirometry testing of lung function or swimming. As shown in FIG. 19E, pneumostoma plug 1940 includes a cover 1942 for covering the external aperture in chest mount 1202. The cover 1242 preferably conforms to the outside surface 1235 of chest mount 1202 to form a functional seal of the aperture. If the exterior surface of cover 1942 is subjected to increased pressure such as by water pressure when swimming, cover 1942 is pushed into better contact with surface 1235 making a better seal and precluding the entry of water.

[00227] Pneumostoma plug 1940 has a recessed handle 1946 or similar gripping mechanism to allow plug 1240 to be grasped by the patient and removed from chest mount 1202 when necessary. One or more tabs 1948 may be provided on the periphery of cover 1942 to allow the cover to be grasped by the patient to remove pneumostoma plug 1940. Tabs 1948 may be provided instead of or addition to handle 1946. Plug 1940 is however preferably low profile so as to avoid being caught and removed accidentally during an activity.

[00228] Below cover 1942 is a chest mount engagement section 1950 (shown in FIG. 19F) which is shaped similarly to the cap of a pneumostoma vent in order to engage the recess of the chest mount. Chest mount engagement section ensures that pneumostoma plug 1940 snaps into place in chest mount 1202 and remains there until removed by patient. Note that cover 1942 and chest mount engagement section 1950 are large enough to preclude pneumostoma plug 1940 from passing through the aperture of the chest mount 1202.

[00229] The only region of pneumostoma plug 1940 that can pass through the aperture of the chest mount is stopple 1952. Stopple 1952 is sized and configured to penetrate through the aperture into the pneumostoma and to fill the pneumostoma tightly so as to prevent the entry or exit of material through the pneumostoma. Stopple 1952 preferably has an atraumatic tip 1954 which is soft, and or curved to facilitate insertion of stopple 1952 and reduce irritation to the pneumostoma. Note that stopple 1952 is relatively short compared to a pneumostoma vent such that stopple 1952 preferably does not penetrate beyond the end of channel of pneumostoma. Stopple 1952 preferably does not penetrate into cavity so
as to preclude contact of stopple 1952 with lung parenchymal tissue during vigorous activity. The surface of stopple 1952 may also be provided with surface features such as ridges (not shown) to make a better seal of the pneumostoma.

FIGS. 19F and 19G illustrate an alternative pneumostoma plug 1960 designed to operate in conjunction with a pneumostoma vent 1204. Pneumostoma plug 1960 comprises a cover 1962 designed to engage the top surface 1235 of a chest mount 1202. Note that pneumostoma plug 1960 is designed such that it will not fit through the aperture of chest mount 1202 even if pneumostoma vent 1204 is absent. Pneumostoma plug 1960 is provided with a ring of releasable adhesive 1964 to secure it to the top surface 1235 of chest mount 1202. Pneumostoma plug 1960 is provided with a handle 1966 or tab 1968 to facilitate application or removal of pneumostoma plug 1960. Pneumostoma plug 1960 is designed to fill the portion of the recess of chest mount 1202 not filled by pneumostoma vent 1204. Unlike the pneumostoma plug 1940 of FIGS. 19E-19F, pneumostoma plug 1960 does not include a stopple 1952. During use of plug 1960, the channel of a pneumostoma will contain the tube 1240 or pneumostoma vent 1204. Pneumostoma plug 1960 is non-porous and may be used to temporarily cover and/or seal a pneumostoma vent 1204 during brief activities such as e.g. spirometry testing, showering or working in a dirty environment.

FIGS. 20A-20D illustrate alternative configurations of adhesive on the contact surface 1232 of a chest mount 1202. Flanges 1222 of each chest mount 1202 have adhesive material 1234 distributed thereon. Adhesive materials may be hydrocolloid adhesives which absorb moisture while retaining good adhesiveness. However, even the best adhesives may cause irritation of the skin during prolonged exposure. Tissue irritation may result from merely from build up of moisture on the skin behind PMD 1200 regardless of the presence of any particular adhesive. However, the distribution of adhesive 1234 may be controlled so as to help reduce irritation to the skin of the patient. One way to achieve this is by reducing the amount of time any particular portion of skin is in contact with adhesive and/or allowing the skin in regions behind PMD 1200 to "breathe" when not in contact with adhesive 1234. Thus, in some embodiments the adhesive may be provided in stripes or patches and absent in other stripes or patches. The adhesive areas may also be elevated slightly above the surface of flange 1222 such that non-adhesive areas of flange 1222 do not contact the skin but leave a slight air gap through which air may circulate and/or moisture may escape. The adhesive patches themselves may comprise a breathable laminate and adhesive so that the prolonged attachment of the PMD does not irritate the skin. Furthermore, a chest mount may be provided with one or more tabs which are free of adhesive. These tabs allow a patient to get a purchase on the chest mount to gently peel the chest mount off the skin when it needs replacement. The adhesive patches may be arranged differently on different chest mounts so as to contact different regions of skin surrounding a pneumostoma. Alternatively the arrangement of adhesive patches may be the same on each chest mount but the registration of the patches may be changed by chance or deliberately each time a chest mount is replaced so that the adhesive patches contact different regions of skin surrounding a pneumostoma.
Referring now to FIG. 2OA where the contact surface 1232 of a flange 1222 of a chest mount 1020 is shown. Adhesive pads 1034, 1035 are located on contact surface 1232 around aperture 1224. The adhesive is selected so as to help maintain the correct position of chest mount 1020 without causing undue irritation to the skin of the patient. As shown in FIG. 2OA, adhesive pads 1034, 1035 are provided in two discrete spaced-apart regions. Each adhesive pad 1034, 1035 preferably comprises a laminate structure with an inner plastic, paper or foam layer (e.g., closed-cell polyethylene foam) sandwiched between layers of adhesive. The adhesive pads 1034, 1035 are elevated above contact surface 1232 by the thickness of the inner layer. Thus, only some portions of skin around a stomata will be in contact with adhesive each time chest mount 1020 is changed. Different chest mounts may be provided with different arrangements of adhesive patches. For example a second chest mount may have adhesive patches located in the empty areas 1036, 1037 of contact surface 1232 such that it will contact different areas of skin. FIG. 2OB shows a sectional view of chest mount 1020 along line B-B. FIG. 2OB shows that contact surface 1232 is spaced apart from the skin of the patient when chest mount 1020 is applied. Air can circulate between the adhesive pads 1034, 1035. As previously described, the adhesive pads may be protected by a protector sheet that is removed prior to use of PMD 1200.

Any medically approved water resistant pressure sensitive adhesive may be used to attach the chest mount to the skin of the patient, such as hydrocolloid adhesives, zinc oxide adhesives and hydrogel adhesives. Particularly effective adhesives in providing the desired adhesive properties to secure the chest mount to the skin of the wearer without irritation are formed from cross-linking polymers with a plasticizer to form a 3-dimensional matrix. Some useful adhesives are disclosed in WO 00/07637, WO 00/45866 WO 00/45766 and U.S. Pat. No. 5,543,151 which are incorporated herein by reference. The adhesive can be applied to the contact surface 1232 of flange 1222 by any means known in the art such as slot coating, spiral, or bead application or printing.

Referring now to FIG. 2OC where a different distribution of adhesive on contact surface 1232 of a chest mount 1040 is shown. As shown in FIG. 2OC, adhesive pads may be distributed in small patches 1042. The adhesive patches 1042 may cover a less than 100% of the contact area 1232. As shown in FIG. 2OC, adhesive patches 1042 cover approximately half of the contact surface 1232 of chest mount 1040. Adhesive patches preferably cover from 10% to 50% of contact surface 1232. With the distribution pattern of FIG. 2OC all chest mounts may have the same distribution of adhesive. Because patches 1042 are small and evenly distributed, variations of the orientation of placement of chest mount 1040 will randomize the location of the patches 1042 relative to the skin of the patient such that a particular region of skin is only in contact with adhesive for a percentage of time similar to the percentage of coverage.

FIG. 2OD illustrates an alternative method for rotating the portions of skin around a pneumostoma that are in contact with adhesive. As shown in FIG. 2OD, chest mount 2050 has eight radial adhesive patches 2052. The patches are arranged in a regular pattern such that the patches are
interspersed with non-adhesive areas 2054. As shown in FIG. 2OD, adhesive patches 2052 cover approximately half of the contact surface 1232 of chest mount 2040. Adhesive patches preferably cover from 10% to 50% of contact surface 1232. A tab 1236 is aligned with one of the adhesive patches 2052. With the chest mount 2050 of FIG. 2OD, the patient deliberately changes the orientation of tab 1236 relative to the pneumostoma each time a chest mount is changed. By changing the rotation of the chest mount 2050 the patient can change which portions of skin are in contact with adhesive patches 2052.

[00236] The functional purpose of the chest mount is: providing an aperture; positioning the aperture in alignment with a pneumostoma; providing a contact surface with which to secure the chest mount to the patient; and providing a coupling to releasably receive a pneumostoma vent and secure the pneumostoma vent through the aperture into the pneumostoma. Thus, different designs of chest mount 2060 may be made without departing from the scope of the invention. FIG. 2OE illustrates an alternative design of a chest mount 2060. Chest mount 2060 is formed in one piece and does not comprise separate flange 1222 and aperture ring 1228 components. As all the components of chest mount 2060 are made from the same material, the desired mechanical properties of portions of chest mount 2060 are achieved by changing design parameters. For example, the desired conformability is achieved in the flange region 2062 of chest mount 2060 by reducing the thickness of the material. Cavity 2064 allows for a reduced thickness of material while maintaining the overall shape of chest mount 2060. The material of chest mount 2060 is also thicker in region 2066 in the vicinity of aperture 1224 so as to make the material around aperture stiffer in order to control the dimensions of aperture 1224.

**Pneumostoma Management System Including A Cover**

[00237] In order to encourage compliance with the treatment protocols its is useful to provide a protective and/or cosmetic cover for a pneumostoma management device. A pneumostoma management system can thus be provided which includes a pneumostoma management device and a cover. The cover serves to protect the pneumostoma management device and/or provide a cosmetic skin to make the pneumostoma management device more acceptable to the patient and thereby encourage patient compliance with a pneumostoma treatment regimen.

