

# National Institute for Health and Clinical Excellence

## 988 – Laparoscopic gastric plication for the treatment of severe obesity

### Consultation Comments table

IPAC date: Thursday 12 July 2012

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response
1	Consultee 1 NHS Professional	1	This procedure should/must be subjected to proper randomised controlled trials against its competitor sleeve gastrectomy. This may be a clever device but its relative safety and efficacy can only be established against existing procedures and odd surgeons experimenting in uncontrolled series is an inappropriate way to proceed. It is inappropriate to apply such lesser standards to medical devices than pharmacological agents in the setting that RCTs are eminently designable in this situation	Please respond to all comments  Thank you for your comment. 1.4 states that further research, including that which makes comparison to alternative procedures, would be useful.
2	Consultee 1 NHS Professional	2.1	A patient may have more than one procedure at the same time - I dont think so.	Thank you for your comment. This sentence has been deleted.
3	Consultee 1 NHS Professional	2.3	All case series - evidence level well below that required for acceptance. Little is known about the impact of this procedure on gastric acid secretion, gastric emptying, gut peptide hormones and all of these may enlighten concepts of MOA, durability and safety.	Thank you for your comment. The Committee agreed that there was limited evidence of efficacy in the short and medium term and more evidence is needed about the long-term efficacy of the procedure. Item 1.4 highlights further areas for research.

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4	Consultee 1 NHS Professional	2.4	Again case series provide no evidence of comparative safety	Please respond to all comments  Thank you for your comment. The Committee has noted in 1.1 and 1.4 that there is inadequate evidence of safety in the long-term and need for further research.

*"Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees."*