Title:	**Intersphincteric injection of silicone biomaterial for severe passive faecal incontinence**
Agency:	Medical Services Advisory Committee (MSAC) Commonwealth Department of Health and Aged Care GPO Box 9848 Canberra ACT 2601 Australia http://www.msac.gov.au
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Aim: To assess the safety, effectiveness and cost-effectiveness of intersphincteric injection of silicone biomaterial (ISISB) for the treatment of adult patients with severe passive faecal incontinence due to diagnostically confirmed internal anal sphincter (IAS) dysfunction, or single or multiple defects of the IAS, for whom all other conservative therapies have failed.

Results and conclusions
Safety: Based on the available evidence, it appears that ISISB for the treatment of severe passive faecal incontinence is safe, as complications were not severe and were infrequent. The majority of complications associated with this procedure (pain and infection) occurred due to the incorrect placement of silicone biomaterial into the submucosal, rather than intersphincteric space. This conclusion is however based on a small number of patients and a relatively short follow-up, compromising our ability to detect rare adverse events.
Effectiveness: Limited data from the available studies have demonstrated that ISISB affords a benefit in terms of continence status and quality of life, in patients with severe passive faecal incontinence in the short term. Both of the studies which utilised the disease-specific, faecal incontinence quality of life (FIQL) index demonstrated a consistent, significant improvement in the domains of lifestyle, coping/behaviour and depression/self perception post-procedure. Based on one study, improvements in continence status and quality of life appear to be better in patients injected under the guidance of endoanal ultrasound compared with those injected under the guidance of digital palpation. A recent conference abstract reported a notable deterioration in function at 36 months follow-up, highlighting potential problems with the durability of the procedure. Therefore, whilst ISISB appears to be effective, it is important to recognise that only a small number of patients were analysed and there was limited follow-up of these patients; hence the long-term effectiveness of this procedure is uncertain.
Cost-effectiveness: Due to the lack of comparative data it was not possible to assess the cost-effectiveness of the procedure. We performed a cost analysis which showed that the main driver of the cost of ISISB was overwhelmingly the cost of the injectable silicone biomaterial. On analysis, the total cost per year for ISISB was estimated to be between $3,072,600 and $3,662,655, depending on the success rate of the procedures. The total cost per year for the current treatment pathway was estimated to be $590,055.

Recommendations: Available evidence suggests that ISISB for severe passive faecal incontinence appears to be safe, and there is some low level evidence of short-term effectiveness but no evidence of long-term effectiveness. In view of the lack of acceptable alternative therapies, a limited assessment of the financial impact was carried out. This demonstrated high cost mainly due to the cost of the prosthesis. MSAC did not recommend public funding for this procedure at this time.

Methods:
The evidence for ISISB for the treatment of severe passive faecal incontinence was systematically assessed. MEDLINE, EMBASE and a number of other databases were searched from January 1989 to June 2006. As it was anticipated that there would be very little evidence, handsearching of relevant online conference proceedings was also undertaken.