

# Memokath-028, 044 and 045 stents for urethral obstruction

Medtech innovation briefing  
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## Summary

- The **technologies** described in this briefing are the Memokath-028, Memokath-044 and Memokath-045 stents. They are used to relieve urethral obstructions and bladder neck or outlet obstructions.
- The **innovative aspects** are that the stents are designed to be easily inserted and removed compared with other urethral stents or indwelling catheters.
- The intended **place in therapy** for Memokath-028 would be as an alternative to self-catheterisation, long-term indwelling catheterisation or some types of surgery in patients with enlarged prostates. The Memokath-044 and 045 stents would be used in addition to urethral dilation, urethrotomy or urethroplasty to maintain urethral width for longer periods, or as an alternative to surgery.

- The **main points from the evidence** summarised in this briefing are from 11 studies. For Memokath-028, there is a systematic review and 3 observational studies (2 in Japan, 1 in the Netherlands) including a total of 1,013 patients. For Memokath-044, there are 4 studies including 1 randomised controlled trial (US), 2 observational studies (Egypt, Australia) and 1 pilot study (Italy) including a total of 153 patients. For Memokath-045, there are 2 retrospective studies (South Africa, UK) and 1 observational study (Switzerland) including a total of 75 patients. These studies reported variable results but generally show that all 3 Memokath stents are effective in treating urethral obstructions. The most commonly reported adverse events were stent migration for Memokath-028, encrustation for Memokath-044 and urinary tract infection and stent failure because of migration for Memokath-045.
- **Key uncertainties** around the evidence or technology are that the evidence base is still developing with, as yet, few relevant direct comparisons.
- The **costs** of Memokath-028, Memokath-044 and Memokath-045 are £945, £945 and £1,150 per unit respectively (exclusive of VAT). The **resource impact** would be similar to standard care, or lower if use of the stents led to fewer infections and reduced usage of other resources, for example through avoiding surgery.

## The technologies

Memokath-028 (PNN Medical) is a prostatic stent used to relieve urethral obstruction caused by enlarged prostate glands. Memokath-044 and Memokath-045 (PNN Medical) are urethral stents. Memokath-044 is used to relieve obstruction in the posterior (bulbar) part of the urethra, whereas Memokath-045 is used to relieve obstruction of the anterior (penile) part of the urethra or at the bladder neck. Different versions of Memokath-045 are available for use in the anterior urethra and at the bladder neck ([PNN Medical](#)). All 3 stents are available in several different lengths.

Memokath stents are made from a nickel-titanium alloy. This expands and becomes rigid when exposed to heat, and softens when cooled. Before insertion, the area to be stented (that is, the length of the obstruction) is measured with a cystoscope to determine the length of stent to be used. The stent is then inserted using the system provided (onto which it is pre-mounted). After insertion, stents are flushed with heated sterile fluid (saline or water, 55 °C to 65°C), which causes 1 (Memokath-028 and Memokath-044) or both (Memokath-045) ends of the stent to expand, anchoring it in the appropriate position. Once expanded, the stent widens the urethral lumen which allows urine to flow freely.

## Innovations

Memokath stents are 'thermo-expandable': that is, they change size and shape depending on temperature. They can be removed from the urethra at any point in the care pathway. They can also be inserted under local anaesthesia and are designed to provide a less invasive method for relieving urethral obstruction than surgery such as transurethral resection of the prostate (TURP) or urethroplasty. Surgery under general or regional anaesthesia is often not an option for people with urethral obstruction ([Kimata 2015](#), [Lee 2005](#), [Papatsoris 2009](#)). In addition, using Memokath stents may reduce the risk of urinary tract infection compared with catheterisation.

Other urethral stents, which may be used currently in the NHS but are not part of standard care, are designed to be permanently implanted. This encourages growth of urethral tissue in and around the stent (epithelialisation) to secure its position in the urethral wall. However, clinicians may wish to remove the stent if the urethral obstruction has been resolved, or because of complications. Although the Memokath stents are designed to stay in place for several years, if necessary they can be easily removed by using cold saline or water (less than 10°C) to soften the alloy. This allows the stent to uncoil into a wire that can be removed with forceps.

For Memokath-044 and Memokath-045, stenting maintains urethral width for longer than urethral dilation or urethrotomy alone, meaning that fewer people may need repeated invasive surgery.

