The Amnio Breathe™ Nebulizer Bundle is designed to deliver our ambient liquid allograft product, Fluid Flow™, as a topical directly onto a patient’s respiratory system (nasal cavity, pharynx, larynx, bronchus, and lungs).
Product Description

Q-Code: Q4206
The Amnio Breathe™ Nebulizer Bundle is designed to deliver our ambient liquid allograft product, Fluid Flow™, as a topical directly onto a patient’s respiratory system (nasal cavity, pharynx, larynx, bronchus, and lungs). Similar to its use on primary relevant conditions (degenerative joint disorders, inflammatory conditions, and soft tissue injuries), the natural growth factors and cytokines that are present in amniotic fluid help to regenerate soft tissue while inhibiting inflammation and scar tissue formation.

Fluid Flow™ Product Description

BioLab Fluid Flow™ is an amniotic liquid allograft derived from the amniotic fluid within the placenta to advance soft tissue repair, replacement, and reconstruction.

Application

The application of our Fluid Flow™ liquid amnion through our Amnio Breathe™ Nebulizer has shown to help patients suffering from COPD and other respiratory conditions such as bronchitis, emphysema, and seasonal allergies. In addition, the Amnio Breathe™ Nebulizer has been used as a general wellness treatment, by systemically circulating the growth factors and cytokines throughout the body to help repair and replace damaged soft-tissue.
Amnio Breathe™ Treatment Outcomes
Dec 21, 2018 – January 24, 2019

- 15 ½ year old male
- Swimmer
- Asthma sufferer for 12 years
- Used maintenance inhaler (mometasone furoate/formoterol fumarate dihydrate) 2x day in AM, rescue inhaler (albuterol sulfate) as needed, one tablet cetirizine daily
- Chronic post-nasal drip; sometimes so severe he cannot swim for fear of the feeling of ‘drowning’.
- Secondary airways consistent at +/- 70% for previous 12 months (possibly longer... compiling data)
- Received 2cc of Amnio Breathe™ through our T-App nebulizer
- 4 days after treatment, all post-nasal drip was cleared; stopped taking Cetirizine
- 4 days after treatment, stopped using chemical inhalers
- Re-tested 34 days later. 22% improvement in secondary airways
Amnio Breathe™
Nebulizer/Compressor Kit Pricing

**Initial Kit Contains:**
- 3 ccs of Fluid Flow™
- Compressor/Nebulizer
- 2 Masks

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<th>Bundle Cost</th>
<th>Rebate Cost</th>
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<td>2 masks</td>
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**Replacement Kits**

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Amnio Breathe™
Nebulizer/Compressor Kit Pricing

Small Nebulizer Bundle - 1 Treatment

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<td>2 masks</td>
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Rebate Price: $3,600
Est. Profit per Kit: $2,400

Initial Kit Contains:
• 3 ccs of Fluid Flow™
• Compressor/Nebulizer
• 2 Masks

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BioLab Sciences
13825 N. Northsight Blvd Suite 101
Scottsdale, AZ 85260
info@biolabsciences.net
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Amnio Breathe™ Nebulizer Bundles

Formulations of human amniotic fluid and methods of use thereof for treatment of lung disorders, and/or injuries have been developed. The formulations are suitable for topical delivery to the lung for treatment of lung disorders including chronic obstructive pulmonary disorders (COPD), asthma, emphysema, bronchiectasis, chronic bronchitis, interstitial lung disease, alpha-1 antitrypsin emphysema, as well as for treatment of acute lung injuries. Methods including administering specifically formulated, diluted sterile human amniotic fluids topically to the lungs, preferably as aerosol droplets, are described. In particular, the methods involving administration of the amniotic fluid formulation in the form of aerosol droplets with size between about 1.5 μm to about 5 μm, preferably from about 2.5 μm to about 3.5 μm, inclusive, using apparatus such as high-efficiency vibrating mesh nebulizers, are described. Formulations described can treat, or prevent one or more symptoms of a chronic lung disorder.

Disorders and Diseases to be Treated

The formulations can be used for various lung disorders, including, but not limited to, any obstructive lung disorders, and restrictive lung disorders. In some embodiments, the disclosed formulations are effective in improving exercise endurance, increasing in baseline blood oxygen saturation, and/or reducing inflammation in the lungs of patients with any obstructive lung disorders, and restrictive lung disorders. In some embodiments, the disclosed formulations are effective in helping patients to be less dependent on using other supplemental treatment such as bronchodilators, and/or oxygen therapy.

The formulations are particularly suited for treatment of COPD and asthma, including, but not limited to, bronchitis, chronic bronchitis, emphysema, and associated cor pulmonale (heart disease secondary to disease of the lungs and respiratory system) with pulmonary hypertension, right ventricular hypertrophy and right heart failure, bronchial asthma, allergic asthma and intrinsic asthma, e.g., late asthma and airway hyper-responsiveness.

Other non-limiting examples include bronchiectasis, interstitial lung disease, and alpha-1 antitrypsin emphysema.

