ASMBS Policy Statement on Gastric Plication
October 6, 2011

The following statement is issued by the American Society for Metabolic and Bariatric Surgery in response to numerous inquiries made to the Society by patients, physicians, society members, hospitals, and others regarding laparoscopic gastric plication as a treatment for obesity. The recommendation is based on current clinical knowledge, expert opinion, and published peer-reviewed scientific evidence available at this time. The statement is not intended as, and should not be construed as, stating or establishing a local, regional, or national standard of care.

Laparoscopic gastric plication, also known as laparoscopic greater curvature plication, has recently emerged as a new bariatric procedure. The rationale for this procedure addresses issues that may limit the acceptance of other bariatric procedures. Specifically, the gastric plication does not involve gastric resection, intestinal bypass, or placement of a foreign body, and this could potentially provide a lower risk alternative that will appeal to patients and referring physicians. The operation involves mobilizing the greater curvature of the stomach similar to the dissection for a sleeve gastrectomy and infolding or imbricating the stomach to achieve gastric restriction. There are increasing numbers of gastric plication procedures being performed worldwide and this operation is being marketed as a new option for surgical weight loss by some practices.
The quantity (4 studies, <300 patients) and quality (prospective or retrospective case series) of the data available at this time is insufficient to draw any definitive conclusions regarding the safety and efficacy of this procedure. The Society will continue to monitor the data on this procedure as it emerges and will issue a formal evidence-based position statement at the appropriate time. In addition to the greater curvature plication procedure, a combination of gastric banding with greater curvature gastric plication has also been described in the literature. This procedure is similar to laparoscopic gastric plication but includes placement of the adjustable gastric band. This combined technique has been suggested to augment the early weight loss after gastric banding with possible decrease in the need for band adjustments. However, to-date there is only one peer-reviewed article describing this technique in 26 patients with one-year follow-up. Because of the limited number of clinical studies (N=1) and lack of long-term follow-up, the combination of gastric banding with greater curvature plication is also considered investigational.

We currently support the following recommendations regarding gastric plication alone or in combination with adjustable gastric band placement for the treatment of obesity:

1. Gastric plication procedures should be considered investigational at this time. This procedure should be performed under a study protocol with third party oversight (local or regional ethics committee, Institutional Review Board, Data Monitoring and Safety Board, or equivalent)
authority) to ensure continuous evaluation of patient safety and to review adverse events and outcomes.

2. Reporting of short- and long-term safety and efficacy outcomes in the medical literature and scientific meetings is strongly encouraged. Data for these procedures should also be reported to a program’s center of excellence database.

3. Any marketing or advertisement for this procedure should include a statement to the effect that this is an investigational procedure.

4. The ASMBS supports research conducted under an IRB protocol as it pertains to investigational procedures and devices. Investigator meetings held to facilitate research are necessary and supported, as is the reporting of all data through BOLD, Bariatric NSQIP or a specific research database. The ASMBS does not support CME courses on investigational procedures and devices held for bariatric surgeons for the purpose of use of investigational procedures outside an IRB research protocol.

These recommendations are not intended to impede innovation within our field. Rather, the Society encourages and supports the development of new and innovative procedures that can benefit our patient population. It is imperative, though, that these procedures be conducted responsibly under appropriate supervision and after appropriate training.