## Current NHS pathway

The NICE guideline on [the management of lower urinary tract symptoms in men](#) recommends that standard care for obstruction because of an enlarged prostate is surgery such as TURP. The guideline recommends that if surgery is unsuitable or a person chooses not to have it, intermittent self-catheterisation or, as a last resort, long-term indwelling catheterisation should be considered. NICE has also produced medical technologies guidance on the [UroLift system](#) and [TURis](#), both of which are recommended as treatment options for benign prostatic enlargement.

A number of treatment options are available to relieve obstructions in the anterior or posterior urethra, including urethral dilation, urethrotomy, clean intermittent self-catheterisation or urethroplasty. The choice of treatment is based on the length, cause and location of the obstruction, as well as patient preference, although urethroplasty is

usually only done in people with obstructions longer than 3 cm. It may sometimes be used for obstructions shorter than 3 cm if there is an incomplete response to the first treatment (for example, urethrotomy; NHS England 2016; [Santucci 2013](#)).

NICE is aware of the following CE-marked devices that appear to fulfil a similar function to the Memokath stents:

- UVENTA Urethral Stent (TaeWoong Medical, Memokath-044)
- Bulbar Urethral Stent (Allium Medical, Memokath-044)
- Triangular Prostatic Stent (Allium Medical, Memokath-028).

NICE is developing medical technologies guidance on the [Memokath-051 stent for ureteral obstruction](#).

## Population, setting and intended user

All the Memokath stents are designed for use by urological surgeons in secondary care. Stent insertion can be done as a day case in an operating theatre. Table 1 describes the population for each of the Memokath stents.

**Table 1 Use of Memokath stents**

Memokath-028	Men with enlarged prostate glands who would otherwise have surgery, self-catheterisation or long-term indwelling catheterisation.
Memokath-044	Men with obstruction of the posterior urethra. The stent would be used in addition to urethral dilation and urethrotomy to maintain urethral width for longer periods.
Memokath-045	Men with obstruction of the anterior urethra. The stent would be used in addition to urethral dilation and urethrotomy to maintain urethral width for longer periods.  People with obstruction of the bladder neck. This would generally be people with detrusor sphincter dyssynergia, which is an obstruction caused by damage to the nervous system ( <a href="#">Stoffel 2016</a> ), usually as a result of spinal cord injury.

## Costs

### Technology costs

The costs of each Memokath stent (excluding VAT) are:

- Memokath-028: £945
- Memokath-044: £945
- Memokath-045: £1,150.

Cost does not vary by length of the stent.

For each stent, the company provides a number of consumables including a disposable insertion system and a cutter to remove the stent from its packaging (this keeps the stent sterile). Memokath-044 comes with an extension tube, and Memokath-45 comes with 2 extension tubes and a 3-way stopcock. These consumables are included in the cost of the stent. Additional consumables and equipment are needed each time a Memokath stent is inserted, such as analgesic gel, lock syringes, sterile fluid, bottle warmers, thermometers, saline bags, measuring tape, drapes and a dilation kit. This equipment should be readily available in hospitals where Memokath is used.

An accompanying X-ray may be needed when inserting Memokath-028 to confirm that the stent is in the correct position. An X-ray costs £30.26. Memokath stents can be removed during a day-case appointment. The national average cost of a day case is £847 per procedure ([NHS reference costs 2015/16](#)).

### Costs of standard care

There are a number of options available to people with urethral obstruction. A common treatment is self- or indwelling catheterisation; the NICE guideline on [the prevention and control of healthcare-associated infections](#) notes that the mean cost of catheter use per patient ranges from £616 to £2,939 per year (updated from 2009/10 to 2015/16 prices using inflation indices), depending on the type of catheter. More minor procedures such as urethral dilation and urethrotomy are generally done as day cases in an inpatient setting, with a national average cost of £847 per procedure ([NHS reference costs 2015/16](#)).

More complicated surgical procedures such as TURP and urethroplasty are also treatment options. National average costs are £2,748 for TURP and £4,157 for urethroplasty (NHS reference costs 2015/16).

## Resource consequences

According to the company, over 25 NHS trusts already use at least 1 of the Memokath stents. No practical difficulties or changes in infrastructure are expected from using Memokath stents.

