

U-Drain for people needing night drainage of urine or dialysis fluid

Medtech innovation briefing

Published: 9 February 2017

www.nice.org.uk/guidance/mib95

Summary

- The **technology** described in this briefing is the U-Drain. It is used for people with a long-term urinary catheter, urinary sheath, urostomy pouch or who have automated peritoneal dialysis, who need night drainage of urine or dialysis fluid.
- The **innovative aspects** are that it is a drainage system that is permanently installed in the user's home. It is used overnight for draining waste fluid directly into the existing soil pipe.
- The intended **place in therapy** would be as an alternative to overnight drainage of urine or waste fluid into a night drainage bag in people with long-term urinary catheters, urinary sheaths, urostomy pouches or those having overnight automated peritoneal dialysis.

- No publicly available **evidence** on the U-Drain system was found. Although conventional clinical-effectiveness studies would not be expected on relatively simple technologies such as U-Drain, evidence of impact on quality of life would be useful.
- The **cost** of the U-Drain device includes the installation at £350 and an annual cost of £130 for urine drainage consumables or £500 per year for automated peritoneal drainage consumables (exclusive of VAT). In usual care, the cost of night drainage bags is between about £13 and £91 per year depending on type, and the cost of peritoneal dialysis waste drainage bags is around £800 per year. Apart from equipment costs, the **resource impact** would be similar to standard care.

The technology

The U-Drain drainage system (U-Drain) is permanently installed in the homes of people who need night urine collection or are having automatic peritoneal dialysis, so avoiding the need for night drainage bags. It allows urine and dialysis fluid to be drained directly into the external waste system (soil pipe) on the outside of the home, while the user is asleep.

The U-Drain system is provided as a set that includes the tubing, wall socket, clips, screws and other items needed to install the system. To fit the U-Drain, the wall socket is installed in an external wall near the bedside. A 13 mm diameter tube passes through this socket and connects to the soil pipe on the outside of the house.

At night, the user connects their urinary catheter bag or sheath, urostomy pouch or automated peritoneal dialysis (APD) waste drain line to the inside face of the socket, using a clear drainage tube that connects to the drainage port of the catheter bag or urostomy pouch or the APD waste line. Urine or waste fluid drains through this tube, through the wall socket and into the soil pipe via the external tubing, throughout the night. The socket has a 1-way valve so that fluid cannot flow back up the tube. This also prevents unpleasant smells from the soil pipe from entering the room. In the morning, the user disconnects the drainage tube from their catheter bag, pouch or APD waste drain and flushes it through with 100 ml of water containing a disinfectant (U-Drain supplies disinfectant, but any disinfectant can be used). The tube is then disconnected from the wall socket and stored. The internal tubing is changed every 7 days for urology patients and every day for APD patients.

The innovation

U-Drain is the only available permanently installed night drainage system. It is designed to replace overnight urine or dialysis fluid drainage bags, which the user has to empty each morning. This can be inconvenient and unpleasant for the user. The company claims that the U-Drain system is clean, odour-free and hygienic.

Current care pathway

Current practice for overnight urine or dialysis waste collection involves connecting the user's catheter bag, urinary sheath, urostomy pouch or APD drain line to a night drainage bag. Urine waste bags are usually 2 litres in capacity and are hung from a floor stand by the side of the bed or placed in a bowl. APD waste bags are 15 litres in capacity and are placed on the floor. Patients may use 2 bags to reduce the weight of each bag, because these can be very heavy for patients or their carers to lift.

In the morning, the bag is emptied into the toilet. Night collection bags can be for single use, after which they are thrown away, or they can be reusable and are washed out with tap water and disinfectant daily for up to 1 week. Once the U-Drain is installed, night collection bags are only needed if the external pipe blocks or freezes, or the person sleeps away from home. Apart from this, no other changes to current practice are anticipated with the use of the U-Drain.

NICE guidance on using [long-term urinary catheters](#) states that a link system should be used to help overnight drainage and keep the catheter and catheter bag intact. These same procedures would apply to the U-Drain system.

NICE is not aware of any CE-marked devices that appear to fulfil a similar function as the U-Drain.

Population, setting and intended user

The U-Drain is designed for home use. It can also be installed in hospitals and care homes, but these settings are not within the scope of this briefing.

The U-Drain is suitable for people with long-term urinary catheters, sheaths or urostomy pouches. It can also be used to drain dialysis fluid from the APD.

