

S-Cath System for suprapubic catheterisation

Medtech innovation briefing

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Summary

The S-Cath System is intended for use in people for whom a suprapubic catheter is indicated, and differs from conventional suprapubic catheters because a guidewire (the Seldinger technique) is used for improved placement. The available evidence is of limited quantity and quality. Three non-comparative studies suggest that suprapubic catheterisation using the S-Cath System is a safe procedure when carried out under appropriate conditions in a dedicated outpatient clinic, with low complication rates. In 1 of these studies, suprapubic catheterisation was moved from an inpatient to an outpatient setting. This was shown to be cost saving, however it is unclear if the S-Cath System was a significant factor in these savings. The S-Cath System costs between £36.39 and £41.92 (excluding VAT and carriage) depending on catheter size and type. The instructions for use state that the catheter is suitable for use for up to 12 weeks.

A Rapid Response Report by the National Patient Safety Agency (2009) recommends that ultrasound is used wherever possible to visualise the bladder and guide the insertion of suprapubic catheters. Ultrasound machines should be available in the relevant areas and staff trained in their use.

<p>Product summary and likely place in therapy</p> <ul style="list-style-type: none"> • The S-Cath System is a suprapubic catheter (SPC) insertion set. It uses the Seldinger technique with a 3-stage guidewire, which is designed to improve the safety and accuracy of catheter insertion. • It would be used as an alternative to conventional SPCs, which do not have a guidewire feature. The use of S-Cath may allow SPC insertion in an out-patient setting. It is recommended that the insertion of any SPC is carried out under ultrasound guidance. 	<p>Effectiveness and safety</p> <ul style="list-style-type: none"> • The evidence is of limited quality and is based on 3 studies; 1 clinician survey and 2 case reports. No comparative studies were identified. In total, 421 SPC insertions with S-Cath were included. • One study of 45 patients with spinal cord injuries reported that 6 patients developed complications after SPC insertion using the S-Cath System, including 2 with autonomic dysreflexia. • One study reported data on the technical success of 322 catheter insertions in a dedicated SPC clinic. Four people had complications, including 3 with bowel perforations. • One study reporting on setting change and technical success included 54 patients who had an SPC inserted using the S-Cath System. The procedure failed in 4 patients and 3 other patients had complications. • A small survey of 6 clinicians found that using the S-Cath System gave them greater confidence in SPC insertion compared with the standard trochar method as well as in its use by junior staff. Improved patient comfort was reported by 3 clinicians, and the 3 other clinicians reported equal patient comfort. Five clinicians reported improved patient safety but 1 reported worse patient safety.
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	<ul style="list-style-type: none"> • Two single case reports described adverse events that are recognised complications of general SPC use.
<p>Technical and patient factors</p> <ul style="list-style-type: none"> • The National Patient Safety Agency published a Rapid Response Report in 2009 after reports of 3 deaths and 7 incidents of serious harm after SPC placement in England and Wales between September 2005 and June 2009. The techniques used could not be established. The report recommends that SPCs be inserted using ultrasound guidance. • The S-Cath System is suitable for children, young people and adults of both sexes. • The device is designed to improve SPC insertion and removal. The variable stiffness guidewire is intended to reduce the risk of injury and enable safer placement. • The device is intended to be used in the hospital setting by appropriately trained clinicians. It is suitable for use with local anaesthetic so SPCs can be inserted in an outpatient setting. • The S-Cath System should only be used for initial SPC insertion and not for replacement catheter insertion. 	<p>Cost and resource use</p> <ul style="list-style-type: none"> • The S-Cath System costs between £36.39 and £41.92 (excluding VAT and carriage) depending on catheter size and type. The instructions for use state that the catheter is suitable for use for up to 12 weeks. • In a UK study, moving suprapubic catheterisation from an inpatient setting (catheter type not specified) to an outpatient setting using the S-Cath System led to an annual cost saving of about £100,000 in an NHS region.

Introduction

A suprapubic catheter (SPC) is a hollow flexible tube, which is inserted into the bladder through an abdominal incision just above the pubic hairline. It is used to drain urine from the bladder in people who are unable to pass urine normally and in whom placement of a urethral catheter is not possible or desirable. The procedure to insert the SPC is called asuprapubic cystostomy (also known as a vesicostomy or epicystostomy). SPCs are often used for long-term catheterisation, for example, in people with spinal cord injuries and conditions such as multiple sclerosis (Jacob et al. 2012). They can also be used in people who only need them for short periods, for example, in people with a traumatic injury to the lower urinary tract (National Patient Safety Agency 2009), and in people with an enlargement of the prostate or a urethral stricture (Lamont et al. 2011). It has been suggested that a typical district general hospital in England or Wales will do over 100 suprapubic catheterisations each year (National Patient Safety Agency 2009).

The conventional technique used to insert SPCs is ultrasound-guided or blind (without ultrasound guidance) percutaneous trocar puncture. In this procedure, a trochar comprising an obturator and a catheter is inserted through the abdominal wall into the bladder through a track made with a needle. The risks of SPC insertion include haemorrhage, infection, pain and injury to the abdominal organs (Harrison et al. 2010). For example, blind insertion can cause bowel injury (Mohammed et al. 2008), although a full bladder usually prevents loops of bowel passing between the bladder and the anterior abdominal wall allowing safe SPC insertion (Jacob et al. 2012). An unpublished survey of British urologists, cited in a Rapid Response Report by the National Patient Safety Agency (2009), found the estimated risk of an individual SPC procedure resulting in bowel perforation to be 0.15% with a 0.05% risk of death. The survey concluded that although reported bowel complications were 'very rare', the true incidence may be higher. A 2006 UK study reported that SPC insertion has a 2.4% risk of bowel injury and a 30-day mortality of 1.8% (Ahluwalia et al. 2006). The Rapid Response Report recommends that ultrasound is used wherever possible to visualise the bladder and guide the insertion of suprapubic catheters (National Patient Safety Agency 2009).

