

Secca System for faecal incontinence

Medtech innovation briefing

Published: 24 May 2016

www.nice.org.uk/guidance/mib66

Summary

The Secca System is a device that is used to apply radiofrequency energy to the internal anal sphincter muscle in the anal canal (known as Secca Therapy) to treat faecal incontinence. The available evidence, which is of limited quality, quantity and generalisability, shows short-term improvements in both faecal incontinence and quality of life, with no significant improvements in the relevant patient-reported scores in the medium and long term (1 and 3 years). The single-use Secca handpiece costs £1,495 and the reusable radiofrequency controller costs £25,000 (both excluding VAT).

<p>Product summary and likely place in therapy</p> <ul style="list-style-type: none">• The Secca System uses thermal energy generated by a radiofrequency (RF) source to treat faecal incontinence in a minimally invasive procedure (known as Secca Therapy).• It is intended for use in people with incontinence of solid or liquid stool at least once a week, whose condition has not responded to conservative management options.• NICE interventional procedure guidance on endoscopic radiofrequency therapy of the anal sphincter for faecal incontinence recommends that the procedure is only carried out in units specialising in assessing and treating faecal incontinence, as one of a range of treatment options, and that further research is done on the procedure.	<p>Effectiveness and safety</p> <ul style="list-style-type: none">• Only 1 relevant study, a follow-up to a study published in 2007, has been published since the development of NICE's interventional procedure guidance on endoscopic radiofrequency therapy of the anal sphincter for faecal incontinence.• This study, which included 31 patients, showed that Secca Therapy resulted in significant improvements in the Vaizey faecal incontinence score and the Faecal Incontinence Quality of Life coping subscore at 6 months when compared with baseline. No significant improvements were found 1 year and 3 years after treatment.
--	---

Technical and patient factors	Cost and resource use
<ul style="list-style-type: none"> • The Secca System consists of a sterile, single-use handpiece and a reusable RF controller. The handpiece includes 4 expandable needle electrodes, which deliver temperature-controlled thermal energy from a RF source to the internal anal sphincter muscle in the anal canal. • Secca Therapy would be done in adults under general anaesthesia as a day case or using local anaesthesia and sedation in an outpatient setting (according to patient and centre preference), by colorectal surgeons trained to use the Secca System. • Treatment takes less than 1 hour. 	<ul style="list-style-type: none"> • The Secca System costs £1,495 for the single-use handpiece and £25,000 for the reusable RF generator, excluding VAT. • No published evidence on resource consequences was found.

Introduction

Faecal incontinence (also described as bowel or anal incontinence) is the involuntary leakage of liquid or solid stool, mucus or gas. Some people get a sudden need to go to the toilet but are unable to reach it in time. This is known as urge incontinence ([NHS Choices 2015](#)). Others do not get this feeling before the leakage, which is known as passive incontinence. These 2 types can occur together or separately (Hull 2007). Faecal incontinence can have a serious effect on quality of life and often results in disability (Frascio et al. 2014). The incidence according to community-based studies ranges from 2% to 17% (Frascio et al. 2014), and it is more common in older people and women (NHS Choices 2015).

The severity of faecal incontinence can be assessed using scoring systems, such as the Vaizey faecal incontinence score, which may help guide treatment decisions. Treatments for faecal incontinence are conservative at first and include dietary changes, medication, muscle-strengthening exercises and biofeedback. If unsuccessful, minimally invasive and surgical options may be considered depending on the cause and severity of incontinence (Wang 2013).

Application of radiofrequency energy to the muscles of the anal canal is a minimally invasive treatment suggested for treating faecal incontinence. The aim of the procedure is to tighten the anal sphincter muscles, increasing the ability to recognise and retain stool, and reduce incontinence, as outlined in NICE's interventional procedure guidance on [endoscopic radiofrequency therapy of the anal sphincter for faecal incontinence](#).

Technology overview

This briefing describes the regulated use of the technology for the indication specified, in the setting described, and with any other specific equipment referred to. It is the responsibility of healthcare professionals to check the regulatory status of any intended use of the technology in other indications and settings.

About the technology

CE marking

The Secca System, originally developed by Curon Medical in 2002, was acquired by Mederi Therapeutics in 2008. The single-use Secca handpiece and reusable radiofrequency (RF) generator (both class IIb) were first CE marked to Mederi Therapeutics in November 2009. Current certification was issued to Mederi Therapeutics in April 2015 and is valid until November 2019. The Secca System is supplied by CJ Medical in the UK.