Using Memokath stents may lead to increased resource use compared with catheterisation and minor surgeries such as urethral dilation, because the stents cost more. This may be offset if the stents could be used as true alternatives to prostatic surgery or urethroplasty. The stents may also reduce costs in terms of fewer urinary tract infections and a reduction in the need for other resources (for example, fewer catheters in cases where repeat catheterisation would normally be needed). However, there is currently no evidence to support this.

## Regulatory information

All 3 Memokath stents received their latest CE markings as class IIb devices in October 2013.

## 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 and advice, 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).

The Memokath-028 and Memokath-044 stents are designed to be used in men only, and cannot be used for women. The devices can only be used in people who have a prostate

and penis, respectively, so may be unsuitable for some people who identify as men.

Sex is a protected characteristic under the Equality Act 2010.

## 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](mailto:mibs@nice.org.uk).

## Published evidence

This briefing summarises 11 studies, including 1 systematic review of other studies relating to Memokath-028 ([Armitage et al. 2006](#)). Nine of the included studies recruited men only (the other 2 studies did not state the sex of the patients; [Wong et al. 2014](#), [Hamid et al. 2003](#)). Wong et al. (2014) used Memokath-044, so it is reasonable to assume that this study also included only men.

Tables 2 to 4 summarise the clinical evidence and its strengths and limitations.

## Overall assessment of the evidence

### Memokath-028

The evidence base is of limited quality with relatively short follow-up periods. There is also a lack of evidence with relevant comparators. However, the existing evidence does suggest that Memokath-028 is a safe and effective treatment for urethral obstruction, particularly for people with benign prostatic hyperplasia who are at high risk from surgery. The evidence also suggests that the device may be able to increase both urinary flow rate and urinary volume. Few adverse events were reported with Memokath-028; the most common adverse event was stent migration, which appeared to be associated with the length of time that the stent remains in place.

## Memokath-044

The evidence suggests that Memokath-044 may lead to improvements in urinary flow rate and a reduction in post-void residual urine volume. However, the studies are contradictory in their conclusions: 2 support the use of the device and 2 do not, with 1 recommending that the stent should only be used on a temporary basis and the other suggesting that Memokath-044 is neither safe nor clinically helpful. Encrustation appears to be the most commonly reported adverse event. Although there is evidence from 1 randomised controlled trial, the study is relatively small with high withdrawal rates. All the other studies are small-scale and non-comparative.

## Memokath-045

All 3 studies suggest that Memokath-045 is safe and effective, and a good medium-term option for urinary obstruction in the context of spinal cord injuries. All 3 studies reported a decrease in post-void residual urine volume. The most commonly reported adverse events were urinary tract infections and stent failure because of stent migration. However, the current evidence base is limited because the studies were relatively small, poorly designed and conducted.

**Table 2 Summary of included studies for Memokath-028**

<u>Armitage et al. (2006)</u>	
Study size, design and location	Systematic review including 14 single-arm observational studies with a total of 839 men. Most patients had urethral obstruction because of BPH, although some studies included those with prostate carcinoma. Studies included in the review were done in Japan, the UK, Denmark, Germany and Greece.
Intervention and comparator(s)	Intervention: Memokath-028. Comparator: none.



Key outcomes	<p>240 (29%) of the 839 stents inserted failed. Immediate failure of the stent occurred in 11 (4%) of the 311 patients, mainly because of incorrect stent length or placement. Failure rates varied widely across the included studies. Two studies reported no stent failure (over follow-up periods of 8 weeks and 14 months), while the highest reported failure rate was 48% (length of follow-up not reported) and 41% (over a mean follow-up of 7 months).</p> <p>7 studies reported increases in post-insertion Qmax of 3–11 mL/s, although the timing of assessments varied. Two additional studies reported increases in mean flow rate.</p> <p>4 studies reported decreases in post-void residual urine volume and 1 study reported an increase in total voided urine volume.</p> <p>All 7 studies reporting symptom scores noted a reduction in symptoms after stenting, associated with reductions of 11–19 points in IPSS scores and 9 points in the Madsen–Iversen score. The statistical significance of these changes was variable and poorly reported at times, but 2 studies reported that IPSS scores were significantly improved after stenting (<math>p &lt; 0.05</math>) but not after 8 and 24 weeks of follow-up.</p> <p>Stent migration was the most commonly reported cause of stent failure.</p> <p>Urinary incontinence, infection and haematuria were the most commonly reported minor complications.</p>
Strengths and limitations	<p>Systematic review study design. Poor methodological quality of included studies; review conducted using funding from PNN Medical, although the authors acted independently in the conduct and publication. Overall numbers of patients experiencing changes in urodynamic measures were not reported.</p>
<u>De Graaf et al. (2013)</u>	
Study size, design and location	<p>Observational study conducted in 10 men with obstructive voiding symptoms after receiving brachytherapy for prostate cancer in a single centre in the Netherlands.</p>
Intervention and comparator(s)	<p>Intervention: Memokath-028 inserted within the first 6 months after brachytherapy.</p> <p>Comparator: none.</p>

