NICE National Institute for Health and Care Excellence

NICE guidance

UroShield for preventing catheter-associated urinary tract infections

Medical technologies guidance
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Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

This guidance replaces MIB191.

1 Recommendations

1.1 More research is recommended on UroShield for preventing catheter-associated urinary tract infections (UTIs). It has potential to provide significant patient and healthcare system benefits but uncertainties in the evidence need to be addressed.

1.2 Research should be comparative, and it should address uncertainties about the effectiveness of UroShield in preventing catheter-associated UTIs and other catheter-related complaints such as blockages. Find out more in the further research section of this guidance.

Why the committee made these recommendations

Standard care for preventing catheter-associated UTIs includes good hygiene, reviewing the frequency of planned catheter changes, increasing fluid intake, and documenting blockages. UroShield is an add-on to standard care.

The evidence on UroShield is limited but it suggests it may reduce bacteria in the urine (bacteriuria), infections, and catheter-related problems. Most of the studies measured bacteria in the urine. But it is not certain that this is the best way to detect changes in catheter-associated UTIs and the effectiveness of UroShield.

There is strong expert and patient support for UroShield. Patients and clinical experts anecdotally describe fewer infections, catheter blockages, and catheter-related problems when using UroShield. It may especially help people with long-term catheters in the community and may address a significant unmet clinical need.

Cost analyses suggest UroShield may be cost saving in hospital and in people with repeated UTIs or catheter blockages in community care. But because the clinical effectiveness of UroShield is uncertain and the published evidence very limited, the cost savings are also uncertain. More research is therefore recommended.

2 The technology

Technology

2.1 UroShield is an ultrasound device designed to reduce the risk of catheter-associated urinary tract infection (UTI) by reducing bacterial colonisation and biofilm formation on indwelling urinary catheters. The technology works by generating low-intensity 90 kHz ultrasonic surface acoustic waves, which propagate throughout the catheter's length on its inner and outer lumens. The company claims these acoustic waves prevent bacteria attaching and forming a biofilm, and also reduce friction between the catheter and the person's internal tissues. It claims this reduces the pain, discomfort, and spasm associated with indwelling urinary catheters.

2.2 UroShield includes 2 components: a driver, which provides the power, and a single-use actuator, which is clipped to the catheter and generates the ultrasonic waves. UroShield can be used with urethral and suprapubic catheters of any material and size ranging from 12 to 22 French gauge. UroShield is worn continuously. The life expectancy of the driver is 2 years while the actuator, according to the instructions for use, should be replaced every 30 days. If the catheter is replaced within 30 days, the actuator can be removed and reattached to the new catheter. UroShield is a CE-marked class IIa medical device. UroShield 3.0 is the current version available in the NHS.

Care pathway

2.3 UroShield is an add-on to standard care to prevent catheter-associated UTI. NICE's guideline on healthcare-associated infections says that the risk of blockages, encrustations, and catheter-associated infections in long-term urinary catheters should be minimised through patient-specific regimens. These include reviewing the frequency of planned catheter changes, increasing fluid intake, and documenting catheter blockages. Catheters should be changed only when clinically necessary or

according to the manufacturer's recommendations. Urinary catheter tools such as a catheter passport, catheter card, and inpatient care plan are used to allow healthcare professionals to document catheter care and share information between care services.

Innovative aspects

2.4 UroShield generates ultrasonic acoustic waves that produce microvibrations. The company claims this prevents bacteria adhering to the catheter surface. It also claims it may alter the quorum sensing (cell-to-cell communication) of the microbes, which helps to delay and disrupt the formation of a biofilm and its extracellular matrix. These mechanisms are believed to generate the bactericidal effects of the device. The clinical experts all considered UroShield to be novel and innovative.

Intended use

2.5 UroShield is intended to reduce the risk of catheter-associated UTIs in adults with urethral or suprapubic indwelling urinary catheters. It is not intended for use in children. This guidance considers the use of UroShield in hospital and community care. UroShield is not MRI compatible and should be removed from the catheter before entering an MRI suite. It is not intended as a treatment for an active UTI.