Acute respiratory distress syndrome (ARDS) is a rapidly progressive disease occurring in critically ill patients. The main complication in ARDS is that fluid leaks into the lungs making breathing difficult or impossible. ARDS may initially be diagnosed as pneumonia or pulmonary edema (fluid in the lungs from heart disease). Patients with ARDS have
shortness of breath, often severe. They also have a cough and many have fever. Those with ARDS also have fast heart rates and rapid breathing. Occasionally, they experience chest pain, especially during inhalation. Some patients who have very low oxygen levels may have bluish coloring of nails and lips from the severely decreased oxygen levels in the blood. Thus, in some embodiments, the disclosed formulations are used for treating, alleviating, or preventing one or more symptoms associated with acute respiratory distress syndrome.

Intensive care unit (ICU) syndrome, or ICU psychosis occurs in Patients who become psychotic in intensive care units, with underlying causes such as anxiety, sleep deprivation, sensory deprivation and overload, immobilization, an unfamiliar environment and pain. Thus, in some embodiments, the disclosed formulations are used for treating, alleviating, or preventing one or more pulmonary symptoms associated with Intensive care unit (ICU) syndrome.

Systemic inflammatory response syndrome (SIRS), sepsis, severe sepsis, septic shock, and multiple organ dysfunction syndrome (MODS) are common risk factors for the development of acute lung injury in patients. Thus, in some embodiments, the disclosed formulations are used for treating, alleviating, or preventing one or more symptoms associated with Systemic inflammatory response syndrome (SIRS), sepsis, severe sepsis, septic shock, or multiple organ dysfunction syndrome (MODS).

Cystic Fibrosis (CF) is an inherited disease that causes thickened mucus to form in the lungs, pancreas and other organs. In the lungs, this mucus blocks the airways, causing lung damage and making it hard to breathe. Thus, in some embodiments, the disclosed formulations are used for treating, alleviating, or preventing one or more symptoms associated with cystic fibrosis.

Pneumonia is a common lung infection caused by bacteria, a virus, fungi or chemicals. It’s commonly a complication of a respiratory infection—especially the flu—but there are more than 30 different causes of the illness. Older adults, children and people with chronic disease, including COPD and asthma, are at high risk for pneumonia. Pneumonia symptoms can vary from mild to severe, depending on the type of pneumonia you have, your age and health. The most common symptoms of pneumonia are cough (with some pneumonias you may cough up greenish or yellow mucus, or even bloody mucus), fever, which may be mild or high, shaking chills, shortness of breath, which may only occur when you climb stairs. In some embodiments, the disclosed formulations are used for treating, alleviating, or preventing one or more symptoms associated with pneumonia.

Sarcoidosis is a disease that causes your immune system to overreact, which can lead to health issues. It can cause lung damage, skin rashes, and eye disease and can affect other organs of the body. Many patients with sarcoidosis experience lung problems, which may include persistent dry cough, shortness of breath, wheezing, and/or chest
pain. In some embodiments, the disclosed formulations and the methods of use thereof are suitable for managing symptoms associated with sarcoidosis in patients.

Idiopathic pulmonary fibrosis (IPF) is a chronic lung disorder characterized by thickening, stiffening and scarring (fibrosis) of tissue within the lungs. Affected individuals develop shortness of breath and progressive lung disease. Ultimately, IPF results in life-threatening complications such as respiratory failure. In some embodiments, the disclosed formulations and the methods of use thereof are suitable for managing idiopathic pulmonary fibrosis in patients. In some embodiments, the disclosed formulations are used for treating, alleviating, or preventing one or more symptoms associated with idiopathic pulmonary fibrosis. In some embodiments, the disclosed formulations are used for reducing, or preventing pulmonary scarring in patients with IPF.

**Acute Inhalation Injury**

The formulations disclosed are suitable for treatment of acute inhalation injury. Inhaled substances may cause injury in pulmonary epithelium at various levels of respiratory tract, leading from simple symptoms to severe disease. Chemical irritants, asphyxiants, toxic metals, products of fires and combustion, and many other substances have been reported to cause acute inhalation injury (Gorguner M et al., *Eurasian J Med.* 42(1): 28-35 (2010)). Some cases of acute inhalation injury may involve more than one substance or mechanism. In some embodiments, the disclosed formulations are used for treating, alleviating, or preventing one or more symptoms associated with an acute inhalation injury.

In some embodiments, the disclosed formulations are used for people who are at increased risk of exposing to toxic agents as a prophylactic measure. Some exemplary high-risk individuals are farmers who work near silos, firefighters, coal miners after firing of explosives, welders who work with acetylene torches in confined spaces, military personnel, hockey rink workers, and chemical workers who may be exposed to byproduct fumes in the manufacture of dyes and lacquers constitute some of the occupations at risk. For example, the disclosed formulations are suitable for treating, alleviating, or preventing one or more symptoms of coal worker's pneumoconiosis.

In some embodiments, the disclosed formulations are used for farmers who are at risk of exposing to dust, particulates for example from harvesting hay, crops, pesticides, herbicides, defoliates, and fungicides such as methyl oxide. Other potential toxic agents include fruit ripening gas such as ethylene, carbon dioxide which inhibits growth of micro-organisms, nitrogen as inert filler, and gas mixtures to preserve fresh appearance of fruits, vegetables and meats e.g., 1-methylcyclopropene.