[00238] FIGS. 21A-21C illustrate views of a pneumostoma management system 2100 including a pneumostoma management device ("PMD") 1200 and a cover 2102 in accordance with an embodiment of the present invention. PMD 1200 is as previously described with respect to FIGS. 12A-12F. FIG. 21A shows a partial cutaway view of cover 2102 mounted to PMD 1200. Cover 2102 comprises a plurality of apertures 2104 through which air may pass from pneumostoma vent 1204. As shown in FIG. 21A, cover 2102 is somewhat dome shaped so as to fit over the surface of PMD 1200. Cover 2102, obscures the proximal side of PMD 1200 including flange 1222 and filter 1248. Cover
2102 provides a protective and/or cosmetic function. The front surface 2108 of cover 2102 may be treated to change the appearance of pneumostoma management system 2100.

[00239] Referring now to FIG. 21B, cover 2102 is preferably retained by PMD 1200 by clips, detents, tabs and the like. Cover 2102 is preferably press-fit to PMD 1200. Cover 2102 may also be adhered to PMD 1200 using an adhesive, for example, a releasable adhesive. In some embodiments, flange 1222 of PMD 1200 may have features at its perimeter that engage features of cover 2102 to retain cover 2102. For example, as shown in FIG. 2B, a plurality of clips 2106 of cover 2102 engage the perimeter of flange 1222. Cover 2102 is thus securely but releasably held to flange 1222. In other embodiments recess 1226 of flange 1222 may have features that engage features of cover 2102 to retain cover 2102.

[00240] Referring now to FIG. 21C which shows a perspective view of cover 2102. Cover 2102 is generally circular but is provided with one or more indents 2110 sized and positioned to fit over tabs 1236 of flange 1222. As shown in FIG. 21C, cover 2102 comprises a plurality of apertures 2104 through which air may pass to and from pneumostoma vent 1204. In some embodiments, cover 2102 is designed so that it does not obstruct air flow to and from pneumostoma vent 1204. This can be achieved by aligning the one or more apertures 2104 with hydrophobic filter 1248 (see FIG 21B). However, as shown in FIG. 21C, apertures 2104 can also be arranged out-of-line with hydrophobic filter 1248 and cover 2102 can be spaced from cap 1242 to allow air flow. Where apertures 2104 are out-of-line with hydrophobic filter 1248, cover 2102 also serves to protect hydrophobic filter 1248 from mechanical injury.

[00241] In alternative embodiments, cover 2102 is designed for intermittent use. In such embodiments, cover 2102 may partially or completely obstruct the air flow to and from pneumostoma vent 1204. Thus cover 2102 may be a protective cover that a patient applies to PMD 1200 when the patient engages in activities that might damage hydrophobic filter 1248 or expose the patient to noxious gas or vapor which might pass through hydrophobic filter 1248 and harm the pneumostoma. Cover 2102 may also be a cosmetic cover that a patient applies to PMD 1200 when the patient engages in activities or wears clothes which expose the region of the chest where PMD 1200 is located (for example wearing a swimsuit).

Use of A Pneumostoma Management System Having A Cover

[00242] FIG. 22A illustrates the positioning of pneumostoma management system 2100 over pneumostoma 110 and pneumostoma 112 of FIG. 1A. As shown in FIG. 22A the low profile of the pneumostoma management system 2100 allows it to be inconspicuously positioned on the chest 100 of a patient in either the frontal 110 or lateral 112 locations. The pneumostoma management system 2100 is designed so as not to interfere with the range of motion or clothing of the patient. The cover 2102 of pneumostoma management system 2100 is designed to provide a protective and/or cosmetic exterior to PMD 1200. This is of importance for a device such as PMD 1200 which should be used
continuously to be effective. Comfort, ease of use and patient acceptance are important if patient compliance with treatment protocols is to be achieved.

[00243] To use PMD 1200, chest mount 1202 is first positioned over a pneumostoma and secured with adhesive to the skin of the patient. In a preferred embodiment, the chest mount remains attached for up to a week thereby avoiding irritation of the skin caused by daily attachment and removal of a mount. Chest mount may be positioned by the patient by manual alignment of the aperture of chest mount 1202 with the aperture of the pneumostoma. Alternatively a pneumostoma vent or an alignment tool may be used to align the chest mount. Cover 2102 may be secured to PMD 1200 after PMD 1200 has been correctly positioned relative to the pneumostoma.

[00244] As shown in FIG. 3A, cover 2102 is designed to cover all or almost all of a PMD 1200. Thus cover 2102 can serve a number of purposes. First, cover 2102 can protect PMD 1200 and in particular pneumostoma vent 1204 (not shown in this view) from damage. Second cover 2102 can conceal PMD 1200. Cover 2102 can conceal PMD 1200 by presenting an exterior surface that is colored to match the patient's skin tone. A number of covers 2100 may be provided in a range of colors from which a patient may select a color that most closely matches their skin-tone at the implant location. Alternatively, Cover 2102 may be custom colored to more closely match the patient's skin-tone. Alternatively, the color of cover 2102 may be selected so as to be inconspicuous relative to the clothing of the patient. Thus the color of cover 2102 may be selected to be a matching color or complimentary color to the patient's clothing. Cover 2102 may be colored blue for example to match blue clothing. The patient may be supplied with a variety of covers to choose from depending on their clothing for a day.

[00245] In alternative embodiments, cover 2102 may be embellished rather than concealed so as to appear to comprise jewelry, a tattoo of the like. Additionally, cover 2102 may be made available in a wide variety of colors and styles without changing the underlying PMD 1200. This is important as alteration to PMD 1200 may require regulatory approval. The different options for the appearance of cover 2102, allow the patient to be comfortable with the PMD without being self conscious. Patient comfort and confidence promotes compliance with protocols for the maintenance of the pneumostoma thereby promoting the health of the patient.

[00246] FIG. 22B shows an alternative cover 2200 in which the cover comprises a large number of small apertures 2202. Apertures 2202 may be approximately 2 mm or less in diameter. Where apertures 2202 are sufficiently small they will not noticeable to the casual observer and will not interfere with the function or cosmetic appearance of cover 2200. However, where there are a large number of small apertures 2202, the apertures, as a group, will allow for sufficient air flow in and out of the pneumostoma vent without undue resistance.

[00247] FIG.22C illustrates an alternative cover 2210 having an ornamental design 2212 in the form of a flower on the outward facing surface (proximal surface). Cover 22100 provides an example of an embellished cover rather than a concealing cover. The ornamental design may be selected from a
range or ornamental design or may be customized by the patient or to the patient's requirements. In some cases, the ornamental design may be printed on a preformed cover using a printer adapted (if necessary) to print on the shape of the surface of the cover.

[00248] In some cases, the pneumostoma management device is replaced periodically such as weekly and/or daily. Covers may be designed so that they may be removed from the pneumostoma management device and then reused on the next pneumostoma management device. Thus, the cover, may, in some circumstances be used for a period of time significantly longer than the components of the PMD which are in direct contact with the patient. Preferably the cover will be made of a material that may be cleaned from time to time. Alternative covers may be designed to be disposable.

Alternative Pneumostoma Management Systems Having Covers

[00249] FIG. 23A illustrates an alternative pneumostoma management system 2300 including a cover 2360 and a pneumostoma management device ("PMD") 2301 in accordance with an embodiment of the present invention. PMD 2301 comprises an implantable sleeve 2310 joined at its proximal end 2311 with a bulb 2320 which may be mounted to the skin of the patient. In a preferred embodiment sleeve 2310 is formed in one piece with bulb 2320. In preferred embodiments, cover 2360, sleeve 2310 and bulb 2320 are formed from biocompatible polymers or a biocompatible metal such stainless steel.

[00250] Sleeve 2310 preferably comprises a rounded distal tip 2312 in order to reduce irritation of damage to the tissues of the pneumostoma or lung during insertion or while in position as shown in FIG. 23A.. Sleeve 2310 has an opening 2314 in tip 2312. Opening 2314 allows the entry of gases from the cavity of the pneumostoma into sleeve 2310 and thence via the lumen 2318 of sleeve 2310 to the bulb 2320.

[00251] Bulb 2320 is connected to the proximal end 2311 of sleeve 2310. In one embodiment, illustrated in FIGS. 23A and 23B, bulb 2320 comprises a flange 2322 and a dome 2324. The flange 2322 and dome 2324 define a chamber 2326. The chamber 2326 has an entrance aperture 2328 and at least one exit aperture 2330. Exhaled air and solid material may flow from lumen 2318 of sleeve 2310 into chamber 2326 through entrance aperture 2328. Exhaled air may exit chamber 2326 through exit aperture 2330 to vent to atmosphere outside of the patient's body. For simplicity of manufacturing, flange 2322, and dome 2324 may be formed in one piece as shown in FIG 23B. Bulb 2320 has a smooth surface and a low profile so it is comfortable for the patient to wear. Bulb 2320 is designed so as not to snag on the patient's clothing or to restrict motion of the patient. Chamber 2326 is sized and configured to receive liquid and/or solid material 2390 such as mucous which may be exhaled from the lung through the pneumostoma 110.

[00252] Flange 2322 is significantly wider than sleeve 2310. Flange 2322 thus comprises a contact surface 2332 perpendicular to sleeve 2310 and surrounding sleeve 2310 which, when the sleeve 2310 of PMD 2301 is positioned in a pneumostoma 110, will contact the skin of the patient surrounding
pneumostoma 110. The contact surface 2332 serves as an insertion limit to prevent over-insertion of sleeve 2310 into a pneumostoma 110. Contact surface 2332 is provided with a biocompatible adhesive 2334, such as a hydrocolloid adhesive, for securing PMD 2301 to the skin 114 of the patient. Adhesive 2334 should be selected so as to help maintain the correct position of PMD 2301 without causing undue irritation to the skin of the patient.

[00253] A flow control device 2340 is positioned in aperture 2328 between lumen 2318 of sleeve 2310 and chamber 2326. Flow control device 2340 is positioned and mounted such that material moving between lumen 2318 and chamber 2326 must pass through flow control device 2340. In the embodiment shown in FIGS. 23A and 23B, flange 2322 is provided with a recess 2336 into which flow control device 2340 may be mounted.