Costs

2.6 The costs of UroShield are £349 for the driver and £50 per actuator (excluding VAT).

For more details, see the website for UroShield.

3 Evidence

NICE commissioned an external assessment centre (EAC) to review the evidence submitted by the company. This section summarises that review. Full details of all the evidence are in the project documents on the NICE website.

Clinical evidence

The clinical evidence comprises 8 studies, including 1 peer-reviewed randomised controlled trial

3.1 Eight studies were relevant to the decision problem in the scope:

- 1 randomised controlled trial (Markowitz et al. 2018)
- 1 before-and-after study (da Silva et al. 2021)
- 1 case series (Turan et al. 2012)
- 2 company reports (Zalut 2007, which is an unpublished case series, and Zillich et al. 2014, which is a non-peer-reviewed randomised study)
- 2 conference abstracts or posters (Ikinger et al.'s 2007 randomised controlled trial, Nagy et al.'s 2011 comparative study)
- 1 clinical trial report (Shenfeld and Haris's 2010 unpublished randomised controlled trial).

3.2 Of these, 3 studies were peer reviewed (da Silva et al. 2021, Markowitz et al. 2018, Turan et al. 2012) and only 1 study was done in the UK (da Silva et al. 2021).

The evidence base is heterogenous in population and duration of use

3.3 Patient populations varied across studies. The clinical evidence included 4 studies on short-term (28 days or fewer) catheterisation (Ikinger et al.

2007, Shenfeld and Haris 2010, Zalut 2007, Zillich et al. 2014), 3 studies on long-term (more than 28 days) catheterisation (da Silva et al. 2021, Markowitz et al. 2018, Nagy et al. 2011), and 1 study of unknown duration (Turan et al. 2012).

3.4 The studies' treatment setting varied. Three studies evaluated use in the community (da Silva et al. 2021, Markowitz et al. 2018, Zalut 2007), while 2 studies were based in hospital (Shenfeld and Haris 2010, Turan et al. 2012). The treatment setting was not clearly reported in 3 studies (Ikinger et al. 2007, Nagy et al. 2011, Zillich et al. 2014).

For full details of the clinical evidence, see section 4 of the assessment report.

The evidence base for UroShield is limited in quantity and quality

3.5 The EAC formally appraised only 2 studies (da Silva et al. 2021, Markowitz et al. 2018) because the remaining studies lacked details about study design and methods. It assessed Markowitz et al. (2018) as having an overall low risk of bias. But the study had a small sample size and statistical multiplicity in the data analysis, which may have increased the risk of a type 1 error. The EAC said da Silva et al. (2021) reported limited detail of participants and study methods. It considered that the evidence for the benefit of UroShield in people with short-term catheters is very limited and cannot be used to definitively support any clinical benefit at this time.

Evidence suggests that UroShield may significantly reduce bacteriuria

3.6 Three studies showed that using UroShield resulted in significantly less bacteriuria than comparators (Markowitz et al. 2018, Nagy et al. 2011, Zillich et al. 2014). But 2 studies reported no statistically significant difference (Ikinger et al. 2007, Shenfeld and Haris 2010). The most significant improvement was in people with long-term indwelling urinary catheters.

3.7 The company did a fixed effects meta-analysis of 4 studies to estimate

the effect of UroShield on bacteriuria (Markowitz et al. 2018, Nagy et al. 2011, Shenfeld and Haris 2010, Zillich et al. 2014). The risk ratio for bacteriuria was 0.25 (95% confidence interval 0.11 to 0.57) in favour of UroShield, indicating a potential 75% reduction in bacteriuria with UroShield compared with comparators. The EAC reran the meta-analysis using both a fixed effects and random effects approach and got similar results to the company (fixed effects: risk ratio 0.27, 95% confident interval 0.12 to 0.57; random effects: risk ratio 0.34, 95% confidence interval 0.17 to 0.71).