The Seldinger technique is a method of accessing blood vessels and hollow organs using a guidewire and is an alternative technique to conventional trochar puncture for inserting SPCs. Using a guidewire could minimise some of the risks associated with SPC insertion by reducing the risk of track loss (the path between the abdomen and the bladder) and catheter misplacement (Goyal et al. 2012).

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

Mediplus was awarded a Class IIb CE mark for the S-Cath System in July 2005, and the most recent date of renewal was December 2015. The CE-mark certification covers all components of the S-Cath suprapubic Foley catheter with introducer set.

Description

The S-Cath System is designed for placing suprapubic catheters using the Seldinger technique. This technique uses a guidewire to place the catheter in the bladder with the aim of reducing the risk of bladder or bowel injury. The S-Cath System uses a 3-stage guidewire in place of a traditional guidewire. Traditional guidewires can kink, preventing the catheter from being inserted into the bladder, and can also injure the surrounding tissues.

The S-Cath System consists of:

- a long needle (16 gauge)
- a guidewire
- a trocar with an outer sheath
- a silicone Foley catheter (available in a variety of sizes and types)
- 2 syringes (10 ml)
- a scalpel.

The guidewire is made up of 3 parts; a 'floppy' tip, a more rigid central section and a third,

solid section with 2 reference marks printed on it. The floppy tip helps prevent injuries to the posterior wall of the bladder, and the central section gives resistance, which allows the user to work out its location. The reference marks on the solid section help with device placement and allow the trocar (a hollow tube with a pointed end) to be safely inserted.

Patients are prepared in the same manner used for conventional suprapubic catheterisation using the trocar puncture method. Ultrasound is recommended to confirm that the bowel is not trapped between the abdomen and bladder. The needle is inserted into the bladder, and once this is in position, the guidewire is inserted through the needle, floppy end first, until the first black mark on the guidewire is reached. The needle can then be withdrawn. The trocar with its sheath is then fed over the guidewire and into the bladder. When it is correctly positioned, the guidewire and trocar can be removed, leaving the sheath in place. The catheter is then inserted and the sheath removed.

S-Cath catheters are removed in the conventional manner, with normal local procedures followed for re-catheterisation. The S-Cath System is indicated for initial SPC insertion only and cannot be used for re-catheterisation, which is outside the scope of this briefing.

The S-Cath catheter has an integrated balloon, unlike most Foley catheters in which the balloon is mounted on the outside of the catheter shaft. Traditional Foley catheters have a tendency to 'cuff', an effect in which the catheter balloon creases or forms ridges when deflated. This can make it more likely that the patient feels pain or discomfort as the catheter is removed. The integrated balloon in the S-Cath System is less likely to 'cuff' and so removal may be more comfortable for the patient.

S-Cath catheters are available in a range of diameters from 8 Fr to 18 Fr, measured using the 'French' scale system (referred to as Fr) with 1 Fr equal to 0.33 mm in diameter. The 8 Fr and 12 Fr versions of the S-Cath System are suitable for children. The catheter is 42 cm in length, and is available in open and closed tip formats. Open tip catheters allow an additional, non-proprietary guidewire to be used to change the catheter. The guidewire is passed through the lumen of the catheter into the bladder and, after deflating the balloon, the catheter can be withdrawn. The new catheter can then be slid into place over the guidewire. Open tip catheters are shorter, which reduces the risk of the tip of the catheter irritating the bladder wall.

Setting and intended use

The S-Cath System is indicated for bladder irrigation or drainage through a needle

puncture or incision. It is suitable for children, young people and adults of both sexes who need an SPC. There is no age limit on its use but its suitability in young children should be based on clinical judgement. The instructions for use state that the catheter can remain in place for up to 12 weeks before being replaced.

SPC insertion is carried out by urologists or other trained and supervised clinical staff in hospital inpatient and outpatient settings. The British Association of Urological Surgeons' practice guidelines on suprapubic catheterisation (Harrison et al. 2010) recommend that ultrasound be used as an adjunct to SPC insertion to find out whether the bladder is distended. They also recommend that ultrasound should only be used to look for interposing bowel loops along the planned catheter track by clinicians who have specific training and experience in this task.

Although its use in pregnancy is not specifically contraindicated, suprapubic catheterisation is absolutely contraindicated in the absence of an easily palpable or ultrasonographically localised distended bladder (National Patient Safety Agency 2009). Other contraindications to using suprapubic catheters are bladder cancer, anticoagulant and antiplatelet treatment, abdominal wall sepsis, a subcutaneous vascular graft in the suprapubic region (for example a femoro-femoral crossover graft; Harrison et al. 2010), uncontrolled blood clotting leading to prolonged or excessive bleeding, pelvic cancer (with or without radiation), and previous abdominal or pelvic surgery (because of the risk of adhesions; National Patient Safety Agency 2009).

Current NHS options

Several options are available for people who are unable to pass urine normally. This includes permanent urinary diversion (British Association of Urological Surgeons 2016), which surgically reroutes urine flow. This may be used in people who have had their bladder removed. People with an intact bladder who have difficulty passing urine normally will more often be fitted with a urinary catheter.