[00254] Flow control device 2340 may comprise a one-way valve assembly such as a flapper valve, Heimlich valve, reed valve, or the like, for allowing air to be exhaled through entrance aperture 2328 into chamber 2326 while restricting the flow of air or other matter into lumen 2318 from chamber 2326. It is desirable to restrict flow of air in through the pneumostoma so as to encourage a reduction in hyperinflation and to prevent the inhalation of solid or liquid matter from into the lung through the pneumostoma. The flow control device 2340, shown in FIG. 23B, comprises a fixed disc 2342 having a number of apertures 2344. Above fixed disc 2342 is a flapper disc 2346. Flapper disc 2346 is kept in place above fixed disc 2342 by hinge 2348. When the air pressure in lumen 2318 is greater than the air pressure in chamber 2326 during exhalation, flapper disc 2346 moves away from fixed disc 2342 and air may pass through a space between fixed disc 2342 and flapper disc 2346 and enter chamber 2326 from lumen 2318. However, when the air pressure in lumen 2318 is less than the air pressure in chamber 2326 during inhalation, flapper disc 2346 moves towards fixed disc 2342 and obstructs the apertures 2344 in fixed disc 2342 such that no air may pass into lumen 2318 from chamber 2326.

[00255] A hydrophobic filter 2350 is positioned in exit aperture 2330 between chamber 2326 and the exterior of bulb 2320. Hydrophobic filter 2350 is positioned and mounted such that material moving between chamber 2326 and the exterior of bulb 2320 must pass through hydrophobic filter 2350. Hydrophobic filter 2350 prevents the flow of water in and out of chamber 2326 through exit aperture 2330. In the embodiment shown in FIGS. 23A and 23B, flange 2322 is provided with a recess 2336 into which flow control device 2340 may be press fit.

[00256] Cover 2360 comprises a plurality of clips 2366 to releasably hold cover 2360 onto the surface of dome 2324. PMD 2301 may be a disposable device and cover 2360 may either be a disposable cover or may be reusable. Where cover 2360 is disposable, it may be preferable to attach cover 2360 to dome 2324 using a permanent adhesive, non-releasable clips or the like. Cover 2360 has an aperture 2362 that is aligned with and sized to fit around a lip surrounding hydrophobic filter 2350. Thus cover 2360 does not interfere with the flow of air through hydrophobic filter 2350. Note that when in use, no part of cover 2360 is in contact with the patient or directly exposed to the interior of
chamber 2326. Cover 2360 may be designed to serve any of the purposes previously discussed with respect to e.g. covers 2100, 2200 and 370.

[00257] As shown in FIG. 23B, a cover 2361 may also be designed to have no apertures and thus block hydrophobic filter 2350 temporarily. Cover 2361 is held in contact with dome 2324 by releasable clips 2366. Cover 2361 prevents flow of air through hydrophobic filter and thus must be removed to allow air to flow through the pneumostoma. The cover 2361 shown in FIG. 23B is useful to temporarily protect hydrophobic filter 2350 from contamination or damage or to temporarily prevent flow of gases in and out of a pneumostoma. Cover 2361 may be used, for example, while a patient is swimming to protect filter 2350 and safeguard against entry of water or other contaminants into chamber 2326. Note that when in use, no part of cover 2361 is in contact with the patient or directly exposed to the interior of chamber 2326. An alternative cover 2361 may be made of a porous material through which air may exit bulb 2320 despite the absence of apertures.

[00258] FIG. 24A illustrates an alternative pneumostoma management system 2400 comprising a PMD 2430 and cover 2460. FIG. 24B shows a perspective cutaway view of cover 2460 of FIG. 24A. As shown in FIG. 24A, PMD 2430 has several threaded fittings to permit PMD 2430 to be dismantled for cleaning and sterilization. Removable dome 2424 is attached to flange 2422 of bulb 2420 by threaded joint 2432. Threaded joint 2432 allows dome 2424 to be removed from flange 2422 to allow entry to chamber 2426 for cleaning/sterilization purposes and for access to flow-control device 2440. As shown in FIG. 24A, sleeve 2410 is attached to flange 2422 by threaded joint 2431. Note that sleeve 2410 must be installed through flange 2422 and shoulder 2433 prevents separation of sleeve 2410 into the pneumostoma. Because sleeve 2410 may be separated from flange 2422, a number of sleeves 2410 of different lengths and/or diameters as required for pneumostomas of different size may be manufactured and mated with a standard bulb 2420. Likewise a second threaded cap 2438 secures hydrophobic filter 2450 over the exit aperture 2430 from chamber 2426. Threaded cap 2438 mounts to threaded fitting 2439 of removable dome 2424 trapping hydrophobic filter 2450 between threaded cap 2438 and threaded fitting 2439. Threaded cap 2438 may thus be removed to allow cleaning and/or replacement of hydrophobic filter 2450. Hydrophobic filter 2450 may be a disposable component that is replaced upon each use of sterilizable PMD 2430 or it may also be reusable.

[00259] Referring again to FIG. 24A, flow-control device 2440 is held in position over lumen 2418 by a threaded cap 2434. Threaded cap 2434 mounts to threaded fitting 2436 trapping flow-control device 2440 between threaded cap 2434 and threaded fitting 2436. When dome 2424 is removed, threaded cap 2434 may also be removed allowing flow-control device 2440 to be cleaned and/or replaced. Flow-control device 2440 is shown in FIG. 24A as a simple flapper valve having a hinged flap 2441 over a plate 2442 with an aperture. As shown in FIG. 24A, the flap 2441 may be connected to the aperture plate 2442 by a living hinge. Flow-control device 2440 may be a disposable component that is replaced upon each use of sterilizable PMD 2430 or it may also be reusable.
control device 2440 allows gasses to exit lumen 2418 into dome 2424 but blocks the materials from entering lumen 2418 from dome 2424.

[00260] Referring again to FIG. 24A, cover 2460 covers the outer surface of dome 2424. Cover 2460 has an aperture 2462 to fit over threaded fitting 2439 of dome 2424. Aperture 2462 is sufficiently small that when threaded cap 2438 is crewed on to threaded fitting 2439, cover 2460 is trapped between threaded cap 2438 and dome 2424. Thus cover 2460 requires no clips or adhesive to secure cover 2460 in position over dome 2424. Also, no part of cover 2460 is in contact with the patient or directly exposed to the interior of chamber 2426. Cover 2460 may be designed for the purposes previously discussed including, for example concealment, ornamentation or protection of PMD 2430 as previously discussed.

[00261] PMD 2430 of FIG. 24A is intended for sterilization and reuse; it is preferable that the reusable components such as sleeve 2410, flange 2422 and dome 2424 be made of a biocompatible metal material such as stainless steel (or a sterilizable polymer). Cover 2460 may be made of a biocompatible polymer but there may be more flexibility in material selection for cover 2460 because cover 2460 does not contact the patient directly. Thus, where dome 2424 is made of, e.g. steel, cover 2460 may be made from a polymer which is available in a range of colors and/or textures.

[00262] Hydrophobic filter 2450 is preferably a disposable component. Because flange 2422 may not be conformable if made of e.g. steel, an annular conformable pad 2443 is provided to fit between flange 2422 and the skin of the patient. The conformable pad 2443 is preferable disposable and may comprise a layer of biocompatible adhesive 2444 on each side to hold it to flange 2422 and the skin of the patient. Each annular conformable pad 2443 preferably comprises a laminate structure with an inner conformable plastic, paper or foam layer (e.g., closed-cell polyethylene foam) sandwiched between adhesive layers 2444. Such foam with an adhesive layer is available commercially from Avery Dennison (Painsville, OH). Threaded caps 2434 and 2438 and flow-control device 2440 may also be made of reusable components.

[00263] FIG. 24C shows a perspective cutaway view of an alternative embodiment of threaded cap 2438 in which the threaded cap is integrated with a cover. The threaded cover 2464 of FIG. 24C can be used in place of the threaded cap 2438 and cover 2460 of FIG. 24A. As shown in FIG. 24C, threaded cover 2464 comprises a threaded fitting 2466 connected to a dome 2468. Threaded fitting 2466 is designed to mate with a threaded fitting of the PMD such as threaded fitting 2439 of FIG. 24A. Threaded fitting 2466 has a lip 2467 for retaining hydrophobic filter 2450 against threaded fitting 2439. Threaded fitting 2466 may be formed in one piece with dome 2468 or formed separately and then joined to dome 2468. Note that when in use, no part of threaded cover 2464 is in contact with the patient or directly exposed to the interior of chamber 2426.

[00264] FIG. 25A illustrates an alternative pneumostoma management system 2500 comprising a PMD 2530 and cover 2560. FIG. 25B shows a sectional view through PMD 2530 and cover 2560 along the line B-B of FIG. 25A. As shown in FIGS. 25A and 25B, PMD 2530 has only two
components. Flange 2520 and sleeve 2510 are formed in one piece and comprise the first component. The second component is hydrophobic filter disc 2550 which may be free-floating or attached to flange 2520 (for example by press fitting or adhesive). Flange 2520 is thin and flexible in order to conform to the skin of the chest of the subject. A biocompatible adhesive 2544 is provided to attach flange 2520 to the skin of the patient.

[00265] Referring again to FIGS. 25A and 25B, cover 2560 is preferably press fit to flange 2520 and held in place by a plurality of clips 2556 at the perimeter. Alternatively cover 2560 may be attached to flange 2520 by adhesive and/or welding for example. Hydrophobic filter disc 2550 is sandwiched between cover 2560 and flange 2520. Cover 2560 and/or flange 2520 may be recessed to accommodate hydrophobic filter disc 2550. Cover is 2560 is preferably thin and flexible so that the device may conform readily to the skin of the patient with the cover in place. Thus, in the preferred embodiment cover 2560 requires no clips or adhesive to secure cover 2560 in position over flange 2520. Also, no part of cover 2560 is in contact with the patient or directly exposed to the interior of sleeve 2510. Cover 2560 may be designed for the purposes previously discussed including, for example concealment, ornamentation or protection of PMD 2530.

