# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## Centre for Health Technology Evaluation

# MTG Review Decision Document

## Review of MTG36: Peristeen transanal irrigation system for managing bowel dysfunction

This guidance was issued in February 2018.

NICE proposes an amendment of published guidance if there are no changes to the technology, clinical environment or evidence base which are likely to result in a change to the recommendations. However, the recommendations may need revision to correct any inaccuracies, usually in relation to providing a more accurate estimate of the results of the cost modelling. The decision to consult on an amendment of published guidance depends on the impact of the proposed amendments and on NICE's perception of their likely acceptance with stakeholders. NICE proposes an update of published guidance if the evidence base or clinical environment has changed to an extent that is likely to have a material effect on the recommendations in the existing guidance.

### 1. Recommendation

Amend the guidance to reflect changes in the technology from Peristeen to Peristeen Plus and the new costs. The factual changes proposed have no material effect on the recommendations.

Do not consult on the review proposal.

Please see Appendix 1 for a list of the options and their explanations for consideration.

### 2. Original objective of guidance

To assess the case for adoption of Peristeen transanal irrigation system for managing bowel dysfunction.

### 3. Current guidance

*1.1 The case for adopting Peristeen for transanal irrigation in people with bowel dysfunction is supported by the evidence. Peristeen can reduce the severity of constipation and incontinence, improve quality of life, and promote dignity and independence.*

*1.2 Peristeen may not be suitable for all people with bowel dysfunction. It may take several weeks before a person is comfortable with using Peristeen, and some people may choose to stop using it. Peristeen is therefore most effective when it is offered with specialist training for users, carers and NHS staff, and structured patient support.*

*1.3 Cost modelling for Peristeen is uncertain, but it is likely that Peristeen provides additional clinical benefits without costing more than standard bowel care.*

## 4. Rationale

Peristeen was updated to Peristeen Plus in July 2021. The company has said that changes to the technology improve its usability, but do not change its functionality. A clinical expert advised that Peristeen and Peristeen Plus are likely to be largely equivalent, and that the evidence on Peristeen would be applicable to Peristeen Plus.

There is new clinical evidence since the original guidance. The external assessment centre (EAC) reviewed this evidence and concluded that it is consistent with the recommendations in MTG36.

For the cost case, the original cost model was updated to current prices for Peristeen Plus and comparators. During this cost update, the EAC found errors in the original cost model submitted by the company for guidance. The EAC corrected these errors in the 2017 cost analysis and found Peristeen to be more cost saving. The 2021 cost update also found that Peristeen Plus remains cost saving compared with standard bowel care alone. The EAC noted that uncertainties in the clinical parameters in the cost model remain. But it concluded that it is unlikely that the new clinical evidence would significantly impact the cost modelling. This is consistent with the recommendations in MTG36. We therefore recommend that the guidance is amended to reflect these changes.

## 5. New evidence

The search strategy from the original assessment report was re-run. References from March 2017 onwards were reviewed. Additional searches of clinical trials registries were also carried out and relevant guidance from NICE and other professional bodies was reviewed to determine whether there have been any changes to the care pathways. The company was asked to submit all new literature references relevant to their technology along with updated costs and details of any changes to the technology itself or the CE marked indication for use for their technology. The results of the literature search are discussed in the 'Summary of new information and implications for review' section below. See Appendix 2 for further details of ongoing and unpublished studies.

### 5.1 Technology availability and changes

The original Peristeen system was discontinued at the end of 2021. From January 2022, only Peristeen Plus is available to the NHS. The company said that Peristeen Plus was developed with feedback from patients, healthcare professionals, and carers. It was designed to be easier to use especially for people with dexterity issues and visual impairment. Changes to the technology to improve its usability include new connections, a new dial design, more intuitive symbols on the control unit, and a temperature indicator on the water bag. All evidence on Peristeen seems to be on the original system which used a balloon catheter. Peristeen Plus can be used with either a balloon catheter or a cone catheter. The cone catheter is available to the NHS from April 2022. Research on the cone catheter is ongoing and no published evidence was available at the time of this review. This review therefore focusses on Peristeen Plus with the balloon catheter.