There are 2 main types of urinary catheters: intermittent catheters that are inserted to empty the bladder and are immediately removed, and indwelling or permanent catheters that stay in place for several days or weeks ([NHS Choices 2015a](#)). Indwelling catheters may be more suitable for some people who need long-term catheterisation because repeated insertions are avoided.

Indwelling catheters may be inserted through the urethra (the tube which carries urine out

of the body) or through a tube inserted above the pubic area (an SPC). SPCs have some advantages over urethral indwelling catheters because they can improve patient comfort and dignity, they are easier to keep clean and are less likely to be pulled out of position. SPCs do not inhibit sexual activity and also reduce the risk of genital damage ([NHS Choices 2015b](#)).

The blind technique of SPC insertion (that is, using a trocar or guidewire but without ultrasound guidance) relies on adequate filling of the bladder to move the bowel away from the site of the needle puncture (Jacob et al. 2012). Ultrasound examination may be used to identify loops of bowel along the planned catheter track, but it is not considered necessary in people with a readily palpable bladder and no history of lower abdominal surgery (Harrison et al. 2010). The National Patient Safety Agency (2009) Rapid Response Report on minimising risks of SPC insertion states that using ultrasound is a safer method especially in people in whom the procedure could be difficult, such as those with a large build or abdominal adhesions, or who are uncooperative. Conventional trocar puncture SPCs may be inserted under general, local or epidural anaesthetic and the procedure is usually carried out in an operating theatre.

NICE has issued a quality statement on [urinary catheters](#) in its quality standard on infection prevention and control, and guidance on the [long-term use of urinary catheters](#) in its clinical guideline on healthcare-associated infections.

NICE is aware of the following CE-marked devices that appear to fulfil a similar function to the S-Cath System:

- Bard Suprapubic Catheterisation Kit with BIOCATH Hydrogel coated Foley catheter, trocar and surgical blade (Bard Medical)
- BD Bonanno suprapubic catheter with introducer needle (BD)
- Supraflow catheter suprapubic set with introducer (Coloplast)
- Stamey Percutaneous Malecot Suprapubic Catheter Set (Cook Medical)
- Suprapubic Balloon Catheter Set (Cook Medical).

Costs and use of the technology

The S-Cath System is sold in boxes of 5 units and is available in several variations

depending on catheter diameter and tip type. The list prices of the different versions range from £36.39 to £41.92 each, excluding carriage and VAT.

The manufacturer's instructions for use advise that the S-Cath suprapubic catheter can be used for up to 12 weeks before replacement.

The manufacturer advises that junior clinicians should have standard training in suprapubic catheterisation and that no additional device-specific training is usually needed. However dedicated on-site training is available, and the manufacturer also employs a dedicated clinical nurse trainer to supplement existing training. All training is free of charge.

Data from the [National Schedule of Reference Costs](#) reports that in 2014–2015 in England there were 14,901 hospital episodes, classified as 'Attention to Suprapubic Bladder Catheter', at a unit cost of £362.46.

NHS tariffs for outpatient attendance (2016–17) relating to urology and paediatric urology services have been provided for information ([NHS National tariff payment system 2016/17](#) [Department of Health 2016]; table 1).

Table 1 NHS Tariffs for relevant outpatient attendance

	Urology	Paediatric urology
First attendance, single professional	£132	£173
First attendance, multi-professional	£203	£304
Follow-up attendance, single professional	£76	£144
Follow-up attendance, multi-professional	£105	£207

The price of similar products may vary depending on the size and type of catheter. Examples from the [NHS Supply Chain](#) website have been included for reference purposes:

- Bard, Hydrogel coated suprapubic catheter with introducer needle £16.10
- BD, BD Bonanno suprapubic catheter tray with catheter, adaptor clamp and needle £31.89
- Coloplast, Supraflow catheter kit with introducer and scalpel £16.96

- Cook Medical, Stamey Percutaneous Suprapubic Catheter Set 10, 12 or 14 Fr £48.25
- Cook Medical, Suprapubic Balloon Catheter Set £105.15.

Likely place in therapy

The S-Cath System can be used in children, young people and adults needing insertion of a suprapubic catheter instead of conventional SPCs. The guidewire system is designed to reduce the risks associated with the traditional blind trocar system and may allow the procedure to be carried out in an outpatient setting.

Specialist commentator comments

Two specialist commentators stated that they currently use S-Cath. One stated that they found it to be safe and effective and the other noted that they recommend its use. Another specialist commentator stated that S-Cath is an advance over the traditional method for inserting an SPC. They added that because it only needs a single puncture compared with the 2 needed for blind trocar insertion, S-Cath reduces the risk of failure and injury associated with suprapubic catheterisation. They also noted that the guidewire offers the additional benefit of keeping the trocar placement on track, which prevents it from finding its own route behind the bladder and possibly causing peritoneal and bowel injuries.

One specialist commentator stated that S-Cath is intuitive to use and users can be easily trained to use the system. Another specialist commentator noted that because it is easier to do suprapubic catheterisation safely with S-Cath it can be carried out in different settings, which may be less costly.

One specialist commentator stated that the procedure can be done under flexible cystoscopy guidance. Another specialist commentator did not support the use of cystoscopic guidance but commented that ultrasound guidance should be used.

One specialist commentator advised that they had 1 incident in which the S-Cath guidewire broke during the procedure. This has resulted in a trust policy, which states that the guidewire must be measured against its tubing cover before and after insertion to check that it is intact.

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, 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).

Indwelling catheters are more often needed by people who are older, have long-term conditions, or who have had surgery or traumatic injury. This may include people with neurological conditions, such as spina bifida, cerebral palsy and paralysis, or people having end-of-life care. Indwelling catheters may help people with these conditions carry out daily activities and improve their quality of life. Age and disability 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 this device. No reports of adverse events were identified from a search of the US Food and Drug Administration (FDA) database: Manufacturer and User Device Facility Experience (MAUDE).

