

## INSTRUMENT FOR INTERVENTIONAL FLEXIBLE TRACHEOSCOPY/ BRONCHOSCOPY

### BACKGROUND OF THE INVENTION

#### 1. Field of the Invention

The present invention relates to an instrument for interventional flexible tracheoscopy/bronchoscopy, particularly for the treatment of central air passage stenoses under local anesthesia with the aid of a flexible fiber bronchoscope.

#### 2. Description of the Related Art

In bronchoscopy or tracheoscopy, the direct observation of the bronchial tree or the trachea is carried out by means of a bronchoscope. In addition to diagnostic observation, bronchoscopy or tracheoscopy also serve for the removal of tissue samples, for the removal of foreign bodies and for carrying out other therapeutic treatments, such as laser therapy or radiation therapy or the placement of prostheses.

There are essentially two methods for carrying out the bronchoscopy or tracheoscopy.

In the first method, a rigid tube, usually equipped with an independent light source, observation magnifier, angular lens system or other lens system, is inserted through the mouth into the trachea. The instruments required for treatment are then introduced through the rigid bronchoscope and are actuated. Respiration of the patient takes place through the tube.

In accordance with the other method, initially a flexible tracheal tube is placed and a flexible fiber bronchoscope is guided through the tube. It is also possible to insert the fiber bronchoscope alone or next to the flexible tube. In this case, respiration of the patient is spontaneous.

The insertion of a respiration tube from the mouth or nose into the larynx or trachea is known from endotracheal intubation. The outer end of the tube is provided with an expandable cuff to provide a complete sealing action. After the tube has been inserted into the trachea and has been placed into the correct position, the cuff is expanded, so that the surface of the cuff rests against the mucous membrane of the trachea and closes off the outer area in an air-tight manner. Such an endotracheal tube is known, for example, from DE-OS 41 15 497. The fiber bronchoscope is then inserted through the tube.

In accordance with another possibility, double lumens are used which are composed of two tubes which are joined to each other, wherein one of the tubes is intended for the respiration of the patient.

Laser operations in the areas of the pharynx and larynx with the aid of endotracheal tubes and bronchoscope have also been carried out successfully in recent years.

So-called stents are used in the treatment of stenoses of the larynx. A stenosis is a congenital or acquired narrowing of a body tube. A stents hold the body tube open as an internal support member and, thus, acts as a spacer member. An appropriate tool is required for the insertion of the stent. Such a tool is known, for example, from WO 91/17789. In that case, the stent is held together in a flexible tube during the insertion process. For placing the stent, the stent is released by means of a pusher. Depending on the type of configuration of the stent, the stent expands into its expanded position either by itself as a result of its natural tension or with the aid of a dilator.

A general problem in the diagnosis and therapy of pulmonary defects, bronchial defects or tracheal defects is the fact that the instruments must be inserted from the mouth or

the nose into the larynx or the trachea, wherein it is necessary to pass the area of the vocal cords in the larynx. However, with a diameter of about 15 mm, the maximum open width of the larynx in the area of the vocal cords is very narrow, so that the inserted instruments take away a very large portion of the free lumen. Consequently, the spontaneous respiration of the patient is impaired. In addition, there is the danger that the vocal cords are injured.

In the case of laser treatment, irritations of the mucous membrane as a result of laser smoke may occur. In the other hand, in the case of radiation treatment (brachytherapy), ulcerous changes can be observed at those locations where the tube carrying the radiation medium rests due to its spring stiffness against the inner wall of the trachea.

Moreover, it appears that the known instruments for inserting and placing stents can be improved. Especially in the case of stents whose activation requires a heat application to the stent, it is useful to provide a suitable tool.

### SUMMARY OF THE INVENTION

Therefore, it is the primary object of the present invention to provide an instrument for tracheoscopy/bronchoscopy which can be inserted gently into the larynx or the trachea, which ensures a good utilization of the available space and which makes it possible to carry out active therapeutic measures, wherein the instrument is to be particularly suitable for the introduction and placement of stents.

In accordance with the present invention, an instrument for interventional flexible tracheoscopy/bronchoscopy includes an outer tube and an inner tube, wherein the outer tube and the inner tube can be displaced relative to each other, and wherein at least one guide element is provided for positioning the inner tube relative to the outer tube and a cuff which can be filled with a medium is arranged in the area of the distal end of the inner tube.

The inner tube is composed of a thin elastic synthetic material, such as polyurethane or Teflon. The inner tube is guided over a conventional fiber bronchoscope. At its proximal end, the inner tube has a standard adaptor or connector. At its distal end, the inner tube is equipped with a cuff which can be filled with a medium. A thin additional duct through which the cuff can be filled and emptied is provided in the wall of the inner tube. However, the supply line for the cuff can also be guided on the inside or the outside of the wall of the inner tube. Gases or liquids can be used for expanding the cuff.

The outer tube is preferably manufactured of stiffer synthetic material. Since the open width of the larynx in the area of the vocal cords is very limited, the outer diameter of the outer tube should not be substantially greater than 11 mm. The length of the outer tube is shorter than that of the inner tube.

An annular gap having a width of about 2.5 mm exists between the inner tube and outer tube. The free space available as a result is sufficient for ensuring a safe respiration, even if the bronchoscope is inserted into the inner tube.

The inner tube and the outer tube can be displaced relative to each other in longitudinal direction as well as in axial direction. Guide elements ensure a problem-free sliding movement and prevent the undesirable contact between the tubes and they prevent closing of the annular gap required for respiration.

On the other hand, the axial position of the inner tube in the outer tube can be determined by the appropriate arrange-