The price of the technology with the balloon catheter has increased from £76.28 to £79.45 per unit, with accessories (15 catheters and 1 water bag) increasing from £132.95 to £138.47. Like Peristeen, Peristeen Plus is a CE-marked class I medical device.

### 5.2 Clinical practice

There have been no changes to NICE's guideline on faecal incontinence in adults: management since the publication of MTG36 Peristeen transanal irrigation system for managing bowel dysfunction (February 2018).

Three clinical experts provided responses for the guidance review. They reported no substantial changes to the clinical pathway since the publication of MTG36. Peristeen Plus is used when conservative measures fail in functional bowel problems. One expert noted that it was not clearly defined when it should be introduced in the care pathway, and this relied on clinical judgement. One expert said Peristeen is an established earlier 'go to' in the management of neurogenic bowel dysfunction. Two experts felt there is still limited evidence on using the technology outside of neurogenic bowel disorder. One expert commented that Peristeen often does not reduce the need for other conservative measures and is an adjunct to standard care.

One expert advised that a care pathway with Peristeen Plus should consider the setting where it will be used. They noted that use is high in settings where training is provided, and support is available. Patient and staff support, and training are available from the company.

### 5.3 NICE facilitated research

None.

### 5.4 New studies

Results from the NICE literature search (March 2017 to June 2021) as well as information from the company and clinical experts were used to assess new evidence. A total of 11 studies were identified as relevant to this guidance review. These included:

- 1 randomised controlled trial (Enriquez-Navascues et al. 2019)
- 1 comparative mixed methods study (McCutchan et al. 2017)
- 5 prospective case series (Ausili et al. 2018, Gordon et al. 2019, Furuta et al. 2021, Martellucci et al. 2018, McCarthy et al. 2020)
- 4 retrospective case series (Alhazmi et al. 2019, Bildstein et al. 2017, Lallemant-Dudek et al. 2020, Patel et al. 2020).

Five studies were in adults and 6 in children. Follow-up ranged from 1 to 118 months. Two studies were in the UK (McCarthy et al. 2020, McCutchan et al. 2017). All published evidence appeared to be on the original Peristeen system which used a balloon catheter. The EAC noted that all studies reported favourable outcomes associated with using Peristeen. But there was a lot of heterogeneity in populations and variability in outcome measures. Few studies did statistical analysis, so the significance of the effect size was not always quantified or readily interpreted. The EAC concluded that the new studies increase the quantity of supporting evidence, but the quality of the evidence remains limited. Details on the study design, population, and key results of each study are summarised below:

*Studies in adults*

Bildstein et al. (2017). Retrospective case series in France in 108 adults (age 18 to 83, median 55) with constipation or fecal incontinence who did not respond to conservative bowel management. The population was heterogenous with bowel dysfunction related to neurological disease, slow-transit constipation, or obstructed defecation syndrome. People were instructed to use Peristeen every 1 to 2 days. After 1 month, 92 people (85%) were still using the system. This dropped to 70 (65%) at 3 months, 59 (55%) at 6 months, and 46 (43%) at 12 months. Reasons for discontinuation included inefficacy (n=18), technical problems (n=16), and too many constraints (n=10). The success of the first training session was the only predictive factor for discontinuation during the first year, with people who stop using Peristeen more likely to have technical problems during this session.

Enriquez-Navascues et al. (2019). Randomised controlled trial in Spain comparing Peristeen (n=13; age 48 to 71, mean 68) with posterior tibial nerve stimulation (PTNS; n=14; age 56 to 76, mean 68) in adults with low anterior resection syndrome (LARS; score >29) who had rectal surgery more than 1 year prior. Peristeen was initially used once a day followed by 3 to 4 times a week for up to 6 months. Results were compared before and after treatment within each group, not as a direct between-group comparison. Peristeen was associated with a clinically significant reduction in LARS score at 6 months compared with baseline (P=0.021). People having PTNS also had statistically significant reductions in LARS score (P=0.045), but this was not considered clinically relevant. Both interventions were associated with improvements in the Vaizey score for fecal incontinence. People using Peristeen also reported improvements in global health status of quality of life at 6 months compared to baseline (P=0.02).

