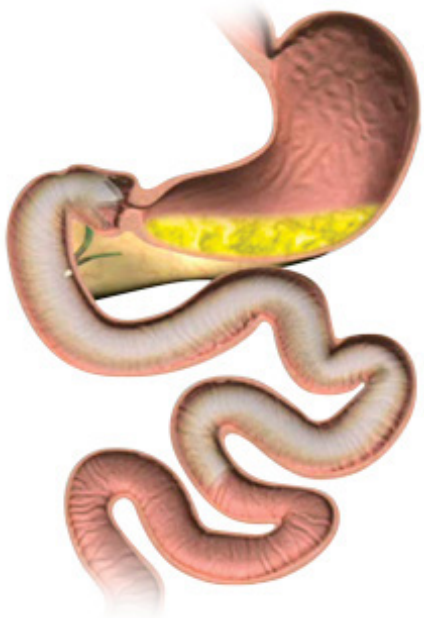
# EndoBarrier® Implantation
## KEY POINTS

The EndoBarrier is a 60cm sheath which lines the duodenum and first part of the small bowel. It is conceptually based on the gastric bypass procedure which has been around for 50 years in various forms and has been shown to induce gut hormones to be released which may favour weight loss and diabetes control.



The device is inserted endoscopically in a 20 minute procedure under anaesthetic which does not require any surgical cuts. The device is anchored to the first part of the duodenum just beyond the stomach by a series of small spikes. The device must always be removed at 12 months as per TGA guidelines. Over 500 devices have been inserted in humans worldwide with varying results. Some people require the device to be removed prior to the 12 month period. Of those who keep the device for 12 months, weight loss and diabetic control is frequently observed.

This device is still considered investigational and further study is required to establish the future role of this device in obesity and diabetes control. Insertion and removal of EndoBarrier does not preclude any subsequent standard weight loss surgery procedure.

*Below is a list of estimated complication rates associated with EndoBarrier placement. Because the device is relatively new these estimates cannot be based on large volume data from publications. Rather they represent my best estimates based on previous and current experience with this and other similar procedures*

| Complication | Frequency | Comment |
|---|---|---|
| | | |
| Death | 1/5000 (??) | No deaths have been reported to my knowledge |
| Duodenal Perforation | 1/100 (??) | Severe complication |
| Aspiration Pneumonia | 2-5% | Stomach fluid refluxed into the lungs due to putting the endoscope and device into the oesophagus |
| | | |
| Unable to place device | 5% | Sometimes the duodenal anatomy does not permit placement of the device |
| Procedure abandoned | 5-10% | Due to discovery of pathology such as peptic ulcer. May not necessarily preclude subsequent placement of the device. |
| Bleeding | 5% | May lead to removal of the device |
| Removal prior to 12 months | 20% | Due to pain, bleeding, vomiting or other |
| Oesophageal rupture | 1% | May be a severe complication |
| Device migration | 10% | May be a reason for removal of the device |
| Obstruction | 5% | Blockage or perhaps inversion of the whole device |

Due to the novel nature of the procedure, it is possible that complications may occur which have never before been described. This is expected to be a rare occurrence.

Please sign and date to indicate your understanding of the above:

Sign: _____ Print Name: _____ Date: _____