

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology guidance

SCOPE

Memokath-051 stent for ureteric obstruction

1 Technology

1.1 *Description of the technology*

Memokath-051 is a thermo-expandable, nickel-titanium alloy ureteric stent. It is intended as an alternative to conventional ureteric stents for people with benign or malignant ureteric obstruction. Stents are used to allow the free flow of urine from the kidneys to the bladder. The nickel-titanium alloy has a shape memory effect which is designed to allow the stent to be more easily inserted and anchored in position. A spiral coil design aims to prevent endothelial ingrowth of the tumour or stricture into the stent so that it can be easily removed. Four different versions of Memokath-051 stents are available (single or double cone, for either antegrade or retrograde insertion), each in several different lengths. Memokath-051 can be used to treat obstructions elsewhere in the urinary tract, but this is outside the scope of this evaluation.

1.2 *Relevant diseases and conditions*

Memokath-051 is intended for use in ureteric obstruction, specifically as a result of malignant or benign strictures.

The number of people who require a long-term ureteric stent as a result of malignant or benign ureteric strictures is hard to estimate, particularly because the most recently available figures are lower than in previous years, possibly due to system restraints during the COVID-19 pandemic. In the NHS in England, between 2020 and 2021, there were 3,272 retrograde insertions and 1,210 retrograde removals of ureteric stents (7,674 and 2,733 respectively

between 2014 and 2015; NHS Digital, [Hospital Admitted Patient Care Activity: Procedures and interventions](#)), but the type of stent (plastic or metallic), or the reason for insertion was not specified. The numbers of people having antegrade insertions are lower with few reliable estimates currently available. There were 51 percutaneous insertions and 23 replacements of ureteric metallic stents between 2020 and 2021 (80 and 22 respectively between 2014 and 2015; NHS Digital, [Hospital Admitted Patient Care Activity: Procedures and interventions](#)).

1.3 Current management

Ureteric obstruction must be treated quickly to avoid the development of obstructive renal failure. Obstructions can be treated by stenting the ureter, creating a nephrostomy or through reconstructive surgery. The [NICE guideline on acute kidney injury](#) states that all people with upper urinary tract obstruction should be referred to a urologist. If appropriate, nephrostomy or stenting should be done as soon as possible (within 12 hours of diagnosis).

NICE has produced specific guidance for malignant obstruction as a result of prostate or bladder cancer. The [NICE guideline on prostate cancer recommends](#) decompression of the upper urinary tract by nephrostomy or inserting a double J stent. The [NICE guideline for bladder cancer recommends](#) nephrostomy or retrograde stenting (if technically feasible) for people with locally advanced or metastatic bladder cancer.

1.4 Regulatory status

The Memokath-051 received a CE mark as a class IIb device in October 1997 for malignant or benign ureteric strictures. Its CE mark was updated in May 2021.

1.5 Claimed benefits

The claimed patient benefits for Memokath-051 are:

- A safe, simple and reliable ureteric stent that is better tolerated by the patient, with fewer stent-related symptoms and complications

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- Avoids the need for replacement procedure surgery every 6 months requiring anaesthesia and overnight hospital stays
- Restores dignity and improves quality of life
- Reduced risk of tissue ingrowth
- Reversibility of procedure if needed with no side effects.

The claimed benefits to the healthcare system for Memokath-051 are:

- Efficient use of theatre time as no major surgery is needed
- Significant cost savings by avoiding surgery every 6 months requiring anaesthesia and overnight hospital stays, with less social care needed
- Reversibility of procedure if needed.

2 Decision problem

Population	Adults with ureteric obstruction as a result of malignant or benign strictures.
Intervention	Memokath-051
Comparator(s)	<ul style="list-style-type: none"> • Double J stents • Nephrostomy • Reconstructive surgery • Metallic and alloy stents (including nitinol stents) <p>(see also 'Cost analysis' below)</p>
Outcomes	<p>The outcome measures to consider include:</p> <ul style="list-style-type: none"> • Number and rate of replacement stents • Number and rate of repeat procedures requiring anaesthesia and surgery • Theatre time and hospital stay • Quality of life including patient tolerability and comfort • Length of time stent remains in situ • Clinical success rate (e.g. improved renal function, no obstruction) • Frequency of stent removal/reversal • Device-related adverse events including procedure related complications, rates of stent migration, encrustation and infection, and information pertaining to the resource use associated with these adverse events • Frequency of follow-up visits • Pain scores including from subsequent bladder irritation
Cost analysis	<p>Comparator(s):</p> <ul style="list-style-type: none"> • Double J stents • Nephrostomy • Reconstructive surgery • Metal and alloy stents <p>Costs will be considered from an NHS and personal social services perspective.</p> <p>The time horizon for the cost analysis will be sufficiently long to reflect any differences in costs and consequences between the technologies being compared.</p> <p>Sensitivity analysis will be undertaken to address uncertainties in the model parameters.</p>
Subgroups to be considered	<ul style="list-style-type: none"> • Patients unfit for surgery • Malignant or benign stricture • Antegrade or retrograde insertion (including the procedure performed either by an interventional radiologist or a urologist)
Special considerations, including those	Memokath-051 is contraindicated in children. Some ureteric obstructions are a result of malignancy - all people with cancer are protected under the Equality Act from the point of diagnosis. People with ureteric strictures may benefit from Memokath-051 as an

related to equality	alternative to double J stents, as it may be associated with a reduced number of replacement procedures and reduced adverse events, which would improve their quality of life. Memokath-051 may also provide an alternative treatment for people with ureteric strictures who cannot tolerate or who have had failed conventional stents, who would otherwise be nephrostomy-dependent and are likely to be classed as disabled under the Equality Act.	
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 characteristics?	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 MTAC will have relevant information to consider equality issues when developing guidance?	No
Any other special considerations	Not applicable	

3 Related NICE guidance

Published

- [Bladder cancer: diagnosis and management](#) (2015) NICE guideline NG2.
- [Prostate cancer: diagnosis and management](#) (2019, updated 2021) NICE guideline NG131
- [Acute kidney injury: prevention, detection and management](#) (2019) NICE guideline NG148
- [Improving outcomes in urological cancers](#) (2002) NICE cancer service guideline CSG2

Under development

None.

4 External organisations

4.1 Professional organisations

The following organisations were asked to comment on the draft scope:

- British Uro-oncology Group (BUG)
- British Association of Day Surgery
- British Association of Urological Surgeons (BAUS)
- British Association of Urological Nurses (BAUN)
- British Association of Paediatric Urology
- British Society of Interventional Radiologists (BSIR)
- UK Kidney Association (previously named The Renal Association)
- Royal College of Physicians
- Royal College of Physicians, Edinburgh
- Royal College of Radiologists
- Royal College of Surgeons
- Royal College of Nursing

4.2 Patient organisations

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

- Action on Bladder Cancer
- Bladder and Bowel Foundation
- British Kidney Patient Association
- Fight Bladder Cancer
- Helen Rollason Cancer Charity
- Help the Hospices
- Jo's Trust
- Kidney Cancer UK (KCUK)
- Kidney Research UK
- Macmillan Cancer Support

- Maggie's Centres
- Marie Curie
- National Council for Palliative Care
- Ovacome
- Ovarian Cancer Action
- Pelvic Pain Support Network
- Prostate Cancer UK (formerly prostate cancer charity)
- Rarer Cancers Foundation
- Sue Ryder
- Target Ovarian Cancer