Martellucci et al. (2018). Prospective case series in France in 33 adults with significant LARS symptoms (score >30) after rectal cancer surgery. The EAC only included findings from the chronic LARS subgroup (n=8; age 42 to 79, median 64) as other patients were out of scope because they started transanal irrigation (TAI) within the post-operative period. Peristeen was used 3 to 4 times a week for 6 months, followed by 3 months of enema therapy. Findings reported a reduction in LARS score during TAI (mean 12.6, range 0 to 21) compared with baseline (mean 36.5, range 31 to 42). No statistical analysis was done.

McCarthy et al. (2020). Prospective case series in the UK in 50 adults with neurogenic bowel dysfunction because of spinal cord injury. The EAC noted that this study had notable weaknesses in its design and reporting of results. Total bowel dysfunction score decreased at 8 weeks (mean 8.8, range 0 to 22) compared with baseline (mean 20.1, range 3 to 38). People also reported fewer incidences of involuntary defecation at follow-up. No statistical analysis.

McCutchan et al. (2017). Mixed methods study in the UK comparing Peristeen (n=15) with usual care (n=6) in adults with LARS (score >20) who had restored bowel continuity for at least 12 weeks after surgery. People using Peristeen had lower LARS scores after 6 months (mean 17.7, range 0 to 41) compared with baseline (mean 35.9, range 21 to 42). Scores in the usual care group were similar at baseline (mean 34.2, range 32 to 37) and 6 months (mean 32.4, range 26 to 37). There was a reduction in fecal incontinence at 6 months compared with baseline for both Peristeen (mean 3.2 versus 9.7) and comparator (mean 5.4 versus 9.3). No statistical analysis was done.

*Studies in children*

Alhazmi et al. (2019). Retrospective case series in Saudi Arabia in 109 children (age 5 to 18, median 7) with myelomeningocele who did not respond to conservative measures for fecal incontinence. Peristeen was used 2 to 3 times a week. Average follow-up was 84.1 months (range 22 to 118 months). 101 people (93%) had complete fecal continence after using Peristeen, with 26 (24%) no longer needing diapers, 48 (44%) occasionally using diapers because of urine incontinence, and 27 (25%) occasionally using diapers because of concerns with soiling.

Ausili et al. (2018). Prospective case series in Italy in 74 children (age 6 to 17, mean 12.7 ±2.2) with spina bifida or anorectal malformations with neurogenic bowel dysfunction. Peristeen was used daily for the first week, and 3 times a week after. Fewer people reported constipation at 3 months (24/72, 33%; P<0.05) and 2 years (30/67, 45%; P<0.05) compared with baseline (60/74, 81%). There was also a reduction in the number of people with fecal incontinence at 3 months (10/72, 14%; p<0.05) and 2 years (14/67, 21%; p<0.05) compared with baseline (33/74, 45%). Significant improvements in quality of life were reported on the global health and bodily pain scale. Complications included balloon bursting or expulsion, fecal leakage during irrigation, no useful effects.

Furuta et al. (2021). Prospective case series in Japan in 11 children (age 6 to 17, mean 10.8 ±3.3) with spina bifida and intractable constipation with moderate to severe NBD score. Peristeen was used every 2 days. There was significant change in the Bristol scale (mean 1.9 versus 3.6; P=0.001) and NBD score (mean 15.6 versus 11.1; P=0.009) from baseline to 3 months after using Peristeen. People also reported less use of tablets for constipation at 3 months (P=0.019).

Gordon et al. (2019). Prospective case series in the US in 70 children (age 3 to 17, mean 8.8) with neurogenic bowel dysfunction who did not respond to other treatments. Peristeen was used daily for 2 weeks, then every 2 days. NBD score improved in 86% (35/40) of people at 3 months and improved or stayed the same in 98% (41/42) at 6 months. NBD score was lower at 1 year than at baseline (n=24; mean 12.5 versus 19.3; P<0.001). There were higher levels of satisfaction at 1 year compared with baseline (n=22; mean 8.6 versus 3.9; P<0.001), with the most significant increase in the first 3 months of treatment. Thirteen people (19%) were not treated successfully with Peristeen and discontinued use. Of these, 8 then had antegrade colonic enema.