Some further chemical agents that can cause pulmonary injuries include defoliant, ecocide, harassing agent, herbicide, pesticide, nerve agent, and antipersonnel agents. For example, Agent Orange used during the Vietnam war is a blend of two herbicides
known as 2,4-D and 2,4,5-T. Two other herbicides, picloram and cacodylic acid, were also used, but in much smaller amounts. In some embodiments, the disclosed formulations are used for treating, and/or alleviating one or more symptoms in subjects with long-term pulmonary injuries due to exposure to agents such as Agent Orange.

Inhalation of a number of gases, mists, aerosols, fumes or dusts may cause irritant lung injury, asphyxiation, or other systemic effects. The use of industrial chemicals with potential toxicity has been on the rise. Accidental spills, explosions, and fires can result in complex exposures to such substances. According to the National Occupational Exposure Survey (NOES 1981-1983), more than one million workers in US are estimated to be under the risk of exposure to respiratory irritants annually; however, data from poison control centers suggest that inhalation injuries occur more frequently in the home environment than in the workplace. The number of people affected varies depending on the environment and may be as high as tens of millions in case of air pollution reaching hazardous levels, for example, due to ozone depletion.

Handling chemicals, working in inadequately ventilated areas, or entering areas of exposure with improper or no protective equipment are generally the reasons for occupational injuries (White S R et al., Emergency medicine: a comprehensive study guide. 6th ed. New York: The Mc Graw Hill Companies, Inc.; 2004). In general environment, random exposures may occur such as mixing household chemicals by mistake, for example bleach and hydrochloric acid mixture, or a gas leak at home, for example carbon monoxide, or smoke containing irritant chemicals, for example pyrolysis products made of synthetic materials when used during a house-fired. Chemicals are used in manufacturing of polyurethane foam, molding, insulation, synthetic rubber, and packaging materials and can induce lung cell injury when inhaled. Chemical toxins and chemical warfare agents, such as tabun, sarin, soman, cyclosarin, VX nerve gas, sulfur mustard, Agent Orange, chlorine, phosgene, and diphosgene, can cause life-threatening lung disease (Kales S N et al., N Engl J Med. 19; 350(8):800-8 (2004); Newman L S et al., N Engl J Med. 28; 333(17):1128-34 (1995)).

Common Chemical Irritants

Chemical irritants in occupational and environmental areas are usually the cause of acute inhalation toxicity. Exemplary chemical irritants include chlorine, hydrogen chloride, ammonia, hydrogen fluoride (HF) and hydrofluoric acid, sulphur dioxide (SO2), nitrogen oxides, phosgene, hydrogen sulfide (H2S). In some embodiments, the disclosed formulations are used for treating, alleviating, or preventing one or more symptoms associated with an acute inhalation injury caused by chemical irritants.

Asphyxiants

In some embodiments, the disclosed formulations are used for treating, alleviating, or preventing one or more symptoms associated with an acute inhalation injury caused by one or more asphyxiants. Unlike chemical irritants, asphyxiant has a different
mechanism. However, some asphyxiants such as hydrogen sulfide may also have a chemical irritation effect. Based on their effects, asphyxiants can be divided into two groups: simple asphyxiants which act by displacing oxygen from inspired air resulting in a reduced fraction of inspired oxygen and subsequent hypoxemia, and chemical asphyxiants, such as carbon monoxide and hydrogen cyanide, which act by interfering with oxygen delivery or utilization. However, any gas in high concentration can act as an asphyxiant. Although, for example, methane, ethane, argon, and helium are more innocent at low concentrations, at high exposure levels they can displace oxygen or block the reaction of cytochrome oxidase or hemoglobin, impairing cellular respiratory and oxygen transport.

**Burns and Smoke**

In some embodiments, the disclosed formulations are used for treating, alleviating, or preventing one or more symptoms associated with an acute inhalation injury caused by burns and/or smoke inhalation. Exposure to heat, particulate matter, and toxic gases are considered the exposure to smoke. Closed-space fires and conditions that cause unconsciousness are often the reason for inhalation injuries. Between 20% and 30% of burn victims suffer from pulmonary complications, with an incidence rate correlating with the severity of the burn and a history of being in enclosed space. Tracheobronchial damage and pulmonary complications, which are common and an important cause of morbidity and mortality, may be accompanied by infection, shock, and the consequences of therapy, including overhydration. The improvements in the treatment of burn shock and sepsis has rendered inhalation injury the main cause of mortality in the burn patients (Hartzell G E, Toxicology. 115(1-3):7-23 (1996)).

“Smoke inhalation” is a generic term that refers to a potential exposure to a wide variety of substances because of the complex chemistry of heat decomposition and pyrolysis. Both firefighters (both urban and wildland) and non-occupational victims can be exposed to substantial numbers of irritants. Thermal injuries typically limited to upper airways; however, those below the vocal cords occur only with steam inhalation. The entire respiratory tract can be affected by smoke inhalation from fires. Smoke contains particulate matter which is formed from incomplete combustion of an organic material, usually less than 0.5 μm in size. Thus, small particles can easily reach the terminal bronchioles and here they can initiate an inflammatory reaction, leading to bronchospasm (Ainslie G, Respir Med. 87(3):169-74 (1993)).