[00266] Referring again to FIGS. 25A and 25B, cover 2560 has a plurality of holes 2562. However, there are no holes in the center region of cover 2560 over the opening to lumen 2518 of sleeve 2510. During exhalation gasses pass radially from the opening in lumen 2518 through holes 2562. However, during inhalation, cover 2560 is designed to deflect towards flange 2520 thereby obstructing lumen 2518 and preventing air from flowing into the pneumostoma. Alternatively, or additionally, the center region of hydrophobic filter disc 2550 may be treated so that it does not transmit air. The deflection of hydrophobic filter disc 2550 would then serve to allow exit of gases from lumen 2518 during inhalation and prevent entry of gases during inhalation. Thus, cover 2560 and/or filter 2550 serve as a one-way valve structure in addition to their other functions. In alternative embodiments, PMD 2530 may be designed without the one-way valve features in which case some air may enter the lung through PMD 2530 during inhalation.

[00267] In some embodiments, the cover may be made of thin flexible adhesive materials which may be printed and/or colored and then applied to the pneumostoma management device in the same way as a decal. FIG. 7A shows the printing of covers 720, 722 on a precut sheet 724. Sheet 724 is precut around covers 720, 722 such they may be peeled away from sheet 724 after they have been printed. Apertures 728 are precut in covers 720, 722 and remain adhered to sheet 724 when the covers are peeled away. In some embodiments sheet 724 may be made of a compliant polymer with an adhesive backing such that it may be adhered to the surface of a pneumostoma management device after customization. Printing covers in response to patient requests and/or needs allows a wide range of different colors and/or patterns of covers to be made available to the patient.

[00268] FIG. 7B shows a sectional view of a cover 730 made from a thin flexible material. Cover 730, although compliant, is contoured such that it is fits a pneumostoma management device having a
Materials

[00269] In preferred embodiments, the pneumostoma vent, chest mount and cover of a pneumostoma management system are formed from biocompatible polymers or biocompatible metals. A patient will typically wear a PMD at all times and thus the materials, particularly of tube 240, should meet high standards for biocompatibility. In general preferred materials for manufacturing a PMD are biocompatible thermoplastic elastomers that are readily utilized in injection molding and extrusion processing. As will be appreciated, other suitable similarly biocompatible thermoplastic or thermoplastic polymer materials can be used without departing from the scope of the invention.

Biocompatible polymers for manufacturing PMD may be selected from the group consisting of polyethylenes (HDPE), polyvinyl chloride, polyacrylates (polyethyl acrylate and polymethyl acrylate, polymethyl methacrylate, polymethyl-coethyl acrylate, ethylene/ethyl acrylate), polycarbonate urethane (BIONATEG), polysiloxanes (silicones), polytetrafluoroethylene (PTFE, GORE-TEX®, ethylene/chlorotirifluoroethylene copolymer, aliphatic polyesters, ethylene/ tetrafluoroethylene copolymer), polyketones (polyaryletheretherketone, polyetheretherketone, polyetheretherketoneketone, polyetheretherketone polyetherketone), polyether block amides (PEBAX, PEBA), polyamides (polyamideimide, PA-11, PA-12, PA-46, PA-66), polyetherimide, polyether sulfone, poly(iso)butylene, polyvinyl chloride, polyvinyl fluoride, polyvinyl alcohol, polyurethane, polybutylene terephthalate, polyphosphazenes, nylon, polypropylene, polybutester, nylon and polyester, polymer foams (from carbonates, styrene, for example) as well as the copolymers and blends of the classes listed and/or the class of thermoplastics and elastomers in general. Reference to appropriate polymers that can be used for manufacturing PMD 1200 can be found in the following documents: PCT Publication WO 02/02158, entitled "Bio-Compatible Polymeric Materials;" PCT Publication WO 02/00275, entitled "Bio-Compatible Polymeric Materials;" and, PCT Publication WO 02/00270, entitled "Bio-Compatible Polymeric Materials" all of which are incorporated herein by reference. Other suitable materials for the manufacture of the PMD include medical grade inorganic materials such stainless steel, titanium, ceramics and coated materials.

[00270] Hydrophobic filter materials should be sufficiently porous to allow air to exit through the filter. Materials for hydrophobic filters are available commercially and filters can be fabricated from any suitable hydrophobic polymer, such as tetrafluoroethylene, PTFE, polyolefins, microglass, polyethylene and polypropylene or a mixture thereof. In preferred examples, the hydrophobic filter is a laminated tetrafluoroethylene e.g. TEFLO® (E.I. du Pont de Nemours Co.) or GORE-TEX® (W.L.
Gore, Inc.) of a controlled pore size. In other examples, the hydrophobic filter may comprise a felted polypropylene; PTFE/polypropylene filter media. The hydrophobic filter material may additionally comprise an antimicrobial, an anti-bacterial, and/or an anti-viral material or agent.

[00271] In general, the various covers disclosed in this application are designed such that they do not contact the pneumostoma. Thus, the materials of the cover do not have to meet the same high standards for biocompatible and implantable materials as the remainder of the pneumostoma management device. However the preferred materials for making the covers include medical grade metals, plastics, acrylics and resins. In a preferred embodiment the cover is made from medical grade ABS (Acrylonitrile-Butadiene-Styrene) plastic colored or painted as required for the application. In some embodiments, the cover may be made of thin flexible adhesive materials which may be printed and/or colored and then applied to the pneumostoma management device in the same way as a decal.

Materials

[00272] In preferred embodiments the pneumostoma management device and its components are formed from biocompatible polymers or biocompatible metals. A patient will typically wear a pneumostoma management device for extended periods and thus the materials, particularly of the tube entering a pneumostoma, should meet high standards for biocompatibility. In general preferred materials for manufacturing pneumostoma management devices are biocompatible thermoplastic elastomers that are readily utilized in injection molding and extrusion processing. As will be appreciated, other suitable similarly biocompatible thermoplastic or thermoplastic polymer materials can be used without departing from the scope of the invention.

[00273] Biocompatible polymers for manufacturing pneumostoma management devices and components thereof may be selected from the group consisting of polyethylenes (HDPE), polyvinyl chloride, polyacrylates (polyethyl acrylate and polymethyl acrylate, polymethyl methacrylate, polymethyl-coethyl acrylate, ethylene/ethyl acrylate), polycarbonate urethane (BIONATEG), polysiloxanes (silicones), polytetrafluoroethylene (PTFE, GORE-TEX®, ethylene/chlorotrifluoroethylene copolymer, aliphatic polyesters, ethylene/ tetrafluoroethylene copolymer), polyketones (polyaryletheretherketone, polyetheretherketone, polyetheretherketoneketone, polyetherketoneetherketoneketone polyetherketone), polyether block amides (PEBAX, PEBA), polyamides (polyamideimide, PA-11, PA-12, PA-46, PA-66), polyetherimide, polyether sulfone, poly(iso)butylene, polyvinyl chloride, polyvinyl fluoride, polyvinyl alcohol, polyurethane, polybutylene terephthalate, polyphosphazenes, nylon, polypropylene, polybutester, nylon and polyester, polymer foams (from carbonates, styrene, for example) as well as the copolymers and blends of the classes listed and/or the class of thermoplastics and elastomers/thermoplastic elastomers in general.
Pneumostoma management devices may be made of a suitable biocompatible plastic/thermoplastic/thermoplastic elastomer. For example in one preferred embodiment the tube is made of Pebax® a block copolymer with suitable mechanical and chemical properties available from Arkema (Colombes, France). Another suitable material is C-FLEX® thermoplastic elastomer available as extruded tube in a variety of dimensions and durometers from Saint-Gobain Performance Plastics in Clearwater, Florida. Reference to appropriate polymers that can be used for manufacturing PMDs can be found, for example, in the following documents: PCT Publication WO 02/02158, entitled "Bio-Compatible Polymeric Materials;" PCT Publication WO 02/00275, entitled "Bio-Compatible Polymeric Materials;" and, PCT Publication WO 02/00270, entitled "Bio-Compatible Polymeric Materials" all of which are incorporated herein by reference. Other suitable materials for the manufacture of the PMD include medical grade inorganic materials such stainless steel, titanium, ceramics and coated materials.

Additionally, the tube of a pneumostoma vent may be treated and/or coated on the exterior surface to facilitate installation. The tube may be treated and/or coated to make the tube smoother and/or more lubricious to reduce resistance to installation of the vent tube in the pneumostoma. The polymer of the tube may also be treated and/or coated to make the surface hydrophilic thereby attracting water molecules as a lubricant. If a coating is used it should be selected so to be biocompatible and not cause irritation of the pneumostoma. Lubricious coatings include, for example hydrophilic, Teflon, and Parylene/Paralyne films/coatings. A lubricious coating may also include a therapeutic agent (see below).

Additionally, the tube of a pneumostoma vent may be designed to deliver a pharmaceutically-active substance. For purposes of the present disclosure, an "pharmaceutically-active substance" is an active ingredient of vegetable, animal or synthetic origin which is used in a suitable dosage as a therapeutic agent for influencing conditions or functions of the body, as a replacement for active ingredients naturally produced by the human or animal body and to eliminate or neutralize disease pathogens or exogenous substances. The release of the substance in the environment of pneumostoma vent has an effect on the course of healing and/or counteracts pathological changes in the tissue due to the presence of pneumostoma vent. In particular, it is desirable in some embodiments to coat or impregnate pneumostoma vent with pharmaceutically-active substances that preserve the potency of pneumostoma and/or are antimicrobial in nature but that do not unduly irritate the tissues of the pneumostoma. However the pneumostoma vent may also deliver, be coated with or be impregnated with time-release therapeutic agents design to have effects on tissues other than the tissues of the pneumostoma.