Key outcomes	<p>In 5 patients who did not have a catheter before stent placement, mean Qmax was 11.2 mL/s at 3 months post-insertion compared with 4.7 mL/s before stent insertion. In 5 patients who did have a catheter before stent placement it was not possible to measure urinary flow rate before stent insertion; however, mean Qmax at 3 months post-insertion was 15 mL/s.</p> <p>Mean IPSS and quality-of-life scores improved from baseline to 3-months in patients who did not have a catheter before stent placement (reduced from 29 to 11 for IPSS and 5 to 1 for quality of life).</p> <p>No encrustation was seen at a follow-up time of 6 months post-insertion.</p> <p>2 stents migrated towards the bladder within 2 days of insertion.</p> <p>In 4 patients, stents were removed at 6 months post-insertion as they experienced minor irritative symptoms, but the patients indicated that they were more satisfied with the stent than before insertion. Perineal pain and irritative voiding were reported in 5 patients and UTI in 1.</p>
Strengths and limitations	<p>Relatively short follow-up period (6 months); small sample size; non-comparative study design.</p>
<p><u>Kimata et al. (2015)</u></p>	
Study size, design and location	<p>Observational study conducted in 2 centres in Japan, including 37 older men with urethral obstruction at high risk from surgery who were previously managed with long-term catheterisation.</p>
Intervention and comparator(s)	<p>Intervention: Memokath prostate stent.</p> <p>Comparator: none.</p>

Key outcomes	<p>Mean (SD) post-void residual volume was 42.7 (66.0) mL (n=34) after stent insertion and 26 patients had a post-void residual volume &lt;50 mL [post-void residual volumes before stent insertion not reported].</p> <p>Pyuria was present in all patients before stent insertion. Following stent placement, pyuria was absent in 54.3% patients and no patients had serious symptoms of the disorder.</p> <p>21 patients (56.7%) were able to urinate unassisted following stent insertion at a mean follow-up time of 33.2 months. 16 patients (43.3%) could not urinate unassisted in the long-term for reasons including stent migration, other adverse events, onset of urethral cancer and lowered ability to perform everyday activities (unrelated to presence of the stent).</p> <p>In 7 patients stents migrated within 3 months of insertion and were removed. Five of these patients had a total prostate volume &lt;20 mL and the authors suggested that patients with lower prostate volume may be more vulnerable to stent migration.</p> <p>Encrustation was not observed in any patients.</p> <p>Other adverse events reported were urinary incontinence (n=6), haematuria (n=1) and persistent UTI that developed into sepsis (n=1).</p>
Strengths and limitations	Non-comparative study design.
<u>Papatsoris et al. (2009)</u>	
Study size, design and location	Retrospective observational study conducted in Japan, including 127 older men with bladder outflow obstruction because of BPH (84%) or prostate carcinoma (16%) who were at high risk from surgery.
Intervention and comparator(s)	<p>Intervention: Memokath-028.</p> <p>Comparator: none.</p>

Key outcomes	<p>41% of stents had to be removed because of encrustation (15%), migration (10%), penile pain (6%), bladder outlet obstruction (5%), urinary incontinence (&lt;3%), tissue granulation (&lt;3%), recurrent UTIs (&lt;3%) or urethral stricture (&lt;3%). Mean indwelling time for a single stent was 1 year.</p> <p>Mean Qmax was 14.6 mL/s compared with 7.6 mL/s before stent insertion.</p> <p>Mean residual urine volume was 21 mL compared with 147 mL before stent insertion.</p> <p>Mean IPSS and quality-of-life index were 12 points and 2 points, respectively, compared with 25 and 5.1 points before stent insertion.</p>
Strengths and limitations	<p>Long study follow-up (mean follow-up was 6 years). Retrospective, non-comparative study design; occurrence of outcomes are only reported as percentages, rather than absolute numbers.</p>
<p>Abbreviations: BPH, benign prostatic hyperplasia; IPSS, International Prostate Symptom Score; SD, standard deviation; Qmax, maximum urinary flow rate; UTI, urinary tract infection.</p>	

