

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology guidance scope

UroShield for preventing catheter-associated urinary tract infections

1 Technology

1.1 *Description of the technology*

UroShield (NanoVibronix) is an ultrasound device designed to prevent bacterial colonisation and biofilm formation on indwelling urinary catheters. UroShield is intended to reduce the risk of catheter associated urinary tract infections (CAUTIs) in people with indwelling urinary catheters. UroShield is intended to be used as an add-on intervention to current standard care.

The technology works by generating low intensity 90kHz ultrasonic surface acoustic waves which propagate throughout the catheter's entire length on both its inner and outer lumens. The company claims the acoustic waves interfere with the attachment of bacteria and formation of the biofilm. The company also claim the same acoustic waves reduce friction between the catheter and the patient's internal tissues, thereby decreasing the pain, discomfort and spasm associated with indwelling urinary catheters.

UroShield includes 2 components:

- a driver (battery- or AC-powered portable unit), which provides the power (it is not water resistant), and
- a single-use actuator which is clipped onto the external portion of any indwelling urinary catheter and generates the ultrasonic waves.

UroShield can be used with catheters made of any material and size ranging from 12 to 22 French Gauge (FG). The UroShield can be powered by the mains or by a rechargeable battery, which can power the device for up to 6 hours when fully charged. The life expectancy of the driver is 2 years. The

actuator is replaced every 30 days and should be disposed of when the catheter is replaced.

UroShield is not intended for use in children. It is not MRI compatible, and should be removed from the catheter before entering an MRI suite.

1.2 *Relevant diseases and conditions*

A urinary catheter is used to empty the bladder and collect urine in a drainage bag. Indwelling catheters remain in place for many days or weeks, and are held in position by an inflated balloon in the bladder. Some people may use catheters for their lifetime. Catheters are usually inserted by a doctor or nurse. An indwelling catheter can either be inserted through the urethra (indwelling urethral catheter) or through a small cut or incision in the lower part of abdomen (indwelling suprapubic catheter). Indwelling catheters may be used short term (usually up to around 14 days) or long term (weeks). Indwelling catheter prevalence varies in patient groups, settings and specialties. A study estimated that over 90,000 people in the UK had long-term catheters in the community ([Gage et al. 2017](#)). The study found most people were initially catheterised in hospital and that prevalence increased with age.

Catheterisation was more common in people with neurological disease; and suprapubic catheterisation was more common in women.

Around half of people who have long-term catheters experience problems such as pain, tissue damage, decreased mobility and hospital attendances associated with blockage ([Khan et al. 2007](#)). People with indwelling urinary catheters are at increased risk of developing CAUTI. Nearly everyone with a catheter develops bacteria in their urine (bacteriuria) during the catheterisation period ([Saint 2000](#)). CAUTI is defined as the presence of symptoms or signs compatible with a urinary tract infection in people with a catheter with no other identified source of infection plus significant levels of bacteria in a catheter or a midstream urine specimen when the catheter has been removed within the previous 48 hours ([NICE 2018](#)).

Urinary tract infection is an important cause of morbidity and mortality in the healthcare setting, accounting for 19% of all hospital-acquired infections. Of

these, it is estimated that between 43% and 56% are CAUTI ([Loveday et al. 2014](#)). However, there is limited data on CAUTIs in primary and community care settings. A local survey in England based on patient records during October 2014 reported that the prevalence of CAUTI in people with catheters in community settings was 8.5% ([Getliffe and Newton, 2006](#)).

CAUTI affects healthcare resources. People who have long-term catheters account for around 4% of a district nurse's caseload in the UK ([Getliffe 1994](#)). Daily management of people with catheters is often undertaken by community nurses, with input from general practitioners or secondary care for urinary tract infection or blockage that occurs out of hours. Health economic modelling estimates there are 52,085 CAUTI across NHS hospitals per year with direct hospital costs of £27.7 million ([Smith et al 2019](#)).

1.3 Current management

The NICE guideline on [healthcare-associated infections](#) states that the risk of blockages, encrustations and catheter-associated infections in long-term urinary catheters 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.

NICE also published a public health guideline on [healthcare-associated infections](#) stating that hospital trusts regularly review evidence-based assessments of new technologies and other innovations to minimise harm from healthcare associated infections and antimicrobial resistance.

Healthcare professionals play a key role in caring for people with indwelling urinary catheters and reducing CAUTI. The doctor, specialist nurse or district nurse decides whether a person needs a catheter and how it should be

managed, based on the individual's needs. The Royal College of Nursing published [a practice guide for healthcare professionals](#), covering aspects of catheter care such as documentation, risk assessment and review of catheter care. In England, [urinary catheter tools](#) such as a catheter passport, catheter card and inpatient care plan have been used to allow healthcare professionals to document catheter care and share information between care services.

1.4 Regulatory status

UroShield is CE marked as a class IIa medical device.

1.5 Claimed benefits

The benefits to patients claimed by the company are:

- Preventing catheter associated urinary tract infection (CAUTI), potentially leading to a reduction in the incidence of CAUTI.
- Improved quality of life in people with indwelling urinary catheters, with minimal disruption to patients' daily activities.
- Reducing catheter-related pain, spasm and discomfort.

