

UroShield for preventing catheter-associated urinary tract infections

Medtech innovation briefing

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Summary

- The **technology** described in this briefing is UroShield. It is used to prevent catheter-associated urinary tract infections (CAUTI) in people with long-term indwelling catheters.
- The **innovative aspects** are that it uses surface acoustic wave technology to prevent the attachment of bacteria to the surface of catheters.
- The **intended place in therapy** would be as well as existing catheter products to help prevent infection in people with indwelling catheters.
- The **main points from the evidence** summarised in this briefing are from 2 randomised controlled studies and 1 prospective non-randomised comparative study involving a total of 122 patients with indwelling urinary catheters. They show that when applied to urinary catheters, UroShield can help reduce the incidence of CAUTI and bacterial load and may help to decrease catheter-related pain.
- **Key uncertainties** around the evidence or technology are that from the evidence identified on UroShield, only 1 study has been published in a peer-reviewed journal, and that study was funded by the company. The evidence is also limited in its generalisability to the NHS because none of the studies were done in the UK.
- The **cost** of the UroShield system is £100 per month (£1,200 per year as a combined cost for the driver and actuator; excluding VAT). The **resource impact** would be an increased cost for buying the technology. There is the potential to release resources if the technology is shown to

- reduce the average number of CAUTIs per patient per year. The available evidence does not currently confirm that this would be the case.

The technology

UroShield (NanoVibronix) is a disposable ultrasound device designed to reduce the risk of catheter-associated urinary tract infection (CAUTI). It reduces bacterial colonisation and biofilm formation on indwelling urinary catheters. UroShield should not be used for treating an active urinary infection. The technology works by generating and propagating low frequency low intensity ultrasonic surface acoustic waves throughout the catheter, which interferes with the attachment of bacteria. The waves are transmitted directly onto the indwelling catheters at frequencies of 90 kHz and propagate throughout the catheter's entire length on both its inner and outer lumens. According to the instructions for use, UroShield can be used with catheters made of any material and sized 14, 16, 18, 20, or 22 French Gauge (FG). The company states that the technology can also be used successfully with 12-FG catheters.

UroShield includes 2 components: a driver (battery- or AC-powered portable unit), which provides the power, and a single-use actuator which is clipped onto the external portion of any indwelling urinary catheter and generates the ultrasonic waves. The actuator component of UroShield can be used for up to 30 days before needing to be replaced. If a catheter is changed within the 30-day lifespan of an existing actuator use, the company states that the actuator can be removed and attached to the new catheter for the remaining days. The company also state that patients or carers can change the actuator component of UroShield themselves. UroShield is not MRI compatible, and should be removed from the catheter before entering an MRI suite.

Innovations

The innovative aspects are that it uses surface acoustic wave technology to prevent bacteria attaching to the surface of catheters. Alternative products designed to address CAUTI usually involve coating the surface of the catheter or adapting the catheter material (such as antibiotic-coated, silver-coated and antiseptic-impregnated catheters). The company claim that UroShield may have the potential to reduce antibiotic use, by reducing the patient's dose or shortening their treatment course. By minimising the exposure of bacteria to antibiotics, the technology has the potential to help reduce antibiotic resistance.

Current care pathway

According to NICE's guideline on [healthcare-associated infections](#), the risk of blockages, encrustations and catheter-associated infections should be minimised through patient-specific

regimens such as reviewing the frequency of planned catheter changes, increasing fluid intake, and documenting catheter blockages. Bladder instillations or washouts should not be used to prevent catheter-associated infections and catheters should be changed only when clinically necessary, or according to the manufacturer's recommendations. Prophylactic antibiotics should not be used routinely for catheter changes and only considered for patients who have a history of symptomatic urinary tract infection after catheter change, or who experience trauma during catheterisation.

Population, setting and intended user

UroShield is intended to be used to prevent CAUTIs in people with indwelling urinary catheters. The technology is likely to be used in hospitals, nursing homes and in a community setting. The technology would typically be administered by healthcare professionals who insert catheters. This may include registrars, general practitioners, urology nurse specialists, district and community nurses, and continence care nurses. The company states that after some training, many patients and carers can manage the device themselves.