**Table 3 Summary of included studies for Memokath-044**

<u>Abdallah et al. (2013)</u>	
Study size, design and location	Observational study conducted in Egypt, including 23 men with recurrent bulbar urethral stricture.
Intervention and comparator(s)	<p>Intervention: Memokath-044 stent.</p> <p>Comparator: none.</p>

Key outcomes	<p>Mean (SD, range) flow rate was 21 (2.5, 17 to 25) mL/s post-insertion compared with 4.6 (1.2, 3 to 7) mL/s before stent insertion.</p> <p>Mean (SD, range) post-void residual volume was 50 (14, 30 to 70) mL post-insertion compared with 165 (19, 130 to 190) mL before stent insertion.</p> <p>Overall, stents failed in 12 patients (52%); 8 were because of adverse events and 4 patients felt uncomfortable and requested removal.</p> <p>In 3 patients (13%) stents were obstructed during the first 6 months of follow-up because of encrustation. The mean (SD) period for encrustation was 9.8 (2) months.</p> <p>In 5 patients (22%) stents migrated and were exchanged. Migration was related to accidental perineal trauma, a faulty trial of catheterisation, and the presence of the stricture close to the sphincter. The mean (SD) period for migration was 10 (3) months.</p> <p>Other adverse events reported were perineal pain that was transient and ceased within a few weeks (n=6), urethral hyperplasia leading to stent removal (n=2), UTIs (n=4) and intermittent gross haematuria (n=3).</p>
Strengths and limitations	Low number of patients; non-comparative study design.
<u>Jordan et al. (2013)</u>	
Study size, design and location	Multicentre randomised controlled trial conducted in the US, including 92 men with recurrent bulbar urethral stricture.
Intervention and comparator(s)	<p>Intervention: dilation or internal urethrotomy followed by insertion of Memokath-044 stent. Scheduled stent removal at 12 months post-insertion (Memokath group, n=63).</p> <p>Comparator: dilation or internal urethrotomy followed by urinary catheter drainage for approximately 1 week (n=29).</p>

Key outcomes	<p>Median time to urethral patency failure (inability to pass a 16Fr cystoscope through the strictured region) was 292 days in the Memokath group compared with 84 days in the control group (<math>p=0.002</math>).</p> <p>Normal urinary flow rates were achieved in 39 Memokath-044 patients (66.1%) and 16 control patients (55.3%) after treatment. At 3, 6, 9 and 12 months of follow-up 60.3%, 50.0%, 43.2% and 36.1% of Memokath patients respectively remained within the normal range of urinary flow rates (as defined by the Siroky nonogram). Comparable figures were not provided for the control group.</p> <p>Mean AUASI scores improved to normal levels in both groups following treatment. Up to 30% of patients in the Memokath group reported transient pain immediately after stent insertion, which decreased significantly during follow-up. Severe pain was reported by 1 patient.</p> <p>Encrustation was observed in 25.9% of Memokath patients. However, only 3 of these cases led to clinically significant decreases in mean Qmax and mean Qavg.</p> <p>Stents were dislocated in 8 patients (12.6%). Minor stent movements of up to 1 cm were observed in 12 patients (19.1%). It was not reported whether any of these migrations were clinically significant and necessitated intervention.</p> <p>31 Memokath patients experienced bacteriuria compared with only 2 patients in the control group. Most (39 out of 53) of these cases were rated as mild, although 1 instance was severe.</p> <p>10 Memokath patients (15.9%) experienced haematuria versus 3.4% of control group patients.</p> <p>Incontinence occurred in 19% of Memokath patients, although this was not considered significant based on IIQ-7 responses.</p>
Strengths and limitations	<p>Randomised, controlled study design. High rates of withdrawal, particularly in the control group (patients were withdrawn after stricture reoccurrence) meant that follow-up was incomplete and comparisons between groups are less reliable; study was funded by the company.</p>
Wong et al. (2014)	

