

## CATHETER SYSTEM FOR DELIVERY OF AEROSOLIZED MEDICINE FOR USE WITH PRESSURIZED PROPELLANT CANISTER

The present application is a division of Ser. No. 08/261, 490, filed Jun. 17, 1994 and now U.S. Pat. No. 5,642,730.

### REFERENCE TO RELATED APPLICATION

The present application incorporates by reference the copending application entitled "Nebulizing Catheter System and Methods of Use and Manufacture" filed by the same inventor of the present application and on even date herewith and assigned Ser. No. 08/261,866.

### BACKGROUND OF THE INVENTION

The present invention relates to the delivery of medication to the lungs and more particularly, the present invention relates to a delivery system for the application of an aerosolized medication to the lungs or to a specific region within the lungs with improved delivery rates, efficiencies, and control.

Many types of medication can be administered to a patient via the respiratory tract. Medication delivered through the respiratory tract may be carried with a patient's inhalation breath as airborne particles (e.g. an aerosol or nebula) into the lungs where the medication can cross through the thin membrane of the lungs and enter the patient's bloodstream. Delivery of medication via the respiratory tract is preferred in many circumstances because medication delivered this way enters the bloodstream very rapidly. Delivery of medication to the lungs may also be preferred when the medication is used in a treatment of a disease or condition affecting the lungs in order to apply or target the medication as close as physically possible to the diseased area.

Although delivery of medication via the respiratory tract has been used for delivery of medications for many years, there are difficulties associated with such prior systems that have limited their use and application. For example, conventional methods have provided for only limited medication delivery rates, efficiency, and control. Conventional methods for aerosol delivery result in a substantial portion of the medicine failing to be delivered to the lungs, and thereby possibly being wasted, or possibly being delivered to other parts of the body, e.g. the trachea.

Aerosols in general are relatively short-lived and can settle out into larger particles or droplets relatively quickly. Aerosols can also impact each other or other objects, settle out as sediment, diffuse, or coalesce. Aerosol particles can also be subject to hygroscopic growth as they travel. Delivery of medicine as airborne particles requires conversion of the medicine, which may be in liquid form, to an aerosol followed relatively quickly by application of the aerosol to the respiratory tract. One such device that has been utilized for this purpose is an inhaler. Inhalers may atomize a liquid to form an aerosol which a person inhales via the mouth or nose. Inhalers typically provide only limited delivery of medication to the alveoli of the lungs since much of the medication is deposited on the linings of the respiratory tract. It is estimated that as little as 10-15% of an aerosol inhaled in this way reaches the alveoli.

Aerosol delivery of a medication to a patient's respiratory tract also may be performed while the patient is intubated, i.e. when an endotracheal tube is positioned in the patient's trachea to assist in breathing. When an endotracheal tube is positioned in a patient, a proximal end of the endotracheal tube may be connected to a mechanical ventilator and the

distal end is located in the trachea. An aerosol may be added to the airflow in the ventilator circuit, conveyed to the endotracheal tube, and carried by the patient's inhalation to the lungs. A significant amount of the aerosolized medication may be deposited inside the endotracheal tube and the delivery rate of the medicine to the lungs is also relatively low and unpredictable.

The low and unpredictable delivery rates of prior aerosol delivery systems have limited the types of medications that are delivered via the respiratory tract. For new medications that are relatively expensive, the amount of wasted medicine may be a significant cost factor in the price of the therapy. Therefore, it would be advantageous to increase the delivery rate or efficiency of a medicine delivered to the lungs.

It may also be advantageous to be able to target medication to a specific bronchus, or specific groups of bronchia, as desired, while avoiding delivery of medication to other portions of the lungs.

Another consideration is that some medications or other agents that can be delivered as aerosols can have adverse side effects. Therefore, it would be advantageous to minimize the overall amount of medication or agent delivered while maintaining the efficacy of the medication by providing the same or a greater amount of the medication to the desired treatment site.

Taking into account these and other considerations, it would be advantageous to improve the delivery rate and efficiency of aerosolized medicines delivery via the respiratory tract.

### SUMMARY OF THE INVENTION

According to a first aspect of the present invention, there are provided an improved system and method for delivery of an aerosolized medicine to a patient's respiratory system. The system uses a pressurized canister that contains a mixture of fine particles of a medicine and a propellant which may be in a liquid state. The canister has an outlet from which the mixture can exit. The system includes an extension catheter that connects at a proximal end to the outlet of the canister. The extension catheter has a length such that a distal end can be positioned either in an endotracheal tube or deep in the respiratory tract of the patient while the proximal end of the extension catheter is connected to the canister which is located outside the patient's body. The extension catheter includes at least one lumen extending therethrough for conveying the medicine/propellant mixture from the canister to a distal exit orifice where an aerosol can be generated as the propellant evaporates. The aerosolized medicine is carried by the patient's inhalation and delivered to the lungs. The extension catheter may be positioned in an endotracheal tube or alternatively may be used with a patient who is not intubated.

Throughout this specification and these claims, the extension catheter is described as used for the delivery of medicine or medication. It is intended that the terms "medication", "medicine", and "drug" be understood to include other agents that can be delivered to the lungs for diagnostic or therapeutic purposes, such as tracers. In addition, although the extension catheter is discussed as being placed in the trachea, it should be understood that unless otherwise noted the extension catheter can be positioned in any airway of the respiratory tract.

### BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a plan view of an embodiment of the present invention shown in place in the trachea of a patient who is intubated.