**Chemical Warfare and Riot Control Agents**

In some embodiments, the disclosed formulations are used for treating, alleviating, or preventing one or more symptoms associated with a pulmonary injury caused by chemical warfare and/or riot control agents. Chemical Warfare and Riot Control Agents of the past, especially during World War I and II, were gases such as Agent Orange, mustard gas, phosgene and chloropicrin. Today, chemical warfare armamentarium includes systemic toxins derived from organophosphate pesticides. Besides being
highly lethal neurotoxins, they also have important respiratory effects, such as bronchorrhea and bronchospasm, which occur via muscarinic receptor stimulation. Riot control agents (crowd control agents, tear gases) aim to incapacitate persons via immediate mucous membrane irritation. Chloroacetophenone and orthochlorobenzamalonitrile are the most common agents worldwide. They have been reported to have mucous membrane effects as well as causing lower respiratory injury. Contrary to tear gases, zinc chloride, which is the primary component of smoke bombs, is a potent lower respiratory tract irritant and may cause severe pulmonary edema. In some embodiments, the disclosed formulations are used to treat, alleviate, or prevent pulmonary edema.

Thus, in some embodiments, the disclosed formulations are used immediately after exposure to any potentially toxic agents to prevent the onset of any pulmonary injuries, and/or to alleviate immediate onset of pulmonary conditions whilst preventing one or more secondary symptoms. In some embodiments, the disclosed formulations are used to treat, alleviate, or prevent any pulmonary tissue scarring. In some embodiments, the disclosed formulations are used to treat veterans who exposed to toxic gas such as Agent Orange, mustard gas during the wars in managing their pulmonary health.

**Toxic Metals**

In some embodiments, the disclosed formulations are used for treating, alleviating, or preventing one or more symptoms associated with a pulmonary injury caused by toxic metals. Cadmium and mercury are the most common metals causing inhalation injury. Welding, brazing, or flame cutting metal under poor ventilation are the typical conditions for cadmium exposure typically, while heated metal reclamation processes involve potential mercury exposure risks. Metals or their compounds such as antimony, manganese, beryllium, vanadium and tributyltin rarely cause inhalation injury through the inhalation of fumes or vapors of the certain metals, acute pneumonitis may develop. Heavy metal pneumonitis has been accounted for by the inhibition of enzymatic and other critical cellular functions. In such cases, chelation treatment may be considered (Nemery B, *Eur Respir J*. 3(2):202-19 (1990)).

**Inhalation Fevers**

In some embodiments, the disclosed formulations are used for treating subjects with inhalation fevers prior to any confirmed lung injuries for preventative uses. Inhalation fever includes metal fume fever, polymer fume fever, and organic dust toxic syndrome, all of which share similar clinical findings and prognosis. Exposure to zinc fume and sometimes to copper and magnesium fume causes metal fume fever. Exposure to heated fluoropolymers and high amounts of endotoxin leads to polymer fume fever and organic dust toxic syndrome, respectively, which are characterized with chills, fever, malaise, and myalgia with onset 4 to 8 hours after intense inhalation of fumes or dust. Common respiratory complaints include cough or mild dyspnea.
Blast Injury

Lung injury is frequently a component of the polytrauma sustained by military personnel surviving blast on the battlefield. Injuries from explosions arise in a number of ways. In temporal order these include tissue damage from; the blast shock wave (primary blast injury), material propelled into the casualty (secondary), the casualty propelled against other objects (tertiary), heat, chemicals and toxins delivered by the device (quaternary) and finally the systemic inflammatory response provoked in the host (quinary). Fatal blast lung injury (BLI) can be sustained in the absence of any other external signs of trauma, thoracic or otherwise. The clinical diagnosis of blast lung is based on context, clinical symptoms and radiology. Symptoms may include respiratory distress, restlessness, and in some cases haemoptysis, associated with cyanosis and hypoxaemia. In some patients symptoms may be significantly delayed. Typical findings described to date include unilateral or bilateral focal opacities, diffuse unilateral or bilateral loss of lung translucency which, if unilateral, may be associated with reduced rib-expansion, and radiological evidence of barotrauma. The latter may include pneumothorax, pneumomediastinum, pneumopericardium, surgical emphysema, interstitial emphysema and haemothorax secondary to pulmonary parenchymal lacerations.

In some embodiments, the disclosed formulations are used for treating, alleviating, or preventing one or more symptoms associated with a pulmonary condition associated with blast injury. In some embodiments, the disclosed formulations are administered to anyone with pulmonary blast-related injuries, or anyone suspected to have exposed to blast injury, within the “Golden Hour” following impact. In some embodiments, the disclosed formulations are administered to anyone who is susceptible to pulmonary blast-related injuries to prevent onset of any symptoms, or to prevent one or more secondary complications associated with the lung. In some embodiments, the disclosed formulations are administered in combination with one or more further interventions such as supplemental oxygen.