Lallemant-Dudek et al. (2020). Retrospective case series in France in 149 people (age 2 to 20, mean 10.6 ±4.1) with fecal incontinence or constipation who did not respond to other treatments. The population was heterogenous and included congenital or acquired neurogenic disorders, congenital

malformations, and other causes. The sample included children as young as 2, but Peristeen is indicated for use from 3 years of age. Most people (70%) used Peristeen every 1 or 2 days. After 9 months, less people reported symptoms of constipation (40/129, 31% versus 122/149, 82%) and fecal incontinence (50/129, 39% versus 130/149, 87%) than at baseline. In total, 129 (87%) people were still using Peristeen at least 9 months after training. Reasons for discontinuation included lack of motivation, poor tolerance, difficulties using the system, inefficacy, not meeting expectations, dependence on carer, or resolution of disorder.

Patel et al. (2020). Retrospective case series in the US in 147 people (age 2 to 21, mean 9 ±4.6) with bowel dysfunction who did not respond to conservative management. The population was heterogenous and included neurogenic bowel dysfunction, refractory constipation, and anorectal malformations. The sample included children as young as 2, but Peristeen is indicated for use from 3 years of age. Peristeen was recommended for use once daily. Mean follow-up was 4.5 months. In total, 114 (78%) people continued using Peristeen at follow-up. Significantly less people reported symptoms of fecal incontinence and constipation at follow-up compared with baseline ($P<0.001$). Significantly less people with neurogenic bowel dysfunction and refractory constipation reported abdominal pain at follow-up than baseline ($P<0.001$). Thirteen people were lost to follow-up and 20 discontinued use. Reasons for discontinuation included personal choice, surgical intervention, insurance issues, pain from using system, technical problems, or resolution of symptoms.

### 5.5 Cost update

The EAC did a cost update for Peristeen Plus to reflect changes in the costs of the technology and comparator. This cost update focussed on Peristeen Plus with a balloon catheter. Cost modelling does not include cone catheters. Peristeen Plus was modelled as an add-on to standard bowel care as needed and compared with standard bowel care.

During the cost update, the EAC found errors in the original cost model. It made the following corrections to both the original model and the cost update:

- removed double counting of anal plugs and incontinence pads
- split follow-up costs for 3rd line treatment between the 3 potential treatment options
- included full costs for adverse events for 3rd line and stoma care states
- ensured calculation for stoma remained positive at longer time horizons

These corrections to the 2017 cost model increased the cost savings of Peristeen from £2,867 to £5,627 per person over a 37-year time horizon. The 2021 cost update found that Peristeen Plus remains cost saving compared with standard bowel care alone. The estimated saving is £5,144 per person

over a 37-year time horizon. The EAC noted that uncertainties in the clinical parameters in the cost model remain.

## 6. Summary of new information and implications for review

The new clinical evidence is consistent with the recommendations in the original guidance. The EAC concluded that all new evidence reported favourable outcomes associated with using Peristeen. The updated cost modelling shows that Peristeen Plus with a balloon catheter remains cost saving. There continues to be some uncertainty about the clinical parameters in the cost model. The EAC considered that the new clinical evidence provides some relevant data on clinical parameters related to incidence of fecal incontinence, frequency of TAI, and long-term rates of adherence or discontinuation. But it concluded that it is unlikely that these outcomes would significantly impact the cost modelling. There is no published evidence on Peristeen Plus with the cone catheter, so it was not included in this review. The recommendations in MTG36 acknowledge the uncertainties in the cost model but conclude that Peristeen is unlikely to cost more than standard bowel care. The EAC has advised that based on its review, the recommendations in MTG36 do not need to be changed.

A search for Peristeen on the US Food and Drug Administration's MAUDE database between 1 March 2017 and 31 January 2022 found 65 reports. Most reports were for bowel perforation. Other reports included excessive bleeding, injury, pain, and device malfunction. There were 3 reports of death, but it was unclear if these were directly caused by using Peristeen. Bowel perforation is a serious but rare adverse event that is potentially linked to the use of Peristeen Plus. MTG36 erred in reporting the rate of bowel perforations as 1 in 2 million irrigations. This should be 2 in 1 million irrigations (Christensen et al. 2016). Bowel perforations may be even rarer in children (1 in 1 million irrigations) as reported in Mosiello et al. (2017).