In 2008, there were about 90,000 people with long-term catheters in the UK ([Gage et al. 2016](#)). Long-term catheter use can be needed for a variety of conditions, including spinal cord injury, multiple sclerosis, prostate problems, diabetes, stroke and Parkinson's disease ([Wilde et al. 2013](#)). Although people of any age may need a long-term catheter, they are more commonly used in older people ([Gage et al. 2016](#)).

A urostomy is a surgical procedure to permanently divert urine from the kidneys and ureters into a stoma that is created from a small section of the bowel. There are various indications for having a urostomy, including bladder cancer and neurological conditions. Urine is collected in a bag or pouch worn on the abdomen. There are around 11,000 people with a urostomy in the UK ([Urostomy Association 2016](#)).

Peritoneal dialysis can be used for people with renal failure. It can be done at home and some users have it overnight, using APD. According to the NICE full guideline on [peritoneal dialysis](#), the prevalence in the UK is age dependent; for adults between 70 and 80 years, it is 1,600 to 2,000 people per million of the population. Up to 30% of adults with chronic kidney disease use peritoneal dialysis, but there are variations in local practice. Peritoneal dialysis is used in about 10% of children with end-stage kidney disease ([Pruthi et al. 2013](#)).

Users would need to make some adjustments when first using the U-Drain, but very little training in addition to that needed for using overnight drainage bags would be needed. Training would be on the cleaning and hygiene aspects of using the U-Drain.

Costs

Device costs

Installation of the U-Drain costs £350, which includes the installation materials. Consumables for the system (internal drainage tubes) cost £130 per year for urine drainage and £500 per year for automated peritoneal drainage.

Table 1 Device costs excluding VAT

Description	Cost	Additional information
-------------	------	------------------------

Installation charge (includes U-Drain installation pack)	£350	<p>Paid by patient needing urine drainage at home.</p> <p>Paid by renal unit for users of automated peritoneal dialysis.</p> <p>Includes consumables for first 6 months.</p> <p>Lifetime of the equipment is estimated to be 10 years.</p>
U-Drain 12-monthly consumables kit	<p>£130 for urine drainage</p> <p>£500 for automated peritoneal dialysis drainage</p>	<p>Contains internal tubing.</p> <p>The manufacturer recommends that the internal tubing that connects the user to the socket is changed every 7 days, or for automated peritoneal dialysis, every day.</p>
U-Drain disinfectant	£6.40	Recommended for use, lasts about 3 months.

Costs of standard care

Two types of overnight bags for urinary catheters are typically used in the home setting. The first is a non-drainable, single-use bag. These are non-sterile, 2-litre bags with a tear strip for emptying. They cost about £2.25 for 10 bags, which equates to about £82 per year. Alternatively, some people use sterile urine bags with a drainage tap that are changed every 7 days. The cost of these ranges from about £2.60 to £7.50 for 10 bags. This equates to about £13.52 to £39.00 per year. Reusable night urine drainage bags that connect to urostomy pouches cost about £12.20 to £18.20 for 10 bags, equating to £61 to £91 per year if changed weekly. There may be additional costs for some pouches that need add-ons. Costs of peritoneal dialysis waste drainage bags are about £2.40 each, equating to around £800 per year or £1,600 if 2 bags per night are used.

Resource consequences

People using U-Drain for urine drainage need to pay the installation charge themselves. For people using U-Drain for APD, installation is paid for by the renal unit. The U-Drain consumables for urine drainage are available on NHS prescription.

Because urine or waste fluid from dialysis is not stored within the system, the risk of users

developing bacterial infections could be reduced, but there is currently no evidence to support this. Any reduction in bacterial infection could decrease NHS resource use. There may be an increased risk of infection from cleaning and reapplying the U-Drain drainage tube to a urinary catheter in people who currently change drainage bags daily.

The U-Drain system could reduce resource use from delivering urine or fluid drainage bags to people's homes and storing large quantities of bags. The manufacturer claims that U-Drain reduces carbon footprint because drainage bags are not needed, and it reduces water usage needed to wash out drainage bags.

Regulatory information

U-Drain was CE-marked as a class 1 device in December 2011. It is manufactured by U-Drain.

A search of the Medicines and Healthcare products Regulatory Agency (MHRA) website revealed that no manufacturer Field Safety Notices or Medical Device Alerts have been issued for this technology.

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).