A report by the National Patient Safety Agency (2009) detailed 3 deaths and 7 incidents of severe harm from suprapubic catheter (SPC) placement between September 2005 and June 2009 in England and Wales. Nine of these involved bowel perforation. A further 249 incidents related to lesser degrees of harm were also reported. The techniques used could not be established.

Clinical evidence

The literature search identified 6 relevant reports: 1 non-comparative observational study (Jelski et al. 2013), 2 case series (Burki et al. 2011; Khan and Abrams 2008) including 1 with a cost analysis (Khan and Abrams 2008); 2 case reports (Jackson et al. 2010; Verwey et al. 2012); and 1 validation study with user survey (Vasdev et al. 2006). Burki et al. (2011) and Jelski et al. (2013) are only available as a conference abstract and poster respectively. Because of the limited amount of clinical data, all 6 studies meeting the selection criteria are included and summarised in this report. Details of these studies and their results are available in the [appendix](#).

A non-comparative observational study by Jelski et al. (2013) reported on a dedicated twice-monthly SPC clinic in a UK hospital, in which the S-Cath System has been used since July 2008 ([table 2](#)). Ultrasound use to locate the bowel began in 2011 (study end date not reported). The clinic was set up to place new SPCs and change difficult SPCs with 322 insertions reported. Insertion under local anaesthetic was not suitable in 2% of cases (whether these were patients or procedures was not stated). All patients were discharged at the end of the clinic session. The authors reported 4 complications; 3 bowel perforations (0.93%) and 1 persistent haematuria. Of the bowel perforations, 1 was confirmed at the time of the procedure and needed surgical repair, 1 was confirmed 3 years after the procedure, and 1 was suspected (at the first change of the SPC at 3 months). There were no bowel perforations after ultrasound scanning started to be used for the procedure. The authors concluded that there were low complication rates, and that a dedicated SPC clinic is safe and feasible and provides a good teaching opportunity.

The case series reported by Burki et al. (2011) included a retrospective analysis of 45 patients with spinal cord injuries ([table 3](#)). The patients had an SPC fitted using the S-Cath System as a day case at a single UK centre. Ultrasound guidance was used in 12 patients with a history of abdominal surgery. The authors of this briefing note that the manufacturer states the use of S-Cath is contraindicated in people who have had abdominal surgery. All procedures were successfully completed; but autonomic dysreflexia occurred in 2 patients. In 4 patients, a urethral catheter was also inserted for irrigation for 6 hours after the procedure. One patient had haematuria, needing a bladder washout in theatre, and 3 patients developed a urinary tract infection. SPCs were first changed in a catheter clinic at 6 weeks and subsequent changes were done in the community by district nurses. Eight of the SPCs (18%) could not be replaced by district nurses and temporary urethral catheters were used while the patients waited for a new SPC. The authors concluded that SPC insertion in this patient group is challenging and should be

performed in theatre with anaesthetic support.

Khan and Abrams (2008) reported an audit exploring local and regional SPC insertion in the south-west region of England ([table 4](#)). The data was used to determine the proportion of patients whose SPCs might be managed in 1 outpatient department. Patients were subsequently followed in a prospective case series of people who had SPCs inserted as day cases. A weekly clinic was started, using the S-Cath System to insert SPCs, to which 54 patients were referred between August 2006 and July 2007. Procedures were done by 1 trainee urologist who inserted the SPCs using local anaesthetic; ultrasound was used in patients whose bladders could not be distended adequately. Insertion was successful in 50 patients. Four people did not have an SPC inserted; difficulty in filling the bladder because of severe pain or urine leakage was the cause in 3 patients, and the procedure was stopped in the fourth patient because of a panic attack. Although there were no serious complications during the procedure in the 50 patients who had successful SPC insertion, 1 patient was admitted with haematuria after insertion and 1 patient had prophylactic antibiotics because of a suspected infection. In another patient, the SPC blocked within 1 week of insertion. It was changed and then stopped draining, necessitating reinsertion under general anaesthetic. The study also reported estimated cost savings, which are described in the cost and resources section of this briefing.

Jackson et al. (2010) presented a case report on a 66 year old man who had an SPC inserted using the S-Cath System without cystoscopic guidance ([table 5](#)). The patient was admitted to hospital overnight because of pain at the catheter insertion site and pyrexia, assumed to be caused by urinary infection. These symptoms later settled. After 3 months, the SPC was changed in the community by an experienced nurse; the type of replacement catheter was not specified. The day after the SPC was changed, the patient presented with small bowel effluent draining from the SPC, although there was no pain or signs of peritonitis or sepsis. Cystoscopy found turbid urine and no sign of the SPC in the bladder. A CT scan showed that the catheter was within a loop of the small bowel. The SPC was removed without further complication. The authors concluded that although it has been suggested that this device may be safer than those used previously, there is still a risk of bowel injury.

The case report presented by Verwey et al. (2012) described an 82-year old woman with a medical history of hysterectomy, cholecystectomy and bilateral hip replacement ([table 6](#)). Although a consultant urologist inserted the SPC using the S-Cath System, there was some difficulty in passing the Seldinger needle into the bladder. The patient was readmitted 11 hours later after collapsing. Investigations suggested she was losing blood.