Evidence suggests long-term use of UroShield may reduce UTI

3.8 Three studies reported urinary tract infection (UTI) as an outcome. People using UroShield had fewer new UTIs requiring antibiotics than those using the sham devices (Markowitz et al. 2018) and had fewer UTIs after approximately 12 weeks of use compared with baseline (da Silva et al. 2021). Nagy et al. (2011) found no symptomatic UTIs in either treatment arm.

Evidence suggests UroShield may reduce catheter-related complaints and improve quality of life

3.9 Da Silva et al. (2021) found significantly fewer catheter blockages and unplanned catheter changes after long-term use of UroShield. Five studies also reported improvements in patient-reported complaints with UroShield compared with baseline or comparators. These included lower levels of pain, discomfort, spasm, and itching and burning. Da Silva et al. (2021) and a patient survey reported that UroShield is easy to use and associated with positive outcomes, including fewer catheter-associated UTIs, more time between catheter changes, and improved quality of life.

Cost evidence

The company's cost model shows UroShield to be cost saving in all hospital settings and in community patients with recurrent UTI

3.10 The company submitted 2 simple decision tree models, which compared the costs and health outcomes associated with using UroShield as an addition to standard care in hospital and community settings. The settings and populations considered were:

- all hospital patients
- hospital patients with short-term catheterisation (28 days or less)
- hospital patients with long-term catheterisation (more than 28 days)
- patients in the intensive care unit (ICU)
- all community patients
- community patients with a recurrent UTI.

Hospital settings had a time horizon of the duration of catheterisation or the duration of treatment for catheter-associated UTI. Community settings were presented as a rolling 30-day model with the same costs and benefits every 30 days. The company's base case showed UroShield saved £1.65 to £42.05 per person in hospital and £7.77 per person in community patients with recurrent UTI. The company model found UroShield incurred costs of £39.95 per person in the all-community patients population. This was because of the low cost of treating community-based catheter-associated UTIs and the relatively low base rate of infection.

For full details of the cost evidence, see section 9 of the assessment report.

The EAC accepted the assumptions in the company's model and identified additional assumptions

3.11 The company included several assumptions in its model, which are

outlined in table 11 of the assessment report. The EAC accepted these assumptions but changed driver use from 100% to 80% because it considered it unlikely that it would be used every day in its lifespan. The EAC also identified and accepted additional assumptions in the model. This included the key assumption that the reduction in significant bacteriuria in the meta-analysis can be extrapolated to symptomatic catheter-associated UTIs requiring treatment. The models also assume that the definition of 'recurrent' UTIs in community patients can be applied to catheter-associated UTI.

The EAC amended the risk of catheter-associated bloodstream infection and the rate of failure of first-line treatment in the community

3.12 The EAC agreed with most of the values of clinical parameters used in the company's model. It amended the risk that catheter-associated UTIs would progress to a catheter-associated bloodstream infection (CABSI) to 6.6% from the 4.8% used by the company. The EAC also changed the proportion of infections in the community that do not respond to first-line treatment to 14%.

The EAC updated costs for treating catheter-associated UTIs in community and hospital settings

3.13 The average cost of treating catheter-associated UTIs in the community was £386.72 in the company's model. The EAC amended this to £453.54 to account for treatment failures and CABSI. In the hospital model, the EAC updated the cost of a bed day in the ICU to the 2019 to 2020 reference costs (£1,620). The mean cost per catheter-associated UTI was calculated from the cost per catheter-associated UTI per patient, plus the cost of CABSIs for the proportion of patients who have them. The company calculated the mean cost per catheter-associated UTI in hospital as £2,131 and in the ICU as £2,964. The EAC calculated these values as £2,192 and £4,436, respectively.

The EAC's changes to the model did not change UroShield from cost saving or cost incurring in any population

3.14 The EAC's base case showed UroShield to save between £2.40 and £70.13 per person in hospital, and £16.63 per person in community patients with recurrent UTI. UroShield continued to be cost incurring by £39.34 in the all-community patients population. The greatest difference to the company's model was in the ICU, with the EAC's model finding UroShield was £40.64 more cost saving than the company's base case.