Complex Exposures

In some embodiments, the disclosed formulations are used for treating, alleviating, or preventing one or more symptoms associated with a pulmonary injury caused by exposure to one or more toxic compounds. Individuals who suffer inhalation injuries are frequently exposed to complex mixtures of toxic compounds, not just a single agent. Though poorly characterized, such mixtures may contain admixtures of combustion products, pyrolysis products, metals, particulates, and gas. Such mixtures have been shown to have the potential to produce a range of airway and diffuse interstitial lung lesions.
Individuals who are accidentally exposed to toxic gases usually recover completely. However, sometimes acute life threatening or chronic severe complications may develop. Thus, in some embodiments, the disclosed formulations are used for preventing one or more symptoms of secondary/chronic pulmonary complications in patients who have had acute inhalation injuries. In some embodiments, the disclosed formulations are used for treating, alleviating one or more symptoms of patients who have had acute inhalation injuries and developed chronic pulmonary complications. Some exemplary chronic pulmonary complications include reactive airway disease syndrome (RADS), bronchiolitis obliterans (BO, also known as constrictive bronchiolitis), cryptogenic organizing pneumonia (COP), and bronchiectasis.

**Dosages and Dosing Regimens**

Dosage and dosing regimens are dependent on the severity of the lung disorder, and is known to those skilled in the art.

The formulation disclosed will be tailored to the individual subject, the nature of the condition to be treated in the subject, and generally, the judgment of the attending practitioner. In yet another embodiment, the formulation is any amount of about 0.1-10 ml combined with any amount of about 0.1-10 ml of sterile water, or saline solution.

For treatment of COPD and asthma, including, but not limited to, chronic bronchitis, emphysema, bronchiectasis, chronic bronchitis, interstitial lung disease, and alpha-1 antitrypsin emphysema using the disclosed formulations, it generally provides a nebulizer and an ampoule containing not less than 0.1 ml of the D-HAF formulation, for example, any amount between 0.1 ml to 10 ml of D-HAF mixed with sterile saline solution or sterile water.

**Mild COPD, Asthma Enduced COPD:** 1ml – 2ml combined with .5-1ml of sterile saline or sterile water.

**Severe COPD, Severe Pulmonary Disease** 2ml-3ml combined with 1ml-2ml of sterile saline or sterile water.

**General Wellness Treatments:** .5ml - 2ml combined with .5-1ml of sterile saline or sterile water.
EXAMPLES

Example 1: Treatment of COPD Patient with Amniotic Fluid Solution

The purpose of the study is to determine appropriate therapeutic treatment of COPD using nebulized amniotic fluid via vibrating mesh nebulizer.

Materials and Methods

Selection Criteria

Patients must be free of cancer as determined by chest computerized tomography (CT) scans. In the case of cancer diagnosis in the past five years, there must be declaration of cancer-free by the treating physician. Patients must also be free of fibrotic disease. Patients must be free of tobacco usage within 6 months prior to the treatment.

Data Collection

Pulmonary function tests were performed at baseline (i.e. just prior to the treatment with the amniotic fluid formulation), at 1 month, and at 6 months. Spirometry data were collected at pre- and post-bronchodilation, 1 week, and 3 months. Oximetry data were collected whilst at rest with room-air at baseline, 30 minutes post treatment, 1 week, 1 month, 3 month, and 6 months. Oximetry data after 6-minute walk test with room air were collected at baseline, 1 week, 1 month, 3 month, 6 months. Blood pressure results were collected at every visit. All results were documented in patient-specific spreadsheet.

Dosage

Amniotic fluid formulation was given at a dosage unit of 0.5 cc unless otherwise indicated. Typically, 0.5 cc of Amniotic fluid mixed in with 3.0 cc normal saline solution is added to a vibrating mesh nebulizer for administering to the patients. Routinely, only one-time treatment is given at the first visit followed by data collection at prescribed times including baseline, 1 month, 2 months, 3 months, etc., depending on the availability of the patients. If a physical visit to the clinic was not feasible an evaluation would be conducted over the phone. In more severe cases of COPD, a higher dose of Amniotic fluid was given for example 1.0 cc. In some instances, additional doses were given.

Results
Treatment of Moderate-to-Severe COPD

Patient (C.T.) was diagnosed with COPD four years prior to the treatment. She had a persistent cough, shortness of breath, and poor skin color.

C.T. was given albuterol treatment, immediately followed by 0.5 cc Amniotic fluid on the initial visit. At 2-week follow-up visit, C.T. appeared to have much improved skin color. C.T. said that since her initial treatment she had been generally much more active, such as carrying out daily activities of going to the mall, walking around the block and vacuuming her house without shortness of breath. She also mentioned that she only had one coughing spell since her treatment, which was remarkable since she was constantly coughing during her first visit. She no longer needed albuterol after her first visit, which she had not experienced in the past six months. Furthermore, C.T. showed a tremendous improvement in her CCQ (Clinical COPD Questionnaire) scores and reported overall improvement in her well-being.

C.T. highly praised Amniotic fluid throughout her 2-week follow-up visit. Clinically she showed great improvement in her cough and her FEV1 was better than her baseline by 0.12, which was measured without any bronchodilation. She also showed a 10-point improvement in PEF score over her baseline. Her oxygenation stayed the same.

4-week follow-up evaluation was conducted over the phone. The patient reported to have continued improvement in her respiratory status. She said she was exercising more whilst still absent of cough. She mentioned that just prior to the phone conversation she vacuumed her house, washed her tile floors and dusted her house without any shortness of breath. She had not needed her bronchodilation since her initial visit to which she praised the amniotic fluid as a miracle.