In particular cases, suitable pharmaceutically-active substances may have an anti-inflammatory and/or antiproliferative and/or spasmylytic and/or endothelium-forming effect, so that the functionality of the pneumostoma is maintained. Suitable pharmaceutically-active substances include: anti-proliferative/antimitotic agents including natural products such as vinca alkaloids (i.e.
vinblastine, vincristine, and vinorelbine), paclitaxel, epidipodophyllotoxins (i.e. etoposide, teniposide),
anti-biotics (dactinomycin (actinomycin D) daunorubicin, doxorubicin and idarubicin), anthracyclines,
mitoxantrone, bleomycins, plicamycin (mithramycin) and mitomycin, enzymes (L-asparaginase which
systemically metabolizes L-asparagine and deprives cells which do not have the capacity to synthesize
their own asparagine); antiplatelet agents such as G(GP) IIb/IIIa inhibitors and vitronectin receptor
antagonists; anti-proliferative/antimitotic alkylating agents such as nitrogen mustards (mechlorethamine,
cyclophosphamide and analogs, melphalan, chlorambucil), ethylenimines and methylmelamines (hexamethylmelamine and thiopeta), alkyl sulfonates-busulfan, nirtosoureas (carmustine (BCNU) and analogs, streptozocin), trazenes - dacarbazine (DTIC); anti-
proliferative/antimitotic antimetabolites such as folic acid analogs (methotrexate), pyrimidine analogs
(fluorouracil, floxuridine, and cytarabine), purine analogs and related inhibitors (mercaptopurine,
thioguanine, pentostatin and 2-chlorodeoxyadenosine {cladribine}); platinum coordination complexes
(cisplatin, carboplatin), procarbazine, hydroxyurea, mitotane, amino glutethimide; hormones (i.e.
estrogen); anti-coagulants (heparin, synthetic heparin salts and other inhibitors of thrombin);
fibrinolytic agents (such as tissue plasminogen activator, streptokinase and urokinase), aspirin,
dipyramidole, ticlopidine, clopidogrel, abciximab; antimigratory; antiseptics; antivertigo agents, antivirals,
appetite stimulants, bacterial

[00278] In some embodiments, the active pharmaceutical substance to be coated upon or
impregnated in the pneumostoma vent is selected from the group consisting of amino acids, anabolics,
analgesics and antagonists, anaesthetics, anti-adrenergic agents, anti-asthmatics, anti-atherosclerotics,
antibacterials, anticholesterolics, anti-coagulants, antidepressants, antidotes, anti-emetics, anti-
epileptic drugs, anti-fibrinolytics, anti-inflammatory agents, antihypertensives, antimetabolites,
antimigraine agents, antymycotics, antinauseants, antineoplastics, anti-obesity agents, antiprotozoals,
antipsychotics, antirheumatics, antiseptics, antivertigo agents, antivirals, appetite stimulants, bacterial
vaccines, bioflavonoids, calcium channel blockers, capillary stabilizing agents, coagulants, corticosteroids, detoxifying agents for cytostatic treatment, diagnostic agents (like contrast media, radiopaque agents and radioisotopes), electrolytes, enzymes, enzyme inhibitors, ferments, ferment inhibitors, gangliosides and ganglioside derivatives, hemostatics, hormones, hormone antagonists, hypnotics, immunomodulators, immunostimulants, immunosuppressants, minerals, muscle relaxants, neuromodulators, neurotransmitters and neurotrophins, osmotic diuretics, parasympathomimetics, peptides, proteins, psychostimulants, respiratory stimulants, sedatives, serum lipid reducing agents, smooth muscle relaxants, sympatholytics, sympathomimetics, vasodilators, vasoprotectives, vectors for gene therapy, viral vaccines, viruses, vitamins, oligonucleotides and derivatives, saccharides, polysaccharides, glycoproteins, hyaluronic acid, and any excipient that can be used to stabilize a proteinaceous therapeutic.

[00279] Hydrophobic filter materials for pneumostoma vents should be sufficiently porous to allow air to exit through the filter. In order to facilitate air flow through the filter a filter material with low to extremely low resistance to air flow is preferred consistent with the structural and size requirements for the filter. Materials for hydrophobic filters are available commercially and filters can be fabricated from any suitable hydrophobic polymer, such as tetrafluoroethylene, PTFE, polyolefins, microglass, polyethylene and polypropylene or a mixture thereof. In preferred examples, the hydrophobic filter is a laminated tetrafluoroethylene e.g. TEFLON®, (E.I. du Pont de Nemours Co.) or GORE-TEX® (W.L. Gore, Inc.) of a controlled pore size. In other examples the hydrophobic filter may comprise a felted polypropylene; PTFE/polypropylene filter media or a reticulated polyurethane-based open cell foam. In a preferred embodiment, the filter is an open cell polyurethane or polyester foam or melt blown polyethylene. Exemplary filter materials include Delpore® DP2001-10P, Delpore® DP2001-20P, and Delpore® DP2001-30P available from Delstar Technologies, Inc. (Middletown, Delaware). A filter may additionally comprise an antimicrobial, an anti-bacterial, and/or an anti-viral material or agent, for example silver.

[00280] The foregoing description of preferred embodiments of the present invention has been provided for the purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise forms disclosed. Many embodiments were chosen and described in order to best explain the principles of the invention and its practical application, thereby enabling others skilled in the art to understand the invention for various embodiments and with various modifications that are suited to the particular use contemplated. It is intended that the scope of the invention be defined by the claims and their equivalents.
CLAIMS

What is claimed is:

1. A pneumostoma management device adapted to allow gases to exit a lung through a pneumostoma in a chest of a patient, wherein the pneumostoma management device comprises;
   a tube adapted to be inserted into the chest through the pneumostoma,
   the tube having a lumen, a proximal end and a distal end
   the distal end of the tube having at least one opening adapted to admit gases from the lung;
   a flange connected to the proximal end of the tube such that an opening in the flange connects to the lumen of the tube,
   the flange projecting a sufficient distance from the tube to preclude passage of flange into the pneumostoma,
   the flange being sufficiently thin and flexible to conform to the chest of the patient;
   the flange having an adhesive coating adapted to releasably secure the flange to the chest of the patient; and
   a filter disposed over the opening in the flange and secured to one of the flange and tube such that gases passing into and out of the lumen of the tube pass through the filter.

2. The pneumostoma management device of claim 1, further comprising:
   a chest mount which comprises a patch;
   the patch being sufficiently thin and flexible to conform to the chest of the patient
   the patch having an aperture larger in diameter than the tube;
   the chest mount having a distal surface having an adhesive coating adapted to releasably secure the chest mount to the chest of the patient;
   whereby the chest mount is adapted to be secured to the chest of the patient by the adhesive coating on the distal surface, the tube is selectively inserted into a pneumostoma through the aperture in the patch, and the pneumostoma management device is selectively secured to the chest mount by the adhesive coating on the flange.

3. The pneumostoma management device of claim 1, further comprising a plug wherein:
   the plug is substantially impermeable and is larger in diameter than the filter; and
   wherein the plug has an adhesive coating that allows the plug to be selectively secured to the flange such that the plug obstructs the filter and substantially prevents the passage of solids, liquids and gases through the tube.
4. The pneumostoma management device of claim 1, wherein the flange and tube are formed in one piece.

5. The pneumostoma management device of claim 1, wherein the tube is an extruded tube which is formed separately from the flange and then bonded to the flange.

6. The pneumostoma management device of claim 1, wherein the tube is connected substantially centrally to the flange.

7. The pneumostoma management device of claim 1, wherein the filter is too large to fit through the lumen of the tube.

8. The pneumostoma management device of claim 1, wherein the adhesive coating comprises a hydrocolloid adhesive configured and adapted to releasably secure the flange to the chest of the patient.

9. The pneumostoma management device of claim 1, wherein the filter is substantially flush with the flange.

10. The pneumostoma management device of claim 1, wherein the flange, filter and adhesive coating is less than 5 mm in thickness in combination.

11. A medical device to allow gases to exit a lung through a pneumostoma in a chest of a patient, wherein the medical device comprises:

   a tube adapted to be inserted into the chest through the pneumostoma,
   the tube having a lumen, a proximal end and a distal end
   the distal end of the tube having an atraumatic tip,
   the distal end of the tube having at least one opening adapted to admit gases from the lung;

   a flange connected to the proximal end of the tube such that an opening in the flange connects to the lumen of the tube,
   the flange projecting a sufficient distance from the tube to preclude passage of flange into the pneumostoma,
   the flange being sufficiently thin and flexible to conform to the chest of the patient;
   the flange having an adhesive coating adapted to releasably secure the flange to the chest of the patient; and
a filter secured to one of the flange and tube such that gases passing through the medical
device pass through the filter.

12. The pneumostoma management device of claim 1 wherein the distal end of the tube has an
atraumatic tip.

13. The pneumostoma management device of claim 1 wherein the distal end of the tube has an
atraumatic tip.

14. A pneumostoma management device adapted to allow gases to exit a lung through a
pneumostoma in a chest of a patient, wherein the pneumostoma management device comprises;
   a tube adapted to be inserted into the chest through the pneumostoma,
   the tube having a lumen, a proximal end and a distal end
   the distal end of the tube having at least one opening adapted to admit gases from
   the lung; and
   a flange connected to the proximal end of the tube such that an opening in the flange connects
to the lumen of the tube,
   the flange projecting a sufficient distance from the tube to preclude passage of flange
   into the pneumostoma,
   the flange being sufficiently thin and flexible to conform to the chest of the patient;
   the flange having an adhesive coating adapted to releasably secure the flange to the
chest of the patient.

15. A medical device for allowing gases to exit a lung of a patient through a pneumostoma in a
chest, wherein the medical device comprises;
   a vent for insertion into the chest through the pneumostoma to permit gases to exit a lung of
   the patient through the pneumostoma via the vent, wherein the vent includes,
   a distal opening in a distal end of the vent adapted to admit gases from the lung,
   a proximal opening in a proximal end of the vent adapted to allow gases from the lung
to exit the vent outside of the chest of the patient, and
   a tubular body adapted to slide into the pneumostoma and sized so as to place the
distal end of the vent within the lung while the proximal end of the vent is a small
distance external to the chest; and
   a chest mount having an adhesive surface for releasably securing the chest mount to the chest
of the patient, wherein the chest mount includes,
   a coupling for releasably engaging the proximal end of the vent, and

70
an aperture through the chest mount wherein the aperture is larger in diameter than the
distal end of the vent, so that the aperture permits the distal end of the vent to be fit
through the aperture into the pneumostoma, but smaller in diameter than the proximal
end of the vent to prevent the proximal end of the vent from passing through the
aperture into the pneumostoma.

whereby the distal end of the vent is adapted to be releasably secured within the lung while the
proximal end of the vent is releasably secured adjacent the chest mount and prevented from passing
into the pneumostoma.