An emergency laparotomy was done and an injury to the small bowel was found, which resulted in a small bowel resection. The patient was discharged to a community hospital after 26 days. The authors concluded that this case illustrates the risk of complications in patients with a history of pelvic or abdominal surgery, and supports the use of ultrasound in these cases. The manufacturer states the use of S-Cath is contraindicated in people who have had abdominal surgery because of the risk of adhesions.

Vasdev et al. (2006; [table 7](#)) evaluated clinicians' experience of using the S-Cath System. Six patients had SPCs inserted by 6 different clinicians, who were asked to complete a 5 domain questionnaire rating their confidence in doing the procedure compared with standard trocar placement. The 5 domains related to confidence in technique, dilator, use by junior staff, patient comfort, and safety of the device. In each of the domains the users preferred the S-Cath System to standard techniques.

Recent and ongoing studies

No ongoing or in-development trials on the S-Cath System for suprapubic catheterisation were identified in the preparation of this briefing.

Costs and resource consequences

A briefing pack on the S-Cath System, published by the former [NHS Technology Adoption Centre](#) (undated), listed several benefits of using the device. These include greater control and accuracy of placement, reduced risk of trauma and tissue damage, improved insertion and removal, and greater user confidence. The briefing suggested that the catheter rarely needs to be inserted under general anaesthetic, so reducing associated risks.

The manufacturer states that the S-Cath System is used in about 80 NHS sites in England and Wales. No additional equipment or facilities beyond those for standard suprapubic catheterisation are needed to use this device, and no difficulties are anticipated in adopting this technology into current care pathways. If adopted in an outpatient setting, the related decrease in hospital stay could lead to a reduction in resource use.

The UK-based study carried out by Khan and Abrams (2008) described in the [clinical evidence](#) section and [table 4](#), assessed the cost savings associated with moving SPC insertion from an inpatient to an outpatient setting. It is not clear which method of SPC insertion was used in the inpatient clinic. In the local inpatient audit, 43 patients had general anaesthetic and 23 had local anaesthetic; the numbers of patients treated with

each anaesthetic in the regional audit is not clearly specified. In the day-case theatre, 50 of 54 patients had an SPC successfully inserted under local anaesthetic. The local mean cost of inpatient theatre insertion of an SPC was £2,400 compared with £462 for a day-case theatre insertion of the S-Cath SPC. The costs included salaries, disposables, instruments and anaesthetics. Inpatient procedure costs also covered time in hospital (mean 4.1 days). Costs for emergency cases were based on elective inpatient costs and prolonged hospital stays were ignored because they may not have been directly related to SPC insertion. For the day-case scenario, costs for the proportion of patients eventually needing hospitalisation were included, as were the costs of additional procedures when outpatient SPC insertion failed. Based on the data collected, it was predicted that 90% of SPC insertion procedures in the south-west region of England could be carried out in an outpatient clinic. The authors estimated that the annual cost benefit of adopting an outpatient management strategy would be about £100,000 in the hospital involved, which, when extrapolated to the region would be £790,000 and to the UK as a whole would be £9.5 million.

A product review of the S-Cath System (McMeekin et al. 2010) compared conventional SPC insertion with the S-Cath System in 1 NHS hospital. The S-Cath technique allowed the authors to move SPC insertion to an outpatient procedure, resulting in a reduction in hospital stay from 2.3 days to 28 minutes. No other details, including the number of patients studied, were specified.

Strengths and limitations of the evidence

The evidence identified was very limited in both quantity and quality, and no large scale or comparative studies were found. Most of the studies involved relatively small numbers of patients. Two case reports (Jackson et al. 2010; Verwey et al. 2012) included single patients and it can be assumed that the outcomes of these reports should not be generalised. In particular, Jackson et al. (2010) report on a patient who developed complications after SPC replacement. The S-Cath System was used during the first SPC procedure, however the replacement catheter was not specified. Because the S-Cath should only be used for initial insertion and not replacement of SPCs, it is unclear if the use of S-Cath was related to these complications. The 2 case series (Burki et al. 2011; Khan and Abrams 2008) both included fewer than 55 patients, with Burki et al. (2011) analysing patients retrospectively, increasing the risk of bias. This study is only available as a conference abstract and so few details are available. It is unclear if the patients were consecutive, again raising concerns about bias.

Both Burki et al. (2011) and Verwey et al. (2012) used the S-Cath System in patients with a history of abdominal surgery, which is contraindicated for SPC insertion. This may have contributed to the complications seen in these studies. Jelski et al. (2013) noted that there were no bowel perforations after ultrasound scanning was started; the instructions for using the S-Cath System recommend the use of ultrasound.

Jelski et al. (2013) included a large number of patients, but because the study is only available as a poster presentation, few details are available and it is unclear if the data were collected prospectively. As conference presentations, Jelski et al. (2013) and Burki et al. (2011) are unlikely to have been peer reviewed.

Neither of the 2 case series (Burki et al. 2011; Khan and Abrams 2008) nor the observational study (Jelski et al. 2013) stated inclusion and exclusion criteria, and Khan and Abrams (2008) did not specify primary outcomes. However, all 3 of these studies seem to report adverse events relatively clearly and include relevant outcomes.

Khan and Abrams (2008) reported the cost savings associated with moving SPC insertion from an inpatient to a day-case setting using the S-Cath System. It is unclear if S-Cath was used in the inpatient setting. Although significant cost savings were found, these mostly resulted from changing SPC insertion from an inpatient to an outpatient procedure, and were not necessarily associated with using the S-Cath System itself. Because the study does not detail why S-Cath was chosen over other similar devices, it is unclear if using the S-Cath System is a significant factor in this cost saving. The study also extrapolated local cost savings to the wider region and the UK. Local and national variations may mean that these estimated savings are inaccurate.