Costs

Technology costs

The annual cost for the UroShield system is around £1,200 (£100 per month as a combined cost for the driver and actuator; excluding VAT). The driver component costs £498 and has a minimum life span of 2 years. The single-use actuators cost £80 per unit and are changed every 30 days.

Costs of standard care

The cost of treating a CAUTI has been estimated as £1,968 per episode ([Loveday et al. 2014](#)), however the authors note that this is not a robust estimate. For a patient with recurrent CAUTIs who experiences 3 or more episodes in a 12-month period, this could equate to an annual treatment cost of £5,904 or more.

According to NHS reference costs 2017/18, the average cost for a treating kidney or urinary tract infections with interventions was £3,871 (healthcare resource group [HRG]: LA04H-M, Kidney or Urinary Tract Infections with interventions; based on non-elective stays excluding excess bed days).

The type of indwelling catheter used may vary depending on the preference of the clinician. This is usually based on clinical experience, patient assessment and materials that induce the least allergic response ([Loveday et al. 2014](#)). Foley catheters can range in price from less than £1 up to around £15 depending on size, coating and technical specification (NHS supply chain, accessed July 2019).

Resource consequences

According to the company the technology is currently being used by at least 7 NHS organisations. There is the potential to release resources in the NHS if the average number of CAUTIs per patient per year would be reduced by the introduction of UroShield. The available evidence does not currently confirm that this would be the case. The company provides basic training free of charge to clinicians, carers and patients, when necessary.

Regulatory information

UroShield is CE marked as a class IIa medical device.

Equality considerations

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

UroShield is used with urinary catheters in people who have problems passing urine. Urinary incontinence is associated with the protected characteristics of age, disability, sex, and pregnancy.

Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the [interim 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

Three studies are summarised in this briefing. The evidence base for UroShield comprises 2 randomised controlled studies and 1 prospective non-randomised comparative study involving a total of 182 patients with indwelling urinary catheters.

Further studies are publicly available but were excluded from this briefing because they were either laboratory studies not involving patients, animal studies or they involved a previous prototype of the device ([Kopel et al. 2011](#); [Hazan et al. 2006](#); [Ikinge et al. 2007](#)).

Table 1 summarises the clinical evidence as well as its strengths and limitations.

Overall assessment of the evidence

Although the evidence base comprises comparative studies (2 of which were randomised controlled studies), the peer-reviewed published evidence for UroShield is limited to 1 study funded by the company (Markowitz et al. 2018). The remaining studies were available as an abstract or as information published on the company's website. Moreover, the quality of some of the studies was difficult to assess given the limited information available. Overall, the evidence available suggests that when applied to urinary catheters UroShield has the potential to help reduce the incidence of CAUTI and bacterial load and may help decrease catheter-related pain. Studies are limited in their generalisability to the NHS given that none of the studies were done in the UK. Further UK-based studies would be helpful to understand the frequency of blockages and premature catheter removals with UroShield compared with standard care, as well as the number of emergency hospital admissions because of blocked catheters and any differences in nursing time. Further evidence on the incidence of device-related complications with UroShield, on patient quality of life, and on the potential for the technology to reduce antibiotic use in those with a history of symptomatic urinary tract infections in line with NICE guidelines, would also be helpful.

Table 1 Summary of selected studies

<u>Markowitz et al. (2018)</u>	
Study size, design and location	Double-blind, randomised controlled trial involving 55 patients with long-term indwelling catheters in a skilled nursing facility being treated with long-term indwelling catheters. Jerusalem, Israel.
Intervention and comparator(s)	UroShield Sham UroShield