Description

The Secca System delivers temperature-controlled thermal energy, generated by an RF source, into the internal anal sphincter muscle from a probe placed in the anal canal (known as Secca Therapy). The manufacturer claims that treatment is non-ablative (that is, it does not remove or destroy tissue).

The Secca System consists of a reusable, pole-mounted 4 channel RF generator and a sterile, single-use RF delivery handpiece. A single-use, gel-type patient return electrode completes the RF circuit. The generator has an integrated irrigation pump to cool the mucosal tissue during therapy and a colour display to guide the user through equipment setup and the treatment procedure. The handpiece consists of a transparent anoscope

probe and 4 expandable needle electrodes, which are spaced 22.5° apart in a line around the barrel of the probe. Electrode tip and surface tissue temperatures are measured by thermocouples in the tip and base of the electrode respectively. Energy delivery is controlled by the operator through a trigger and release button, both located on the handpiece.

The probe is inserted into the anal canal until a marker on the probe is aligned with the anatomical dentate line, which acts as a reference point for starting the therapy. The manufacturer recommends that Secca Therapy is done with the anal canal being divided into 4 sections or quadrants. Five evenly spaced levels are treated within each quadrant, with each treatment level spaced 5 mm apart. When the handpiece trigger is pressed, the needle electrodes expand and push through the anal wall into the internal anal sphincter muscle. Low power (up to 8 watts), temperature controlled (65°C and 85°C) RF energy is delivered for 1 minute at each treatment level. The needle electrodes are then retracted using the needle release button on the handpiece. When all 5 levels have been treated within a quadrant, the handpiece is rotated through 90° and treatment starts in the next quadrant (Efron 2004). The procedure is complete when all 4 quadrants have been treated, resulting in 80 separate treatment sites in total.

Setting and intended use

According to the NICE guidance on [endoscopic radiofrequency therapy of the anal sphincter for faecal incontinence](#), the procedure is usually done in secondary care endoscopy units that specialise in assessing and treating faecal incontinence. The procedure typically takes less than 1 hour to complete and is done under general anaesthesia as a day case or under local anaesthesia and sedation in an outpatient setting (according to patient or centre preference), by colorectal surgeons specifically trained to use the Secca System. People typically return to normal activity within 1 to 3 days.

[Contraindications](#) to Secca therapy are listed on the company website. Secca therapy is only done as a single procedure and, in UK practice, is not repeated if the initial procedure does not work.

The Secca System is intended as a minimally invasive surgical option for treating faecal incontinence in adults:

- who have incontinence of solid or liquid stool at least once a week, and

- whose condition has not responded to conservative options, such as dietary changes, physiotherapy and medication.

Current NHS options

NICE guidance on managing [faecal incontinence in adults](#) recommends starting with conservative methods (including dietary changes, addressing bowel habits, and medication), and specialised conservative methods (such as pelvic floor training, bowel retraining, specialist dietary assessment, biofeedback, electrical stimulation and rectal irrigation). If faecal incontinence continues after conservative management, specialist assessments (such as endoanal ultrasound, anorectal physiology studies and proctography) are considered with the aim of treating the condition using minimally invasive or surgical options. Minimally invasive treatments include sacral nerve stimulation and injectable bulking agents. Surgical treatments include anal sphincteroplasty (which repairs or creates a new sphincter from adjacent skeletal muscle), graciloplasty (which creates a new sphincter from gracilis muscle from the thigh), implantation of an artificial anal sphincter or bowel device, or permanent colostomy.

NICE is not aware of any other CE-marked devices that have a similar function to the Secca System.

Costs and use of the technology

Mederi Therapeutics has provided the following list prices (excluding VAT) for each component of the Secca System:

- Handpiece: £1,495 (single use, 1 per patient procedure).
- RF generator: £25,000 (re-usable).

In addition, 1 patient return electrode (costing £4.04) is needed for each procedure. The single-use Secca handpiece has been validated for a 3-year shelf life. The Secca RF generator, which comes with a 12 month warranty, has an anticipated lifespan of 5 years (or 1,000 uses). Free training on using the Secca System is provided, and includes web-based, hands-on, and supervised training during the first 6 procedures. The manufacturer recommends annual maintenance for the Secca System, which includes safety testing and checking RF output level.