The effectiveness of UroShield and the risk of catheter-associated UTIs are the key cost drivers

3.15 The company submitted a one-way sensitivity analysis that varied parameters by the ranges taken from the source evidence or by 25% less than or 25% more than the base values. Its results suggested that the effectiveness of UroShield is the key cost driver in all models. The EAC also did one-way and two-way sensitivity analyses in all 6 populations. For hospital settings, the parameters with the largest impact on cost savings were the effectiveness of UroShield, the rate of catheter-associated UTI, and the cost of treating them. Changes in any of these parameters could convert the base case to cost incurring in populations with small cost savings (all-hospital and short-term use). For the all-community population, only a risk of catheter-associated UTIs greater than 25% (compared with a base rate of 8.5%) independently converts the base case to cost saving. The EAC noted that these rates may occur in nursing homes. In the recurrent UTI community group, UroShield's effectiveness is the only parameter that can independently convert the base case to cost incurring.

The reduction in catheter blockages independent of catheter-associated UTIs may reduce the costs of using UroShield in community settings

3.16 The EAC did an additional two-way sensitivity analysis (see the assessment report addendum on blockages and bacteriuria threshold), altering the risk of catheter-associated UTIs and the risk of catheter

blockage. This was done to explore how reducing catheter blockages independent of catheter-associated UTIs may affect the base case. The EAC assumed an equivalent effectiveness for UroShield on blockages and catheter-associated UTI (as suggested by da Silva et al. 2021). Based on this, the risk of blockage at which the base case for UroShield becomes cost-neutral is 1.87 blockages per patient per 30 days. For patients at high risk of catheter-associated UTI, UroShield is always cost saving. UroShield was also found to be cost saving for people who do not get catheter-associated UTIs but who have more than 3 blockages per 30 days that require a catheter change.

Increasing staff time for catheter changes does not change whether UroShield is cost saving or incurring in community settings

3.17 The EAC explored the effect of increased nursing time for unscheduled visits on the cost modelling for the community populations. Results showed that if nurse visit time was increased to 45 minutes, as suggested by the experts, the cost savings increased in the population in the community with recurrent infections. UroShield continued to be cost incurring in the all-community population. Further details and the results of a threshold analysis are in the assessment report addendum on increased staff time for catheter change.

4 Committee discussion

Unmet need

UroShield is potentially life changing and could address an important unmet need among people with long-term catheters in the community

4.1 The patient expert and patient survey comments described UroShield as simple and easy to use. The patient expert reported several benefits from using UroShield in the past 3 years. These included a significant reduction in urinary tract infections (UTIs) and no catheter blockages. They liked that UroShield was not a drug and said that since using the device they no longer needed to take prophylactic antibiotics. The committee heard during consultation several comments strongly supporting these patient benefits. UroShield was described by the patient expert, patient survey, and several consultees as life changing and transformational. The committee heard how recurrent UTIs can have a devastating impact on a person's quality of life. It considered that preventing catheter-associated UTIs and blockages is a significant unmet need, especially in people in the community with long-term catheters. It concluded that UroShield showed promise in addressing this unmet need and strongly encouraged further research in this patient population.

Clinical-effectiveness overview

The evidence shows that UroShield may reduce bacteriuria, infection, and catheter-related complaints but there are considerable uncertainties

4.2 The committee considered that the clinical evidence showed that UroShield had promise for reducing bacteriuria, infection, and catheter-related complaints including blockages. However, it considered that the

limited clinical evidence raised uncertainties about the effectiveness of UroShield in preventing catheter-associated UTIs. The 2 key studies (da Silva et al. 2021, Markowitz et al. 2018) had methodological concerns. While Markowitz et al. (2018) was a double-blinded randomised controlled trial, it was limited by a small sample size (n=55), risk of multiplicity in the data analysis, and its reporting of significant improvement in bacterial load to a threshold of 100,000 colony forming units (CFU). The committee also noted the limitations of the study by da Silva et al. (2021), such as the small sample size (n=23), and the uncontrolled before-and-after study design. This meant it could not control for other potential changes to standard care with the introduction of UroShield, such as increased catheter care and attention.