TABLE 1 Summary for patient C.T. Pre- Week 2 Week 4 Time Pre- TX/Post Post Follow- Follow- 3 Month point treatment Albuterol treatment up Change up Change Follow-up Change FEV1 1.71 1.45 1.8 1.83 0.12 via via phone phone PEF 182 184 224 192 10 via via phone phone O2 Rest 97 98 98 98 1 via via phone phone O2 98 — Exercise Exercise 2 mins 120 ft time CCQ 36 13 −23 9 −27 9 −27 Dose 0.5 cc

During the 3-month follow-up visit, the patient reported continued success on Amniotic fluid. However, she did feel as if her improvement in her respiratory status had plateaued at this time point. She was given a second dose of 0.5 cc Amniotic fluid the following day.

Treatment of Severe COPD

Patient (J.R.) was a 73-year old female diagnosed with COPD nine years prior to the treatment. The patient had suffered from severe COPD. J.R. had undergone treatment at the Lung Institute with no success or improvement. She routinely exercised three times per week; utilizing a treadmill for 8 mins, 8 mins, 8 mins, and 6 mins. She was
given a prescription of 2 liters per minute (lpm) of oxygen for ambulation, and for night time when necessary. Her FEV1 and PEF could not be measured during this visit due to the severity of her condition. She received 1.0 ml Amniotic fluid mixed with 2.0 ml of NaCl via a vibrating mesh nebulizer.

At the two-week follow-up visit, patient had improved skin color. It was determined that she had some improvement. Specifically, J. R. could exercise on the treadmill at 10 minute intervals compared to 8-minute intervals prior to the treatment. She had also reduced utilization of her oxygen at home—she was using it every morning for 15-20 minutes after waking up prior to the treatment but she had not used it since the first dose of Amniotic fluid. She reported that her nasal passages had been chronically swollen but had not been swollen since her treatment. Her CCQ score, which evaluated her abilities to perform functions, was reduced from 39 at her initial visit to 19, indicating a significant improvement. J.R. reported overall improvement in her well-being and would like to further her improvement from further treatment. She also recognized that due to the severity of her condition, it would take longer to realize the gains from Amniotic fluid. Clinically, she was the same as her initial visit. Her oxygenation stayed the same. However, she has not utilized her oxygen as much at home.

At four week follow-up, the patient reported increased exercise tolerance where she could exercise up to 20 minutes on the treadmill at 1.1 mph. Clinically, it was possible to obtain her FEV1 and PEF scores from her at this time point. She had also further reduced her CCQ scores. Additional doses of 0.5 cc of Amniotic fluid were further administered at week 4 and week 5.

At three month follow-up, the patient reported to be using more oxygen although her exercise levels remained the same. The patient described that the Amniotic fluid had not helped and might even be causing pain. However, based on clinical data of exercise tolerance, her condition had vastly improved.

TABLE 2 Summary for patient J.R. Pre- Week 2 Week 4 Pre- TX/Post Post Follow- Follow- Time point treatment Albuterol treatment up Change up Change FEV1 0 0 0 0 0.36 0.36 PEF 0 0 0 0 0.83 0.83 O2 Rest 96 96 94 97 1 98 2 O2 84 — Exercise Exercise 2 mins 90 ft time CCQ 39 19 −20 18 −21 Dose 1.0 cc 0.5 cc

Treatment of Asthma-Induced COPD

Patient (M.R.) had a history of asthma with frequent wheezes. She suffered from asthma-induced COPD, and had been dependent on prednisone for a long time. She was very limited in her abilities to work, to walk, or to perform any muscle movements. She had also suffered from obstructive sleep apnea, and was using continuous positive airway pressure with 2.5 liters per minute (lpm) of oxygen at night. During daytime, she was given a prescription of administration of oxygen when necessary. She used bronchodilation with metered dose inhaler (MDI) 3 to 5 times a week. M.R. was also on nebulizer twice a day and she used her ancillary breathing muscles frequently.
One week after her initial treatment with the Amniotic fluid, she reported that she only used her rescue inhaler once. She had seen an increase in her exercise tolerance, as well as a decrease in her prednisone dosage in agreement with physician’s orders. She further reported that she had felt better in the mornings, whereas prior to the treatment waking up had always been a chore. Generally, she was also experiencing less shortness of breath. Her CCQ improved dramatically, reduced from 46 to 7. Her PEF and FEV1 remained the same. M.R. was administered a second dose of 0.5 cc Amniotic fluid during her 2-week visit.

At the three-week follow-up visit, M.R.’s exercise tolerance and physiological markers both improved. Her prednisone usage was reduced to a half of pre-treatment usage. She had not required her asthma infusion for 2 months since her last infusion. A third dose of 0.5 ml Amniotic fluid was given during this visit.

TABLE 3 Summary for patient M.R. Pre- Week 2 Week 3 Pre- TX/Post Post Follow- Follow- Time point treatment Albuterol treatment up Change up Change FEV1 0.61 0.63 0.6 0.58 −0.03 0.64 0.03 PEF 162 157 160 135 −27 175 13 O2 Rest 98 95 96 O2 91 90 Exercise Exercise 2 min 240 ft 6 min; time 27 sec 950 ft CCQ 46 7 −39 6 −40 Dose 0.5 cc 0.5 cc 0.5 cc

Treatment of Severe Pulmonary Disease

Patient (B.B.) was a 71-year old male with severe pulmonary disease. CT scan showed significant scaring, but no active fibrotic disease process. The result indicated a combination of signs and symptoms of COPD, and possibly of reactive airway diseases. The patient was highly oxygen-dependent, using 3 liters per minute (lpm) of oxygen at rest, 4 liters per minute (lpm) of oxygen with ambulation and at night. He had also used noninvasive positive-pressure ventilation (NPPV) 10/6 for assistance when sleeping. Walk test revealed minimal exertion (42 ft) resulted in O2 saturation of 88%, with resting O2 saturation of 91%, both of which were measured whilst being administered O2.

