

## SELF-ILLUMINATING INTRODUCER

### BACKGROUND OF THE INVENTION

#### 1. Field of the Invention

This invention relates to endotracheal catheters or tubes and more particularly to introducers that facilitate the intubation of catheters or tubes into the patient. Specifically, the present invention is directed to a pliable introducer tube that includes at its front end, a sealed chemiluminescent vial. When the tube is bent or pressed, the vial reacts by emitting a light at the front end of the introducer tube.

#### 2. Description of the Related Art

During the course of many surgical operations; emergency situations, both pre-hospital and hospital; ICU and long term critical care, patients often require endotracheal intubation. This is accomplished by the insertion of an endotracheal catheter or tube. Usually, unless one of the lungs is being operated on, it is desirable to place the distal end of the endotracheal catheter proximally of the junction between the bronchi. Endotracheal intubation can be difficult even for an experienced anesthesiologist; often the endotracheal catheter can be inadvertently placed down the esophagus instead of the windpipe. Moreover, even if the catheter is correctly placed at the onset of an operation, it can become dislodged as a consequence of the movements of the patient during the operative procedures. Thus, it is necessary to periodically determine the location of the endotracheal catheter during an operation.

The positioning of an endotracheal catheter is determined currently by three methods. First, the anesthesiologist listens to the lungs during a lung oxygenation or pressurization step. The sounds heard with a properly placed endotracheal catheter generally differ from the sounds heard with an improper placement. Second, the carbon dioxide content of gases expelled via the endotracheal catheter is measured. If the catheter is properly placed in the trachea, there is carbon dioxide present in the outgoing gases. Third, tissue oxygenation is measured to determine whether the blood is carrying oxygen to the patient's tissues. The tissue oxygenation can be measured from a patient's finger, for example, or other areas of the body that do not interfere with the operation being performed. Although these methods are the most commonly utilized, none are completely effective in determining exact endotracheal catheter placement.

During some operations, fiber optic endoscopes or lighted stylets are inserted into a body cavity to provide a remote image of the body cavity. Due to the ability of the doctor to actually see the placement of the fiber optic endoscope or stylet, proper placement is usually easier to accomplish and maintain in the course of an operation. In recent years, several versions of a fiber optic endoscope or lighted stylet have been introduced. These include: The Fiberoptic Lighted Intubation Stilette (Benson Medical Industries, Inc. Markham, Ontario, Canada), Flexilum (Concept Corporation, Clearwater, Fla.), Tubestat (Concept Corporation), Fiberoptic Lighted Stylet (Fiberoptic Medical Products, Inc., Allentown, Pa.), and the Trachlight. After more than a decade of use, these devices have proven to be an effective and safe method for insertion of an endotracheal tube.

A fiber optic endoscope or a lighted stylet typically includes an insertion section which is adapted to be inserted into a body cavity and an external control section. The insertion section includes a light carrying bundle of optical fibers or other light source, such as a lightbulb, an optical objective lens and a means for carrying an optical image to

the control section. The control section includes a light source, processing means for processing the image received and a display source.

In some types of endoscopes, the insertion section of the endoscope can be shaped or bent in a controlled manner, by external manipulation, to guide the endoscope through a body cavity. This allows the insertion section to be maneuvered through the body cavity without causing harm to the patient.

One area of medicine in which an endoscope has found limited use is in the insertion of the previously mentioned endotracheal catheter. This medical procedure, in which the endotracheal catheter is inserted into the trachea, supplies oxygen or anesthetic gases to the lungs. In some cases, endotracheal intubation is difficult to accomplish. The intubation process, if incorrectly performed, may cause injuries to the patient, such as tears and damage to the larynx, trachea, nasopharynx and bronchi. It is apparent that an external visual image and, especially improved illumination, would be helpful for use in these type of medical intubation processes.

The applicant's prior U.S. Pat. Nos. 3,957,055; 4,185,639; and 4,655,214 pertain to improvements in the intubation of endotracheal catheters and tubes.

A search of the prior art did not disclose any patents that read directly on the claims of the instant invention however, the following U.S. patents were considered related:

U.S. Pat. No.	INVENTOR	ISSUED
5,400,771	Pirak, et al	28 March 1995
5,329,940	Adair	19 July 1994
5,285,778	Mackin	15 February 1994
5,277,173	Cantele	11 January 1994

The U.S. Pat. No. 5,400,771 Pirak, et al patent discloses an endotracheal intubation assembly and related method. During and after insertion of an endotracheal tube into the trachea of a patient, an image is transmitted along the endotracheal tube from a distal end to a proximal end. This transmitted image enables an operator to determine proper placement of the endotracheal tube. Upon determination that an incoming image is different from a stored reference image, an alert signal is automatically issued to an operator. The signal indicates that the distal end of the endotracheal tube has moved from a predetermined position within the patient's trachea.

The U.S. Pat. No. 5,329,940 Adair patent discloses an endotracheal catheter intubation assist device in which an endoscope is utilized. The endoscope provides a visual image as an aid in performing the intubation of an endotracheal tube into a patient's trachea. The assist device includes a handle, a malleable elongated insertion section and an endoscope assembly having a viewing end mounted within the insertion section to provide a visual image of the trachea. In use, the endotracheal catheter is placed around the insertion section and removably attached to the handle for insertion into the trachea. The malleable insertion section can be bent by the attending medical personnel in order to provide a custom fit for the patient. The handle of the assist device is also formed with an oxygen supply conduit for supplying oxygen to the patient during the intubation process. Additionally, the handle includes a suction port for attaching a suction tube for evacuation of the trachea during the intubation process.

The U. S. Pat. No. 5,285,778 Mackin patent discloses an endotracheal catheter that includes a main tube having a