No information on the costs of alternative minimally invasive treatment options (for example, sacral nerve stimulation and injectable bulking agents) was identified in the public domain.

Likely place in therapy

Secca Therapy is a minimally invasive treatment option available for people with incontinence of solid or liquid stool at least once a week, in whom conservative management options have not controlled symptoms.

Specialist commentator comments

One specialist commentator stated that the Secca Therapy procedure is easy to learn and straightforward to use in practice. They also noted that Secca Therapy may prevent the need for more invasive treatments. Two specialist commentators stated that the procedure is better tolerated as a day case procedure under a short general anaesthetic rather than under local anaesthesia with sedation.

One specialist commentator noted that the mechanism of action is uncertain, but it can result in subjective and objective improvements in quality of life for people with faecal incontinence when conservative measures have failed. Another specialist commentator stated that the mechanism of action proven in animal models is a combination of fibrosis and myelofibroblast stimulation to bulk internal sphincter muscle.

One specialist commentator stated that the published evidence on Secca Therapy did not differentiate between the type of faecal incontinence (that is, urge or passive). The specialist commentator noted that sacral nerve stimulation was now considered the standard for persistent urge incontinence after conservative treatment, but it has little efficacy in passive incontinence. Due to the lack of comparative data, the specialist commentator felt there was no evidence to justify Secca Therapy over sacral nerve stimulation. One specialist commentator stated that the reported complications of Secca Therapy are few and not major, and felt a failed Secca Therapy procedure would not preclude other therapies or interventions.

One specialist commentator noted that Secca Therapy is not widely used. However both this commentator and another suggested that the indications for using Secca Therapy could be widened. The first of these specialist commentators suggested it could be used

to treat passive incontinence when conservative treatment, such as biofeedback, has failed and anal bulking agents, artificial sphincter insertion, or sphincter repair are being considered. They also suggested that Secca Therapy could be used for urge or mixed incontinence when sacral nerve stimulation is unsuitable or sphincter repair or an artificial sphincter is inappropriate, or after failure of sacral nerve stimulation or sphincter repair. One specialist commentator suggested that Secca Therapy may be more effective in the early treatment of faecal incontinence, rather than in treating end-stage faecal incontinence.

One specialist commentator acted as a specialist adviser to the Interventional Procedures Advisory Committee in the production of NICE's interventional procedure guidance on endoscopic radiofrequency therapy of the anal sphincter for faecal incontinence.

Equality considerations

NICE is committed to promoting equality, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. In producing guidance and advice, NICE aims to comply fully with all legal obligations to:

- promote race and disability equality and equality of opportunity between men and women
- eliminate unlawful discrimination on grounds of race, disability, age, sex, gender reassignment, marriage and civil partnership, pregnancy and maternity (including women post-delivery), sexual orientation, and religion or belief (these are protected characteristics under the Equality Act 2010).

Faecal incontinence is more common in older people and in women (NHS Choices 2016). Age and sex are protected characteristics under the Equality Act 2010.

Evidence review

Clinical and technical evidence

Regulatory bodies

A search of the Medicines and Healthcare Products Regulatory Agency website revealed no manufacturer Field Safety Notices or Medical Device Alerts for the Secca System or Secca Therapy procedure.

A search for 'Secca' on the US Food and Drug Administration (FDA) database: Manufacturer and User Device Facility Experience (MAUDE) identified 2 records (both dated September 2011). Both records were reports of injuries, which included known complications: pain, bleeding, fistula, thermal mucosal injury with infection and necrosis.

Clinical evidence

A systematic literature search identified 10 studies reporting the use of the Secca System. This included 9 prospective single-arm studies and 1 retrospective review of medical records.

A retrospective study (Abbas et al. 2012) was excluded from this briefing because it was of lower quality evidence. Eight of the 9 identified prospective studies have been reviewed before and are summarised in the overview of NICE interventional procedure guidance on [endoscopic radiofrequency therapy of the anal sphincter for faecal incontinence](#). The guidance states that the evidence on endoscopic radiofrequency therapy of the anal sphincter for faecal incontinence raises no major safety concerns. It also states that there is evidence of efficacy in the short term, but in a limited number of patients, and recommends that this procedure should only be used with special arrangements for clinical governance, consent and audit or research. Only 1 study has been published since the guidance (Lam et al. 2014), which included the follow-up of a cohort included in an earlier published study by Felt-Bersma et al. (2007).