The Vasdev et al. (2006) validation study did not give any patient data but did include a user survey from a small number of clinicians. All the clinicians surveyed were urology staff, so may have been more experienced in SPC insertion than other S-Cath System users. Less experienced users may have different viewpoints. Also, the questionnaire used in the study was not provided and it is unclear if it had been validated. The study may therefore have been open to bias.

Khan and Abrams (2008) and Vasdev et al. (2006) acknowledged the S-Cath System manufacturer for permission to reproduce illustrations. No other conflicts of interest are declared by any authors.

All of the studies appear to be UK-based, so the results are likely to be generalisable to the

NHS setting.

Relevance to NICE guidance programmes

NICE has issued the following guidance:

[Infection prevention and control](#) (2014) NICE quality standard 61

[Urinary incontinence in women: management](#) (2013) NICE guideline CG171

[Urinary incontinence in neurological disease: assessment and management](#) (2012) NICE guideline CG148

[Healthcare-associated infections: prevention and control in primary and community care](#) (2012) NICE guideline CG139

[Lower urinary tract symptoms in men: management](#) (2010) NICE guideline CG97

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Table 2 Overview of the Jelski et al. (2013) observational study

Study component	Description
Objectives/hypotheses	To show that a dedicated SPC clinic is safe and feasible.

Study design	Single-arm, observational study.
Setting	Dedicated SPC clinic in a UK hospital.
Intervention	Mediplus S-Cath System using the Seldinger technique.
Primary outcomes	Feasibility and safety of SPC insertions.
Patients included	322 SPC insertions (number of patients not reported).
Background	<p>A dedicated, twice-monthly SPC clinic, led by a trained specialist nurse, was set up in a procedure room in July 2008. Ultrasound scanning started in 2011. Two aspects:</p> <ul style="list-style-type: none"> • clinic: GP referrals – discussions on SPC suitability and problematic catheters • procedural: insertion of new SPC, change of difficult catheters.
Results/ outcomes	SPC insertion under local anaesthetic was not suitable for 2% (whether this was patients or procedures was not stated). All patients were discharged by the end of the clinic session.
Adverse events	<ul style="list-style-type: none"> • 1 persistent haematuria • 3 bowel perforations (0.93% risk, but none since ultrasound scanning started): 2 confirmed (1 at the time of the procedure, which needed surgery, and 1 after 3 years); 1 suspected when the SPC was changed after 3 months.
Conclusions	<p>'A dedicated SPC clinic can be safe and feasible if guidelines are followed.</p> <p>Low complication rates.</p> <p>Provides invaluable teaching opportunities (controlled environment, high concentration of patients, high turnover).</p> <p>May be of value in future to increase use of SPC in acute and chronic setting' (extract from the poster, no further details given).</p>

Abbreviation: SPC, suprapubic catheter.

Table 3 Overview of the Burki et al. (2011) case series

Study component	Description
Objectives/ hypotheses	Selected patients with a SCI, who had a neuropathic bladder, had SPC insertion as a day case, with the first change of SPC in a catheter clinic at 6 weeks and subsequent changes done in the community by district nurses. Experience with this technique over a 1-year period is presented.
Study design	Retrospective case series.
Setting	A single UK hospital and community setting. Patients treated between June 2009 and June 2010.
Intervention	Mediplus S-Cath System.
Primary outcomes	Problems encountered during the procedure and post-operative complications.
Patients included	n=45 Mean age was 54 years (range 15–88 years) Male to female ratio was 2.75:1 Spinal cord injury was described as: cervical=28; thoracic=9; lumbar=4; multiple sclerosis=2; post-sacrectomy=1; cauda equina=1.
Background	The procedure was done as a day case under appropriate anaesthesia and ultrasound guidance was used when there was a history of abdominal surgery.
Results	All procedures were successfully completed. Ultrasound scan was used in 12 people. Filling the bladder was difficult in most of the people because of small contracted bladders. Urinary leakage around the urethral orifice was a problem, especially in women. Importantly, positioning the patient for insertion of the cystoscope and SPC was challenging. In 4 people, a urethral catheter was inserted to perform irrigation for 6 hours after SPC insertion.

Adverse events	One patient with haematuria needed bladder washout in theatre. Three patients developed UTIs. Autonomic dysreflexia occurred in 2 patients during the procedure. All patients had a successful first change of SPC in a catheter clinic after 6 weeks, but 18% (8/45) of the SPCs could not subsequently be replaced by district nurses. These 8 patients had temporary urethral catheters and were booked for reinsertion of SPC.
Conclusions	SPC insertion in patients with a SCI is a challenging procedure and should be done under controlled conditions in theatre with an anaesthetist present and using ultrasound when appropriate. There is a high reinsertion rate, but this may be related to changing the SPC in the community.
Abbreviations: SCI, spinal cord injury; SPC, suprapubic catheterisation; UTI, urinary tract infection.	

Table 4 Overview of the Khan and Abrams (2008) case series

Study component	Description
Objectives/hypotheses	To explore, by an audit, the regional practice of inserting an SPC, and to prospectively determine the proportion of SPCs that can be successfully managed on an outpatient basis in 1 department.
Study design	Retrospective audit and clinician survey that gathered data on all patients who had an SPC inserted between April 2005 and March 2006. Prospective case series that gathered data on patients scheduled for SPC insertion using the S-Cath System from August 2006 and July 2007.
Setting	Retrospective audit: urology departments in 12 UK hospitals in the south-west of England. Prospective audit: SPC clinic in 1 UK hospital in south-west England.
Intervention	Mediplus S-Cath System.
Primary outcomes	Not applicable.

