NICE National Institute for Health and Care Excellence

NICE guidance

Artificial anal sphincter implantation

HealthTech guidance
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www.nice.org.uk/guidance/htg39

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 IPG66.

1 Recommendations

1.1 Current evidence on the safety and efficacy of artificial anal sphincter implantation does not appear adequate for this procedure to be used without special arrangements for consent and for audit or research.

1.2 Clinicians wishing to undertake artificial anal sphincter implantation should take the following actions.

- Inform the clinical governance leads in their Trusts.
- Ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. Use of NICE's information for the public is recommended.
- Audit and review clinical outcomes of all patients having artificial anal sphincter implantation.

1.3 Publication of safety and efficacy outcomes will be useful in reducing the current uncertainty. NICE may review the procedure on publication of further evidence.

1.4 It is recommended that this procedure is carried out only in units with a specialist interest in faecal incontinence.

2 The procedure

2.1 Indications

2.1.1 The causes of faecal incontinence are diverse. Existing treatment options include medical therapy, biofeedback techniques and surgery in selected patients. Surgical treatments include sphincter repair, sacral nerve stimulation, encirclement procedures and muscle transposition (for example, dynamic graciloplasty). Some patients may require acolostomy if other treatments fail.

2.2 Outline of the procedure

2.2.1 Implantation of an artificial anal sphincter is used to treat severe faecal incontinence. In this procedure, a fluid-filled cuff is implanted around the anal canal. Tubing from the cuff is channelled under the skin of the perineum and connected to a control pump placed subcutaneously in the scrotum or labia. The control pump is connected by tubing to a pressure-regulating balloon implanted in the abdominal wall. The cuff simulates the natural function of the sphincter muscle; when the fluid is displaced from the cuff to the balloon via the patient-controlled pump, defecation can take place. Once defecation is complete, the fluid is slowly returned to the cuff and continence is again achieved. For more details, refer to the Sources of evidence section.

2.3 Efficacy

2.3.1 No controlled studies were identified. Some of the studies identified were small and some had high losses to follow-up. Among the studies identified, removal of the artificial sphincter system was required in 19% (10 of 53) to 41% (7 of 17) of patients. In patients who had not undergone explantation, all the studies showed improvement in continence. However, different measures of continence were used in the studies. The studies that reported manometric results showed increased mean anal pressures after implantation. For more details, see the overview.

2.3.2 The specialist advisors considered the main efficacy concern to be the frequent need to remove the implanted artificial sphincter.

2.4 Safety

2.4.1 The largest study identified reported that device-related complications occurred in 86% of patients (99 of 115). The most common adverse events reported in this study were: infection 33% (38 of 115); pain 32% (37 of 115); erosion 21% (24 of 115); faecal impaction 18% (21 of 115); faecal incontinence 18% (21 of 115); constipation 17% (20 of 115); surgical injury 13% (15 of 115); wound problems 10% (11 of 115); difficult evacuation 9% (10 of 115); and wound dehiscence 9% (10 of 115). For more details, see the overview.

2.4.2 The specialist advisors considered the main safety concerns to be infection, erosion and evacuation difficulties.

2.5 Other comments

2.5.1 The procedure may have a place in the treatment of patients who are unsuitable for sacral nerve stimulation.

2.5.2 There is a significant rate of complications, such as infection, cuff erosion, wound dehiscence and haematoma, and patients may require revisional surgery or removal of the device. Fully informed consent is therefore particularly important.

3 Further information

Sources of evidence

The evidence considered by the committee is in the overview.

Information for patients

NICE has produced information on this procedure for patients and carers. It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

Update information

Minor changes since publication

January 2026: Interventional procedures guidance 66 has been migrated to HealthTech guidance 39. The recommendations and accompanying content remain unchanged.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.