NICE National Institute for Health and Care Excellence

NICE guidance

Self-expanding implant insertion into the intersphincteric space for faecal incontinence

HealthTech guidance

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www.nice.org.uk/guidance/htg564

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

This guidance replaces IPG685.

1 Recommendations

1.1 Evidence on the safety and efficacy of self-expanding implant insertion into the intersphincteric space for faecal incontinence is inadequate in quality and quantity. Therefore, this procedure should only be used in the context of research. Find out what only in research means on the NICE interventional procedures guidance page.

1.2 NICE encourages further research into self-expanding implant insertion into the intersphincteric space for faecal incontinence. This could be randomised controlled trials or registry-based research to capture long-term outcomes.

2 The condition, current treatments and procedure

The condition

2.1 Faecal incontinence is an inability to control bowel movements, resulting in the involuntary passage of faeces. The process of defaecation and its control is complex. Causes of incontinence include problems in the colon and rectum (including constipation and diarrhoea), problems with the sphincter muscles (such as damage caused by childbirth or surgery), or nerve damage (such as multiple sclerosis, stroke or spina bifida). Faecal incontinence can also be caused by loss of higher-level cerebral control in conditions such as dementia or severe learning disability.

2.2 NICE's guideline on faecal incontinence in adults states that there is no consensus on methods of classifying the symptoms and causes of faecal incontinence. It is most commonly classified according to symptom, character of the leakage, patient group or presumed primary underlying cause. For many people faecal incontinence is the result of a complex interplay of contributing factors, some of which may be relatively simple to reverse. Therefore, a detailed initial assessment and structured approach to management is needed, starting with addressing reversible factors and, only if this fails to restore continence, progressing to specialised management.

Current treatments

2.3 Initial management of faecal incontinence includes interventions related to diet, bowel habit, toilet access and medication. Specialised management options depend on the underlying cause and include pelvic floor muscle training, bowel retraining, specialist dietary assessment and management, biofeedback, electrical stimulation and rectal irrigation. The main surgical treatment is anal sphincter repair. Sacral nerve stimulation may be offered to people for whom sphincter surgery is not appropriate. If a trial of sacral nerve stimulation is

unsuccessful, a neosphincter may be considered (stimulated graciloplasty or an artificial anal sphincter).

The procedure

2.4 Self-expanding implant insertion into the intersphincteric space for faecal incontinence is done using local or general anaesthesia, with ultrasound guidance. About 6 to 10 small (2 mm) incisions are made in the perianal skin, equidistant to each other, about 2 cm from the anal margin. An introducer is inserted into each incision in turn, pushed through a short subcutaneous tunnel and into the intersphincteric space. The implant is deployed in the desired position within the intersphincteric space. This is repeated around the entire circumference of the internal anal sphincter. The incisions are sutured with resorbable material. Patients are advised to avoid any heavy physical activity for a few days after surgery. One type of implant is a solid polyacrylonitrile cylinder (non-biological) that becomes thicker, shorter and softer over 1 day to 2 days after implantation. The implants expand and press together, forming a ring that creates an artificial sphincter. The aim is to give the person more control over their ability to control defaecation.

3 Committee considerations

The evidence

3.1 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 12 sources, which was discussed by the committee. The evidence included 10 case series, 1 non-randomised comparative study of 2 devices, and 1 case report. It is presented in table 2 of the overview. Other relevant literature is in the appendix of the overview.

3.2 The professional experts and the committee considered the key efficacy outcomes to be: reduced incontinence in the short and long term, improved quality of life, and reduced need for later invasive procedures.

3.3 The professional experts and the committee considered the key safety outcomes to be: infection, bleeding, pain, and device extrusion or migration.

3.4 Patient commentary was sought but none was received.

Committee comments

3.5 The committee noted that there is more than 1 size of device that can be used for the procedure.

3.6 The committee noted that there is a registry for this procedure.

Update information

Minor changes since publication

January 2026: Interventional procedures guidance 685 has been migrated to HealthTech guidance 564. The recommendations and accompanying content remain unchanged.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.