Study size, design and location	Prospective observational study conducted in Australia, including 22 patients (gender not stated) with recurrent bulbar urethral strictures who had previously undergone dilation or urethrotomy.
Intervention and comparator(s)	Intervention: dilation or urethrotomy followed by insertion of a Memokath-044 stent. Scheduled removal of the stent after 3 months. Comparator: dilation or DVIU alone conducted previously in the same patient population (n not reported).
Key outcomes	<p>Mean Qmax 3 months post-insertion was 33.1 mL/s, compared with 4.5 mL/s before stent insertion. Mean Qmax decreased at 6 and 12 months post-insertion to 31.8 mL/s and 28.4 mL/s, respectively (not statistically significant).</p> <p>Strictures recurred in 5 patients (22%). Two further patients complained of lower urinary tract symptoms at 15 and 18 months post-insertion. Kaplan-Meier survival analysis was performed examining stricture and symptom recurrence. The mean (SD) time to recurrence without stenting was 2 (0.4) months versus 23 (2.5) months when a stent was inserted [reported that this was 'highly significant' but no p value given].</p> <p>No patients had significant stent encrustation.</p> <p>In 1 patient stent migration occurred at 10 weeks post-insertion and the stent was removed.</p>
Strengths and limitations	<p>Prospective study with some use of comparative data, although the study design was non-comparative.</p> <p>Poor quality of reporting: statistical significance was reported without p values, numbers of patients included in analyses was not always stated, and figures and data presented within them were not fully explained.</p>
<u>Barbagli et al. (2017)</u>	
Study size, design and location	A phase IIa pilot study conducted in Italy, including 16 men with recurrent bulbar urethral stricture who had previously undergone treatment.

Intervention and comparator(s)	Intervention: Urethrotomy (n=4) or dilation (n=12) followed by insertion of a Memokath-044 stent. Scheduled stent removal at 12 months post-insertion. Comparator: none.
Key outcomes	<p>Mean (range) time of stent retention was 10 (4–13) months.</p> <p>Median (range) Qmax was 11 (3.8-33.7) mL/s post-insertion, compared with 5.8 (2.0–8.6) mL/s before stent insertion.</p> <p>11 patients (69%) had to undergo internal urethrotomy in spite of stenting. Also, 1 stent had to be removed because of intra-stent stricture.</p> <p>No statistically significant differences were found in mean symptom scores relating to voiding, storage, and urinary leakage before and after stent insertion.</p> <p>Encrustation was reported in 5 patients (31%), although this was only sufficient to need removal in 1 case.</p> <p>In 1 patient the stent was removed because of dislocation into the penile urethra.</p> <p>Other adverse events reported were chronic pain 4 to 9 months after implantation (n=5) and bacteriuria (n=5).</p>
Strengths and limitations	<p>Thorough reporting of stent-related complications; prospective study design.</p> <p>Small sample size; potential effect of learning curve (surgeon inexperienced in insertion of the stent); non-comparative study design.</p>
<p>Abbreviations: AUASI, American Urological Association Symptom Index; IIQ-7, Incontinence Impact Questionnaire-Short Form; SD, standard deviation; Qavg, average urinary flow rate; Qmax, maximum urinary flow rate; UTI, urinary tract infection.</p>	

**Table 4 Summary of included studies for Memokath-045**

Hamid et al. (2003)



Study size, design and location	Retrospective observational study conducted in the UK, including 25 patients (gender not stated) with DSD following spinal cord injury.
Intervention and comparator(s)	Intervention: Memokath-045. Comparator: none.
Key outcomes	<p>19 stents were removed over the course of follow-up, 9 within 2 years post-insertion and 10 between 2 and 3 years post-insertion. Reasons for stent removal were migration (n=7), encrustation and stone formation (n=5), autonomic dysreflexia (n=3), incomplete bladder emptying (n=3), and issues with fertility (n=1). Six patients (24%) had a functioning stent in place at a mean follow-up time of 34.7 months.</p> <p>Mean (SD) maximum detrusor pressure at 6 months post-insertion was 61.8 (16.6) cmH<sub>2</sub>O compared with 79.1 (44.3) cmH<sub>2</sub>O before stent insertion (p&lt;0.05).</p> <p>Mean (SD) duration of detrusor contraction at 6 months post-insertion was 79.3 (37.2) seconds compared with 116 (53.6) seconds before stent insertion (p&lt;0.05).</p> <p>Mean (SD) residual urine volume at 6 months post-insertion was 155 (174.9) mL compared with 362.5 (320.3) mL before stent insertion (p&lt;0.05).</p> <p>2 patients experienced severe autonomic dysreflexia symptoms within 3 weeks of insertion and the stents were removed. However, all remaining patients experienced a decrease in autonomic dysreflexia-like symptoms (headaches, sweating and hypertension).</p> <p>There were 15 cases of UTI before stent placement, with 10 improving post-insertion. In 3 patients at a mean (range) of 25 (22-29) months the bladder did not generate sufficient pressure to empty and recurrent UTIs occurred. Stents in these patients were removed.</p> <p>There were no cases of hydronephrosis post-insertion compared with 4 cases before stent placement.</p>
Strengths and limitations	<p>Rigorous reporting of outcomes, including tests for statistical significance; UK setting.</p> <p>Non-comparative study design.</p>

