

### Background

Thoracic surgery frequently requires isolation of one lung from the other. Successful lung isolation with cessation of ventilation to one lung, whilst maintaining ventilation of the other lung, enhances surgical access, provides protection against contamination by infected debris and fluid spreading from one lung to the other and enables control of the distribution of ventilation.

Current techniques of lung isolation involve the use of either a double lumen tube with a cuffed endobronchial limb or use of a single lumen tube in conjunction with a torque controlled bronchus blocker.

Occasionally there can be difficulties with both techniques;

Conventional double lumen tubes can be difficult to pass through the larynx and their endobronchial limb can prove difficult to position within the appropriate bronchus.

Torque controlled bronchus blockers require the use of a fiberoptic bronchoscope for guidance into position and can be time consuming and difficult to get into, and maintain, in a satisfactory position.

The currently used combination of a single lumen endotracheal tube and torque controlled blocker provides a mechanically unstable means of occlusion of a bronchus. As the blocker cuff has no forces acting to hold it in position, it is prone to displacement on movement of the patient or the endotracheal tube or on surgical handling of the lungs, thus compromising the surgical field and patient safety.

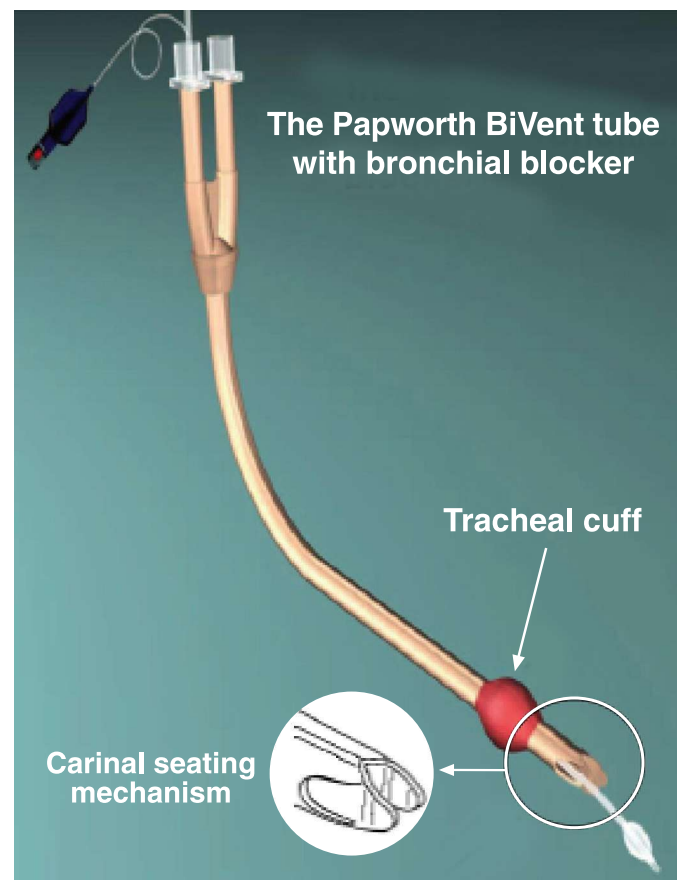
### A new solution

The Papworth BiVent tube is a novel double lumen endotracheal tube specifically designed to combine the benefits of double lumen tubes and bronchus blockers, but without the drawbacks of either.

The Papworth BiVent tube is designed to act as a means for rapidly and easily guiding a bronchus blocker into either main bronchus and to stabilise the blocker in position.

### Benefits of the new design

- Easier and quicker to pass through the larynx and correctly position.
- Bifurcated tip design allows ET tube to sit on the carina in a stable position.
- Bronchus blocker can be rapidly passed through either lumen directly into the bronchus, considerably reducing the time from intubation to lung isolation.
- Bifurcated tip design stabilises the inflated blocker cuff in position by preventing herniation of the blocker cuff into the trachea or dislodgement of the blocker from the bronchial orifice.



### Use in clinical practice

The shape and configuration of the BiVent tube allows it to be passed almost as easily as a single lumen tube through the larynx and down the trachea.

Once the tip of the tube is seated on the carina, the tracheal cuff is inflated to provide a gas tight seal and further stabilise the tube in position. With the tube stabilised in position a bronchus blocker, either non-wired or torque controlled, can rapidly be passed through either of the lumens into the bronchus adjacent to that lumen. Inflation of the blocker cuff isolates that lung from ventilation and from the opposite lung. The design of the tube promotes the maintenance of the blocker in position.

### Pre-clinical trial

A pre-clinical trial was carried out using the Laerdal Airway Management Training Manikin to compare the speed and ease of successful lung isolation by eight skilled Thoracic Anaesthetists using the Papworth BiVent tube and bronchus blocker, a conventional single lumen tube and bronchus blocker and a conventional double lumen tube.

It was found that the Papworth BiVent tube;

- 1 Allowed most rapid attainment of successful lung isolation.
- 2 Was almost as easy to intubate with as an ordinary single lumen endotracheal tube.
- 3 Was scored as the easiest technique for lung isolation.

### Market potential

Approximately 500,000 surgical procedures requiring lung isolation are carried out each year. This number is likely to increase with the growing demand for thoracic surgery as diagnostic and therapeutic procedures evolve.

The novel design of double lumen tube to guide and stabilise bronchus blockers in position will be of enhanced benefit in general procedures requiring access to structures in the chest, for example oesophagectomy, sympathectomy and in specialist thoracic surgical operations on the lungs and pleura.

The device also has potential benefits in clinical areas where rapid lung isolation is required, for example in the Accident and Emergency or armed forces settings, where there is no simple, satisfactory device that can be used for rapid lung isolation.

### Current Development

P3 Medical Limited has exclusive commercial rights for this device and a clinical evaluation at Papworth Hospital NHS Foundation Trust is currently being planned.

### The device is protected by Patents and Registered Design Rights.

For further information please contact Customer Services at P3 Medical Limited.