## 7. Implementation

The company reported that Peristeen Plus is used in over 60 NHS sites. It is prescribed in functional bowel, spinal injury, neurology, paediatric, community, gastroenterology, and colorectal services. NHSBSA NHS Electronic Drug Tariff data on Peristeen (NHSBSA Copyright 2022) showed 76,673 prescription items of Peristeen between 2017/18 to 2020/21. Of these, 10,795 (14%) were in children and young people (birth to 19 years) and 46,028 (58%) were in people 40 to 69. This data is for primary care in England only.

There have been 5 NICE shared learning examples on the adoption of Peristeen:

- Aintree University Hospital NHS Foundation Trust (August 2018)
- Manchester University NHS Foundation Trust (September 2018)
- St Helens and Knowsley Teaching Hospitals NHS trust (November 2018)

- Alder Hey Children's NHS Foundation Trust (January 2019)
- Salisbury Healthcare NHS Foundation Trust (December 2019)

Key learning points from these shared learning examples were:

- Peristeen should be adopted in a dedicated clinic with a holistic approach to bowel management and multidisciplinary team support. When using with children, this dedicated service should have play therapy input.
- Healthcare professionals should be trained on selecting patients for TAI and providing the ongoing support needed for successful adoption.
- There should be thorough patient assessment and selection. Patients should be motivated to use TAI and given detailed information before considering use.
- Patients should be trained on using TAI and should have regular review and ongoing support. When using with children, the introduction to Peristeen and training should be tailored to the child and carers' needs.
- A locally agreed care pathway should be developed for consistent adoption.
- General practitioners prescribing TAI should be given information about its potential patient and system benefits, and the patient's history and needs.

## 8. Equality issues

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

Faecal incontinence and constipation can be related to disability and can be socially stigmatising. The evidence shows that Peristeen Plus may help reduce symptoms associated with bowel dysfunction. It is indicated for both adults and children from 3 years of age. Peristeen Plus is not suitable for everyone. It is contraindicated for use during the first 3 months following anal or colorectal surgery or for people with the following conditions: anal or colorectal stenosis, colorectal cancer, acute inflammatory bowel disease, acute diverticulitis, and ischaemic colitis. Peristeen is also not suitable for people with bowel routines that must take place on a bed.

No new equality issues were identified during guidance review.

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# Appendix 1 – explanation of options

If the published Medical Technologies Guidance needs updating NICE must select one of the options in the table below:

| **Options** | **Consequences** | **Selected – 'Yes/No'** |
|---|---|---|
| Amend the guidance and consult on the review proposal | The guidance is amended but the factual changes proposed have no material effect on the recommendations. | No |
| Amend the guidance and do not consult on the review proposal | The guidance is amended but the factual changes proposed have no material effect on the recommendations. | Yes |
| Standard update of the guidance | A standard update of the Medical Technologies Guidance will be planned into NICE's work programme. | No |
| Update of the guidance within another piece of NICE guidance | The guidance is updated according to the processes and timetable of that programme. | No |

If the published Medical Technologies Guidance does not need updating NICE must select one of the options in the table below:

| **Options** | **Consequences** | **Selected – 'Yes/No'** |
|---|---|---|
| Transfer the guidance to the 'static guidance list' | The guidance remains valid and is designated as static guidance. Literature searches are carried out every 5 years to check whether any of the Medical Technologies Guidance on the static list should be flagged for review. | No |
| Defer the decision to review the guidance | NICE will reconsider whether a review is necessary at the specified date. | No |
| Withdraw the guidance | The Medical Technologies Guidance is no longer valid and is withdrawn. | No |

# Appendix 2 – supporting information

### Relevant Institute work

*Published*

Faecal incontinence in adults: management (2007, last checked in 2018) NICE clinical guideline CG49.

Metastatic spinal cord compression in adults: risk assessment, diagnosis and management (2008, currently being updated). NICE clinical guideline CG75.