Patients included	<p>Retrospective audit</p> <p>Locally:</p> <ul style="list-style-type: none">• 66 patients (mean age 70 years, range 26–93)• 49 patients had an elective procedure (7 were day cases), 17 were emergency admissions• 43 patients had a GA and 23 patients had LA• median (range) hospital stay was 3.5 (1–85) days. <p>Regionally:</p> <ul style="list-style-type: none">• 480 SPCs were inserted in theatre, of which 52% (249) were as elective inpatients, 11% (52) were day cases, and 37% (179) were emergency admissions• a nurse-led outpatient service was available in 2 hospitals, where 89% of clinic patients had successful insertion under LA, and 11% were referred for insertion under GA. <p>Prospective case series</p> <p>An SPC was successfully inserted in 50 of 54 patients in the new SPC clinic.</p>
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Background	<p>Local practice was determined by a retrospective analysis of the hospital database between April 2005 and March 2006. Regional practice was identified by contacting regional hospitals. A questionnaire was also e-mailed to each of the 11 urology departments. This aimed to determine the departmental practice of SPC insertion regarding method, type of anaesthesia, preferred method of filling the bladder, and whether ultrasound guidance was used. Participants were also asked about factors influencing their decision to insert the SPC in the operating theatre, and whether outpatient-based SPC insertion was attempted first.</p> <p>As a result of the audit, a new once-weekly SPC clinic was set up. All SPCs were inserted by 1 trainee urologist using the S-Cath System under LA. Patients stayed under observation for 1–2 hours after the procedure. The first catheter change was done in a nurse-led clinic 4 weeks later, after which patients were discharged to primary care. Locally, mean costs were calculated for outpatient, inpatient and day-case procedures. The cost differential to the trust of adopting outpatient SPC insertion was estimated and this was extrapolated to the region and to the UK as a whole.</p>
Results/ outcomes	<p>Outpatient SPC insertion was successful in 50 patients and unsuccessful in 4 patients. Difficulty in filling the bladder because of severe pain or urine leakage was the reason for 3 of the unsuccessful procedures (all had small-capacity bladders due to multiple sclerosis). In the fourth patient, the procedure was stopped because of a panic attack.</p>
Adverse events	<p>Of the 50 successful procedures, 1 patient was given prophylactic antibiotics because of a suspected infection. There were no serious complications during the procedure. One patient was admitted with haematuria after insertion. In 1 patient, the SPC stopped draining after it had been changed due to a blockage within the first week of insertion, and needed reinsertion under GA.</p>
Conclusions	<p>SPC is safe and feasible as an outpatient procedure for most patients, and its widespread use would produce considerable cost savings.</p>
<p>Abbreviations: GA, general anaesthetic; LA, local anaesthetic; SPC, suprapubic catheter.</p>	

Table 5 Overview of the Jackson et al. (2010) case report

Study component	Description
Objectives/ hypotheses	To present a case of small intestine injury after suprapubic catheterisation.
Study design	Retrospective descriptive case report.
Setting	UK-hospital setting.
Intervention	Mediplus S-Cath System.
Primary outcomes	Not applicable.
Patients included	n=1 66 year old man with chronic retention and obstructive uropathy.
Background	Urethral catheterisation was done and the patient's renal function stabilised. A trial without a catheter after 3 months was unsuccessful. An SPC was inserted under local anaesthetic, without cystoscopic guidance. Overnight admission and IV antibiotics were needed because of pain at insertion site and low-grade pyrexia, assumed to be caused by a urinary infection. These symptoms settled, and the patient was discharged home with a short course of ciprofloxacin.
Adverse events	After 3 months, an experienced nurse in the community changed the SPC. The patient presented to the admissions unit the next day, with a greenish fluid, identified as small bowel effluent, draining from the SPC. He remained pain-free and systemically well, with no evidence of sepsis or peritonitis. Flexible cystoscopy showed turbid urine in the bladder, and no sign of the SPC. The bladder was catheterised urethrally. A CT scan was done with contrast instilled through the SPC, which showed that the catheter lay within a loop of small bowel. The injury was managed conservatively as a controlled entero-cutaneous fistula.
Results/ outcomes	The SPC was removed after 2 weeks and a dry dressing applied. The patient recovered without further complication.

Conclusions	This case shows that the risk of bowel injury can still occur despite using the S-Cath System.
Abbreviations: IV, intravenous; SPC, suprapubic catheter.	

Table 6 Overview of the Verwey et al. (2012) case report

Study component	Description
Objectives/ hypotheses	Not applicable.
Study design	Retrospective descriptive case report.
Setting	UK-hospital setting.
Intervention	Mediplus S-Cath System.
Primary outcomes	Not applicable.
Patient included	An 82-year old woman with a medical history of hysterectomy, atrial fibrillation, hypertension, bilateral hip replacement and open cholecystectomy.
Background	A consultant urologist inserted an SPC using the S-Cath System. The bladder was filled using a flexible cystoscope before locating it with the Seldinger needle. There was some difficulty in passing the Seldinger needle into the bladder, but thereafter, it was a straight forward insertion. The patient felt well after the procedure and was discharged later that day.
Results/ outcomes	Post-operatively the patient needed intensive care in the form of fluid balance and inotropic support in ITU. Post-operative recovery was complicated by confusion, generalised weakness and sepsis of unknown source. The patient gradually improved and was discharged after 26 days to a community hospital for 15 days of further rehabilitation.