<u>Pannek et al. (2011)</u>	
Study size, design and location	Observational study conducted in Switzerland, including 22 men with urinary dysfunction following spinal cord injury.
Intervention and comparator(s)	Intervention: Memokath stent. Comparator: none.
Key outcomes	<p>Mean residual urine volume was 105 mL post-insertion compared with 229 mL before stent insertion (<math>p=0.0075</math>) (<math>n=18</math>). Fourteen patients (77.8%) had residual urine &lt;100 mL (classified as successful) during follow-up.</p> <p>Mean (SD) maximum detrusor pressure was 64.7 (34.5) cmH<sub>2</sub>O post-insertion compared with 61.1 (47.2) cmH<sub>2</sub>O before stent insertion (<math>p=0.484</math>) (<math>n=18</math>).</p> <p>Retrograde external sphincter perfusion pressure was 61 cmH<sub>2</sub>O compared with 70 cmH<sub>2</sub>O before stent insertion (<math>p=0.008</math>; <math>n=18</math>).</p> <p>The rate of symptomatic UTIs was 1.2 in 6 months after stent insertion, compared with 4.3 in 6 months before.</p>
Strengths and limitations	<p>Reporting of outcomes includes tests for statistical significance.</p> <p>Non-comparative study design.</p>
<u>van der Merwe et al. (2012)</u>	
Study size, design and location	Retrospective observational study conducted in South Africa, in 28 men with bladder dysfunction following spinal cord injury.
Intervention and comparator(s)	Intervention: dual-flange Memokath stent. Comparator: none.

Key outcomes	<p>15 (45%) of the 33 stents placed were removed during the mean follow-up time of 18 months. The mean (range) time to stent failure was 15.7 (0.25 to 38.0) months. Stents failed because of stone formation (n=7), migration (n=3), large post-void residual urine volume (n=3), haematuria (n=1), and autonomic dysreflexia (n=1).</p> <p>In patients with stent placement lasting more than 20 months (n=11) mean (range) post-void residual volume decreased from 143 (32 to 330) to 2.5 (0 to 28) mL. In patients with stents removed before 20 months (n=10), mean (range) post-void residual volume decreased from 222 (32–330) to 122 (0–28) mL.</p> <p>There were 7 cases of autonomic dysreflexia post-insertion compared with 17 cases before stent placement (p=0.003). One patient (3%) experienced severe autonomic dysreflexia post-insertion and the stent was removed. There were 7 cases of UTI post-insertion compared with 22 cases before stent placement (p&lt;0.001). There was 1 case of hydronephrosis post-insertion compared with 2 cases before stent placement.</p>
Strengths and limitations	Non-comparative study design.
Abbreviations: DSD, detrusor sphincter dyssynergia; SD, standard deviation; UTI, urinary tract infection.	

Overall, the evidence base for Memokath stents is limited, with poor study design and very few comparative trials. Future randomised controlled trials comparing Memokath stents with standard care (including prostatic and urethral surgery and self- and indwelling catheterisation) and with other stents for treating urethral obstruction would be useful to provide more evidence. Trials with follow-up of more than 1 year would provide evidence on longer-term outcomes.

## Recent and ongoing studies

No ongoing or in-development trials were identified.