A single-centre study by Felt-Bersma et al. (2007) was carried out in the Netherlands. It included 11 patients and reported outcomes up to 1 year after Secca Therapy. The study showed significant improvement in the Vaizey faecal incontinence score at 3 months after

Secca Therapy compared with baseline, lasting 'after 6 and 12 months' (as stated in the paper). This study showed no significant change in physiological measurements at 3 months. One patient (9%) reported moderate discomfort during RF delivery.

The single centre study by Lam et al. (2014), conducted in the same setting, included 31 patients (the original 11 patients reported by Felt-Bersma et al. [2007] and an additional 20 patients) and reported outcomes 3 years after Secca Therapy. This study showed significant improvement in the Vaizey faecal incontinence score at 6 months after Secca Therapy (compared with baseline), with no significant improvement in the score at 1 and 3 years. Significant improvement in the Faecal Incontinence Quality of Life (FIQL) Scale coping subscore was seen at 6 months (compared with baseline) but not in the lifestyle, depression or embarrassment subscores. A stable increase in FIQL was seen at 1 and 3 years after Secca, but this was not deemed to be a statistically significant improvement. The study showed no significant difference in anorectal function between patients with and without a clinical response – defined as patients with a decrease in Vaizey score greater or equal to 20% – at 6 months after Secca Therapy. Reported complications included minor bleeding or haematoma, antibiotic-associated diarrhoea, urinary tract infection, and mucosal discharge. An overview and summary of the results of the Lam et al. (2014) study can be found in [table 1](#) and [table 2](#) of the appendix.

Recent and ongoing studies

No ongoing or in-development trials on the Secca System were found.

Costs and resource consequences

Secca Therapy would be an additional minimally invasive treatment option in people for whom conservative management options have failed, and would incur NHS costs and resources. The additional costs could be offset if Secca Therapy resulted in a reduction in the number of hospital visits, medications prescribed, or the number of subsequent surgical interventions needed to control faecal incontinence symptoms. No published evidence on resource consequences was found.

Strengths and limitations of the evidence

Only 1 study, including 31 patients, has been published since NICE's interventional procedure guidance on [endoscopic radiofrequency therapy of the anal sphincter for faecal](#)

incontinence. This was a 3-year follow-up of an original study (of 11 patients) which was previously reviewed in the production of the guidance.

The Lam et al. (2014) study reported outcomes at baseline and 6 months, 1 year and 3 years after Secca Therapy. This study reported that the minority of patients noted a clinically significant response and that the response was of a temporary nature. However, this study failed to apply appropriate repeated measures statistics when monitoring changes in the Vaizey faecal incontinence score and the FIQL in the same cohort of patients over time. The authors did state that none of the 31 patients had any additional surgical intervention after Secca Therapy, however they failed to report the use of protective pads and medications before and after Secca Therapy. This study was set in the Netherlands, which may further limit the generalisability of the study findings if Secca Therapy was applied in a UK setting.

There is a lack of comparative data showing the advantages of Secca Therapy over other minimally invasive or surgical treatment options, or when the placebo effect is accounted for. Although multiple published papers (Hull 2007; Felt-Bersma 2014; Parisien and Corman 2005) mention an ongoing randomised sham controlled trial, the authors of this briefing have been unable to identify any published results from comparative studies or any ongoing trials using Secca Therapy.

Relevance to NICE guidance programmes

NICE has issued the following guidance:

Insertion of a magnetic bead band for faecal incontinence (2014) NICE interventional procedure guidance 483

Percutaneous tibial nerve stimulation for faecal incontinence (2011) NICE interventional procedure guidance 395

Endoscopic radiofrequency therapy of the anal sphincter for faecal incontinence (2011) NICE interventional procedure guidance 393

Transabdominal artificial bowel sphincter implantation for faecal incontinence (2008) NICE interventional procedure guidance 276

Faecal incontinence in adults: management (2007) NICE guideline CG49

[Injectable bulking agents for faecal incontinence](#) (2007) NICE interventional procedure guidance 210