16. The medical device of claim 15, wherein the aperture passes centrally through the chest
mount.

17. The medical device of claim 15, wherein the vent comprises a cap connected to the proximal
end of the tubular body and wherein the cap includes a filter.

18. The medical device of claim 15, wherein the vent comprises a cap connected to the proximal
end of the tubular body wherein each component of the cap is too large to pass completely through the
aperture such that the aperture prevents each component of the cap from passing into the
pneumostoma.

19. The medical device of claim 15, wherein the vent comprises a cap connected to the proximal
end of the tubular body wherein the cap includes a filter and wherein each component of the cap,
including the filter, is too large to pass completely through the aperture such that the aperture prevents
each component of the vent cap from passing into the pneumostoma.

20. The medical device of claim 15, wherein the chest mount includes a recess adjacent the
aperture and the proximal end of the vent is adapted to fit within the recess such that it is substantially
flush with the chest mount when the vent is positioned in the pneumostoma.

21. The medical device of claim 15, wherein the vent comprises a cap connected to the proximal
end of the tubular body and wherein the proximal end of the tubular body is larger than the diameter of
the aperture so that the aperture prevents the proximal end of the tubular body from passing into the
pneumostoma.

22. The medical device of claim 15, wherein the chest mount is adapted to remain secured to the
chest of the patient when the vent is removed.
23. The medical device of claim 15, wherein the coupling of the chest mount includes a recess adjacent the aperture and the proximal end of the vent is adapted to fit within the recess substantially flush with the chest mount.

24. The medical device of claim 15, wherein the chest mount comprises:
   an aperture plate of a first material which defines the aperture; and
   a flange of a second more elastic material having the adhesive surface for releasably securing the chest mount to the chest of the patient wherein the flange is larger than the aperture and wherein the flange is adapted to conform to the chest of the patient.

25. A medical device for allowing gases to exit a lung of a patient through a passage which passes through a chest wall into the lung through a region of pleurodesis between visceral and parietal membranes surrounding the lung, wherein the medical device comprises;
   a vent for insertion into the chest through the pneumostoma to permit gases to exit a lung of the patient through the passage via the vent, wherein the vent includes,
      a distal opening in a distal end of the vent adapted to admit gases from the lung,
      a proximal opening in a proximal end of the vent adapted to allow gases from the lung to exit the vent outside of the chest of the patient, and
      a tubular body adapted to slide into the passage and sized so as to place the distal end of the vent within the lung while the proximal end of the vent is a small distance external to the chest; and
   a chest mount having an adhesive surface for releasably securing the chest mount to the chest of the patient, wherein the chest mount includes,
      a coupling for releasably engaging the proximal end of the vent, and
      an aperture through the chest mount wherein the aperture is larger in diameter than the distal end of the vent, so that the aperture permits the distal end of the vent to be fit through the aperture into the passage, but smaller in diameter than the proximal end of the vent to prevent the proximal end of the vent from passing through the aperture into the passage.

26. A pneumostoma management system comprising:
   a cover and a pneumostoma management device;
wherein the pneumostoma management device comprises a tube adapted to be inserted in a pneumostoma, said tube connected to an external section in order to secure the pneumostoma management device to a chest of a patient;

wherein the cover is configured to attach to the pneumostoma management device such that said cover presents an outward surface which substantially obscures the external section of the pneumostoma management device from view;

wherein the outward surface of the cover is designed to have a preferred visual appearance compared to the external section of the pneumostoma management device.

27. The pneumostoma management system of claim 26, wherein the cover comprises one or more clips configured to releasably attach the cover to the pneumostoma management device.

28. The pneumostoma management system of claim 26, wherein the cover comprises an adhesive surface configured to attach the cover to the pneumostoma management device.

29. The pneumostoma management system of claim 26, further comprising a threaded coupling that can releasably attach the cover to the pneumostoma management device.

30. The pneumostoma management system of claim 26, wherein the cover comprises one or more apertures to allow gases to escape from the pneumostoma management device.

31. The pneumostoma management system of claim 26, wherein the outward surface of the cover is color-matched with a skin color of a patient in order for the cover to have a preferred visual appearance compared to the external section of the pneumostoma management device.

32. The pneumostoma management system of claim 26, wherein the outward surface of the cover is provided with an ornamental pattern in order for the cover to have a preferred visual appearance compared to the external section of the pneumostoma management device.

33. The pneumostoma management system of claim 26, wherein the outward surface of the cover is provided with a patient-customizable pattern in order for the cover to have a preferred visual appearance compared to the external section of the pneumostoma management device.

34. The pneumostoma management system of claim 26, wherein the outward surface of the cover is a printable surface and wherein at least one of a customizable pattern and color is printed on the outward surface prior to use of the cover in order for the cover to have a preferred visual appearance compared to the external section of the pneumostoma management device.
35. The pneumostoma management system of claim 26, wherein the cover comprises a plurality of apertures which are large enough to allow gases to escape from the pneumostoma management device but are too small to be visible to a casual observer from a distance of four feet or more.

36. A cover for a pneumostoma management device wherein the pneumostoma management device comprises a tube adapted to be inserted in a pneumostoma said tube connected to an external section in order to secure the pneumostoma management device to a chest of a patient and wherein the cover comprises:

- a body having an outward surface and an attachment surface;
- wherein the attachment surface is configured to attach the cover to a pneumostoma management device;
- wherein the outward surface is adapted to substantially obscure the external section of the pneumostoma management device from view;
- wherein the outward surface of the body is designed to have a preferred visual appearance compared to the external section of the pneumostoma management device.

37. The cover of claim 36, wherein the attachment surface of the cover comprises one or more clips configured to releasably attach the cover to the pneumostoma management device.

38. The cover of claim 36, wherein the attachment surface of the cover comprises an adhesive surface configured to attach the cover to the pneumostoma management device.

39. The cover of claim 36, wherein the cover comprises one or more apertures to allow gases to escape from the pneumostoma management device.

40. The cover of claim 36, wherein the outward surface of the cover is color-matched with a skin color of a patient in order for the cover to have a preferred visual appearance compared to the external section of the pneumostoma management device.

41. The cover of claim 36, wherein the outward surface of the cover is provided with an ornamental pattern in order for the cover to have a preferred visual appearance compared to the external section of the pneumostoma management device.

42. The cover of claim 36, wherein the outward surface of the cover is provided with a patient-customizable pattern in order for the cover to have a preferred visual appearance compared to the external section of the pneumostoma management device.
43. A medical device to allow gases to exit a lung through a pneumostoma in a chest of a patient, wherein the medical device comprises;

- a substantially planar flange having a contact surface adapted to contact the chest of the patient and an outer surface;
- the flange being substantially larger in size than a pneumostoma,
- the flange being sufficiently thin and flexible to conform to the chest;
- the contact surface having an adhesive coating adapted so that the flange can be releasably secured to the chest of the patient,
- the flange having an opening;

a tube projecting from the flange;
- the tube adapted to be inserted into the chest through the pneumostoma,
- the tube having a lumen, a proximal end and a distal end
- the distal end of the tube having at least one opening adapted to admit gases from the lung,
- the proximal end of the tube being connected to the flange such that the opening in the flange communicates with the lumen of the tube; and

a filter disposed over the opening in the flange and secured to one of the flange and tube such that gases passing into and out of the lung pass through the filter.

44. The medical device of claim 43, further comprising:

a chest mount which comprises a patch at least as large in diameter as the flange;
- the patch being sufficiently thin and flexible to conform to the chest of the patient
- the patch having an aperture larger in diameter than the tube;
- the chest mount having a distal surface having an adhesive coating adapted to releasably secure the chest mount to the chest of the patient;

whereby the chest mount is adapted to be secured to the chest of the patient by the adhesive coating on the distal surface of the chest mount, the tube is selectively inserted into a pneumostoma through the aperture in the patch, and the pneumostoma vent is selectively secured to the chest mount by the adhesive coating on the flange.

45. The medical device of claim 43, further comprising a plug wherein:

- the plug is substantially impermeable and is larger in diameter than the filter; and
- wherein the plug has an adhesive coating that allows the plug to be selectively secured to the flange such that the plug obstructs the filter and substantially prevents passage of solids, liquids and gases through the medical device.

46. The medical device of claim 43, wherein the flange and tube are formed in one piece.
47. The medical device of claim 43, wherein the tube is an extruded tube which is formed separately from the flange and then bonded to the flange.

5 48. The medical device of claim 43, wherein the filter is too large to fit into through the lumen of the tube.

49. The medical device of claim 43, wherein the adhesive coating comprises a hydrocolloid adhesive configured adapted to releasably secure the flange to the chest of the patient.

50. The medical device of claim 43, wherein the filter is substantially flush with the flange.

51. The medical device of claim 43, wherein the flange, filter and adhesive coating is less than 5 mm in thickness in combination.

52. A medical device to allow gases to exit a lung through a pneumostoma in a chest of a patient, wherein the pneumostoma vent comprises:
   a tube adapted for insertion into the chest through the pneumostoma,
       the tube having a lumen, a proximal end and a distal end;
       the distal end of the tube having at least one opening adapted to admit gases from the lung;
       the proximal end of the tube having one or more arms projecting a sufficient distance from the tube to preclude passage of proximal end of the tube into the pneumostoma,
   a hydrocolloid ring surrounding the tube;
   a hydrophobic filter disposed over the proximal end of the tube adapted to allow gases to escape the tube but retain liquids or solids within the tube;
       an adhesive film having an aperture smaller than the filter and positioned such that the adhesive cover secures the filter over the proximal end of the tube, and the adhesive cover is secured to the arms of the tube and at least a portion of the hydrocolloid ring.