## Specialist commentator comments

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

Comments were received from 3 specialists, 1 of whom had not used the Memokath stents before, but was familiar with their use. Another specialist commentator was only familiar with the Memokath-028 prostatic stent, and so only provided comments in relation to this technology. The third specialist commentator had experience of using earlier versions of the Memokath stents, but did not use the stents in their current practice.

## Level of innovation

Two of the commentators agreed that the stents were innovative, with 1 noting that the stents represented a variation on existing technologies and that the innovative aspect was their thermo-expandable properties. The third commentator thought that the stents represented a modification on a device that has been available for almost 20 years.

## Potential patient impact

One specialist commentator thought that the Memokath stents could improve health outcomes in people who cannot have general anaesthetic and surgery, and another noted that they could be particularly beneficial to older men with urinary retention. A third commentator thought that the Memokath stents could be beneficial in the short term for men with spinal cord injuries, as well as those who cannot have prostatic surgery, but noted that higher quality evidence with longer follow-up times and cost analyses were needed to confirm this.

The commentators noted that using Memokath stents could mean fewer hospital visits and less invasive treatment options for patients, although 1 noted that more evidence was needed to prove these potential benefits. One commentator compared the Memokath-028 favourably with long-term indwelling catheterisation, saying that quality of life would be improved and there would be reduced risk of catheter-associated urinary tract infection, and therefore reduced hospital admissions.

## Potential system impact

All of the commentators noted that users of the Memokath stents would need special training, for example in how to deploy the stent and how to assess the length of stent needed. They thought that no or very few changes to current NHS facilities or infrastructure would be needed for the stents to be used.

One commentator thought that that use of the Memokath stents was unlikely to lead to cost savings for the NHS and could actually increase costs. Another commentator thought that use of the stents would have a positive impact on NHS services because fewer hospital attendances and admissions would be needed. They added that there may be reduced demand for community nursing services from men who had a Memokath stent inserted, because they may need less frequent catheter changes. The commentator thought that cost savings for the NHS could be significant through a reduced need for consumables such as catheters and associated equipment.

A third commentator stated that using Memokath-028 has been shown to be less expensive overall than long-term catheterisation or TURP.

## General comments

Two of the commentators noted that although the company states that the Memokath-045 can be used in both women and men, they would not support the use of the stent in the female urethra. They felt that there was insufficient evidence to support its use in women.

One commentator felt strongly that the quality of the evidence supporting the use of the Memokath stents was very poor, and that robust randomised controlled trials and cost-effectiveness studies were needed before they could be actively promoted into wider clinical practice. They argued that, at present, the stents should only be used in a research setting and not in clinical practice.

One commentator remarked that, in their experience, permanent urethral stents are no longer used in NHS clinical practice.

None of the specialist commentators were aware of any safety issues associated with any of the Memokath stents.

## Patient organisation comments

A representative of Prostate Cancer UK provided the following comments on the Memokath-028 stent specifically.

Memokath-028 could potentially improve urinary symptoms or avoid the need for long-term indwelling catheterisation. It can also be removed more easily than other stents.

Memokath-028 is a more convenient alternative to self-catheterisation for benign prostatic enlargement, because men would be able to urinate normally rather than needing a catheter. Memokath-028 may improve quality of life and could also reduce risk of urinary tract infections. Finally, using the stent would mean that men were less reliant on healthcare workers (for example, for catheter replacement) and could care for themselves better at home without the need for district nursing services.

Some men may choose to use Memokath-028 as a less invasive option compared with surgery for benign prostatic enlargement.

The commentator was not aware of any safety alerts for the Memokath-028, but noted that they would like to see more high-quality evidence, including quality-of-life data and long-term studies looking at complications.

## Specialist commentators

The following clinicians contributed to this briefing:

- Mr Trevor Dorkin, consultant urological surgeon, Freeman Hospital Newcastle-upon-Tyne. No relevant conflicts of interest.
- Mr Malcolm Crundwell, consultant urologist, Royal Devon and Exeter Hospital. Mr Crundwell has received payment for using Memokath-028 in private practice.
- Mr Mark Speakman, consultant urological surgeon, Taunton and Somerset NHS Foundation Trust. Mr Speakman has been paid by Astellas for chairmanship and presentation at the European Association of Urology Meeting in London March 2017.

Representatives from the following patient organisations contributed to this briefing:

- Prostate Cancer UK.

## Development of this briefing

This briefing was developed for NICE by the Newcastle and York external assessment centre. 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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