[Stimulated graciloplasty for faecal incontinence](#) (2006) NICE interventional procedure guidance 159

[Sacral nerve stimulation for faecal incontinence](#) (2004) NICE interventional procedure guidance 99

[Artificial anal sphincter implantation](#) (2004) NICE interventional procedure guidance 66

References

Abbas MA, Tam MS, Chun LJ (2012) [Radiofrequency treatment for fecal incontinence: is it effective long-term?](#) *Diseases of the Colon & Rectum* 55: 605–10

Efron JE (2004) [The SECCA procedure: a new therapy for treatment of fecal incontinence.](#) *Surgical Technology International* 13: 107–10

Felt-Bersma RJF (2014) [Temperature-controlled radiofrequency energy in patients with anal incontinence: an interim analysis of worldwide data.](#) *Gastroenterology Report* 2: 121–5

Felt-Bersma RJ, Szojda MM, Mulder CJ (2007) [Temperature controlled radiofrequency energy \(SECCA\) to the anal canal for the treatment of faecal incontinence offers moderate improvement.](#) *European Journal of Gastroenterology & Hepatology* 19: 575–80

Frascio M, Mondolino F, Imperatore M et al. (2014) [The SECCA procedure for faecal incontinence: a review.](#) *Colorectal Disease* 16: 167–72

Hull T (2007) [Fecal incontinence.](#) *Clinics in Colon and Rectal Surgery* 20: 118–24

Lam TJ, Visscher AP, Meurs-Szojda MM et al. (2014) [Clinical response and sustainability of treatment with temperature-controlled radiofrequency energy \(Secca\) in patients with faecal incontinence: 3 years follow-up.](#) *International Journal of Colorectal Disease* 29: 755–61

NHS Choices (2015) [Bowel incontinence](#) [online; accessed 7 March 2016]

Parisien CJ, Corman ML (2005) The Secca Procedure for the treatment of fecal incontinence: definitive therapy or short-term solution. Clinics in Colon and Rectal Surgery 18: 42–5

Wang JY (2013) Current management of fecal incontinence. The Permanente Journal 17: 65–73

Appendix

Contents

Data tables

Table 1: Overview of the Lam et al. (2014) study

Table 2: Summary of results from the Lam et al. (2014) study

Table 1 Overview of the Lam et al. (2014) study

Study component	Description
Objectives/ hypotheses	To evaluate the clinical response and sustainability of Secca Therapy for faecal incontinence.
Study design	Prospective single-arm study.
Setting	Secca treatments done at a single centre (Netherlands) between 2005 and 2010.
Inclusion/ exclusion criteria	Inclusion criteria: patients with a VS ≥ 12 , whose condition had not improved with conservative treatment (including physiotherapy for 3 months). Exclusion criteria: significant comorbidities (undefined), diarrhoea, large sphincter defect (>25% circumference), inflammatory bowel disease, relevant surgical history (low anterior resection, Pelvic implantation), rectocele, proctitis and anal atresia.

Primary outcomes	<p>VS at 6, 12 and 36 months (a clinically significant improvement was defined as $\geq 50\%$ reduction in VS).</p> <p>FIQL.</p> <p>Secondary outcomes: anorectal manometry, rectal compliance, adverse events, procedural tolerability.</p>
Statistical methods	<p>Differences were analysed using a paired t-test or Wilcoxon rank test when a non-Gaussian distribution was present. The independent t-test was used to compare patients with and without a response. The Fisher's exact test was used to compare proportions. A p-value < 0.05 was considered to be statistically significant.</p>
Patients included	<p>Total cohort n=31 consisting of a cohort of 11 patients previously reported (Felt-Bersma et al. 2007) and 20 additional patients.</p>
Results	<p>Significant improvement in VS at 6 months. No significant improvement in VS at 12 and 36 months when compared with VS at 6 months, after Secca Therapy.</p> <p>Significant improvement in FIQL Scale coping subscore only (no significant change in lifestyle, depression and embarrassment subscores) at 6 months. No significant improvement in FIQL Scale subscores between 6, 12 and 36 months after Secca Therapy.</p> <p>No significant change in anorectal manometry and rectal compliance at 3 months. No differences in anorectal function between patients with and without a clinical response were found.</p>
Conclusions	<p>The authors concluded that these were disappointing outcomes for the Secca procedure, with clinically significant responses being of a temporary nature.</p>
<p>Abbreviations: FIQL, Faecal Incontinence Quality of Life; n, number of patients; VS, Vaizey score.</p>	