53. The medical device of claim 51, further comprising a plug, wherein:
   the plug comprises a substantially impermeable patch larger in diameter than the aperture of the adhesive film; and
   wherein the patch has an adhesive to temporarily secure the patch to the adhesive film such that the patch obstructs the aperture and substantially prevents the passage of solids, liquids and gases through the tube.
54. The medical device of claim 51, wherein the flange and arms are formed in one piece.

55. The medical device of claim 51, wherein the tube is an extruded tube which is formed separately from the arms and then bonded to the arms.

56. The medical device of claim 51, wherein the adhesive cover is a transparent breathable polymer film having one adhesive surface configured to releasably secure the medical device to the chest of the patient.

57. The medical device of claim 51, wherein the medical device is provided to the patient in at least two pieces.

58. The medical device of claim 51, wherein the medical device is provided preassembled to the patient and further comprising at least one protective sheet which protects the adhesive surfaces of the medical device prior to use.

59. The medical device of claim 51, wherein the cover film, arms, filter and hydrocolloid adhesive coating are less than 3 mm in thickness in combination.

60. The medical device of claim 51, wherein there are at least three arms.

61. The medical device of claim 51, wherein there are at least four arms.

62. A pneumostoma management device adapted to allow gases to exit a lung through a pneumostoma in a chest of a patient, wherein the pneumostoma management device comprises;
   a tube adapted to be inserted into the chest through the pneumostoma,
   the tube having a lumen, a proximal end and a distal end
   the distal end of the tube having at least one opening adapted to admit gases from the lung;
   a flange connected to the proximal end of the tube such that an opening in the flange connects to the lumen of the tube, and
   the flange projecting a sufficient distance from the tube to preclude passage of flange into the pneumostoma.
WHAT IS CLAIMED IS:

1. A pneumostoma management device adapted to allow gases to exit a lung through a pneumostoma in a chest of a patient, wherein the pneumostoma management device comprises:
   a tube adapted to be inserted into the chest through the pneumostoma,
   the tube having a lumen, a proximal end and a distal end
   the distal end of the tube having at least one opening adapted to admit gases from the lung;
   a flange connected to the proximal end of the tube such that an opening in the flange connects to the lumen of the tube,
   the flange projecting a sufficient distance from the tube to preclude passage of flange into the pneumostoma,
   the flange being sufficiently thin and flexible to conform to the chest of the patient;
   the flange having an adhesive coating adapted to releasably secure the flange to the chest of the patient; and
   a filter disposed over the opening in the flange and secured to one of the flange and tube such that gases passing into and out of the lumen of the tube pass through the filter.

2. The pneumostoma management device of claim 1, further comprising:
   a chest mount which comprises a patch;
   the patch being sufficiently thin and flexible to conform to the chest of the patient
   the patch having an aperture larger in diameter than the tube;
   the chest mount having a distal surface having an adhesive coating adapted to releasably secure the chest mount to the chest of the patient;
   whereby the chest mount is adapted to be secured to the chest of the patient by the adhesive coating on the distal surface, the tube is selectively inserted into a pneumostoma through the aperture in the patch, and the pneumostoma management device is selectively secured to the chest mount by the adhesive coating on the flange.

3. The pneumostoma management device of claim 1, further comprising a plug wherein:
   the plug is substantially impermeable and is larger in diameter than the filter; and
   wherein the plug has an adhesive coating that allows the plug to be selectively secured to the flange such that the plug obstructs the filter and substantially prevents the passage of solids, liquids and gases through the tube.
4. The pneumostoma management device of claim 1, wherein the flange and tube are formed in one piece.

5. The pneumostoma management device of claim 1, wherein the tube is an extruded tube which is formed separately from the flange and then bonded to the flange.

6. The pneumostoma management device of claim 1, wherein the tube is connected substantially centrally to the flange.

7. The pneumostoma management device of claim 1, wherein the filter is too large to fit through the lumen of the tube.

8. The pneumostoma management device of claim 1, wherein the adhesive coating comprises a hydrocolloid adhesive configured and adapted to releasably secure the flange to the chest of the patient.

9. The pneumostoma management device of claim 1, wherein the filter is substantially flush with the flange.

10. The pneumostoma management device of claim 1, wherein the flange, filter and adhesive coating is less than 5 mm in thickness in combination.

11. A medical device to allow gases to exit a lung through a pneumostoma in a chest of a patient, wherein the medical device comprises;

   a tube adapted to be inserted into the chest through the pneumostoma, the tube having a lumen, a proximal end and a distal end the distal end of the tube having an atraumatic tip, the distal end of the tube having at least one opening adapted to admit gases from the lung;

   a flange connected to the proximal end of the tube such that an opening in the flange connects to the lumen of the tube, the flange projecting a sufficient distance from the tube to preclude passage of flange into the pneumostoma, the flange being sufficiently thin and flexible to conform to the chest of the patient; the flange having an adhesive coating adapted to releasably secure the flange to the chest of the patient; and
a filter secured to one of the flange and tube such that gases passing through the medical
device pass through the filter.

12. The pneumostoma management device of claim 1 wherein the distal end of the tube has an
atraumatic tip.

13. The pneumostoma management device of claim 1 wherein the distal end of the tube has an
atraumatic tip.

14. A pneumostoma management device adapted to allow gases to exit a lung through a
pneumostoma in a chest of a patient, wherein the pneumostoma management device comprises;
   a tube adapted to be inserted into the chest through the pneumostoma,
   the tube having a lumen, a proximal end and a distal end
   the distal end of the tube having at least one opening adapted to admit gases from
   the lung; and
   a flange connected to the proximal end of the tube such that an opening in the flange connects
to the lumen of the tube,
   the flange projecting a sufficient distance from the tube to preclude passage of flange
   into the pneumostoma,
   the flange being sufficiently thin and flexible to conform to the chest of the patient;
   the flange having an adhesive coating adapted to releasably secure the flange to the
chest of the patient.

15. A medical device for allowing gases to exit a lung of a patient through a pneumostoma in a
chest, wherein the medical device comprises;
   a vent for insertion into the chest through the pneumostoma to permit gases to exit a lung of
   the patient through the pneumostoma via the vent, wherein the vent includes,
   a distal opening in a distal end of the vent adapted to admit gases from the lung,
   a proximal opening in a proximal end of the vent adapted to allow gases from the lung
to exit the vent outside of the chest of the patient, and
   a tubular body adapted to slide into the pneumostoma and sized so as to place the
distal end of the vent within the lung while the proximal end of the vent is a small
distance external to the chest; and
   a chest mount having an adhesive surface for releasably securing the chest mount to the chest
of the patient, wherein the chest mount includes,
   a coupling for releasably engaging the proximal end of the vent, and
an aperture through the chest mount wherein the aperture is larger in diameter than the
distal end of the vent, so that the aperture permits the distal end of the vent to be fit
through the aperture into the pneumostoma, but smaller in diameter than the proximal
end of the vent to prevent the proximal end of the vent from passing through the
aperture into the pneumostoma.

whereby the distal end of the vent is adapted to be releasably secured within the lung while the
proximal end of the vent is releasably secured adjacent the chest mount and prevented from passing
into the pneumostoma.

16. The medical device of claim 15, wherein the aperture passes centrally through the chest
mount.

17. The medical device of claim 15, wherein the vent comprises a cap connected to the proximal
end of the tubular body and wherein the cap includes a filter.

18. The medical device of claim 15, wherein the vent comprises a cap connected to the proximal
end of the tubular body wherein each component of the cap is too large to pass completely through the
aperture such that the aperture prevents each component of the cap from passing into the
pneumostoma.

19. The medical device of claim 15, wherein the vent comprises a cap connected to the proximal
end of the tubular body wherein the cap includes a filter and wherein each component of the cap,
including the filter, is too large to pass completely through the aperture such that the aperture prevents
each component of the vent cap from passing into the pneumostoma.

20. The medical device of claim 15, wherein the chest mount includes a recess adjacent the
aperture and the proximal end of the vent is adapted to fit within the recess such that it is substantially
flush with the chest mount when the vent is positioned in the pneumostoma.

21. The medical device of claim 15, wherein the vent comprises a cap connected to the proximal
end of the tubular body and wherein the proximal end of the tubular body is larger than the diameter of
the aperture so that the aperture prevents the proximal end of the tubular body from passing into the
pneumostoma.

22. The medical device of claim 15, wherein the chest mount is adapted to remain secured to the
chest of the patient when the vent is removed.
23. The medical device of claim 15, wherein the coupling of the chest mount includes a recess adjacent the aperture and the proximal end of the vent is adapted to fit within the recess substantially flush with the chest mount.

24. The medical device of claim 15, wherein the chest mount comprises:
   an aperture plate of a first material which defines the aperture; and
   a flange of a second more elastic material having the adhesive surface for releasably securing the chest mount to the chest of the patient wherein the flange is larger than the aperture and wherein the flange is adapted to conform to the chest of the patient.

25. A medical device for allowing gases to exit a lung of a patient through a passage which passes through a chest wall into the lung through a region of pleurodesis between visceral and parietal membranes surrounding the lung, wherein the medical device comprises;
   a vent for insertion into the chest through the pneumostoma to permit gases to exit a lung of the patient through the passage via the vent, wherein the vent includes,
      a distal opening in a distal end of the vent adapted to admit gases from the lung,
      a proximal opening in a proximal end of the vent adapted to allow gases from the lung to exit the vent outside of the chest of the patient, and
      a tubular body adapted to slide into the passage and sized so as to place the distal end of the vent within the lung while the proximal end of the vent is a small distance external to the chest; and
   a chest mount having an adhesive surface for releasably securing the chest mount to the chest of the patient, wherein the chest mount includes,
      a coupling for releasably engaging the proximal end of the vent, and
      an aperture through the chest mount wherein the aperture is larger in diameter than the distal end of the vent, so that the aperture permits the distal end of the vent to be fit through the aperture into the passage, but smaller in diameter than the proximal end of the vent to prevent the proximal end of the vent from passing through the aperture into the passage.
   whereby the distal end of the vent is adapted to be releasably secured within the lung while the proximal end of the vent is releasably secured adjacent the chest mount and prevented from passing into the passage.