Adverse events	<p>The patient began feeling unwell and collapsed twice. There were no cardiac symptoms or history of a fall. Two further episodes of dizziness were followed by unresponsiveness lasting 30 seconds. Respiratory examination found crackles in the left lung base. Investigations showed raised WBC count (14.9×10^9/litre), haemoglobin of 11.4 g/dl, and an INR of 3.1. BP was 180/92 mmHg. There was abdominal tenderness, particularly in the epigastric area. The SPC was draining clear urine but there was a small amount of blood leaking from around the insertion site. Fluid resuscitation corrected 2 hypotensive episodes.</p> <p>A CT scan showed that the SPC was in place and high-density fluid was present in the abdomen and pelvis, in keeping with haemorrhage. An emergency laparotomy showed a small bowel injury, a large haematoma in the mesentery, and about 2,400 ml of blood with clots in the peritoneal cavity. A small bowel resection with end-to-end anastomosis was done.</p>
Conclusions	<p>This case shows that the risk of complications during SPC insertion is increased in patients with previous abdominal or pelvic surgery, and offers strong support for using ultrasound guidance when carrying out the procedure in these patients.</p>
<p>Abbreviations: BP, blood pressure; dl, decilitre (100 ml); INR, international normalised ratio; ITU, intensive therapy unit; SPC, suprapubic catheter; WBC, white blood cell.</p>	

Table 7 Overview of the Vasdev et al. (2006) validation study

Study component	Description
Objectives/hypotheses	To present an evaluation of a new Seldinger technique for SPC describing the technique and post-procedure results.
Study design	Validation study (user experience survey).
Setting	A single UK hospital.
Intervention	Mediplus S-Cath System.
Primary outcomes	To evaluate patient safety and the clinician's perception of a new Seldinger technique for SPC.

Patients included	Six patients who had SPCs inserted by 6 members of the urology department (specialist registrars and consultants).
Background	All clinicians completed a questionnaire after doing the procedure, rating their confidence in the new device compared with the standard technique across 5 domains, each using a simple scale. The rating scale for the questionnaire ranged from -100% to +100%.
Results/ outcomes	Confidence (mean [range]): <ul style="list-style-type: none"> • technique +38% (range 0% to +95%) • dilator +47% (range -40% to +95%) • patient comfort +17% (range 0% to +50%) • use by junior staff +39% (range -50% to +80%) • safety +37% (range -50% to +80%).
Adverse events	Not reported.
Conclusions	Overall, users expressed greater confidence in application, patient comfort, and safety compared with standard trochar placement. Given the current drive to minimise risk, these devices appear to represent a significant advance over standard methods and merit consideration for routine use.
Abbreviation: SPC, suprapubic catheter.	

Search strategy and evidence selection

Search strategy

The following search strategy was used to search Ovid MEDLINE (R) 1946 to January week 3 and Ovid MEDLINE (R) In Process & Other Non-Index Citations, February 1, 2016:

1 (mediplus and catheter).tw. (1)

2 "s-cath system".tw. (0)

3 "mediplus SPC".tw. (0)

4 "mediplus guidewire".tw. (0)

5 ((Seldinger or mediplus) and suprapubic catheter*).tw. (3)

6 or/1-5 (3)

Similar search strategies were adapted for Embase, Cochrane Library (all relevant components), ECONLit, Web of Science, Scopus, NHS Evidence and Pubmed. The searches returned a total of 12 references after duplicate removal. A further 3 articles were identified from citation tracking (1 article) and from the manufacturer (2 articles) resulting in 15 articles.

ClinicalTrials.gov, the UK Clinical Research Network (UKCRN) and the International Clinical Trials Registry Platform (ICTRP) were searched to identify ongoing or in-development trials.

Evidence selection

Retrieved results were sifted by 2 researchers using the selection criteria below.

- Population – men or women patients of any age:
 - in whom urethral catheterisation failed, or was difficult or complex or
 - who needed medium to long-term catheterisation.
- Intervention: S-Cath System for suprapubic catheterisation.
- Comparator:
 - standard blinded suprapubic catheterisation
 - ultrasound-guided suprapubic catheterisation.

- Outcomes:
 - improved device placement
 - length of hospital stay
 - NHS costs
 - procedural complications
 - quality of life
 - patient comfort
 - infection
 - clinical ease of use.

From the 15 records obtained from the searches, 6 records were identified that met the selection criteria: 2 case series; 2 case reports; 1 observational study, and 1 validation study with user survey. Two of these were only available as conference abstracts. Due to the paucity of data, all 6 studies meeting the selection criteria were included.

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 Cedar. 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

Cedar

Medical Technologies Evaluation Programme, NICE

Peer reviewers and contributors

- Mrs Kathleen Withers, Researcher, Cedar
- Dr Helen Morgan, Information Specialist, Cedar
- Dr James Evans, Researcher, Cedar
- Dr Alistair Ray, Researcher, Cedar
- Dr Judith White, Researcher, Cedar
- Dr Grace Carolan-Rees, Director, Cedar

Specialist commentators

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

- Mr Hashim Hashim, Consultant Urological Surgeon, Southmead Hospital, Bristol
- Professor Christopher Chapple, Consultant Urological Surgeon, Royal Hallamshire Hospital, Sheffield
- Mr Angus MacCormick, Urology Speciality Nurse, Musgrove Park Hospital, Somerset
- Professor Mark Emberton, Consultant Urological Surgeon, University College London Hospitals, London

Declarations of interest

Christopher Chapple has acted as: a consultant, speaker and trial participant for Allergan, Astellas, Medtronic and Recordati; a consultant and speaker for Lilly; and a speaker for Ranbaxy. He has also acted as a trial participant and speaker for ONO and Pfizer.

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