Key outcomes	All patients in the study had an indwelling urinary or suprapubic catheter for over a year and had had treatment for a UTI in the 90 days before study enrolment. Of the 55 patients enrolled, 26 were randomised to the control group and 29 to the treatment group. The UroShield was shown to be effective in significantly reducing the number of CFUs in patients with indwelling catheters. Compared with the sham control, UroShield resulted in a mean decrease of 87,200 CFUs at day 30, 87,500 at day 60 and 79,300 at day 90 (all $p < 0.001$). UroShield was also shown to be effective in reducing the number of treated UTIs. At day 90, the number of reported infections was 3 in the UroShield group and 14 needing antimicrobial therapy in the control group ($p = 0.001$).
Strengths and limitations	This was a randomised, double-blind study with a follow-up period that extended 60 days after treatment. The study included patients with both suprapubic and urethral catheters (proportion of patients for each catheter type was not reported). The study only evaluated the distal tip of the catheter and retained urine. It did not evaluate the entire catheter. The study was funded by the company.
<u>Zillich et al. (2014)</u>	
Study size, design and location	Prospective randomised 2-arm study involving 40 patients with urinary catheter after radical prostatectomy. Heidelberg, Germany.
Intervention and comparator(s)	Post-operative single dose of Ceftriaxon 2 g and active UroShield (treatment group) Post-operative dose of Ceftriaxon 2 g on days 1 to 3 and trimetoprim 2×200 mg per day until the end of the study (control group).
Key outcomes	Of the 40 patients recruited, 20 were randomised to the treatment group and 20 to the control group. The average age was 66.7 and 60.7 years for the treatment group and the control group, respectively. The average catheter days was 8.4 days and 8.3 days for the treatment group and the control group, respectively. In the treatment group, there was 1 case of bacteriuria at the end of the study (bacteriuria rate=5%). In the control group there were 4 cases of bacteriuria at the end of the study (bacteriuria rate=20%).

Strengths and limitations	This was a randomised 2-arm study. However, it has not been peer-reviewed and results are available on the company's website only. Full study details, patient baseline demographics and statistical analyses were limited or lacking. The catheter dwell time was short (8 days for each group) and reasons for removal were not reported. Results may be limited in their generalisability to the NHS, because routine use of prophylactic antibiotics is not recommended by NICE for catheter changes.
<u>Nagy et al. (2011)</u>	
Study size, design and location	Prospective non-randomised comparative study involving a total of 27 patients having long-term urinary catheterisation between August 2009 and September 2010. Budapest, Hungary.
Intervention and comparator(s)	UroShield Urinary catheters without UroShield devices
Key outcomes	Of the 27 patients recruited, 14 had a UroShield device for 8 weeks and 13 patients had urinary catheters without a UroShield device (control group) for 8 weeks. At the time of catheter insertion and after every 2 weeks, urine cultures were taken, and health condition checked. Catheter-related pain was also documented on a numerical scale of 1 to 10. More than 10 ⁵ CFU/ml of 1 organism was defined as significant bacteriuria. At the end of week 8 a small piece of the catheter was sent to electromicroscopy to determine the rate of biofilm formation and incrustation. At the end of week 8, significant bacteriuria was detected in 4 patients (33%) in the UroShield group and in 9 patients (81%) in the control group. No significant biofilm producing <i>P. aeruginosa</i> bacteria were detected in the UroShield group, while <i>P. aeruginosa</i> bacteria rate was 27% in the control group. In the UroShield group, significant <i>E. coli</i> bacteriuria was half that in the control group. Catheter-related pain scores decreased by 1.6 in the UroShield group, while they increased by 1.3 in the control group. In patients with at least moderate symptoms (≥ 3) at baseline, there was a decrease of 2.4 points in the UroShield group and a 2.0 increase point increase in pain scores in the control group.

Strengths and limitations	This study reported patient outcomes for pain and evaluated the long-term (8 weeks) use of UroShield. However, the study was a non-randomised study that did not use a sham device as a control. No statistical analyses were done on outcomes between groups and there was no follow-up after treatment. The results were presented in a conference poster to the Annual Congress of the European Association of Urology and have not been published in a peer-reviewed journal.
Abbreviations: CFU, colony-forming unit; UTI, urinary tract infection.	

Recent and ongoing studies

- [Low Energy Surface Waves to Prevent Urinary Infections and Catheter Associated Symptoms Among Patients With Neurogenic Bladder Dysfunction](#). ClinicalTrials.gov identifier: NCT03785262. Status: Enrolling by invitation. Indications: Neurogenic Bladder, Urinary Tract Infections. Devices: UroShield, sham UroShield.
- [The Use of the UroShield Device in Patients With Indwelling Urinary Catheters](#). ClinicalTrials.gov identifier: NCT00446732. Status: Unknown. Indication: Urinary Tract Infection. Device: UroShield.

Specialist commentator comments

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

Two out of 4 of the specialists were familiar with or had used this technology before.