More information is needed about whether UroShield's effect is maintained after people stop using it

4.3 Markowitz et al. (2018) reported continued positive effects of UroShield on bacterial load and the number of new UTIs requiring antibiotics for up to 60 days after stopping its use. The committee considered that this prolonged effect did not align with the instructions for use, which specify that the device should be used continuously. The company said that, while it advised continuous use of the device for optimal effects, real-world use may differ. It reported that laboratory testing suggested it took some time for bacteria to re-establish on catheters after people stopped using UroShield. The company attributed this prolonged effect to changes in the quorum sensing (cell-to-cell communication) of the bacteria. The committee considered that more information into the prolonged effect of UroShield would be valuable and may help patients better understand how to use the device effectively.

Outcome measures

There is uncertainty about using bacteriuria as a proxy outcome for catheter-associated UTI

4.4 Bacteriuria was the most reported outcome in the clinical evidence. The clinical experts said that bacteria are the root cause of both catheter-

associated UTI and blockages. But they advised that bacteriuria only indicates the presence of bacteria in the urine and not catheter-associated UTI, and it may not cause symptoms in everyone. The committee recognised that bacteriuria is easy to measure but considered that the presence of a catheter-associated UTI is a more reliable outcome. It acknowledged that symptoms from other health conditions may present similarly to the symptoms of a UTI. Therefore, for the purposes of further research on UroShield, the committee considered a pragmatic definition of catheter-associated UTI would be a reasonable choice to reflect how it is captured in clinical practice, that is, clinical judgement of UTI symptoms, visual inspection of urine, and microbiological inspection of bacteriuria.

More evidence is needed on the effect of UroShield on catheter blockages independent of catheter-associated UTI

4.5 The committee heard during consultation and from the clinical experts that catheter blockages are a major source of patient complaints and unscheduled healthcare visits, which may affect around 33% to 50% of people with long-term catheters. Catheters can become blocked with or without an associated UTI. The committee recognised that the patient and clinical experts and several consultees strongly supported using UroShield to prevent or reduce catheter blockages. It considered that UroShield had the potential to address an important unmet need and that its use could result in cost savings associated with a reduction in blockages. But there is little clinical evidence on the effect of UroShield on blockages, with only 1 study (da Silva et al. 2021) reporting catheter blockages as an outcome. The committee therefore considered that more evidence was needed on the effectiveness of UroShield in preventing catheter blockages independent of catheter-associated UTI.

Other patient benefits or issues

The main challenge to using UroShield is its short battery life

4.6 The main challenge reported by the patient expert and patient survey was UroShield's battery life, which lasts around 6 to 7 hours. The patient

expert said that they charged it overnight from the mains electricity. They also recharged the device during the day as needed using either the mains electricity or a rechargeable battery pack they had bought themselves. The company said that it was planning to improve battery life.

Many people report benefits from using UroShield, but it may not be appropriate for everyone

4.7 The evidence and comments from the patient and clinical experts and several consultees showed that most people have positive experiences of using UroShield. But the device may not suit everyone. Some people may have difficulty handling the device, for example people with neurological conditions that affect manual dexterity. Some people may also find the hum emitted from the device annoying. The patient expert said that this low-level hum is less noticeable with time. The company said that the hum may reassure people that the device is still working, and believed it is hardly noticeable once the device is worn under clothes. The committee accepted that patient preferences and their capacity to manage the device are important considerations.

Relevance to the NHS

The evidence is broadly generalisable to NHS practice

4.8 The evidence on UroShield included people with short- and long-term catheterisation in hospital and community care. Only 1 study was in the UK (da Silva et al. 2021). The clinical experts said that the evidence was broadly generalisable to the NHS but noted a few differences in practice, such as the frequency of catheter changes. The company said that the instructions for use recommend the actuator is changed every 30 days to align with practice in the US. The patient expert noted that their catheter and actuator are changed every 6 weeks. The company said that it is continuing work on the technology to make it more country specific. The committee considered that more evidence for using UroShield in addition to standard care in the NHS was needed.