26. A pneumostoma management system comprising:
   a cover and a pneumostoma management device;
wherein the pneumostoma management device comprises a tube adapted to be inserted in a pneumostoma, said tube connected to an external section in order to secure the pneumostoma management device to a chest of a patient;

wherein the cover is configured to attach to the pneumostoma management device such that said cover presents an outward surface which substantially obscures the external section of the pneumostoma management device from view;

wherein the outward surface of the cover is designed to have a preferred visual appearance compared to the external section of the pneumostoma management device.

27. The pneumostoma management system of claim 26, wherein the cover comprises one or more clips configured to releasably attach the cover to the pneumostoma management device.

28. The pneumostoma management system of claim 26, wherein the cover comprises an adhesive surface configured to attach the cover to the pneumostoma management device.

29. The pneumostoma management system of claim 26, further comprising a threaded coupling that can releasably attach the cover to the pneumostoma management device.

30. The pneumostoma management system of claim 26, wherein the cover comprises one or more apertures to allow gases to escape from the pneumostoma management device.

31. The pneumostoma management system of claim 26, wherein the outward surface of the cover is color-matched with a skin color of a patient in order for the cover to have a preferred visual appearance compared to the external section of the pneumostoma management device.

32. The pneumostoma management system of claim 26, wherein the outward surface of the cover is provided with an ornamental pattern in order for the cover to have a preferred visual appearance compared to the external section of the pneumostoma management device.

33. The pneumostoma management system of claim 26, wherein the outward surface of the cover is provided with a patient-customizable pattern in order for the cover to have a preferred visual appearance compared to the external section of the pneumostoma management device.

34. The pneumostoma management system of claim 26, wherein the outward surface of the cover is a printable surface and wherein at least one of a customizable pattern and color is printed on the outward surface prior to use of the cover in order for the cover to have a preferred visual appearance compared to the external section of the pneumostoma management device.

73
35. The pneumostoma management system of claim 26, wherein the cover comprises a plurality of apertures which are large enough to allow gases to escape from the pneumostoma management device but are too small to be visible to a casual observer from a distance of four feet or more.

36. A cover for a pneumostoma management device wherein the pneumostoma management device comprises a tube adapted to be inserted in a pneumostoma said tube connected to an external section in order to secure the pneumostoma management device to a chest of a patient and wherein the cover comprises:
   a body having an outward surface and an attachment surface;
   wherein the attachment surface is configured to attach the cover to a pneumostoma management device;
   wherein the outward surface is adapted to substantially obscure the external section of the pneumostoma management device from view;
   wherein the outward surface of the body is designed to have a preferred visual appearance compared to the external section of the pneumostoma management device.

37. The cover of claim 36, wherein the attachment surface of the cover comprises one or more clips configured to releasably attach the cover to the pneumostoma management device.

38. The cover of claim 36, wherein the attachment surface of the cover comprises an adhesive surface configured to attach the cover to the pneumostoma management device.

39. The cover of claim 36, wherein the cover comprises one or more apertures to allow gases to escape from the pneumostoma management device.

40. The cover of claim 36, wherein the outward surface of the cover is color-matched with a skin color of a patient in order for the cover to have a preferred visual appearance compared to the external section of the pneumostoma management device.

41. The cover of claim 36, wherein the outward surface of the cover is provided with an ornamental pattern in order for the cover to have a preferred visual appearance compared to the external section of the pneumostoma management device.

42. The cover of claim 36, wherein the outward surface of the cover is provided with a patient-customizable pattern in order for the cover to have a preferred visual appearance compared to the external section of the pneumostoma management device.
43. A medical device to allow gases to exit a lung through a pneumostoma in a chest of a patient, wherein the medical device comprises;
   a substantially planar flange having a contact surface adapted to contact the chest of the patient and an outer surface;
   the flange being substantially larger in size than a pneumostoma,
   the flange being sufficiently thin and flexible to conform to the chest;
   the contact surface having an adhesive coating adapted so that the flange can be releasably secured to the chest of the patient,
   the flange having an opening;
   a tube projecting from the flange;
   the tube adapted to be inserted into the chest through the pneumostoma,
   the tube having a lumen, a proximal end and a distal end
   the distal end of the tube having at least one opening adapted to admit gases from the lung,
   the proximal end of the tube being connected to the flange such that the opening in the flange communicates with the lumen of the tube; and
   a filter disposed over the opening in the flange and secured to one of the flange and tube such that gases passing into and out of the lung pass through the filter.

44. The medical device of claim 43, further comprising:
   a chest mount which comprises a patch at least as large in diameter as the flange;
   the patch being sufficiently thin and flexible to conform to the chest of the patient
   the patch having an aperture larger in diameter than the tube;
   the chest mount having a distal surface having an adhesive coating adapted to releasably secure the chest mount to the chest of the patient;
   whereby the chest mount is adapted to be secured to the chest of the patient by the adhesive coating on the distal surface of the chest mount, the tube is selectively inserted into a pneumostoma through the aperture in the patch, and the pneumostoma vent is selectively secured to the chest mount by the adhesive coating on the flange.

45. The medical device of claim 43, further comprising a plug wherein:
   the plug is substantially impermeable and is larger in diameter than the filter; and
   wherein the plug has an adhesive coating that allows the plug to be selectively secured to the flange such that the plug obstructs the filter and substantially prevents passage of solids, liquids and gases through the medical device.

46. The medical device of claim 43, wherein the flange and tube are formed in one piece.
47. The medical device of claim 43, wherein the tube is an extruded tube which is formed separately from the flange and then bonded to the flange.

48. The medical device of claim 43, wherein the filter is too large to fit into through the lumen of the tube.

49. The medical device of claim 43, wherein the adhesive coating comprises a hydrocolloid adhesive configured adapted to releasably secure the flange to the chest of the patient.

50. The medical device of claim 43, wherein the filter is substantially flush with the flange.

51. The medical device of claim 43, wherein the flange, filter and adhesive coating is less than 5 mm in thickness in combination.

52. A medical device to allow gases to exit a lung through a pneumostoma in a chest of a patient, wherein the pneumostoma vent comprises:
   a tube adapted for insertion into the chest through the pneumostoma,
   the tube having a lumen, a proximal end and a distal end;
   the distal end of the tube having at least one opening adapted to admit gases from the lung;
   the proximal end of the tube having one or more arms projecting a sufficient distance from the tube to preclude passage of proximal end of the tube into the pneumostoma,
   a hydrocolloid ring surrounding the tube;
   a hydrophobic filter disposed over the proximal end of the tube adapted to allow gases to escape the tube but retain liquids or solids within the tube;
   an adhesive film having an aperture smaller than the filter and positioned such that the adhesive cover secures the filter over the proximal end of the tube, and the adhesive cover is secured to the arms of the tube and at least a portion of the hydrocolloid ring.

53. The medical device of claim 52, further comprising a plug, wherein:
   the plug comprises a substantially impermeable patch larger in diameter than the aperture of the adhesive film; and
   wherein the patch has an adhesive to temporarily secure the patch to the adhesive film such that the patch obstructs the aperture and substantially prevents the passage of solids, liquids and gases through the tube.
54. The medical device of claim 52, wherein the flange and arms are formed in one piece.

55. The medical device of claim 52, wherein the tube is an extruded tube which is formed separately from the arms and then bonded to the arms.

56. The medical device of claim 52, wherein the adhesive cover is a transparent breathable polymer film having one adhesive surface configured to releasably secure the medical device to the chest of the patient.

57. The medical device of claim 52, wherein the medical device is provided to the patient in at least two pieces.

58. The medical device of claim 52, wherein the medical device is provided preassembled to the patient and further comprising at least one protective sheet which protects the adhesive surfaces of the medical device prior to use.

59. The medical device of claim 52, wherein the cover film, arms, filter and hydrocolloid adhesive coating are less than 3 mm in thickness in combination.

60. The medical device of claim 52, wherein there are at least three arms.

61. The medical device of claim 52, wherein there are at least four arms.

62. A pneumostoma management device adapted to allow gases to exit a lung through a pneumostoma in a chest of a patient, wherein the pneumostoma management device comprises:

- a tube adapted to be inserted into the chest through the pneumostoma, the tube having a lumen, a proximal end and a distal end
  - the distal end of the tube having at least one opening adapted to admit gases from the lung;
- a flange connected to the proximal end of the tube such that an opening in the flange connects to the lumen of the tube, and
  - the flange projecting a sufficient distance from the tube to preclude passage of flange into the pneumostoma.
Instructions For Use
Replace MOUNT weekly and/or as indicated

Obtain replacement MOUNT and prepare

Remove disposable MOUNT from pneumostoma and dispose of MOUNT

Remove cleaning swab from sterile package

Clean skin surrounding pneumostoma

Inspect skin surrounding pneumostoma

Remove new MOUNT from sterile package

Remove backing from adhesive pad.

Align MOUNT with pneumostoma and place adhesive pad in contact with skin.
Instructions For Use
Replace VENT daily and/or as indicated

Obtain replacement VENT and prepare and verify size

Remove used VENT

Clean chest mount or skin of chest

Inspect pneumostoma

Remove new VENT from sterile package

Remove protective cover

Align VENT with MOUNT and insert until fully inserted
FIG. 17A

1720 Instructions For Use
Replace MOUNT weekly and/or as indicated

1722 Obtain replacement MOUNT and prepare and verify size

1724 Remove disposable MOUNT from pneumostoma and dispose of MOUNT

1726 Remove cleaning swab from sterile package

1728 Clean skin surrounding pneumostoma

1730 Inspect skin surrounding pneumostoma

1732 Remove new MOUNT from sterile package

1734 Remove backing from adhesive pad.

1736 Align MOUNT with pneumostoma and place adhesive pad in contact with skin.
38/48

FIG. 17B

1740 Instructions For Use
Replace VENT daily and/or as indicated

1742 Obtain replacement VENT and prepare and verify size

1744 Insert removal tool into used VENT and push button on removal tool to secure

1746 Remove used VENT from MOUNT using removal tool

1748 Inspect pneumostoma

1750 Remove new VENT from sterile package using insertion tool

1752 Align VENT with MOUNT and insert until cap of VENT clicks into place

1754 Pull handle to release insertion tool

1756 Remove and discard insertion tool