Just four days following the initial treatment, the patient called to report that his oxygenation had improved. Prior to the treatment, he had been hindered in carrying out activities of daily living due to shortness of breath. However, he reported that after the first treatment he was able to take off his oxygen to do self-care, which would usually result in his oxygen level to drop to 77% but it stayed at 88%.

At the two-week follow-up visit, the patient continued to improve his ADL abilities and experienced less oxygen desaturation in the absence of external supply of oxygen. At this time, the patient could stay off oxygen supply for 10 minutes before oxygen level dropped to 80%.

At the three-week follow-up visit, the patient further improved his ADL abilities as well as his exercise tolerance. The patient also had an increased PEF score, and a reduced CCQ score. Within three weeks following the initial treatment, the patient’s spouse
reported that B.B. had much improved well-being and could participate in much more physical activities such as going to the mall, and playing with their grandchild.

At the four-week follow-up visit, B.B. reported improved memory and prolonged activity time to about 20 min in the absence of external supply of oxygen. B.B. was also much less dependent on oxygen, dropping oxygen consumption to 50% compared to pre-treatment levels.

Seven weeks after initial visit, B.B. reported that he could be off oxygen for 40-50 min whilst active and 4 hours at rest.

At the nine-week follow-up visit, B.B. was significant improved than at the first visit. He could stay off oxygen for up to 4 hours whilst at rest, and up to 1 hour with activity. His ADLs were much improved—B.B. started off with not being able to perform any ADLs at the first visit and now he could perform ADLs without assistance, SOB, or fatigue. The patient could perform additional activities such as blowing bubbles with his grandchildren, doing yard maintenance, and light carpentry. Clinically, the improvement were observed in the following areas, 17% improvement in FEV1, 33% improvement in PEF, and 92% reduction in CCQ score (reduced score indicates greater ADLs and QOL), where PEF/FEV were performed without bronchodilation. In terms his oxygen requirement, his saturation levels were stable on room air, his supplemental O₂ dependency was reduced by 25%, and recovery time was shortened to less than 2 mins.

**TABLE 4 Summary for patient B.B.**

| Time Pre-TX/Post | Albuterol treatment up Change | up Change | Post Follow | Follow | Follow- point treatment Albuterol treatment up Change up Change | FEV1 | 1.43 | 1.4 | 1.5 | 0.07 | 1.5 | 0.07 | 1.68 | 0.25 | PEF | 278 214 280 2 349 71 369 91 O₂ Rest | 91 91 91 88 O₂ 88 Exercise Exercise | 0 min | 42 ft time CCQ 47 15 | –32 Dose | 0.5 cc | 0.5 cc | 0.5 cc |

**Treatment of Severe Persistent Asthma**

Patient (D.S.) was a 14-year old male with severe persistent asthma with acute exacerbations. He was diagnosed with asthma at the age of 4. Since then he always had occasional exacerbations and required daily pharmacological maintenance. D.S. was a track athlete and he used inhaler prior to, and/or post-track events. Since he was an active teenage, CCQ score and exercise test were not very informative in comparing pre- and post-treatment effects. Therefore, his race times and recovery were used to determine the effects of the Amniotic fluid treatment. After the initial dose of Amniotic fluid received on the first visit, D.S. would only receive further doses if he was symptomatic.

In addition to the usual clinical scores, computed tomography (CT) scan was also performed on this patient. Contiguous contract and non-contrast enhanced axial CT images were obtained of the chest from the thoracic inlet through the lung bases with
breath hold in expiration, pre- and post-therapy. Multiplanar reformatted images were generated and reviewed with both soft tissue and lung windows. 140 ml ULTRAVIST® 370. Contrast Volume Discarded: 0 ml. BUN/Creatinine not required.

Computed tomography findings were as follows:

1) Pre-therapy: there was anterior bowing of the posterior membranous trachea consistent with expiration; there was significant respiratory motion artifact which likely represented difficulty with breath holding and/or mild respiratory distress; there was mild hyper expansion; evaluation of pulmonary vasculature was limited by respiratory motion artifact but grossly normal.

2) Post-therapy: there was anterior bowing of the posterior membranous trachea consistent with expiration; there was minimal respiratory motion artifact present only at the lung bases; the lungs were normally expanded; there was normal pulmonary vasculature.

3) The thyroid appeared normal. Minimal normal residual thymus was demonstrated. There was no axillary, mediastinal, or hilar lymphadenopathy. The airways were patent. There was no focal consolidation, pleural effusion or pneumothorax. There were no pulmonary nodules. The cardiac silhouette was normal without pericardial effusion. The aorta was normal in size. There was normal three-vessel anatomy. The pulmonary artery was normal in size.