Level of innovation

All the commentators considered UroShield to be an innovative or novel concept or design. None of the commentators was aware of any competing or alternative technologies available to the NHS that have similar function or mode of action to UroShield. One commentator noted that there are other devices available that aim to reduce urinary tract infections in indwelling catheters for example Farco-Fill and polyhexanide. However, these are installed using a catheter balloon or are inserted directly into the bladder. UroShield is the first device developed to be fitted externally.

Potential patient impact

Reduced blockages and catheter-associated urinary tract infections (CAUTIs), potentially resulting in better patient quality of life, less pain and discomfort, and fewer hospitalisations and acute settings visits for some people were identified by commentators as the potential benefits to patients from using UroShield. A reduced need for antibiotics and reduced risk of antimicrobial resistance was also identified by 1 of the commentators. People with indwelling urethral catheters who have blockages and recurrent CAUTIs despite current management, and patients with autoimmune suppressive conditions such as multiple sclerosis were identified by commentators as people who would particularly benefit from UroShield. One commentator said the technology appeared relevant to all catheterised patients.

Potential system impact

Reduced use of antibiotics, fewer hospital admissions and fewer visits by community staff having to either unblock or change catheters, as well as fewer emergency admissions because of CAUTIs were identified by commentators as the potential benefits to the NHS from using UroShield. One commentator noted that UroShield may help reduce the risk of *E. Coli*, which is now a recordable bacteria target for the NHS. All of the commentators thought that UroShield would be an addition to current standard care. One commentator thought there would be little cost improvement based on the studies done so far. Another commentator thought that UroShield would cost more than current practice, which involves changing catheters (costing £8 to £10 each) every 12 weeks or more often if a patient has CAUTIs, or silver-coated catheters (costing around £11 each) every 4 weeks.

One commentator responded that based on experience in their trust, there would be a cost saving for some patients with just over half of patients having a cost-neutral impact. The remaining commentator said that cost savings would be dependent on achieving reductions in blockages or infections. None of the commentators identified any facility or infrastructure changes needed to adopt this technology. One commentator said that adopting the technology may increase demands on care staff, in terms of fitting the device and trouble-shooting non-function issues. Two commentators noted that product-specific training would be needed for healthcare professionals. None of the commentators were aware of any safety concerns or regulatory issues surrounding the technology.

General comments

According to 2 of the commentators, UroShield is not yet widely used in the NHS. One of the

commentators said that UroShield is very easy to use, and that patients and their families have been able to remove and replace the device and attach the battery charger without difficulty. One commentator felt that the device may be inconvenient for users because of its size and location. According to 1 commentator, UroShield, would not be needed for every patient with an indwelling urethral or suprapubic catheter, but only for those with recurrent infections or blockages. One comment highlighted that, according to the instructions for use, UroShield cannot be used with 12-French Gauge (FG) catheters; adding that this is the most commonly used catheter size in most healthcare settings. The company has since confirmed that although not in the instructions for use, the technology can be used with 12-FG catheters. Initial problems with the battery pack failing to keep its charge were mentioned by 1 commentator, however they added that the company had been very quick in replacing the defective packs. Commentators thought that the following research would be needed to strengthen the evidence base: data from a UK healthcare setting, data on device-related adverse events and possible contraindications to use, medium-term data (1 year) on CAUTI and blockage rates, and efficacy data comparing UroShield with other available catheters (such as silver-coated catheters and antibiotic-impregnated catheters). One commentator did not consider the current body of evidence robust enough to recommend routine use of UroShield in the NHS. They highlighted that some of the studies relied on patient-reported outcomes and involved the use of urinalysis and the treatment of suspected CAUTIs, which are not recommended in the UK.

Specialist commentators

The following clinicians contributed to this briefing:

- Jane Miles, urology nurse specialist for benign disease, Frimley Health Foundation Trust, was asked to speak about UroShield at the Infection Prevention and Control Conference in London, February 2019 and was paid to attend this meeting.
- Ann Yates, director of continence services, Cardiff and Vale University Health Board, did not declare any interests.
- Mr Mustafa Hilmy, consultant urological surgeon, York Teaching Hospital, did not declare any interests.
- Professor Marcus Drake, professor of physiological urology, University of Bristol, did not declare any interests.

Development of this briefing

This briefing was developed by NICE. 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.

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