Constipation in children and young people: diagnosis and management (Last updated 2017) NICE clinical guideline [CG99]. A 2018 exceptional surveillance on this guidance was done after MTG36 to consider adding transanal irrigation to the guideline. It concluded that the scope for MTG36 differed from CG99 and there was not enough evidence to support adding transanal irrigation to CG99 at that time.

Percutaneous tibial nerve stimulation for faecal incontinence (2011) NICE interventional procedures guidance IPG395.

*In progress*

None found.

### Registered and unpublished trials

| Trial name and registration number | Details |
|---|---|
| A Randomized Controlled Study of the Effect of Treatment of Low Anterior Resection Syndrome (LARS) After Rectal Cancer Surgery<br><br>Trial number: NCT03215017 | Randomised controlled trial comparing Peristeen with medication to help control bowel movement in people with low anterior resection syndrome after rectal cancer surgery.<br>Recruitment status: Active, not recruiting (last updated August 2021)<br>Estimated end date: December 2022<br>Estimated enrolment: 100 people<br>Location: Sweden |
| Randomized Clinical Trial Assessing the Effect of Transanal Irrigation With Cone Catheter Versus Conservative Bowel Management on Symptoms of Low Anterior Resection Syndrome After Rectal Resection<br><br>Trial number: NCT04586634 | Randomised trial comparing Peristeen Plus with cone catheter with conservative bowel management in people with major low anterior resection syndrome<br>Recruitment status: Completed (last updated February 2022)<br>Estimated end date: December 2021<br>Enrolment: 32 people<br>Location: France |

| Trial name and registration number | Details |
| --- | --- |
| Characteristics of intestinal dysfunction in patients with multiple sclerosis.<br><br>Trial number: NCT04599595 | Prospective cohort study assessing intestinal disorders in people with multiple sclerosis and the effectiveness of Peristeen in treating constipation and fecal incontinence.<br>Recruitment status: Completed (last updated October 2020)<br>Estimated end date: April 2020<br>Enrolment: 100 people<br>Location: Italy |

# Appendix 3 – changes to guidance

**Table 1: proposed corrections to original guidance [2017]**

| Section of MTG | Original MTG | Proposed amendment |
|---|---|---|
| 3.8 | The company's base-case results showed that using Peristeen could lead to cost savings of £21,768 per patient over 37 years. However, the EAC identified limitations in the company's base case. It made a number of changes and corrections to the model, including:<br><br>• incorporating the costs of standard care for people who stop using Peristeen within the Peristeen arm<br>• adjusting transition probabilities<br>• changing the costs of pressure ulcers and urinary tract infections<br>• adding background mortality.<br><br>These changes decreased the cost savings associated with Peristeen to £2,867 per patient over the same period. For full details of these changes, see section 4.5 of the assessment report. | The company's base-case results showed that using Peristeen could lead to cost savings of £21,768 per patient over 37 years. However, the EAC identified limitations in the company's base case. It made a number of changes and corrections to the model, including:<br><br>• incorporating the costs of standard care for people who stop using Peristeen within the Peristeen arm<br>• adjusting transition probabilities<br>• changing the costs of pressure ulcers and urinary tract infections<br>• adding background mortality.<br><br>These changes decreased the cost savings associated with Peristeen to £5,627 per patient over the same period. For full details of these changes, see section 4.5 of the assessment report. [corrected 2022] |
| 4.14 | The committee accepted the external assessment centre's (EAC) suggested changes to the company's model, and concluded that its results were more plausible than the company's base case. The EAC's updated model showed that using Peristeen could result in cost savings of £2,867 per patient over 37 years. | The committee accepted the external assessment centre's (EAC) suggested changes to the company's model, and concluded that its results were more plausible than the company's base case. The EAC's updated model showed that using Peristeen could result in cost savings of £5,627 per patient over 37 years. [corrected 2022] |