Table 2 Summary of results from the Lam et al. (2014) study

	Baseline: before Secca	Follow-up: after Secca	Analysis

Efficacy	n=31 ^a	n=31 ^a	
Primary outcome: VS (mean±SD)	18±3	6 months: 14±5	<p>p<0.001</p> <p>At 6 months, 5 patients (16%) showed a ≥50% decrease in VS, and 12 patients^b (38%) showed a ≤20% decrease in VS.</p> <p>At 12 months, 3 patients (10%) showed a ≥50% decrease in VS compared with baseline.</p> <p>At 36 months, 2 patients (6.5%^b) showed a ≥50% decrease in VS, and 6 patients^b (19%) showed a ≤20% decrease in VS compared with baseline.</p> <p>Comparison of VS at 12 and 36 months (compared with 6 months) showed no significant improvement over time.</p>
Selected secondary outcomes			
FIQL (median):	NR	6 months:	p=NS
• lifestyle	1.5±0.5	NR	p=0.008
• coping	NR	1.9±0.7	p=NS
• depression	NR	NR	p=NS
• embarrassment	NR	NR	Comparison of FIQL subscores at 12 and 36 months (compared with 6 months) showed no significant improvement over time.
Anorectal function	NR	NR	No significant difference in anorectal function between patients with and without a clinical response – defined as patients with a decrease in Vaizey score greater or equal to 20% – at 6 months.
Maximal basal pressure (mean±SD, mmHg)	43±14	3 months: 40±16	p=0.07

Maximum squeeze pressure (mean±SD, mmHg)	22±10	3 months: 24±11	p=0.13
Threshold volume of initial rectal sensation (mean±SD, ml)	78±43	3 months: 79±40	p=0.91
Urge to defecate (mean±SD, ml)	136±57	3 months: 132±53	p=0.62
Maximum rectal distention (mean±SD, ml)	188±12	3 months: 180±11	p=0.43
Additional interventions	None of the 31 patients had any additional surgical intervention after Secca Therapy.		
Safety	n=31		
Adverse events	Minor bleeding or haematoma (n=8) Antibiotic-related diarrhoea (n=7) Urinary tract infection (n=1) Temporary discharge of mucus (n=1) No long-term complications were reported		
Tolerability: Pain VAS (mean [range], cm)	3.9 (0–10) during procedure 3.3 (0–9) after 1 week 1.2 (0–6) after 3 weeks		
Abbreviations: FIQL, Faecal Incontinence Quality of Life; ml, millilitres; n, number of patients; NR, not reported; NS, not significant; SD, standard deviation; VAS, visual analogue scale; VS, Vaizey Score. ^a Includes 11 patients from the Felt-Bersma et al. (2007) study. ^b Number of patients calculated by the authors of this briefing.			

Search strategy and evidence selection

Search strategy

The search strategy was designed to identify evidence on the clinical and cost effectiveness of Secca Therapy in people with faecal incontinence.

The strategy was developed in MEDLINE (Ovid interface), and devised using a combination of subject indexing terms and free text search terms in the title, abstract and keyword heading word fields. The search terms were identified through discussion within the research team, scanning background literature, browsing database thesauri and using the [PubMed PubReMiner](#) tool. The strategy reflected the nature of the MIB assessments as rapid evidence reviews, with a relatively pragmatic approach being taken.

The main structure of the draft strategy comprised 2 concepts, combined as: faecal incontinence AND Secca therapy. Terms for the faecal incontinence concept included variants, such as bowel incontinence, anal incontinence and bowel control disorder. Terms for Secca Therapy included terms for the technology used (radiofrequency therapy) and the manufacturer name. The device name was searched as a separate stand-alone term.

The strategy excluded animal studies using a standard algorithm. Non-English language publications were also excluded from the search results. The search was restricted to studies published from 2002 to date; 2002 was identified by the research team as the date when Secca was FDA cleared.

