

## OROEESOPHAGEAL, INSTRUMENT INTRODUCER ASSEMBLY AND METHOD OF USE

### TECHNICAL FIELD

This invention relates generally to oral, instrument introducers and, in particular, to an oroesophageal, instrument introducer assembly and a method of introducing large instruments such as an echotransducer positioned on the distal tip of a steerable gastroscope shaft through the introducer assembly.

### BACKGROUND OF THE INVENTION

A conventional echocardiographic study is performed on the chest of a patient using a hand-held high frequency or ultrasound transducer for achieving a non-invasive examination of cardiac structures, function, and flow patterns. In some cases, however, the transducer beam cannot adequately image a particular cardiac structure or area due to the thickness of a patient's chest wall, surgical dressings positioned on the patient's chest wall, or a medical condition such as a chronic lung problem (emphysema).

A solution to these limitations in echocardiographic study is the transesophageal technique, which utilizes a miniaturized echotransducer positioned on the tip of a steerable gastroscope shaft. This transducer is introduced into the esophagus through the mouth, and the echocardiographic study is performed through the esophageal wall or stomach by directing the transducer beam toward the heart. A transesophageal echotransducer, which is commonly 14 by 13 mm in rectangular cross-sectional dimension, is traditionally positioned on the distal end of a gastroscope and inserted into the esophagus adjacent the heart. The transducer is moved and repositioned for attaining various images. In addition, a transducer is often removed and replaced with a different transducer for imaging a different angle, particularly since small bi-plane transducers are not commercially available.

A problem with the introduction and positioning of a transducer in the esophagus of a patient is that transducer movement causes gagging and considerable discomfort to conscious patients. As a result, sedation or even general anesthesia is used. Furthermore, transducer movement causes trauma to the esophagus as well as other complications such as aspiration, respiratory depression, esophageal perforation, and bleeding. Several anatomical structures, such as a sphincter, the lateral piriform recesses near the cricopharyngeal region, and the right angle arrangement between the mouth floor and the esophagus in the pharynx, present problematic areas for the physician to negotiate during the introduction, positioning, and exchange of a transducer.

A possible approach to minimizing these negative effects is to introduce a transducer through an endotracheal tube, which is conventionally used for establishing or maintaining an airway in a patient with respiratory problems. A limitation of endotracheal tubes is that they are used for providing an airway lumen. As a result, endotracheal tubes typically have a relatively small inside diameter and are formed of relatively stiff and unkinkable material. Therefore, endotracheal tubes are unsuitable for protecting the esophageal wall during introduction, positioning, and exchange of one or more transducers therethrough.

### SUMMARY OF THE INVENTION

The foregoing problems are solved and a technical advance is achieved in an illustrative oroesophageal introducer assembly for introducing therethrough large instruments such as an echotransducer positioned on the distal tip of a steerable gastroscope for performing an echocardiographic procedure. The introducer assembly comprises an outer sheath having an atraumatic tapered distal end and a passage extending longitudinally therethrough that is sized for passing a large instrument such as the echotransducer and gastroscope therethrough. Advantageously, the size of the outer sheath passage is significantly larger than the passage of an endotracheal or nasopharyngeal tube to pass the diagnostic instrument therethrough. The tapered distal end of the outer sheath advantageously minimizes trauma during introduction of the sheath into the esophagus. To further advantageously minimize trauma to the esophagus during introduction, the introducer assembly includes a dilator positioned in the passage and extending from the tapered distal end of the outer sheath. The tapered distal end of the dilator has an outermost cross-sectional shape approximating that of the passage of the outer sheath to minimize any space therebetween and further minimize trauma to the esophagus during introduction of the assembly.

The introducer assembly further includes a guide tube having a closed, atraumatic distal end for oral insertion into the stomach of the patient by way of the esophagus. The introduced guide tube has a cross-sectional shape significantly less than that of the outer sheath to facilitate easy insertion into the esophagus and to atraumatically introduce the outer sheath thereover into the esophagus. The dilator also includes a passageway extending longitudinally therethrough approximating the cross-sectional shape of the guide tube to again minimize any space therebetween and further minimize trauma to the esophagus during introduction of the assembly into the esophagus of the patient. The guide tube further includes a plurality of side ports positioned proximate the closed, atraumatic distal end thereof to permit the attending physician to introduce air into the stomach using a syringe and confirm proper placement of the guide tube by auscultating over the stomach area. The guide tube further includes a removable connector fitting positioned in the passage of the guide tube proximate the proximal end thereof for connection to a syringe and introduction of air into the patient's stomach. The guide tube also includes a visible marker positioned on the outer surface of the tube a specified distance from the closed, atraumatic distal end thereof to further aid proper positioning of the guide tube into patient's stomach.

The dilator includes a distal tip piece of a semirigid material forming the tapered distal end of the dilator for advantageously dilating the esophagus during introduction therein. The dilator also includes an inner sheath of flexible material and a detachable connector fitting positioned in the passage proximate the proximal end of the inner sheath. The inner sheath has an outermost cross-sectional dimension substantially smaller than the innermost dimension of the cross-sectional shape of the outer sheath passage for advantageously maintaining the flexibility of the introducer assembly during oral introduction through the airway and into the esophagus. The introducer assembly also includes a mouth-piece positioned in the passage proximate the proximal