**Table 2: proposed amendments to original guidance**

| Section of MTG | Original MTG | Proposed amendment |
|---|---|---|
| Throughout the MTG except where reporting studies and committee considerations | Peristeen | Peristeen Plus |
| 2.1 | Peristeen (Coloplast) is a transanal irrigation system for managing bowel dysfunction. The company's instructions for use in this indication recommend that it should be used every other day to empty the rectum and distal sigmoid colon, in order to prevent uncontrolled bowel movements (faecal incontinence) or to relieve and prevent constipation. Peristeen is usually self-administered while sitting on a toilet, commode or shower chair. It comprises a rectal catheter with inflatable balloon, a manual control unit with pump, leg straps and a bag to hold water. Peristeen uses a constant-flow pump which does not rely on gravity so that the user does not need to hang the bag up for the water to flow. Peristeen needs a new catheter each time it is used. | Peristeen Plus (Coloplast) is a transanal irrigation system for managing bowel dysfunction. The company's instructions for use in this indication recommend that it should be used every other day to empty the rectum and distal sigmoid colon, in order to prevent uncontrolled bowel movements (faecal incontinence) or to relieve and prevent constipation. Peristeen Plus is usually self-administered while sitting on a toilet, commode or shower chair. It comprises a rectal catheter with inflatable balloon or a cone catheter, a manual control unit with pump, leg straps and a bag with temperature gauge to hold water. Peristeen Plus uses a constant-flow pump which does not rely on gravity so that the user does not need to hang the bag up for the water to flow. Peristeen Plus needs a new catheter each time it is used.<br><br>There is no published evidence on Peristeen Plus with the cone catheter. This guidance therefore focusses on Peristeen Plus with the balloon catheter. [2022] |
| 2.2 | The cost of Peristeen is £76.28 per system (comprising a Peristeen pump, 2 catheters, 2 straps and a water bag) and £132.95 per consumable pack of 15 catheters and replacement water bag (excluding VAT). | The cost of Peristeen Plus with the balloon catheter is £79.45 per system (comprising a Peristeen Plus pump, 2 catheters, 2 straps and a water bag) and £138.47 per consumable pack of 15 catheters and replacement water bag (excluding VAT). [2022] |
| 3.1 | The evidence for Peristeen assessed by the external assessment centre (EAC) comprises 13 studies in adults | All studies evaluated the original Peristeen system, which is assumed to be equivalent to Peristeen Plus with the balloon |

| | | |
|---|---|---|
| | and 11 studies in children, plus 2 studies and 1 audit that were included specifically to provide information on adverse events. Only 1 study was a randomised controlled trial (Christensen et al. 2006); all others were observational studies. For full details of the clinical evidence, see section 3 of the assessment report. | catheter. The evidence for Peristeen assessed by the external assessment centre (EAC) comprises 13 studies in adults and 11 studies in children, plus 2 studies and 1 audit that were included specifically to provide information on adverse events. Only 1 study was a randomised controlled trial (Christensen et al. 2006); all others were observational studies. For full details of the clinical evidence, see section 3 of the assessment report. [2022] |
| 3.5 | Bowel perforation is a serious adverse event that is potentially linked to the use of Peristeen. It was a rare complication (1 in 2 million irrigations) reported in the global audit by Christensen et al. (2016). Other, less serious adverse events such as abdominal pain, rectal bleeding and nausea were more common. For full details of the adverse events, see section 3.7 of the assessment report. | Bowel perforation is a serious adverse event that is potentially linked to the use of Peristeen. It was a rare complication (2 in 1 million irrigations) reported in the global audit by Christensen et al. (2016). It may be even rarer in children (1 in 1 million irrigations) as reported in a review of best practice by Mosiello et al. (2017). Other, less serious adverse events such as abdominal pain, rectal bleeding and nausea were more common. For full details of the adverse events, see section 3.7 of the assessment report. [2022] |
| 4 | **Committee discussion** | **Committee discussion**<br>The committee discussion was on the original Peristeen system, which is assumed to be equivalent to Peristeen Plus with the balloon catheter. [2022] |
| 4.19 | | For the guidance review, the EAC revised the model to reflect 2021 costs (original guidance values given in brackets). Costs were revised for Peristeen Plus with the balloon catheter, standard bowel care, third line treatment, and adverse events. Details of the parameter changes are in the costing update report. Base case results for the 2021 revised model shows the cost saving associated with Peristeen Plus was £5,144 (£5,627) per person over a 37-year time horizon. Cost modelling |

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| | | was not done for Peristeen Plus with cone catheters [2022]. |

## References


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