The draft Ovid MEDLINE strategy successfully retrieved all 18 potentially relevant studies identified by the research team at project start. The final Ovid MEDLINE strategy was translated appropriately for the other databases searched. The PubMed search was limited to records not fully indexed for MEDLINE. Reflecting the scope of MIBs, records indexed as conference-related publication types (conference abstract, conference paper, conference proceeding, conference review) were excluded from the Embase search.

The following databases were searched: Cochrane Central Register of Controlled Trials (Cochrane Library, Wiley); Cochrane Database of Systematic Reviews (Cochrane Library, Wiley); Database of Abstracts of Reviews of Effects (Cochrane Library, Wiley); Embase (Ovid SP); Health Technology Assessment Database (Cochrane Library, Wiley); MEDLINE In-Process & Other Non-Indexed Citations and MEDLINE(Ovid SP); NHS Economic

Evaluation Database (Cochrane Library, Wiley); [PubMed](#).

Evidence selection

A total of 265 records were retrieved from the literature search. After removal of duplicates, 172 records remained and were sifted against the inclusion criteria at title and abstract level.

Records were sifted independently by 2 researchers. Any disagreements were discussed and agreement was reached in all cases, so a third independent arbiter was not required. The first sift removed 146 records based on the following exclusion criteria:

- articles of poor relevance against search terms
- publication types that were out of scope
- non-English language studies
- conference abstracts
- review articles.

Of the remaining 26 studies, full articles were retrieved for 25 (1 was unavailable). Full text assessment was done independently by 2 researchers to identify relevant primary research addressing the key clinical outcomes of interest. Fifteen studies were excluded for the following reasons:

- review studies/editorials: 13
- non-English translation unavailable: 1
- review with primary studies already included: 1.

A total of 10 studies remained, which reported on using the Secca System and addressed the key clinical outcomes of interest.

The retrospective study (Abbas et al. 2012) was excluded from this review due to being of lower quality evidence. Eight of the 9 remaining studies have been reviewed before and summarised in the overview of NICE interventional procedure guidance on [endoscopic radiofrequency therapy of the anal sphincter for faecal incontinence](#). Only 1 study has

been published since the guidance (Lam et al. 2014).

About this briefing

Medtech innovation briefings summarise the published evidence and information available for individual medical technologies. The briefings provide information to aid local decision-making by clinicians, managers and procurement professionals.

Medtech innovation briefings aim to present information and critically review the strengths and weaknesses of the relevant evidence, but contain no recommendations and **are not formal NICE guidance**.

Development of this briefing

This briefing was developed for NICE by Newcastle and York External Assessment Centre. The [interim process and methods statement](#) sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

Project team

Newcastle and York External Assessment Centre

Medical Technologies Evaluation Programme, NICE

Peer reviewers and contributors

- Kim Keltie, Research Scientist, Newcastle upon Tyne Hospitals NHS Foundation Trust
- Mick Arber, Information Specialist, York Health Economics Consortium
- Derek Bousfield, Senior Clinical Technologist, Newcastle upon Tyne Hospitals NHS Foundation Trust
- Emma Belilios, Administrator, Newcastle upon Tyne Hospitals NHS Foundation Trust
- Matthew Dunn, Research Scientist, Newcastle upon Tyne Hospitals NHS Foundation Trust

- Frank McArdle, Head of Service – Clinical Scientist, Newcastle upon Tyne Hospitals NHS Foundation Trust

Specialist commentators

The following specialist commentators provided comments on a draft of this briefing:

- Mr Richard Cohen (Consultant Colorectal Surgeon, University College London Hospitals NHS Foundation Trust)
- Mr Stefan Plusa (Consultant Colorectal Surgeon, Newcastle upon Tyne NHS Foundation Trust)
- Ms Andrea Read (Colorectal Nurse Specialist, Newcastle upon Tyne NHS Foundation Trust)
- Mr Anil Reddy (Consultant Laparoscopic Colorectal/pelvic Floor Surgeon, James Cook University Hospital; Senior lecturer, University of Newcastle upon Tyne; Honorary Senior Lecturer, Teeside University)

Declarations of interest

No relevant interests declared.

Copyright

© National Institute for Health and Care Excellence, 2016. All rights reserved. NICE copyright material can be downloaded for private research and study, and may be reproduced for educational and not-for-profit purposes. No reproduction by or for commercial organisations, or for commercial purposes, is allowed without the written permission of NICE.

ISBN: 978-1-4731-1865-2