The benefits to the healthcare system claimed by the company are:

- Reduction in costs and resources that could be associated with treating CAUTI such as unplanned hospital admissions, increased hospital length of stay and the use of antibiotics.
- Reduction in health service resource use that could be associated with the use of catheter such as avoiding catheter blockages, a reduction in the frequency of catheter changes and bladder washouts.
- Reducing the use of antibiotic prophylaxis.
- Ease of implementation; minimal changes in facilities or infrastructure needed if UroShield adopted in standard practice.

2 Decision problem

Population	People with indwelling urinary catheters across hospital and community settings.
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Intervention	UroShield in addition to standard care
Comparator(s)	Standard care for preventing catheter associated urinary tract infection, including clinical observation such as documenting catheter blockages, reviewing the frequency of planned catheter changes, increasing fluid intake, and using prophylactic antibiotics when needed.
Outcomes	<p>The outcome measures to consider include:</p> <ul style="list-style-type: none"> • Incident rate of catheter associated urinary tract infection (CAUTI) • Rate of recurrence of CAUTI • Bacterial count in urine samples • Bacterial colonization levels (i.e. colony forming units) • Biofilm formation on the catheter lumen • Number of catheter changes • Number of catheter blockage • Antibiotics use • Number of outpatient visits • Number of hospital admissions including emergency admission to hospital • Reported pain and spasm • Ease of use (for patients and healthcare professionals) • Device acceptability and patient satisfaction • Health-related quality of life • Device-related adverse events
Cost analysis	<p>Costs will be considered from an NHS and personal social services perspective.</p> <p>The time horizon for the cost analysis will be long enough to reflect differences in costs and consequences between the different treatment options being compared.</p> <p>Sensitivity analysis will be undertaken to address uncertainties in the model parameters, which will include scenarios in which different numbers and combinations of devices are needed.</p>
Subgroups to be considered	<ul style="list-style-type: none"> • People at high risk of developing CAUTI (for example, those with co-morbidities including diabetes or underlying neurological conditions; those in clinical settings such as critical care units). • People who have recurrent episodes of urinary tract infection (for example, 2 or more episodes in a 6-month period).
Special considerations, including those related to equality	<p>In adults, women are more likely to develop a catheter-associated urinary tract infection than men. Cerebrovascular disease and paraplegia are associated with an increasing likelihood of catheter-associated urinary tract infection. Sex and disability are protected characteristics under the Equality Act.</p> <p>Urinary tract infection is an important cause of morbidity and antibiotic use in older adults. Age is a protected characteristic under the Equality Act.</p>

Special considerations, specifically related to equality	Are there any people with a protected characteristic for whom this device has a particularly disadvantageous impact or for whom this device will have a disproportionate impact on daily living, compared with people without that protected characteristic?	No
	Are there any changes that need to be considered in the scope to eliminate unlawful discrimination and to promote equality?	No
	Is there anything specific that needs to be done now to ensure the Medical Technologies Advisory Committee will have relevant information to consider equality issues when developing guidance?	No

3 Related NICE guidance

Published

- [Urinary tract infection in under 16s: diagnosis and management](#) (2018) NICE clinical guideline CG 54.
- [Urinary tract infection \(catheter-associated\): antimicrobial prescribing](#) (2018) NICE NG113.
- [Urinary tract infection \(recurrent\): antimicrobial prescribing](#) (2018) NICE NG 112.
- [Pyelonephritis \(acute\): antimicrobial prescribing](#) (2018) NICE NG 111.
- [Urinary tract infection \(lower\): antimicrobial prescribing](#) (2018) NICE guideline NG 109.
- [Healthcare-associated infections: prevention and control in primary and community care](#) (2017) NICE clinical guideline CG139.
- [Healthcare-associated infections: prevention and control](#) (2011) NICE public health guideline PG 36.

4 External organisations

4.1 Professional

The following organisations have been asked to comment on the draft scope:

- Royal College of General Practitioners (RCGP)
- Royal College of Nursing (RCN)
- Royal College of Obstetricians and Gynaecologists

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- Royal College of Pathologists
- Royal College of Physicians
- Royal College of Surgeons
- Association for Continence Advice
- Association of Physicians' Assistants
- Association of Healthcare Cleaning Professionals
- British Association of Urological Nurses
- British Association of Urological Surgeons
- British Infection Association
- British Nursing Association
- Community District Nurses Association
- Infection Prevention Society
- National Association of Primary Care
- Royal British Nurses' Association

4.2 Patient

NICE's [Public Involvement Programme](#) contacted the following organisations for patient commentary and alerted them to the availability of the draft scope for comment:

- Action Bladder Cancer UK
- Bladder and Bowel Community
- Bladder and Bowel UK
- Bladder Health UK
- Brain and Spine Foundation (UK)
- Multiple Sclerosis Society
- Multiple Sclerosis Trust
- Multiple Sclerosis-UK
- Spinal Injuries Association
- Spinal Injuries Scotland (SIS)
- Urology User Group Coalition
- Urostomy Association
- WellBeing of Women

- Women's Health Concern