Long-term catheter use may be more common in older people or in those with disabilities. They may also be more commonly used in men than in women. Age, disability and sex are protected characteristics under the Equality Act.

Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the published [process and methods statement](#). This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting mibs@nice.org.uk.

Published evidence

No publicly available evidence was found about the use of U-Drain.

Overall assessment of the evidence

Conventional evidence of clinical effectiveness covering a range of clinical outcomes would not be expected for a relatively simple technology such as U-Drain, where the potential benefits relate mainly to improving user experience.

Studies would be useful to show the impact on quality of life as well as on selected clinical outcomes such as reducing infection risk.

Recent and ongoing studies

No ongoing or in-development trials were identified from a search of clinical trial databases. The manufacturer has confirmed that 1 NHS trust is running a trial of the U-Drain for people having automated peritoneal dialysis in the home.

Specialist commentator comments

Comments on this technology were invited from clinical experts working in the field and relevant patient organisations. The comments received are individual opinions and do not represent NICE's view.

Two of 4 specialist commentators were familiar with this technology. One commentator has used it 8 times.

Level of innovation

Three specialist commentators felt that the U-Drain was a novel approach to overnight drainage. None of the commentators felt that any significant user training would be needed and none were aware of any technologies that had superseded U-Drain.

Potential patient impact

Three of the specialist commentators identified potential benefits from using U-Drain; however, 2 felt that there was a lack of evidence to determine these. One specialist commentator reported that people who have used it report that they feel more in control of their urine drainage. They added that U-Drain provides people with another option for managing night drainage from their urostomy.

One specialist commentator thought that use of U-Drain would improve patient outcomes, reduce infections and leakages as well as ensuring good night drainage. People with long-term catheters would particularly benefit from U-Drain. One commentator speculated that U-Drain could help to reduce infections, but another stated that research to establish the impact on kidney infection rates for urostomy patients would be useful.

One commentator highlighted some concerns around the practicalities of installing U-Drain. These include the risk of the external drainage pipe freezing in the winter, and the risk of tripping over the tubing inside the room. They note that the person may need to sleep in a room close to the external soil pipe, and this may not be the best room for them to sleep in. The position of the bed and proximity to the external wall may also be a consideration. They also queried whether the system is under negative pressure because this can cause occlusion of the bladder mucosa in catheter users. One specialist commentator was unsure how well it would work in the community rather than in a residential care setting.

Potential system impact

Commentators noted that the use of the U-Drain may increase NHS costs for those people having night drainage of urine but there may be a reduction in staffing costs for emptying and changing night bags, and potential for cost savings if infections are reduced. The cost for installation is met by the patient using urine bags and by the NHS for people having automated peritoneal dialysis.

One specialist commentator believed that the U-Drain could reduce care staff attendance to empty the used night urine bag, which could be of particular benefit to people who are unable to leave their rooms.

Patient organisation comments

The [Urostomy Association](#) gave the following comments on U-Drain.

They noted that the U-Drain is significantly different to current treatment options for people needing night urine drainage. Although it cannot improve health outcomes, U-Drain could be a useful alternative to night drainage bags.

People considering U-Drain need to be fully aware of all of the options for urine drainage before making a decision. It is important to note, for example, that people who choose U-Drain may not be able to get night drainage bags on prescription anymore, and these are needed when they wish to stay away from home.

Specialist commentators

The following clinicians contributed to this briefing:

- Professor Christopher Chapple, Consultant Urological Surgeon, Royal Hallamshire Hospital. He has no conflicts of interests in the technology but is the Urinary Continence Management Theme Lead for Devices for Dignity, a National Institute for Health Research (NIHR) Healthcare Technology Cooperative, which delivers innovative technology solutions focused on dignity and independence, for people with long-term conditions.
- Alison Wileman, Continence Service Lead/Advanced Clinical Nurse Specialist – Continence, Royal College of Nursing Continence Forum Committee Member, Southern Health NHS Foundation Trust. No conflicts.
- Sister Amanda Smith, Specialist Stoma Care Nurse, Salford Royal NHS Foundation Trust. No conflicts.
- Ms Lucy Bowman, MacMillan Urology Clinical Nurse Specialist. Stepping Hill Hospital. No conflicts.

Representatives from the following patient organisations contributed to this briefing:

- The [Urostomy Association](#).

Development of this briefing

This briefing was developed for NICE by Birmingham and Brunel Consortium. 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.

ISBN: 978-1-4731-2327-4