NHS considerations overview

UroShield may most benefit people who need a long-term catheter in community care

4.9 The clinical experts said that people in long-term care in the community who have a long-term catheter have the highest rates of catheter-associated UTIs and catheter blockages. They said that UroShield would most benefit people with a high risk of catheter-associated UTI. Some factors related to increased risk of catheter-associated UTIs were:

- long-term catheterisation
- genetic predisposition to UTI
- history of catheterisation or UTI
- comorbidities such as neurogenic bladder, diabetes, and multiple sclerosis
- female sex.

Also, UTIs are a noted cause of morbidity and antibiotic use in older people. The clinical experts advised that catheter-associated UTI may present differently in elderly people and may be associated with confusion. This can affect the presentation and self-reporting of UTIs, so additional steps to prevent morbidity are especially important. The clinical and patient experts believed people with recurrent UTIs would be highly motivated to use UroShield. From comments during consultation, the committee recognised that UroShield may be most appropriate for people with a long-term catheter who have frequent infections or blockages. The clinical experts advised that these people cannot be identified in advance. But they said structured protocols could be developed by community teams to identify appropriate patients who are already experiencing frequent infections or blockages. The committee considered this approach may be reasonable to guide patient selection.

UroShield is not widely used in the NHS so healthcare professionals and patients may need support

4.10 UroShield has only been used by about 80 patients in the NHS. The clinical experts said that patient education and counselling is important to understand how to wear and use the device. This may be especially important for people who use it outside their home. Healthcare professionals may also need training because most would be unfamiliar with the technology. Training and support are available through the company, including online training sessions, a specialist nurse adviser, and a helpdesk team.

Side effects and adverse events

Evidence shows UroShield is safe to use

4.11 The evidence did not identify any device-related adverse events. Clinical and patient experts, and the patient survey, did not attribute any adverse events to UroShield. The committee noted that some patients could use UroShield for years and it considered that real-world evidence on using UroShield for longer periods would be valuable.

Cost modelling

The meta-analysis data on UroShield's effectiveness is too uncertain to use in the cost modelling

4.12 The committee considered that the economic case for UroShield was uncertain because the effectiveness of UroShield relied on the findings of the meta-analysis. The committee had notable concerns with the meta-analysis, including the quantity and quality of the evidence used, the heterogeneity of the studies, and the use of bacteriuria as a proxy for catheter-associated UTIs.

Cost savings

UroShield has the potential to be cost saving if it is effective

4.13 The committee considered that the results from the cost models suggested that UroShield could be cost saving in hospital, and in the community for people with recurrent infection or blockages. But it noted that this depends on whether it is effective in preventing catheter-associated UTIs or blockages.

Further research

Further research is needed on the effectiveness of UroShield

4.14 The committee concluded that more research is needed on the effectiveness of UroShield in preventing catheter-associated UTIs and blockages. There is an ongoing non-comparative study by the University of Southampton (National Institute for Health Research clinical research network [NIHR CRN] portfolio CPMS ID 48290) in 30 people with long-term catheters in the community who have frequent infection or blockages. The committee considered that while this study may provide additional evidence on patient experiences and the effect of UroShield on the microbiota in the urine, it will not resolve the uncertainties in effectiveness. A randomised controlled trial (at the individual or group level) is considered to be the most robust and efficient design to confirm the promising results of the studies presented. The external assessment centre (EAC) advised that a well-designed before and after study may also be appropriate. The committee considered that the study should be powered to detect statistically significant differences in clinically confirmed catheter-associated UTIs (see section 4.4). Secondary outcomes of interest should include catheter blockages and bacteriuria. Patient-reported outcomes and resource utilisation outcomes would also be welcomed.

5 Committee members and NICE project team

Committee members

This topic was considered by NICE's medical technologies advisory committee, which is a standing advisory committee of NICE.

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The minutes of the medical technologies advisory committee, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

NICE project team

Each medical technologies guidance topic is assigned to a team consisting of 1 or more health technology assessment analysts (who act as technical leads for the topic), a health technology assessment adviser and a project manager.

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Accreditation