4) Limited images through the upper abdomen demonstrated normal upper abdominal contents. Bone windows demonstrated no aggressive appearing osseous lesions. There was no scoliosis or spinal asymmetry. There were no vertebral body anomalies. The subcutaneous soft tissues appeared normal.

Radiologist/Physician interpreted that mildly hyperexpanded lungs with significant respiratory motion artifact was consistent with difficulty breath holding and/or mild respiratory distress in the pre-therapy scans; and normally expanded lungs with only minimal respiratory motion artifact was consistent with significant response to therapy in the post-therapy scans.

Four days after the treatment, D.S. reported that he had not had to use rescue inhaler since the initial visit. Furthermore, he did baseline running events without the need of bronchodilation pre- or post-events.

**TABLE 5 Summary for patient D. S.**

<table>
<thead>
<tr>
<th>Time point</th>
<th>Pre-treatment</th>
<th>Pre-TX</th>
<th>FEV1</th>
<th>2.61</th>
<th>2.83</th>
</tr>
</thead>
<tbody>
<tr>
<td>PEF</td>
<td>359</td>
<td>383</td>
<td>O₂ Rest</td>
<td>98</td>
<td>98</td>
</tr>
<tr>
<td>O₂ Exercise</td>
<td>N/A</td>
<td>Exercise time</td>
<td>N/A</td>
<td>CCQ</td>
<td>N/A</td>
</tr>
<tr>
<td>Dose</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Unless defined otherwise, all technical and scientific terms used herein have the same meanings as commonly understood by one of skill in the art to which the disclosed.
invention belongs. Publications cited herein and the materials for which they are cited are specifically incorporated by reference.

Those skilled in the art will recognize, or be able to ascertain using no more than routine experimentation, many equivalents to the specific embodiments of the invention described herein. Such equivalents are intended to be encompassed by the following claims.

**Claims**

1. A method of treating or preventing a lung disorder or injury in a human, horse, dog or cat comprising administering to the lung of the human, horse, dog or cat in need of treatment a sterile amniotic fluid, in an amount effective to treat, alleviate, or prevent one or more symptoms of the lung disorder or injury, wherein the amniotic fluid is devoid of amniotic cells, micronized membrane, and chorion particles.

2. The method of claim 1 wherein the amniotic fluid is administered in a dosage unit between about 0.1 cc and about 10.0 cc.

3. The method of claim 3 wherein the amniotic fluid is diluted with sterile water, saline or buffer.

4. The method of claim 1 wherein the amniotic fluid is administered to the pulmonary or nasal system.

5. The method of claim 1 wherein the amniotic fluid is administered in the form of aerosol or with a nebulizer.

6. The method of claim 6 wherein the aerosol produces droplets having a size between about 1.5 and 5 microns.

7. The method of claim 7 wherein at least 30% of the aerosol droplets have a size between 1.5 and 5 microns in diameter.

8. The method of claim 6 wherein the amniotic fluid is administered via a nebulizer.

9. The method of claim 1 wherein the amniotic fluid is administered in combination with one or more therapeutic, prophylactic or diagnostic agents.

10. The method of claim 10 wherein the amniotic fluid is administered in combination with one or more agents selected from the group consisting of bronchodilators, corticosteroids, methylxanthines, phosphodiesterase-4 inhibitors, anti-angiogenesis agents, antimicrobial agents, antioxidants, anti-inflammatory agents, growth factors, immunosuppressant agents, anti-allergic agents, and combinations thereof.
11. The method of claim 1 wherein the lung disorder is selected from the group consisting of chronic obstructive pulmonary disorders (COPD), asthma, emphysema, bronchiectasis, chronic bronchitis, interstitial lung disease, alpha-1 antitrypsin emphysema, and combinations thereof.

12. The method of claim 1 wherein the lung injury is an acute inhalation injury caused by exposure to a toxic condition selected from the group consisting of chemical irritants, asphyxiants, burns and smokes, chemical warfare and riot control agents, toxic metals, blast injuries, and combinations thereof.

13. The method of claim 1 wherein the amniotic fluid is in an amount effective for improving exercise endurance, increasing baseline blood oxygen saturation, and/or reducing inflammation in the lungs.
To Whom It May Concern;

I have used Amnio Breathe, Biolab’s liquid allograft to reduce respiratory inflammation particularly reactive airway disorders.

I came across this product for myself because of seasonal allergies and exercise induced wheezing. I am unable to tolerate the usual anti-allergy medications due to side effects. I have used Amnio Breath now every six months and do not require the use of any medications. I can exercise without wheezing and have very few allergies even outdoors.

My patients who have used this product, also found that it positively affects and improves inflammatory joint and muscle and skeletal pain for several months.

Amnio Breathe is rich in important regenerative proteins such as IL-10, IL1 receptor antagonist and Myeloperoxidase. All these protein markers can help to reduce inflammation in human soft tissue as well as the respiratory system and viruses affecting the respiratory system generate toxic inflammatory Cytokines.

A safe modality such as the Amnio Breathe, by combating inflammatory cytokines, can be very effective in fighting the viral diseases and improving the Airway immunity.

Thanks!

Raj M Singh M.D
NeuroPhysiatrist
Barrow Brain and Spine
Barrow Neurological Institute
480-767-0555